Clinical trial results:
A Phase 1b/2 Study of TAK-981 Plus Pembrolizumab to Evaluate the Safety, Tolerability, and Antitumor Activity of the Combination in Patients With Select Advanced or Metastatic Solid Tumors

Summary

EudraCT number	2020-004325-23
Trial protocol	LT LV HR
Global end of trial date	29 October 2024

Results information

Result version number	v1
This version publication date	13 November 2025
First version publication date	13 November 2025

Trial information

Trial identification

Sponsor protocol code	TAK-981-1502

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04381650
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	95 Hayden Ave, Lexington, MA, United States, 02421
Public contact	Study Director, Takeda, TrialDisclosures@takeda.com
Scientific contact	Study Director, Takeda, TrialDisclosures@takeda.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	29 October 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	29 October 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main aim of the study is to evaluate the safety, tolerability, and preliminary efficacy of TAK-981 in combination with pembrolizumab in pariticipants who have select advanced or metastatic solid tumors.

Protection of trial subjects:

Participant signed an informed consent form (ICF) before participating in the study.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 August 2020
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	Brazil: 35
Country: Number of subjects enrolled	Japan: 18
Country: Number of subjects enrolled	China: 13
Country: Number of subjects enrolled	Croatia: 5
Country: Number of subjects enrolled	Latvia: 3
Country: Number of subjects enrolled	Lithuania: 5
Country: Number of subjects enrolled	Poland: 18
Country: Number of subjects enrolled	Switzerland: 6
Country: Number of subjects enrolled	United States: 58
Worldwide total number of subjects	161
EEA total number of subjects	31

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)	103
From 65 to 84 years	57
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at various investigative sites throughout the world from 17 August 2020 to 29 October 2024.

Pre-assignment

Screening details:

Participants with a diagnosis of advanced or metastatic solid tumors were enrolled in this study consisting of Phase 1b (Dose Escalation cohorts), and Phase 2 (Dose Expansion cohorts) periods to receive TAK-981 and pembrolizumab.

Period 1

Period 1 title	Phase 1b (Dose Escalation)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Dose Escalation: TAK-981 40 mg + Pembrolizumab

Arm description:

Participants received TAK-981 40 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).

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

Dosage and administration details:

Pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Investigational medicinal product name	TAK-981
Investigational medicinal product code	
Other name	Subasumstat
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

TAK-981 40 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle.

Arm title	Dose Escalation: TAK-981 60 mg + Pembrolizumab

Arm description:

Participants received TAK-981 60 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).

Arm type	Experimental
Investigational medicinal product name	TAK-981
Investigational medicinal product code	
Other name	Subasumstat
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

TAK-981 60 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle.

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

Dosage and administration details:

Pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Arm title	Dose Escalation: TAK-981 90 mg + Pembrolizumab

Arm description:

Participants received TAK-981 90 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).

Arm type	Experimental
Investigational medicinal product name	TAK-981
Investigational medicinal product code	
Other name	Subasumstat
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

TAK-981 90 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle.

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

Dosage and administration details:

Pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Arm title	Dose Escalation: TAK-981 120 mg + Pembrolizumab

Arm description:

Participants received TAK-981, 120 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).

Arm type	Experimental
Investigational medicinal product name	TAK-981
Investigational medicinal product code	
Other name	Subasumstat
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

TAK-981 120 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle.

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

Dosage and administration details:

Pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Number of subjects in period 1[1]	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab
Started	3	6	33
Completed	2	2	9
Not completed	1	4	24
Consent withdrawn by subject	-	-	11
Reason Not Specified	-	1	1
Progressive Disease	1	3	12
New anti-cancer therapy	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1[1]	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Started	19
Completed	4
Not completed	15
Consent withdrawn by subject	4
Reason Not Specified	1
Progressive Disease	8
New anti-cancer therapy	1
Lost to follow-up	1

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial because this is a two-phase study wherein participants were newly recruited in each phase.

Period 2

Period 2 title	Phase 2 (Dose Expansion)
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

The arms in Period 2: Dose Expansion are mutually exclusive. However, due to database limitation which does not allow a greater number of participants to be present in the subsequent period [as compared to the preceding period], an alternative selection has been made.

Arms

Are arms mutually exclusive?	No

Arm title	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg

Arm description:

Participants with non-squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

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

Dosage and administration details:

Pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Investigational medicinal product name	TAK-981
Investigational medicinal product code	
Other name	Subasumstat
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

TAK-981 40 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle.

Arm title	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg

Arm description:

Participants with non-squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Arm type	Experimental
Investigational medicinal product name	TAK-981
Investigational medicinal product code	
Other name	Subasumstat
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

TAK-981 40 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle.

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

Dosage and administration details:

Pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Arm title	Dose Expansion: Cohort B: Cervical Cancer

Arm description:

Participants with cervical cancer received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Arm type	Experimental

Investigational medicinal product name	TAK-981
Investigational medicinal product code	
Other name	Subasumstat
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

TAK-981 40 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle.

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

Dosage and administration details:

Pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Arm title	Dose Expansion: Cohort C: MSS-CRC

Arm description:

Participants with MSS-CRC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Arm type	Experimental
Investigational medicinal product name	TAK-981
Investigational medicinal product code	
Other name	Subasumstat
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

TAK-981 40 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle.

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

Dosage and administration details:

Pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Arm title	Dose Expansion: Cohort D: Cutaneous Melanoma

Arm description:

Participants with cutaneous melanoma received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Arm type	Experimental
Investigational medicinal product name	TAK-981
Investigational medicinal product code	
Other name	Subasumstat
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

TAK-981 40 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle.

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

Dosage and administration details:

Pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Arm title	Dose Expansion: Cohort E: Squamous NSCLC

Arm description:

Participants with squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Arm type	Experimental
Investigational medicinal product name	TAK-981
Investigational medicinal product code	
Other name	Subasumstat
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

TAK-981 40 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle.

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

Dosage and administration details:

Pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Arm title	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC

Arm description:

Participants with CPI refractory squamous or non-squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Arm type	Experimental
Investigational medicinal product name	TAK-981
Investigational medicinal product code	
Other name	Subasumstat
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

TAK-981 40 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle.

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

Dosage and administration details:

Pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Number of subjects in period 2	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg	Dose Expansion: Cohort B: Cervical Cancer
Started	14	9	21
Completed	8	5	17
Not completed	6	4	4
Consent withdrawn by subject	1	2	4
Reason Not Specified	-	-	-
Progressive Disease	2	1	-
New anti-cancer therapy	3	1	-
Lost to follow-up	-	-	-

Number of subjects in period 2	Dose Expansion: Cohort C: MSS-CRC	Dose Expansion: Cohort D: Cutaneous Melanoma	Dose Expansion: Cohort E: Squamous NSCLC
Started	9	28	15
Completed	2	23	4
Not completed	7	5	11
Consent withdrawn by subject	2	1	4
Reason Not Specified	1	-	-
Progressive Disease	3	3	4
New anti-cancer therapy	-	-	2
Lost to follow-up	1	1	1

Number of subjects in period 2	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC
Started	4
Completed	1
Not completed	3
Consent withdrawn by subject	1
Reason Not Specified	-
Progressive Disease	2
New anti-cancer therapy	-
Lost to follow-up	-

Baseline characteristics

Reporting groups	
Reporting group title	Dose Escalation: TAK-981 40 mg + Pembrolizumab
Reporting group description:	
Participants received TAK-981 40 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).	
Reporting group title	Dose Escalation: TAK-981 60 mg + Pembrolizumab
Reporting group description:	
Participants received TAK-981 60 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).	
Reporting group title	Dose Escalation: TAK-981 90 mg + Pembrolizumab
Reporting group description:	
Participants received TAK-981 90 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).	
Reporting group title	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Reporting group description:	
Participants received TAK-981, 120 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).	

Reporting group values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab
Number of subjects	3	6	33
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	66.0	53.5	56.2
standard deviation	± 5.57	± 7.23	± 11.91
Gender categorical Units: Subjects			
Female	1	5	16
Male	2	1	17
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	4	8
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	3
White	3	2	17
More than one race	0	0	0
Unknown or Not Reported	0	0	5
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	2	1	6

Not Hispanic or Latino	1	5	25
Unknown or Not Reported	0	0	2

Reporting group values	Dose Escalation: TAK-981 120 mg + Pembrolizumab	Total	
Number of subjects	19	61	
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	59.8		
standard deviation	± 13.32	-	
Gender categorical Units: Subjects			
Female	8	30	
Male	11	31	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	7	19	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	1	4	
White	9	31	
More than one race	0	0	
Unknown or Not Reported	2	7	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	10	
Not Hispanic or Latino	18	49	
Unknown or Not Reported	0	2	

Subject analysis sets

Subject analysis set title	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with non-squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Subject analysis set title	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with non-squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Subject analysis set title	Dose Expansion: Cohort B: Cervical Cancer
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with cervical cancer received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Subject analysis set title	Dose Expansion: Cohort C: MSS-CRC
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with MSS-CRC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Subject analysis set title	Dose Expansion: Cohort D: Cutaneous Melanoma
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with cutaneous melanoma received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Subject analysis set title	Dose Expansion: Cohort E: Squamous NSCLC
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Subject analysis set title	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with CPI refractory squamous or non-squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Reporting group values	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg	Dose Expansion: Cohort B: Cervical Cancer
Number of subjects	14	9	21
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	63.3	68.7	51.8
standard deviation	± 10.83	± 9.12	± 13.24
Gender categorical Units: Subjects			
Female	6	5	21
Male	8	4	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	3	1	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0

White	10	8	17
More than one race	0	0	2
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	5	0	12
Not Hispanic or Latino	8	9	9
Unknown or Not Reported	1	0	0

Reporting group values	Dose Expansion: Cohort C: MSS-CRC	Dose Expansion: Cohort D: Cutaneous Melanoma	Dose Expansion: Cohort E: Squamous NSCLC
Number of subjects	9	28	15
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	49.6	55.9	67.5
standard deviation	± 9.22	± 13.95	± 7.66
Gender categorical Units: Subjects			
Female	5	12	1
Male	4	16	14
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	4	5
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0
White	7	23	10
More than one race	0	0	0
Unknown or Not Reported	0	1	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	14	0
Not Hispanic or Latino	9	14	14
Unknown or Not Reported	0	0	1

Reporting group values	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC		
Number of subjects	4		
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	73.5		
standard deviation	± 3.70		

Gender categorical Units: Subjects			
Female	1		
Male	3		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	0		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	0		
White	4		
More than one race	0		
Unknown or Not Reported	0		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0		
Not Hispanic or Latino	4		
Unknown or Not Reported	0		

End points reporting groups

Reporting group title	Dose Escalation: TAK-981 40 mg + Pembrolizumab

Reporting group description:

Participants received TAK-981 40 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).

Reporting group title	Dose Escalation: TAK-981 60 mg + Pembrolizumab

Reporting group description:

Participants received TAK-981 60 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).

Reporting group title	Dose Escalation: TAK-981 90 mg + Pembrolizumab

Reporting group description:

Participants received TAK-981 90 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).

Reporting group title	Dose Escalation: TAK-981 120 mg + Pembrolizumab

Reporting group description:

Participants received TAK-981, 120 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).

Reporting group title	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg

Reporting group description:

Participants with non-squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Reporting group title	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg

Reporting group description:

Participants with non-squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Reporting group title	Dose Expansion: Cohort B: Cervical Cancer

Reporting group description:

Participants with cervical cancer received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Reporting group title	Dose Expansion: Cohort C: MSS-CRC

Reporting group description:

Participants with MSS-CRC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Reporting group title	Dose Expansion: Cohort D: Cutaneous Melanoma

Reporting group description:

Participants with cutaneous melanoma received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Reporting group title	Dose Expansion: Cohort E: Squamous NSCLC

Reporting group description:

Participants with squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1

and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Reporting group title	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC

Reporting group description:

Participants with CPI refractory squamous or non-squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Subject analysis set title	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with non-squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Subject analysis set title	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with non-squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Subject analysis set title	Dose Expansion: Cohort B: Cervical Cancer
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with cervical cancer received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Subject analysis set title	Dose Expansion: Cohort C: MSS-CRC
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with MSS-CRC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Subject analysis set title	Dose Expansion: Cohort D: Cutaneous Melanoma
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with cutaneous melanoma received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Subject analysis set title	Dose Expansion: Cohort E: Squamous NSCLC
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Subject analysis set title	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC
Subject analysis set type	Full analysis

Subject analysis set description:

Participants with CPI refractory squamous or non-squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Primary: Phase 1: Number of Participants With One or More Treatment Emergent Adverse Events (TEAEs)

End point title	Phase 1: Number of Participants With One or More Treatment Emergent Adverse Events (TEAEs)[1]

End point description:

An adverse event (AE) is any untoward medical occurrence in a participant administered a medicinal investigational drug. The untoward medical occurrence does not necessarily have to have a causal relationship with treatment. A TEAE is defined as an AE that occurs after administration of first dose of study drug and through 30 days after last dose of study drug or until start of subsequent antineoplastic therapy. AEs were evaluated according to National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE), Version 5.0 except cytokine release syndrome (CRS), which was graded according to American Society for Transplantation and Cellular Therapy (ASTCT) Consensus Grading for CRS. Safety Analysis Set included participants who received at least 1 dose, even if incomplete, of study drug.

End point type	Primary

End point timeframe:

Up to approximately 24 months

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analysis were planned for this endpoint.

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	33	19
Units: participants	3	6	33	19

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Number of Participants With One or More Serious Adverse Events (SAEs)

End point title	Phase 1: Number of Participants With One or More Serious Adverse Events (SAEs)[2]

End point description:

An SAE is any untoward medical occurrence that results in death; is life-threatening; requires inpatient hospitalization or prolongation of present hospitalization; results in persistent or significant disability/incapacity; is a congenital anomaly/birth defect or is a medically important event that may not be immediately life-threatening or result in death or hospitalization, but may jeopardize the participant or may require intervention to prevent one of other outcomes listed in definition above, or involves suspected transmission via a medicinal product of an infectious agent. Safety Analysis Set included participants who received at least 1 dose, even if incomplete, of study drug.

End point type	Primary

End point timeframe:

Up to approximately 24 months

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive analysis were planned for this endpoint.

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	33	19
Units: participants	0	3	17	10

Statistical analyses

No statistical analyses for this end point

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

End point title	Phase 1: Number of Participants With Dose Limiting Toxicities (DLTs)[3]

End point description:

DLTs were evaluated according to NCI CTCAE Version 5.0 except CRS, which was graded according to ASTCT Consensus Grading for CRS. The DLT-evaluable Analysis Set included participants enrolled in Phase 1b of the study and who experienced a DLT at any time after receiving the first dose of TAK-981 during the DLT assessment period (Cycle 1) or who received all planned TAK-981 doses and 1 administration of pembrolizumab in Cycle 1.

End point type	Primary

End point timeframe:

Up to Cycle 1 (each cycle was of 21 days)

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: Only descriptive analysis were planned for this endpoint.

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	30	19
Units: participants	0	0	2	1

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Number of Participants With Grade 3 or Higher Treatment Emergent Adverse Events (TEAEs)

End point title	Phase 1: Number of Participants With Grade 3 or Higher Treatment Emergent Adverse Events (TEAEs)[4]

End point description:

AE means any untoward medical occurrence in a participant administered a pharmaceutical product. An AE can therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product whether or not it is related to the medicinal product. A TEAE was defined as an adverse event which occurred on or after the first dose of study drug and no more than 30

days after the last dose of study drug. A severity grade was evaluated as per the NCI CTCAE Version 5.0, except for CRS, which was assessed by ASTCT Consensus Grading for CRS.DLTs were evaluated according to NCI CTCAE Version 5.0 except CRS, which was graded according to ASTCT Consensus Grading for CRS. Safety Analysis Set included participants who received at least 1 dose, even if incomplete, of study drug.
Reporting Groups

End point type	Primary

End point timeframe:

Up to approximately 24 months

Notes:

[4] - 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: Only descriptive analysis were planned for this endpoint.

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	33	19
Units: participants	0	2	20	15

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Number of Participants with One or More TEAEs Leading to Dose Modifications and Treatment Discontinuation

End point title	Phase 1: Number of Participants with One or More TEAEs Leading to Dose Modifications and Treatment Discontinuation[5]

End point description:

An AE is any untoward medical occurrence in a participant administered a medicinal investigational drug. The untoward medical occurrence does not necessarily have to have a causal relationship with treatment. A TEAE is defined as an AE that occurs after administration of first dose of study drug and through 30 days after last dose of study drug or until start of subsequent antineoplastic therapy. Pembrolizumab is denoted as Pem. Safety Analysis Set included participants who received at least 1 dose, even if incomplete, of study drug.

End point type	Primary

End point timeframe:

Up to approximately 24 months

Notes:

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

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	33	19
Units: participants				
TEAE Resulting in Dose Modifications of TAK-981	0	3	22	11

TEAE Resulting in Dose Modifications of Pem	0	3	15	4
TEAE Resulting in Drug Discontinuation of TAK-981	0	1	3	2
TEAE Resulting in Drug Discontinuation of Pem	0	1	4	1

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Overall Response Rate (ORR) as Assessed by the Investigator According to RECIST, Version 1.1

End point title	Phase 2: Overall Response Rate (ORR) as Assessed by the Investigator According to RECIST, Version 1.1[6]

End point description:

ORR is defined as the percentage of participants who achieve Complete Response (CR) and Partial Response (PR) (determined by the investigator) during the study according to Response Evaluation Criteria in Solid Tumors (RECIST) Version 1.1. Response-Evaluable Analysis Set included participants who had received at least 1 dose of study drug, had sites of measurable disease at baseline, and 1 postbaseline disease assessment, or were discontinued due to symptomatic deterioration or death before a postbaseline evaluation happened.

End point type	Primary

End point timeframe:

Up to approximately 25 months

Notes:

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

End point values	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg	Dose Expansion: Cohort B: Cervical Cancer	Dose Expansion: Cohort C: MSS-CRC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	8	20	9
Units: percentage of participants				
number (confidence interval 95%)	20 (2.52 to 55.61)	0 (0.00 to 36.94)	30 (11.89 to 54.28)	0 (0.00 to 33.63)

End point values	Dose Expansion: Cohort D: Cutaneous Melanoma	Dose Expansion: Cohort E: Squamous NSCLC	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	28	13	4	
Units: percentage of participants				
number (confidence interval 95%)	25 (10.69 to 44.87)	7.7 (0.19 to 36.03)	0 (0.00 to 60.24)	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Number of Participants With Clinically Significant Laboratory Values

End point title	Phase 1: Number of Participants With Clinically Significant Laboratory Values[7]

End point description:

Laboratory parameters included clinical chemistry, hematology, and urinalysis. Participants with at least 1 Grade 3 or 4 Lab Abnormalities were reported. Safety Analysis Set included participants who received at least 1 dose, even if incomplete, of study drug.

End point type	Primary

End point timeframe:

Up to approximately 24 months

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: Only descriptive analysis were planned for this endpoint.

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	33	19
Units: participants				
Hematology	1	3	7	6
Serum Chemistry	1	1	7	5
Coagulation	0	0	0	1

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Cmax: Maximum Observed Plasma Concentration for TAK-981

End point title	Phase 1: Cmax: Maximum Observed Plasma Concentration for TAK-981

End point description:

Pharmacokinetic (PK) Analysis Set included participants with sufficient dosing and PK data to reliably estimate 1 or more PK parameters. 'n' denotes number of participants available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Cycle 1 (each cycle is 21 days) Days 1 and 8 pre-dose and at multiple timepoints (up to 24 hours)

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	33	19
Units: nanograms per milliliter (ng/ml)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1(n=3,6,33,19)	335 (± 282)	728 (± 396)	888 (± 423)	1290 (± 571)
Cycle 1 Day 8(n=3,6,30,17)	280 (± 167)	448 (± 206)	780 (± 524)	1270 (± 770)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Tmax: Time to Reach the Maximum Plasma Concentration (Cmax) for TAK-981

End point title	Phase 1: Tmax: Time to Reach the Maximum Plasma Concentration (Cmax) for TAK-981

End point description:

PK Analysis Set included participants with sufficient dosing and PK data to reliably estimate 1 or more PK parameters. 'n' denotes number of participants available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Cycle 1 (each cycle is 21 days) Days 1 and 8 pre-dose and at multiple timepoints (up to 24 hours)

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	33	19
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1(n=3,6,33,19)	1.22 (1.20 to 1.23)	1.27 (1.00 to 1.47)	1.17 (1.00 to 1.88)	1.20 (1.00 to 1.72)
Cycle 1 Day 8(n=3,6,30,17)	1.18 (1.17 to 1.25)	1.41 (1.00 to 1.70)	1.22 (1.00 to 3.10)	1.28 (0.98 to 1.50)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: AUC0-t: Area Under the Plasma Concentration-time Curve from Time 0 to Time t Over the Dosing Interval for TAK-981

End point title	Phase 1: AUC0-t: Area Under the Plasma Concentration-time Curve from Time 0 to Time t Over the Dosing Interval for TAK-981

End point description:

PK Analysis Set included participants with sufficient dosing and PK data to reliably estimate 1 or more PK parameters. Subjects analyzed is the number of participants with data available for analysis. 'n' denotes number of participants available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Cycle 1 (each cycle is 21 days) Days 1 and 8 pre-dose and at multiple timepoints (up to 24 hours)

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	32	18
Units: hours*ng/mL				
arithmetic mean (standard deviation)				
Cycle 1 Day 1(n=3,6,32,18)	880 (± 427)	1370 (± 517)	1950 (± 735)	2580 (± 949)
Cycle 1 Day 8(n=3,5,28,16)	814 (± 290)	976 (± 232)	1780 (± 908)	2640 (± 1260)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: AUC∞: Area Under the Plasma Concentration-time Curve from Time 0 to Infinity for TAK-981

End point title	Phase 1: AUC∞: Area Under the Plasma Concentration-time Curve from Time 0 to Infinity for TAK-981

End point description:

PK Analysis Set included participants with sufficient dosing and PK data to reliably estimate 1 or more PK parameters. Subjects analyzed is the number of participants with data available for analysis. 'n' denotes number of participants available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Cycle 1 (each cycle is 21 days) Days 1 and 8 pre-dose and at multiple timepoints (up to 24 hours)

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	32	17
Units: hours*ng/mL				
arithmetic mean (standard deviation)				
Cycle 1 Day 1(n=3,6,32,17)	909 (± 432)	1400 (± 530)	2020 (± 760)	2660 (± 1020)
Cycle 1 Day 8(n=3,5,27,16)	845 (± 292)	1010 (± 233)	1830 (± 942)	2750 (± 1320)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: t1/2z: Terminal Disposition Phase Half-life for TAK-981

End point title	Phase 1: t1/2z: Terminal Disposition Phase Half-life for TAK-981

End point description:

PK Analysis Set included participants with sufficient dosing and PK data to reliably estimate 1 or more PK parameters. Subjects analyzed is the number of participants with data available for analysis. 'n' denotes number of participants available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Cycle 1 (each cycle is 21 days) Days 1 and 8 pre-dose and at multiple timepoints (up to 24 hours)

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	32	17
Units: hours				
median (full range (min-max))				
Cycle 1 Day 1(n=3,6,32,17)	5.88 (5.82 to 6.16)	5.58 (5.04 to 6.03)	5.72 (3.31 to 10.43)	6.79 (5.93 to 8.14)
Cycle 1 Day 8(n=3,5,27,16)	5.83 (5.69 to 6.33)	5.68 (5.22 to 6.44)	6.06 (4.18 to 9.13)	6.67 (5.26 to 8.08)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: CL: Total Clearance After Intravenous Administration for TAK-981

End point title	Phase 1: CL: Total Clearance After Intravenous Administration

	for TAK-981

End point description:

PK Analysis Set included participants with sufficient dosing and PK data to reliably estimate 1 or more PK parameters. Subjects analyzed is the number of participants with data available for analysis. 'n' denotes number of participants available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Cycle 1 (each cycle is 21 days) Days 1 and 8 pre-dose and at multiple timepoints (up to 24 hours)

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	32	17
Units: liters per hour (L/h)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1(n=3,6,32,17)	51.1 (± 23.2)	47.2 (± 14.8)	51.3 (± 19.6)	51.0 (± 18.4)
Cycle 1 Day 8(n=3,5,27,16)	51.7 (± 19.3)	62.5 (± 15.5)	57.0 (± 21.8)	53.8 (± 26.8)

Statistical analyses

No statistical analyses for this end point

Secondary: Phases 1 and 2: Disease Control Rate (DCR)

End point title	Phases 1 and 2: Disease Control Rate (DCR)

End point description:

DCR is defined as the percentage of participants who achieved stable disease (SD) or better (CR + PR + SD determined by the investigator) >6 weeks during the trial in the response-evaluable population. Response-Evaluable Analysis Set included participants who had received at least 1 dose of study drug, had sites of measurable disease at baseline, and 1 postbaseline disease assessment, or were discontinued due to symptomatic deterioration or death before a postbaseline evaluation happened.

End point type	Secondary

End point timeframe:

Phase 1: Up to approximately 24 months, Phase 2: Up to approximately 25 months

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	6	8
Units: percentage of participants				
number (confidence interval 95%)	33.3 (0.84 to 90.57)	80.0 (44.39 to 97.48)	50.0 (11.81 to 88.19)	62.5 (24.49 to 91.48)

End point values	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Expansion: Cohort B: Cervical Cancer	Dose Escalation: TAK-981 120 mg + Pembrolizumab	Dose Expansion: Cohort C: MSS-CRC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	20	18	9
Units: percentage of participants				
number (confidence interval 95%)	30.3 (15.59 to 48.71)	55.0 (31.53 to 76.94)	44.4 (21.53 to 69.24)	22.2 (2.81 to 60.01)

End point values	Dose Expansion: Cohort D: Cutaneous Melanoma	Dose Expansion: Cohort E: Squamous NSCLC	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	28	13	4	
Units: percentage of participants				
number (confidence interval 95%)	67.9 (47.65 to 84.12)	30.8 (9.09 to 61.43)	0 (0.00 to 60.24)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Vss: Volume of Distribution at Steady State After Intravenous Administration for TAK-981

End point title	Phase 1: Vss: Volume of Distribution at Steady State After Intravenous Administration for TAK-981

End point description:

PK Analysis Set included participants with sufficient dosing and PK data to reliably estimate 1 or more PK parameters. Subjects analyzed is the number of participants with data available for analysis. 'n' denotes number of participants available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Cycle 1 (each cycle is 21 days) Days 1 and 8 pre-dose and at multiple timepoints (up to 24 hours)

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	32	17
Units: liters (L)				
arithmetic mean (standard deviation)				
Cycle 1 Day 1(n=3,6,32,17)	312 (± 203)	181 (± 56.9)	240 (± 115)	240 (± 98.5)
Cycle 1 Day 8(n=3,5,27,16)	323 (± 178)	314 (± 109)	300 (± 129)	271 (± 150)

Statistical analyses

No statistical analyses for this end point

Secondary: Phases 1 and 2: Durable Response Rate (DRR)

End point title	Phases 1 and 2: Durable Response Rate (DRR)

End point description:

DRR is defined as the rate of objective responses (CR + PR) maintained for at least 6 months initiating at any time within 12 months of commencing therapy. Response-Evaluable Analysis Set included participants who had received at least 1 dose of study drug, had sites of measurable disease at baseline, and 1 postbaseline disease assessment, or were discontinued due to symptomatic deterioration or death before a postbaseline evaluation happened.

End point type	Secondary

End point timeframe:

Phase 1: Up to approximately 24 months, Phase 2: Up to approximately 25 months

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	10	6	8
Units: percentage of participants				
number (confidence interval 95%)	0 (0.00 to 70.76)	10.0 (0.25 to 44.50)	16.7 (0.42 to 64.12)	0 (0.00 to 36.94)

End point values	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Expansion: Cohort B: Cervical Cancer	Dose Escalation: TAK-981 120 mg + Pembrolizumab	Dose Expansion: Cohort C: MSS-CRC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	20	18	9
Units: percentage of participants				

number (confidence interval 95%)	6.1 (0.74 to 20.23)	0 (0.00 to 16.84)	0 (0.00 to 18.53)	0 (0.00 to 33.63)

End point values	Dose Expansion: Cohort D: Cutaneous Melanoma	Dose Expansion: Cohort E: Squamous NSCLC	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	28	13	4	
Units: percentage of participants				
number (confidence interval 95%)	10.7 (2.27 to 28.23)	0 (0.00 to 24.71)	0 (0.00 to 60.24)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phases 1 and 2: Duration of Response (DOR)

End point title	Phases 1 and 2: Duration of Response (DOR)

End point description:

DOR is defined as a time from the time of first documentation of tumor response to the first recorded occurrence of disease progression (PD) or death from any cause (whichever occurs first), through end of study. Response-Evaluable Analysis Set included participants who had received at least 1 dose of study drug, had sites of measurable disease at baseline, and 1 postbaseline disease assessment, or were discontinued due to symptomatic deterioration or death before a postbaseline evaluation happened. Subjects analysed is the number of participants with events. '-999' and '999' denotes lower and upper limit of 95% Confidence Interval (CI) was not estimable for a single participant. '99999' denotes upper limit of 95% CI was not estimable due to censoring. '9999' denotes median and upper limit of 95% CI was not estimable due to censoring.

End point type	Secondary

End point timeframe:

Phase 1: Up to approximately 24 months, Phase 2: Up to approximately 25 months

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[8]	1	1	0[9]
Units: hours				
median (confidence interval 95%)	(to)	7.62 (-999 to 999)	17.12 (-999 to 999)	(to)

Notes:

[8] - No participants with the event were available for analysis.

[9] - No participants with events were available for analysis.

End point values	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Expansion: Cohort B: Cervical Cancer	Dose Escalation: TAK-981 120 mg + Pembrolizumab	Dose Expansion: Cohort C: MSS-CRC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	1	0[10]
Units: hours				
median (confidence interval 95%)	7.39 (4.17 to 99999)	9999 (4.67 to 9999)	3.71 (-999 to 999)	(to)

Notes:

[10] - No participants with events were available for analysis.

End point values	Dose Expansion: Cohort D: Cutaneous Melanoma	Dose Expansion: Cohort E: Squamous NSCLC	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	3	1	0[11]	
Units: hours				
median (confidence interval 95%)	9999 (7.26 to 9999)	4.34 (-999 to 999)	(to)	

Notes:

[11] - No participants with events were available for analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Phases 1 and 2: Progression-free Survival (PFS)

End point title	Phases 1 and 2: Progression-free Survival (PFS)

End point description:

PFS is defined as time from the date of the first dose administration to the date of first documentation of PD or death due to any cause whichever occurs first, through the end of the study. Response-Evaluable Analysis Set included participants who had received at least 1 dose of study drug, had sites of measurable disease at baseline, and 1 postbaseline disease assessment, or were discontinued due to symptomatic deterioration or death before a postbaseline evaluation happened. Subjects analysed is the number of participants with events. '-999' and '999' denotes lower and upper limit of 95% CI was not estimable for a single participant. '99999' denotes upper limit of 95% CI was not estimable due to censoring.

End point type	Secondary

End point timeframe:

Phase 1: Up to approximately 24 months, Phase 2: Up to approximately 25 months

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	8	5	7

Units: months				
median (confidence interval 95%)	2.00 (2.00 to 99999)	3.71 (3.29 to 9.20)	4.21 (2.00 to 99999)	4.59 (1.97 to 99999)

End point values	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Expansion: Cohort B: Cervical Cancer	Dose Escalation: TAK-981 120 mg + Pembrolizumab	Dose Expansion: Cohort C: MSS-CRC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28	15	16	8
Units: months				
median (confidence interval 95%)	1.99 (1.77 to 3.91)	4.14 (2.14 to 8.87)	2.11 (1.41 to 6.57)	1.64 (1.28 to 2.00)

End point values	Dose Expansion: Cohort D: Cutaneous Melanoma	Dose Expansion: Cohort E: Squamous NSCLC	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	17	11	4	
Units: months				
median (confidence interval 95%)	8.97 (2.37 to 12.42)	2.07 (1.87 to 2.30)	1.28 (0.99 to 999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phases 1 and 2: Time to Response (TTR)

End point title	Phases 1 and 2: Time to Response (TTR)

End point description:

TTR is defined as time from the date of the first dose administration to the date of first documented PR or better. Response-Evaluable Analysis Set included participants who had received at least 1 dose of study drug, had sites of measurable disease at baseline, and 1 postbaseline disease assessment, or were discontinued due to symptomatic deterioration or death before a postbaseline evaluation happened. Subjects analysed is the number of participants with events. '99999' denotes upper limit of 95% CI was not estimable due to censoring. '9999' denotes median and upper limit of 95% CI was not estimable due to censoring. '9999', '-9999' and '9999' denotes median, lower limit and upper limit of 95% CI was not estimable due to censoring.

End point type	Secondary

End point timeframe:

Phase 1: Up to approximately 24 months, Phase 2: Up to approximately 25 months

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[12]	2	2	0[13]
Units: months				
median (confidence interval 95%)	(to)	4.01 (3.98 to 99999)	4.17 (1.91 to 99999)	(to)

Notes:

[12] - No participants with the event were available for analysis.

[13] - No participants with events were available for analysis.

End point values	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Expansion: Cohort B: Cervical Cancer	Dose Escalation: TAK-981 120 mg + Pembrolizumab	Dose Expansion: Cohort C: MSS-CRC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	1	0[14]
Units: months				
median (confidence interval 95%)	99999 (3.94 to 99999)	6.01 (4.04 to 99999)	9999 (-9999 to 9999)	(to)

Notes:

[14] - No participants with events were available for analysis.

End point values	Dose Expansion: Cohort D: Cutaneous Melanoma	Dose Expansion: Cohort E: Squamous NSCLC	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	1	0[15]	
Units: months				
median (confidence interval 95%)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	(to)	

Notes:

[15] - No participants with events were available for analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Overall Survival (OS)

End point title	Phase 2: Overall Survival (OS)

End point description:

OS is defined as the time from the date of the first dose administration to the date of death. Participants without documentation of death at the time of analysis were censored at the date last known to be alive. Response-Evaluable Analysis Set included participants who had received at least 1 dose of study drug, had sites of measurable disease at baseline, and 1 postbaseline disease assessment, or were discontinued due to symptomatic deterioration or death before a postbaseline evaluation happened. Subjects analysed is the number of participants with events. '99999' denotes upper limit of 95% CI was not estimable due to censoring. '9999' denotes median and upper limit of 95% CI was not estimable due to censoring. '9999', '-9999' and '9999' denotes median, lower limit and upper limit of 95% CI was not estimable due to censoring.

End point type	Secondary

End point timeframe:

Up to approximately 25 months

End point values	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg	Dose Expansion: Cohort B: Cervical Cancer	Dose Expansion: Cohort C: MSS-CRC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	4	9	2
Units: months				
median (confidence interval 95%)	9999 (-9999 to 9999)	10.12 (5.16 to 99999)	14.55 (5.42 to 99999)	9999 (4.21 to 9999)

End point values	Dose Expansion: Cohort D: Cutaneous Melanoma	Dose Expansion: Cohort E: Squamous NSCLC	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	8	1	1	
Units: months				
median (confidence interval 95%)	9999 (11.43 to 9999)	9999 (-9999 to 9999)	99999 (1.28 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phases 1 and 2: Time to Progression (TTP)

End point title	Phases 1 and 2: Time to Progression (TTP)

End point description:

TTP is defined as the from the date of the first dose administration to the date of the first documentation of PD as defined by standard disease criteria. Response-Evaluable Analysis Set included participants who had received at least 1 dose of study drug, had sites of measurable disease at baseline, and 1 postbaseline disease assessment, or were discontinued due to symptomatic deterioration or death before a postbaseline evaluation happened. Subjects analysed is the number of participants with events. '99999' denotes upper limit of 95% CI was not estimable due to censoring.

End point type	Secondary

End point timeframe:

Phase 1: Up to approximately 24 months, Phase 2: Up to approximately 25 months

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	8	5	6
Units: months				
median (confidence interval 95%)	2.00 (2.00 to 99999)	3.71 (3.29 to 9.20)	4.21 (2.00 to 99999)	4.01 (1.97 to 99999)

End point values	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Expansion: Cohort B: Cervical Cancer	Dose Escalation: TAK-981 120 mg + Pembrolizumab	Dose Expansion: Cohort C: MSS-CRC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	13	15	6
Units: months				
median (confidence interval 95%)	2.07 (1.87 to 4.04)	5.34 (2.20 to 8.87)	2.07 (1.41 to 6.93)	1.76 (1.28 to 99999)

End point values	Dose Expansion: Cohort D: Cutaneous Melanoma	Dose Expansion: Cohort E: Squamous NSCLC	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	14	11	4	
Units: months				
median (confidence interval 95%)	9.17 (4.11 to 99999)	2.07 (1.87 to 2.30)	1.28 (0.99 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Fold Change from Baseline in TAK-981-/Small Ubiquitin-like Modifier (SUMO) Adduct Formation in Peripheral Blood Lymphocytes

End point title	Fold Change from Baseline in TAK-981-/Small Ubiquitin-like Modifier (SUMO) Adduct Formation in Peripheral Blood Lymphocytes

End point description:

The level of TAK-981-SUMO adduct formation was evaluated by flow cytometry as the percentage of adduct formed in peripheral blood lymphocytes. Positive change denotes improvement. Pharmacodynamic Analysis Set included participants who provided evaluable blood samples (Cycle 1, Day 1 predose sample and at least 1 postdose sample). Subjects analysed is the number of participants with data available for analysis. 'n' denotes the number of participants available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 (1 hour, 4 hours, 8 hours) and Day 8 (Pre-dose, 1 hour, 4 hours and 8 hours) (Cycle length = 21 days)

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	18	13
Units: ratio				
arithmetic mean (standard deviation)				
Cycle 1 Day 1: 1 Hour Post Dose(n=3,6,18,13)	8.1 (± 1.06)	7.0 (± 3.12)	8.5 (± 3.38)	8.4 (± 2.40)
Cycle 1 Day 1: 4 Hours Post Dose(n=3,6,18,13)	5.1 (± 0.82)	5.0 (± 1.90)	6.0 (± 1.80)	6.3 (± 1.70)
Cycle 1 Day 1: 6-8 Hours Post Dose(n=3,6,18,13)	4.6 (± 0.61)	4.5 (± 1.87)	5.3 (± 1.58)	5.5 (± 1.29)
Cycle 1 Day 8: Predose(n=3,6,16,12)	3.5 (± 0.53)	2.6 (± 0.96)	2.7 (± 1.43)	2.0 (± 0.68)
Cycle 1 Day 8: 1 Hour Post Dose(n=3,6,16,10)	11.9 (± 3.52)	7.7 (± 2.88)	9.2 (± 4.68)	8.7 (± 2.01)
Cycle 1 Day 8: 4 Hours Post Dose(n=3,6,14,11)	7.5 (± 1.52)	6.0 (± 2.66)	6.4 (± 2.90)	6.1 (± 2.12)
Cycle 1 Day 8: 6-8 Hours Post Dose(n=3,6,14,11)	6.5 (± 1.08)	5.1 (± 2.30)	5.7 (± 2.64)	5.6 (± 1.96)

Statistical analyses

No statistical analyses for this end point

Secondary: Fold Change from Baseline in SUMO 2/3 Inhibition in Peripheral Blood Lymphocytes

End point title	Fold Change from Baseline in SUMO 2/3 Inhibition in Peripheral Blood Lymphocytes

End point description:

SUMO pathway inhibition in blood was evaluated by flow cytometry in peripheral blood lymphocytes with an antibody recognizing SUMO 2/3 chains. Pharmacodynamic Analysis Set included participants who provided evaluable blood samples (Cycle 1, Day 1 predose sample and at least 1 postdose sample). Subjects analysed is the number of participants with data available for analysis. 'n' denotes the number of participants available for analysis during the specified time-point.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1 (1 hour, 4 hours, 8 hours) and Day 8 (Pre-dose, 1 hour, 4 hours and 8 hours) (Cycle length = 21 days)

End point values	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	18	13
Units: ratio				
arithmetic mean (standard deviation)				
Cycle 1 Day 1: 1 Hour Post Dose(n=3,6,18,13)	0.7 (± 0.14)	0.6 (± 0.21)	0.6 (± 0.18)	0.5 (± 0.08)
Cycle 1 Day 1: 4 Hours Post Dose(n=3,6,18,13)	0.8 (± 0.07)	0.6 (± 0.12)	0.9 (± 0.54)	0.6 (± 0.11)
Cycle 1 Day 1: 6-8 Hours Post Dose(n=3,6,18,13)	0.8 (± 0.08)	0.7 (± 0.19)	1.0 (± 0.68)	0.7 (± 0.34)
Cycle 1 Day 8: Predose(n=3,6,16,12)	0.9 (± 0.24)	1.0 (± 0.35)	0.9 (± 0.36)	0.7 (± 0.39)
Cycle 1 Day 8: 1 Hour Post Dose(n=3,6,16,10)	0.6 (± 0.14)	0.6 (± 0.23)	0.7 (± 0.34)	0.4 (± 0.15)
Cycle 1 Day 8: 4 Hours Post Dose(n=3,6,14,11)	0.7 (± 0.22)	0.6 (± 0.15)	0.8 (± 0.58)	0.5 (± 0.17)
Cycle 1 Day 8: 6-8 Hours Post Dose(n=3,6,14,11)	0.7 (± 0.29)	0.6 (± 0.11)	0.9 (± 0.53)	0.6 (± 0.22)

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Percentage of Participants With One or More Treatment Emergent Adverse Events (TEAEs)

End point title	Phase 2: Percentage of Participants With One or More Treatment Emergent Adverse Events (TEAEs)

End point description:

An AE is any untoward medical occurrence in a participant administered a medicinal investigational drug. The untoward medical occurrence does not necessarily have to have a causal relationship with treatment. A TEAE is defined as an AE that occurs after administration of first dose of study drug and through 30 days after last dose of study drug or until start of subsequent antineoplastic therapy. AEs were evaluated according to NCI CTCAE, Version 5.0 except CRS, which was graded according to ASTCT Consensus Grading for CRS. Safety Analysis Set included participants who received at least 1 dose, even if incomplete, of study drug.

End point type	Secondary

End point timeframe:

Up to approximately 25 months

End point values	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg	Dose Expansion: Cohort B: Cervical Cancer	Dose Expansion: Cohort C: MSS-CRC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	9	21	9
Units: percentage of participants				
number (not applicable)	100	100	100	100

End point values	Dose Expansion: Cohort D: Cutaneous Melanoma	Dose Expansion: Cohort E: Squamous NSCLC	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	28	15	4	
Units: percentage of participants				
number (not applicable)	100	93.3	100	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Participants With Grade 3 or Higher Treatment Emergent Adverse Events (TEAEs)

End point title	Phase 2: Number of Participants With Grade 3 or Higher Treatment Emergent Adverse Events (TEAEs)

End point description:

An AE means any untoward medical occurrence in a participant administered a pharmaceutical product. An AE can therefore be any unfavorable and unintended sign, symptom, or disease temporally associated with the use of a medicinal product whether or not it is related to the medicinal product. A TEAE was defined as an adverse event which occurred on or after the first dose of study drug and no more than 30 days after the last dose of study drug. A severity grade was evaluated as per the NCI CTCAE Version 5.0, except for CRS, which was assessed by ASTCT Consensus Grading for CRS. Safety Analysis Set included participants who received at least 1 dose, even if incomplete, of study drug.

End point type	Secondary

End point timeframe:

Up to approximately 25 months

End point values	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg	Dose Expansion: Cohort B: Cervical Cancer	Dose Expansion: Cohort C: MSS-CRC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	9	21	9
Units: participants	7	5	18	8

End point values	Dose Expansion: Cohort D: Cutaneous Melanoma	Dose Expansion: Cohort E: Squamous NSCLC	Dose Expansion: Cohort F: CPI Refractory Squamous or	

			NSCLC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	28	15	4	
Units: participants	14	4	2	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Participants with One or More TEAEs Leading to Dose Modifications and Treatment Discontinuation

End point title	Phase 2: Number of Participants with One or More TEAEs Leading to Dose Modifications and Treatment Discontinuation

End point description:

An AE is any untoward medical occurrence in a participant administered a medicinal investigational drug. The untoward medical occurrence does not necessarily have to have a causal relationship with treatment. A TEAE is defined as an AE that occurs after administration of first dose of study drug and through 30 days after last dose of study drug or until start of subsequent antineoplastic therapy. Pembrolizumab is denoted as Pem. Safety Analysis Set included participants who received at least 1 dose, even if incomplete, of study drug.

End point type	Secondary

End point timeframe:

Up to approximately 25 months

End point values	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg	Dose Expansion: Cohort B: Cervical Cancer	Dose Expansion: Cohort C: MSS-CRC
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14	9	21	9
Units: participants				
TEAE Resulting in Dose Modifications of TAK-981	11	6	15	5
TEAE Resulting in Dose Modifications of Pem	7	5	12	4
TEAE Resulting in Drug Discontinuation of TAK-981	1	1	6	0
TEAE Resulting in Drug Discontinuation of Pem	1	3	4	0

End point values	Dose Expansion: Cohort D: Cutaneous Melanoma	Dose Expansion: Cohort E: Squamous NSCLC	Dose Expansion: Cohort F: CPI Refractory Squamous or NSCLC	

Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	28	15	4	
Units: participants				
TEAE Resulting in Dose Modifications of TAK-981	15	6	4	
TEAE Resulting in Dose Modifications of Pem	13	2	4	
TEAE Resulting in Drug Discontinuation of TAK-981	6	1	0	
TEAE Resulting in Drug Discontinuation of Pem	3	1	0	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Phase 1: Up to approximately 24 months, Phase 2: Up to approximately 25 months

Adverse event reporting additional description:

Safety Analysis Set included participants who received at least 1 dose, even if incomplete, of study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Dose Escalation: TAK-981 40 mg + Pembrolizumab

Reporting group description:

Participants received TAK-981 40 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).

Reporting group title	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg

Reporting group description:

Participants with non-squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Reporting group title	Dose Expansion: Cohort B: Cervical Cancer

Reporting group description:

Participants with cervical cancer received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Reporting group title	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg

Reporting group description:

Participants with non-squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Reporting group title	Dose Expansion: Cohort D: Cutaneous Melanoma

Reporting group description:

Participants with cutaneous melanoma received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Reporting group title	Dose Expansion: Cohort F: CPI Refractory Squamous/NSCLC

Reporting group description:

Participants with CPI refractory squamous or non-squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Reporting group title	Dose Expansion: Cohort E: Squamous NSCLC

Reporting group description:

Participants with squamous NSCLC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Reporting group title	Dose Expansion: Cohort C: MSS-CRC

Reporting group description:

Participants with MSS-CRC received TAK-981 as IV infusion on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle up to disease progression or 24-months and pembrolizumab 200 mg IV infusion as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle for a maximum of 24 months.

Reporting group title	Dose Escalation: TAK-981 120 mg + Pembrolizumab

Reporting group description:

Participants received TAK-981, 120 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).

Reporting group title	Dose Escalation: TAK-981 90 mg + Pembrolizumab

Reporting group description:

Participants received TAK-981 90 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).

Reporting group title	Dose Escalation: TAK-981 60 mg + Pembrolizumab

Reporting group description:

Participants received TAK-981 60 mg, IV infusion, on Days 1, 4, 8 and 11 or Days 1 and 8 in each 21-day Treatment Cycle and pembrolizumab 200 mg, IV infusion, as a fixed dose every 3 weeks on Day 1 of 21-day Treatment Cycle until the RP2D was determined (for a maximum of 24 months).

Serious adverse events	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg	Dose Expansion: Cohort B: Cervical Cancer
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	4 / 9 (44.44%)	11 / 21 (52.38%)
number of deaths (all causes)	2	4	9
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (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
Cervix carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic malignant melanoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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			
Aortic aneurysm rupture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
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 system disorders			

Anaphylactic shock			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
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 lung disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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			
Mental status changes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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			
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (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
Injury, poisoning and procedural complications			
Tracheal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis radiation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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 complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-related acute lung injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemothorax			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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			
Ischaemic stroke			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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			

Aplasia pure red cell			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	2 / 21 (9.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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 / 3 (0.00%)	2 / 9 (22.22%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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 function abnormal			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant biliary obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatomyositis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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			
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
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			
Myalgia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	2 / 21 (9.52%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (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			
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
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	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg	Dose Expansion: Cohort D: Cutaneous Melanoma	Dose Expansion: Cohort F: CPI Refractory Squamous/NSCLC
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 14 (21.43%)	14 / 28 (50.00%)	3 / 4 (75.00%)
number of deaths (all causes)	2	8	1
number of deaths resulting from adverse events	0	2	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix carcinoma			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			

subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected neoplasm			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (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
Metastases to central nervous system			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (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
Metastatic malignant melanoma			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (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
Vascular disorders			
Aortic aneurysm rupture			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
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%)	1 / 28 (3.57%)	0 / 4 (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			
Fatigue			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
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 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (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
Device related thrombosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
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%)	1 / 28 (3.57%)	0 / 4 (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
Malaise			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (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
Oedema peripheral			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			

Anaphylactic shock			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytokine release syndrome			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
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 lung disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
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 / 14 (0.00%)	1 / 28 (3.57%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (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

Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
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			
Platelet count decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
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			
Tracheal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis radiation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (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 complication			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion-related acute lung injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemothorax			

subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
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			
Arrhythmia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (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
Atrioventricular block			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
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			
Ischaemic stroke			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	0 / 4 (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
Spinal cord compression			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Aplasia pure red cell			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
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 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			

subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
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 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
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 function abnormal			

subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
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 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant biliary obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatomyositis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
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			
Hydronephrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
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			
Myalgia			

subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (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
Gastroenteritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (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 infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (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

Serious adverse events	Dose Expansion: Cohort E: Squamous NSCLC	Dose Expansion: Cohort C: MSS-CRC	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 15 (33.33%)	4 / 9 (44.44%)	10 / 19 (52.63%)
number of deaths (all causes)	2	2	4
number of deaths resulting from adverse events	1	1	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervix carcinoma			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected neoplasm			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Metastases to central nervous system			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-small cell lung cancer			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastatic malignant melanoma			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic aneurysm rupture			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypotension			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related thrombosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			

Anaphylactic shock			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytokine release syndrome			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated lung disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Platelet count decreased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Tracheal obstruction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis radiation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Transfusion-related acute lung injury			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Traumatic haemothorax			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Aplasia pure red cell			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea haemorrhagic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			

subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	2 / 19 (10.53%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic function abnormal			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant biliary obstruction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatomyositis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Myalgia			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	
Total subjects affected by serious adverse events			
subjects affected / exposed	17 / 33 (51.52%)	3 / 6 (50.00%)	
number of deaths (all causes)	8	2	
number of deaths resulting from adverse events	4	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Acute myeloid leukaemia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cancer pain			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervix carcinoma			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colorectal cancer			

subjects affected / exposed	0 / 33 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Infected neoplasm			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant neoplasm progression			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Metastases to central nervous system			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-small cell lung cancer			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Malignant melanoma			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic malignant melanoma			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Aortic aneurysm rupture			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related thrombosis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malaise			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			

Anaphylactic shock			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cytokine release syndrome			
subjects affected / exposed	3 / 33 (9.09%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated lung disease			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Tracheal obstruction			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis radiation			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion related reaction			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transfusion-related acute lung injury			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Traumatic haemothorax			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	0 / 33 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			

Aplasia pure red cell			
subjects affected / exposed	0 / 33 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea haemorrhagic			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal obstruction			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 33 (0.00%)	1 / 6 (16.67%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Impaired gastric emptying			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis acute			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic function abnormal			

subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant biliary obstruction			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatomyositis			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Hydronephrosis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Myalgia			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orchitis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 2	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Dose Escalation: TAK-981 40 mg + Pembrolizumab	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 120 mg	Dose Expansion: Cohort B: Cervical Cancer
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	9 / 9 (100.00%)	21 / 21 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Nervous system neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Colon cancer			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Poor peripheral circulation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vasculitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Early satiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 9 (33.33%)	4 / 21 (19.05%)
occurrences (all)	0	3	5
Chills			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Fatigue			
subjects affected / exposed	2 / 3 (66.67%)	5 / 9 (55.56%)	6 / 21 (28.57%)
occurrences (all)	3	8	6
Feeling cold			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Injection site pain			

subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	2 / 21 (9.52%)
occurrences (all)	0	1	3
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	4 / 9 (44.44%)	11 / 21 (52.38%)
occurrences (all)	0	19	40
General physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Injection site erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	3
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	2 / 21 (9.52%)
occurrences (all)	0	2	3
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Swelling face			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Localised oedema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	2
Reproductive system and breast disorders			
Epididymal cyst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Penile oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Perineal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	3
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 9 (11.11%)	2 / 21 (9.52%)
occurrences (all)	1	2	2
Oropharyngeal pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	2 / 21 (9.52%)
occurrences (all)	0	1	2
Libido decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	4 / 21 (19.05%)
occurrences (all)	0	2	10
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 3 (0.00%)	4 / 9 (44.44%)	4 / 21 (19.05%)
occurrences (all)	0	6	11
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	4 / 21 (19.05%)
occurrences (all)	0	5	9
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
CD4 lymphocytes decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	3
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			

subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram ST-T segment abnormal			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Interleukin level increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	4 / 21 (19.05%)
occurrences (all)	0	0	10
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Procalcitonin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	5
N-terminal prohormone brain natriuretic peptide increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
T-lymphocyte count decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	6
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	2 / 21 (9.52%)
occurrences (all)	0	1	2
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	7
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	13
Oral contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Paroxysmal arrhythmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Hypoaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	2

Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Burning sensation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	13 / 21 (61.90%)
occurrences (all)	0	5	24
Anaemia of chronic disease			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Anaemia of malignant disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Neutropenia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	2 / 21 (9.52%)
occurrences (all)	0	10	12
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 21 (4.76%)
occurrences (all)	0	4	4
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 21 (4.76%)
occurrences (all)	0	1	2
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	6
Lymph node pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Ocular hyperaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	5 / 21 (23.81%)
occurrences (all)	0	1	5
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Angular cheilitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	1 / 3 (33.33%)	2 / 9 (22.22%)	7 / 21 (33.33%)
occurrences (all)	1	4	8
Defaecation urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	4
Cheilitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	2 / 21 (9.52%)
occurrences (all)	0	1	2
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Large intestine polyp			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Intestinal polyp			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	6 / 9 (66.67%)	9 / 21 (42.86%)
occurrences (all)	1	10	14

Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Lip oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 3 (66.67%)	2 / 9 (22.22%)	5 / 21 (23.81%)
occurrences (all)	2	2	5
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cholangitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dermatitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	4
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Dermatitis bullous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dermatitis psoriasiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Perioral dermatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Psoriasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	2 / 21 (9.52%)
occurrences (all)	0	2	3
Rash vesicular			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	9
Rash macular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Cystitis noninfective			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	2 / 21 (9.52%)
occurrences (all)	0	1	2
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Hydronephrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 21 (4.76%)
occurrences (all)	0	1	1
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	5 / 21 (23.81%)
occurrences (all)	0	0	5
Adrenal insufficiency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Musculoskeletal and connective tissue disorders			
Joint stiffness			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Arthralgia			
subjects affected / exposed	2 / 3 (66.67%)	1 / 9 (11.11%)	4 / 21 (19.05%)
occurrences (all)	2	2	4
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Bone disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	3 / 21 (14.29%)
occurrences (all)	0	0	35
Musculoskeletal stiffness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	1 / 3 (33.33%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	1	2	0
Polyarthritis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Osteoarthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	2
Tendon disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Balanitis candida			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Dengue fever			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	2
Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	2
Gastroenteritis norovirus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0

Eye infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Kidney infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	2 / 21 (9.52%)
occurrences (all)	0	3	5
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Orchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Pulpitis dental			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 9 (11.11%)	1 / 21 (4.76%)
occurrences (all)	1	1	2

Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Urethritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	6 / 21 (28.57%)
occurrences (all)	0	1	10
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	1 / 21 (4.76%)
occurrences (all)	0	0	1
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			

subjects affected / exposed	0 / 3 (0.00%)	4 / 9 (44.44%)	4 / 21 (19.05%)
occurrences (all)	0	6	4
Abnormal weight gain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Abnormal loss of weight			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	3 / 21 (14.29%)
occurrences (all)	0	1	4
Hypochloraemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	1 / 21 (4.76%)
occurrences (all)	0	1	17
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	3	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 9 (22.22%)	1 / 21 (4.76%)
occurrences (all)	0	2	1
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	0 / 21 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 9 (0.00%)	2 / 21 (9.52%)
occurrences (all)	0	0	3
Steroid diabetes			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	2 / 21 (9.52%)
occurrences (all)	0	1	20
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	2 / 21 (9.52%)
occurrences (all)	0	4	3
Hypokalaemia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 9 (22.22%)	1 / 21 (4.76%)
occurrences (all)	2	5	3
Hypoproteinaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	2	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 9 (11.11%)	0 / 21 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Dose Expansion: Cohort A: Non-squamous NSCLC TAK-981 90 mg	Dose Expansion: Cohort D: Cutaneous Melanoma	Dose Expansion: Cohort F: CPI Refractory Squamous/NSCLC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 14 (100.00%)	28 / 28 (100.00%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Nervous system neoplasm			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour associated fever			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Cancer pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Colon cancer			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Hypotension			
subjects affected / exposed	1 / 14 (7.14%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	7	2	0
Poor peripheral circulation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 14 (0.00%)	3 / 28 (10.71%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Vasculitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Early satiety			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	1 / 4 (25.00%)
occurrences (all)	0	2	2
Chills			
subjects affected / exposed	5 / 14 (35.71%)	4 / 28 (14.29%)	1 / 4 (25.00%)
occurrences (all)	8	6	1
Fatigue			
subjects affected / exposed	5 / 14 (35.71%)	9 / 28 (32.14%)	1 / 4 (25.00%)
occurrences (all)	9	12	1
Feeling cold			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Injection site pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			

subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	9 / 14 (64.29%)	11 / 28 (39.29%)	1 / 4 (25.00%)
occurrences (all)	21	80	1
General physical health deterioration			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Influenza like illness			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Infusion site extravasation			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Injection site erythema			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	2 / 14 (14.29%)	5 / 28 (17.86%)	0 / 4 (0.00%)
occurrences (all)	5	5	0
Pain			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Malaise			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Swelling face			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			

Cytokine release syndrome			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	1	3	0
Reproductive system and breast disorders			
Epididymal cyst			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Penile oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Perineal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 14 (14.29%)	10 / 28 (35.71%)	0 / 4 (0.00%)
occurrences (all)	2	11	0
Dyspnoea exertional			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dysphonia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	2 / 14 (14.29%)	1 / 28 (3.57%)	2 / 4 (50.00%)
occurrences (all)	2	1	2
Oropharyngeal pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Rhinorrhoea			

subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	1 / 14 (7.14%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Pleural effusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Psychiatric disorders			
Agitation			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Anxiety			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Depression			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Hallucination			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Libido decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 14 (14.29%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	3	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	4 / 14 (28.57%)	3 / 28 (10.71%)	0 / 4 (0.00%)
occurrences (all)	9	3	0
Alanine aminotransferase increased			

subjects affected / exposed	4 / 14 (28.57%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	5	3	0
Blood bilirubin increased			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Blood creatinine increased			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	1 / 4 (25.00%)
occurrences (all)	1	1	2
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CD4 lymphocytes decreased			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 14 (0.00%)	5 / 28 (17.86%)	0 / 4 (0.00%)
occurrences (all)	0	8	0
Brain natriuretic peptide increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	2 / 4 (50.00%)
occurrences (all)	0	1	3
Blood pressure increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ejection fraction decreased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Electrocardiogram ST-T segment abnormal			

subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Interleukin level increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 14 (7.14%)	3 / 28 (10.71%)	0 / 4 (0.00%)
occurrences (all)	7	5	0
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Procalcitonin increased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	1 / 14 (7.14%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	4	3	0
Neutrophil count decreased			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
N-terminal prohormone brain natriuretic peptide increased			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
T-lymphocyte count decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Oral contusion			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	4	1	0
Atrial flutter			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Cardiac failure			

subjects affected / exposed	1 / 14 (7.14%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Palpitations			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pericardial effusion			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paroxysmal arrhythmia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Cerebrovascular accident			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	3 / 14 (21.43%)	5 / 28 (17.86%)	0 / 4 (0.00%)
occurrences (all)	3	12	0
Hypoaesthesia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Paraesthesia			
subjects affected / exposed	2 / 14 (14.29%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0

Burning sensation			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Parosmia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 14 (21.43%)	7 / 28 (25.00%)	2 / 4 (50.00%)
occurrences (all)	5	9	7
Anaemia of chronic disease			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anaemia of malignant disease			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Neutropenia			
subjects affected / exposed	4 / 14 (28.57%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	8	3	0
Thrombocytopenia			

subjects affected / exposed	2 / 14 (14.29%)	2 / 28 (7.14%)	1 / 4 (25.00%)
occurrences (all)	8	4	1
Lymphopenia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Leukocytosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Leukopenia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Lymph node pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Visual acuity reduced			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Ocular hyperaemia			

subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Abdominal distension			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anal fissure			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Angular cheilitis			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
subjects affected / exposed	3 / 14 (21.43%)	7 / 28 (25.00%)	1 / 4 (25.00%)
occurrences (all)	3	17	1
Defaecation urgency			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Cheilitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Flatulence			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	3 / 14 (21.43%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	3	1	0
Dysphagia			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Large intestine polyp			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Intestinal polyp			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Odynophagia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Nausea			
subjects affected / exposed	3 / 14 (21.43%)	13 / 28 (46.43%)	1 / 4 (25.00%)
occurrences (all)	6	40	1
Mouth ulceration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Lip oedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tongue ulceration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	4 / 14 (28.57%)	4 / 28 (14.29%)	1 / 4 (25.00%)
occurrences (all)	5	19	6
Stomatitis			
subjects affected / exposed	4 / 14 (28.57%)	8 / 28 (28.57%)	0 / 4 (0.00%)
occurrences (all)	4	16	0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cholangitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertransaminasaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dermatitis acneiform			

subjects affected / exposed	0 / 14 (0.00%)	4 / 28 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	7	0
Alopecia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Erythema			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dermatitis bullous			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis psoriasiform			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Perioral dermatitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	2	0

Psoriasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Pruritus			
subjects affected / exposed	1 / 14 (7.14%)	6 / 28 (21.43%)	0 / 4 (0.00%)
occurrences (all)	1	9	0
Rash vesicular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 14 (7.14%)	3 / 28 (10.71%)	0 / 4 (0.00%)
occurrences (all)	1	6	0
Rash macular			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vitiligo			
subjects affected / exposed	0 / 14 (0.00%)	7 / 28 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	10	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cystitis noninfective			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Leukocyturia			

subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Proteinuria			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	2 / 14 (14.29%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Dysuria			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Hydronephrosis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal impairment			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Urinary incontinence			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypothyroidism			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Adrenal insufficiency			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			

Joint stiffness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	5	0	0
Arthralgia			
subjects affected / exposed	4 / 14 (28.57%)	5 / 28 (17.86%)	0 / 4 (0.00%)
occurrences (all)	13	5	0
Back pain			
subjects affected / exposed	3 / 14 (21.43%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	3	2	0
Bone disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	1 / 14 (7.14%)	5 / 28 (17.86%)	0 / 4 (0.00%)
occurrences (all)	1	9	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Musculoskeletal pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Neck pain			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Polyarthritis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Pain in extremity			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Osteoarthritis			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Spinal pain			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tendon disorder			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Balanitis candida			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
COVID-19			
subjects affected / exposed	3 / 14 (21.43%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	3	2	0
Dengue fever			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye infection			

subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Herpes zoster			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Kidney infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	2 / 14 (14.29%)	0 / 28 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	2
Oral candidiasis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Orchitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pulpitis dental			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	1 / 14 (7.14%)	2 / 28 (7.14%)	1 / 4 (25.00%)
occurrences (all)	1	2	2
Upper respiratory tract infection			

subjects affected / exposed	1 / 14 (7.14%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	1	2	0
Urethritis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	1 / 14 (7.14%)	5 / 28 (17.86%)	0 / 4 (0.00%)
occurrences (all)	3	7	0
Sinusitis			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Skin candida			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Tinea pedis			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	1 / 14 (7.14%)	5 / 28 (17.86%)	3 / 4 (75.00%)
occurrences (all)	1	6	4

Abnormal weight gain			
subjects affected / exposed	0 / 14 (0.00%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	0	4	0
Abnormal loss of weight			
subjects affected / exposed	1 / 14 (7.14%)	3 / 28 (10.71%)	1 / 4 (25.00%)
occurrences (all)	1	3	1
Hypochloraemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	2 / 14 (14.29%)	3 / 28 (10.71%)	3 / 4 (75.00%)
occurrences (all)	9	3	3
Hyperuricaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hyperphosphataemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	2 / 14 (14.29%)	2 / 28 (7.14%)	0 / 4 (0.00%)
occurrences (all)	2	2	0
Steroid diabetes			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 14 (7.14%)	1 / 28 (3.57%)	0 / 4 (0.00%)
occurrences (all)	1	2	0

Hypomagnesaemia			
subjects affected / exposed	1 / 14 (7.14%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Hypokalaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoproteinaemia			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 14 (0.00%)	0 / 28 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Dose Expansion: Cohort E: Squamous NSCLC	Dose Expansion: Cohort C: MSS-CRC	Dose Escalation: TAK-981 120 mg + Pembrolizumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 15 (93.33%)	9 / 9 (100.00%)	19 / 19 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Nervous system neoplasm			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Tumour associated fever			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Tumour pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Cancer pain			
subjects affected / exposed	0 / 15 (0.00%)	2 / 9 (22.22%)	1 / 19 (5.26%)
occurrences (all)	0	3	1
Colon cancer			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	2 / 19 (10.53%)
occurrences (all)	0	3	3

Poor peripheral circulation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Hot flush			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Vasculitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Early satiety			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	3 / 15 (20.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	3	0	0
Chills			
subjects affected / exposed	1 / 15 (6.67%)	1 / 9 (11.11%)	11 / 19 (57.89%)
occurrences (all)	1	1	20
Fatigue			
subjects affected / exposed	0 / 15 (0.00%)	5 / 9 (55.56%)	4 / 19 (21.05%)
occurrences (all)	0	8	9
Feeling cold			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed	6 / 15 (40.00%)	3 / 9 (33.33%)	14 / 19 (73.68%)
occurrences (all)	22	4	59
General physical health deterioration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	3 / 19 (15.79%)
occurrences (all)	0	0	5
Infusion site extravasation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Injection site erythema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	3 / 19 (15.79%)
occurrences (all)	0	0	5
Pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 15 (6.67%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Swelling face			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Localised oedema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	8

Reproductive system and breast disorders			
Epididymal cyst			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Penile oedema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Perineal pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 15 (0.00%)	2 / 9 (22.22%)	4 / 19 (21.05%)
occurrences (all)	0	2	4
Dyspnoea exertional			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Epistaxis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Haemoptysis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Dysphonia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	4 / 19 (21.05%)
occurrences (all)	0	1	6
Oropharyngeal pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Rhinorrhoea			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Productive cough			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Depression			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Hallucination			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Libido decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 15 (6.67%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	1	1	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 15 (6.67%)	2 / 9 (22.22%)	2 / 19 (10.53%)
occurrences (all)	2	3	2
Alanine aminotransferase increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Blood bilirubin increased			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
CD4 lymphocytes decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Brain natriuretic peptide increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Ejection fraction decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Electrocardiogram ST-T segment abnormal			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			

subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Interleukin level increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	2 / 15 (13.33%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	9	0	1
SARS-CoV-2 test positive			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Procalcitonin increased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Platelet count decreased			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	3 / 19 (15.79%)
occurrences (all)	1	0	7
Neutrophil count decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
N-terminal prohormone brain natriuretic peptide increased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
T-lymphocyte count decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	2 / 19 (10.53%)
occurrences (all)	0	2	4
White blood cell count decreased			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Injury, poisoning and procedural complications			
Limb injury			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Infusion related reaction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	4
Oral contusion			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Fall			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Sinus tachycardia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	2 / 19 (10.53%)
occurrences (all)	1	0	2
Supraventricular tachycardia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Atrial fibrillation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Atrial flutter			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cardiac failure			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	1 / 19 (5.26%)
occurrences (all)	0	1	2
Pericardial effusion			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Paroxysmal arrhythmia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Depressed level of consciousness			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 15 (0.00%)	2 / 9 (22.22%)	1 / 19 (5.26%)
occurrences (all)	0	2	1
Headache			
subjects affected / exposed	0 / 15 (0.00%)	2 / 9 (22.22%)	4 / 19 (21.05%)
occurrences (all)	0	4	4
Hypoaesthesia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Burning sensation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1

Seizure			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Parosmia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Polyneuropathy			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 15 (13.33%)	3 / 9 (33.33%)	6 / 19 (31.58%)
occurrences (all)	2	8	7
Anaemia of chronic disease			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Anaemia of malignant disease			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	2	0	0
Neutropenia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 9 (11.11%)	4 / 19 (21.05%)
occurrences (all)	1	1	18
Lymphopenia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Lymph node pain			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Tinnitus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Visual acuity reduced			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ocular hyperaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 15 (0.00%)	3 / 9 (33.33%)	1 / 19 (5.26%)
occurrences (all)	0	4	1
Abdominal distension			
subjects affected / exposed	0 / 15 (0.00%)	2 / 9 (22.22%)	0 / 19 (0.00%)
occurrences (all)	0	2	0
Anal fissure			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Angular cheilitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	3 / 15 (20.00%)	3 / 9 (33.33%)	9 / 19 (47.37%)
occurrences (all)	5	4	12
Defaecation urgency			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Cheilitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Dry mouth			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Large intestine polyp			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Intestinal polyp			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Rectal haemorrhage			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Odynophagia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 15 (6.67%)	2 / 9 (22.22%)	5 / 19 (26.32%)
occurrences (all)	1	2	5
Mouth ulceration			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Lip oedema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Tongue ulceration			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 15 (6.67%)	2 / 9 (22.22%)	5 / 19 (26.32%)
occurrences (all)	1	2	6
Stomatitis			
subjects affected / exposed	1 / 15 (6.67%)	3 / 9 (33.33%)	8 / 19 (42.11%)
occurrences (all)	5	4	11
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Cholangitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hyperbilirubinaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	3
Hypertransaminasaemia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Dermatitis			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Alopecia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Erythema			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Dermatitis bullous			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Dermatitis psoriasiform			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Hyperhidrosis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Ingrowing nail			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Perioral dermatitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	2 / 19 (10.53%)
occurrences (all)	0	0	2
Psoriasis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1

Rash erythematous			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	3 / 19 (15.79%)
occurrences (all)	0	0	4
Rash vesicular			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	4 / 19 (21.05%)
occurrences (all)	0	0	6
Rash macular			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Vitiligo			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Cystitis noninfective			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Haematuria			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hydronephrosis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Renal impairment			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Urinary retention			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Adrenal insufficiency			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Joint stiffness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Arthralgia			

subjects affected / exposed	1 / 15 (6.67%)	2 / 9 (22.22%)	3 / 19 (15.79%)
occurrences (all)	1	2	6
Back pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Bone disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal stiffness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Polyarthritis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Osteoarthritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Spinal pain			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tendon disorder			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Balanitis candida			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Dengue fever			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal infection			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis norovirus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Eye infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Herpes simplex reactivation			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Herpes zoster			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Kidney infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	3 / 19 (15.79%)
occurrences (all)	0	1	3
Oral candidiasis			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Orchitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pulpitis dental			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 15 (6.67%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	1	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urethritis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	1 / 19 (5.26%)
occurrences (all)	0	1	1

Sinusitis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Skin candida			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Skin infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Tinea pedis			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Dehydration			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	1 / 19 (5.26%)
occurrences (all)	0	2	2
Decreased appetite			
subjects affected / exposed	1 / 15 (6.67%)	3 / 9 (33.33%)	6 / 19 (31.58%)
occurrences (all)	1	4	7
Abnormal weight gain			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Abnormal loss of weight			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Hypochloraemia			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	2
Hypoalbuminaemia			
subjects affected / exposed	2 / 15 (13.33%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	3	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	1 / 19 (5.26%)
occurrences (all)	0	0	1
Hyperphosphataemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Steroid diabetes			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 15 (6.67%)	1 / 9 (11.11%)	0 / 19 (0.00%)
occurrences (all)	3	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 15 (0.00%)	1 / 9 (11.11%)	1 / 19 (5.26%)
occurrences (all)	0	1	1
Hypokalaemia			
subjects affected / exposed	2 / 15 (13.33%)	1 / 9 (11.11%)	5 / 19 (26.32%)
occurrences (all)	4	2	7
Hypoproteinaemia			

subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 15 (0.00%)	0 / 9 (0.00%)	0 / 19 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Dose Escalation: TAK-981 90 mg + Pembrolizumab	Dose Escalation: TAK-981 60 mg + Pembrolizumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 33 (100.00%)	6 / 6 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Nervous system neoplasm			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tumour associated fever			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tumour pain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cancer pain			
subjects affected / exposed	0 / 33 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Colon cancer			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Hypotension			
subjects affected / exposed	3 / 33 (9.09%)	0 / 6 (0.00%)	
occurrences (all)	3	0	
Poor peripheral circulation			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Hypertension			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vasculitis			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	3	0	
General disorders and administration site conditions			
Early satiety			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Asthenia			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	3	0	
Chills			
subjects affected / exposed	12 / 33 (36.36%)	1 / 6 (16.67%)	
occurrences (all)	27	1	
Fatigue			
subjects affected / exposed	13 / 33 (39.39%)	1 / 6 (16.67%)	
occurrences (all)	15	1	
Feeling cold			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Injection site pain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Peripheral swelling			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	17 / 33 (51.52%)	1 / 6 (16.67%)	
occurrences (all)	37	5	
General physical health deterioration			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Influenza like illness			

subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Infusion site extravasation			
subjects affected / exposed	0 / 33 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Injection site erythema			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 33 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Oedema peripheral			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Pain			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Malaise			
subjects affected / exposed	4 / 33 (12.12%)	0 / 6 (0.00%)	
occurrences (all)	7	0	
Swelling face			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Localised oedema			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	3 / 33 (9.09%)	0 / 6 (0.00%)	
occurrences (all)	4	0	
Reproductive system and breast disorders			
Epididymal cyst			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Penile oedema			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Perineal pain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 33 (9.09%)	0 / 6 (0.00%)	
occurrences (all)	3	0	
Dyspnoea exertional			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Haemoptysis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dysphonia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Dyspnoea			
subjects affected / exposed	5 / 33 (15.15%)	0 / 6 (0.00%)	
occurrences (all)	5	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rhinorrhoea			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Productive cough			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pleural effusion			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Agitation			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Anxiety			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Depression			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Hallucination			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Libido decreased			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	5 / 33 (15.15%)	0 / 6 (0.00%)	
occurrences (all)	5	0	
Aspartate aminotransferase increased			
subjects affected / exposed	13 / 33 (39.39%)	0 / 6 (0.00%)	
occurrences (all)	17	0	
Alanine aminotransferase increased			
subjects affected / exposed	7 / 33 (21.21%)	0 / 6 (0.00%)	
occurrences (all)	8	0	
Blood bilirubin increased			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood creatinine increased			

subjects affected / exposed	3 / 33 (9.09%)	0 / 6 (0.00%)		
occurrences (all)	7	0		
Blood thyroid stimulating hormone increased				
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
CD4 lymphocytes decreased				
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Blood lactate dehydrogenase increased				
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)		
occurrences (all)	2	0		
Brain natriuretic peptide increased				
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
C-reactive protein increased				
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Blood pressure increased				
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Ejection fraction decreased				
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Electrocardiogram QT prolonged				
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)		
occurrences (all)	1	0		
Electrocardiogram ST-T segment abnormal				
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Gamma-glutamyltransferase increased				
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)		
occurrences (all)	1	0		
Interleukin level increased				

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Lipase increased			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Lymphocyte count decreased			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
SARS-CoV-2 test positive			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Procalcitonin increased			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Platelet count decreased			
subjects affected / exposed	6 / 33 (18.18%)	0 / 6 (0.00%)	
occurrences (all)	14	0	
Neutrophil count decreased			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	5	0	
N-terminal prohormone brain natriuretic peptide increased			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
T-lymphocyte count decreased			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Weight decreased			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
White blood cell count decreased			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	4	0	
Injury, poisoning and procedural complications			

Limb injury			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Infusion related reaction			
subjects affected / exposed	7 / 33 (21.21%)	0 / 6 (0.00%)	
occurrences (all)	19	0	
Oral contusion			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Fall			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Sinus tachycardia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Supraventricular tachycardia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Atrial fibrillation			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Atrial flutter			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cardiac failure			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Palpitations			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pericardial effusion			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Paroxysmal arrhythmia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cerebrovascular accident			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Depressed level of consciousness			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dizziness			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Dysgeusia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Headache			
subjects affected / exposed	6 / 33 (18.18%)	1 / 6 (16.67%)	
occurrences (all)	7	1	
Hypoaesthesia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Burning sensation			
subjects affected / exposed	0 / 33 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	2	
Restless legs syndrome			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Seizure			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tremor			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Parosmia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Polyneuropathy			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	16 / 33 (48.48%)	1 / 6 (16.67%)	
occurrences (all)	32	3	
Anaemia of chronic disease			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Anaemia of malignant disease			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Neutropenia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Thrombocytopenia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Lymphopenia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Leukocytosis			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Leukopenia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Lymph node pain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vertigo			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tinnitus			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Diplopia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Visual acuity reduced			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Ocular hyperaemia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Abdominal pain lower			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	3 / 33 (9.09%)	0 / 6 (0.00%)	
occurrences (all)	3	0	
Abdominal distension			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Anal fissure			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Angular cheilitis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			
subjects affected / exposed	9 / 33 (27.27%)	0 / 6 (0.00%)	
occurrences (all)	16	0	
Defaecation urgency			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	3 / 33 (9.09%)	1 / 6 (16.67%)	
occurrences (all)	3	1	
Cheilitis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Ascites			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Flatulence			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dyspepsia			
subjects affected / exposed	1 / 33 (3.03%)	1 / 6 (16.67%)	
occurrences (all)	3	1	
Dry mouth			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dysphagia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Large intestine polyp			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Intestinal polyp			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rectal haemorrhage			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Odynophagia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nausea			
subjects affected / exposed	8 / 33 (24.24%)	0 / 6 (0.00%)	
occurrences (all)	10	0	
Mouth ulceration			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Lip oedema			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Haemorrhoids			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tongue ulceration			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	7 / 33 (21.21%)	0 / 6 (0.00%)	
occurrences (all)	7	0	
Stomatitis			
subjects affected / exposed	8 / 33 (24.24%)	0 / 6 (0.00%)	
occurrences (all)	13	0	
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cholangitis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyperbilirubinaemia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Hypertransaminasaemia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Angioedema			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dermatitis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dermatitis acneiform			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Alopecia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Erythema			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Dermatitis bullous				
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Dry skin				
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)		
occurrences (all)	1	0		
Dermatitis psoriasiform				
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Hyperhidrosis				
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)		
occurrences (all)	3	0		
Ingrowing nail				
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Rash				
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Perioral dermatitis				
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Palmar-plantar erythrodysaesthesia syndrome				
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		
Night sweats				
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)		
occurrences (all)	1	0		
Psoriasis				
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)		
occurrences (all)	1	0		
Skin ulcer				
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)		
occurrences (all)	0	0		

Rash erythematous			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rash vesicular			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Rash maculo-papular			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	4	0	
Rash macular			
subjects affected / exposed	0 / 33 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Urticaria			
subjects affected / exposed	0 / 33 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Vitiligo			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Cystitis noninfective			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Leukocyturia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Proteinuria			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Haematuria			

subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Dysuria			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hydronephrosis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Renal impairment			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Urinary retention			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Urinary incontinence			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	3	0	
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Hypothyroidism			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Adrenal insufficiency			
subjects affected / exposed	0 / 33 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Musculoskeletal and connective tissue disorders			
Joint stiffness			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Bone pain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Arthralgia			

subjects affected / exposed	5 / 33 (15.15%)	2 / 6 (33.33%)	
occurrences (all)	5	2	
Back pain			
subjects affected / exposed	3 / 33 (9.09%)	1 / 6 (16.67%)	
occurrences (all)	4	1	
Bone disorder			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	3 / 33 (9.09%)	0 / 6 (0.00%)	
occurrences (all)	4	0	
Musculoskeletal stiffness			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal pain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Neck pain			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Muscular weakness			
subjects affected / exposed	1 / 33 (3.03%)	1 / 6 (16.67%)	
occurrences (all)	2	1	
Polyarthritis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	4	0	
Osteoarthritis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Spinal pain			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tendon disorder			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Balanitis candida			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
COVID-19			
subjects affected / exposed	1 / 33 (3.03%)	1 / 6 (16.67%)	
occurrences (all)	1	1	
Dengue fever			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal infection			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Influenza			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Infection			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis norovirus			
subjects affected / exposed	0 / 33 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Eye infection			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Herpes simplex reactivation			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Herpes zoster			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

Kidney infection			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Paronychia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Oral herpes			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Oral candidiasis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Orchitis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pulpitis dental			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Urethritis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	4 / 33 (12.12%)	0 / 6 (0.00%)	
occurrences (all)	5	0	

Sinusitis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin candida			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Skin infection			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Tinea pedis			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Viral infection			
subjects affected / exposed	1 / 33 (3.03%)	1 / 6 (16.67%)	
occurrences (all)	1	1	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 33 (0.00%)	1 / 6 (16.67%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Diabetes mellitus			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Dehydration			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Decreased appetite			
subjects affected / exposed	10 / 33 (30.30%)	0 / 6 (0.00%)	
occurrences (all)	12	0	
Abnormal weight gain			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Abnormal loss of weight			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	1	0	
Hypochloraemia			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypocalcaemia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypoalbuminaemia			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	3	0	
Hyperuricaemia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyperphosphataemia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypertriglyceridaemia			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hyperglycaemia			
subjects affected / exposed	1 / 33 (3.03%)	0 / 6 (0.00%)	
occurrences (all)	2	0	
Steroid diabetes			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Hypophosphataemia			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	3	0	
Hyponatraemia			
subjects affected / exposed	2 / 33 (6.06%)	0 / 6 (0.00%)	
occurrences (all)	4	0	
Hypomagnesaemia			
subjects affected / exposed	3 / 33 (9.09%)	1 / 6 (16.67%)	
occurrences (all)	4	1	
Hypokalaemia			
subjects affected / exposed	3 / 33 (9.09%)	1 / 6 (16.67%)	
occurrences (all)	4	1	
Hypoproteinaemia			

subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 33 (0.00%)	0 / 6 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
22 April 2020	The following changes were made as per amendment 01: 1. Modified inclusion and exclusion criteria. 2. Added a 90-day follow-up visit after last dose with the study treatment to capture any late-onset immune-related AEs. 3. Added AESI definition, procedure for recording and reporting AESIs, and monitoring of AESIs.
10 February 2021	The following changes were made as per amendment 02: 1.Modified inclusion criteria. 2. Added DCR, DRR, TTP, and OS as secondary endpoints for disclosure for phase 2.
23 April 2021	The following changes were made as per amendment 03: 1. Incorporated additional local laboratory assessments for safety during Cycle 1. 2. Provided guidance on COVID-19 vaccination and procedures during the trial.
09 September 2021	The primary reason for amendment 04 was to update the translational strategy for sample collection for analysis of biomarkers in phase 2.
01 July 2022	The primary reason for amendment 05 was to expand phase 2 enrollment in Cohort A to evaluate the dose regimen of subasumstat at 120 mg QW in addition to the 90 mg BIW dose regimen.
22 June 2023	The primary reason for amendment 06 was to remove nonsquamous NSCLC, SCLC, and MSI-H/dMMR CRC populations.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported