Clinical trial results:
An Open Label, Dose-Escalation, Phase 1/2 Study to Evaluate the Safety, Tolerability, Preliminary Efficacy, and Pharmacokinetics of TAK-981 in Adult Patients With Advanced or Metastatic Solid Tumors or Relapsed/Refractory Hematologic Malignancies

Summary

EudraCT number	2020-003947-27
Trial protocol	PL ES BE
Global end of trial date	14 December 2023

Results information

Result version number	v1 (current)
This version publication date	09 November 2024
First version publication date	09 November 2024

Trial information

Trial identification

Sponsor protocol code	TAK-981-1002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03648372
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Takeda
Sponsor organisation address	95 Hayden Avenue, Lexington, United States, MA 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	14 December 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 December 2023
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The purpose of phase 1 was to determine the safety and tolerability of TAK-981 as a single agent in participants with advanced or metastatic solid tumors and lymphomas and to establish the recommended phase 2 dose (RP2D) of TAK-981 and for phase 2 was to evaluate preliminary efficacy of TAK-981 in participants with select solid tumors or relapsed/refractory CD20+ non-Hodgkin lymphoma (NHL) indications.

Protection of trial subjects:

This study was conducted with the highest respect for the individual participants, according to the protocol, the ethical principles that have their origin in the Declaration of Helsinki, the informed consent regulations stated in Title 21 CFR, Part 50, in accordance with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) GCP E6 §4.8, and all applicable local regulations.
Each investigator conducted the study according to applicable local or regional regulatory requirements and aligned his or her conduct in accordance with the responsibilities of the investigator. The Declaration of Helsinki ethical principles were addressed through the protocol and appendices containing requirements for informed consent and investigator responsibilities.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 October 2018
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	Belgium: 4
Country: Number of subjects enrolled	Spain: 2
Country: Number of subjects enrolled	China: 2
Country: Number of subjects enrolled	Poland: 9
Country: Number of subjects enrolled	United States: 92
Worldwide total number of subjects	109
EEA total number of subjects	15

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	66
From 65 to 84 years	43
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants took part in the study at 17 investigative sites in Poland, Belgium, Spain, the United States and China from 01 October 2018 to 14 December 2023.

Pre-assignment

Screening details:

Participants were enrolled in Phase 1 (Dose Escalation) and in Phase 2 (Dose Expansion) to receive TAK-981 doses.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Phase 1, Dose Escalation: TAK-981 3 mg BIW

Arm description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 3 milligram (mg), infusion, intravenously, twice weekly (BIW) on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 3 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 1.

Arm title	Phase 1, Dose Escalation: TAK-981 6 mg BIW

Arm description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 6 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 6 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 1.

Arm title	Phase 1, Dose Escalation: TAK-981 10 mg BIW

Arm description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 10 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or

discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 10 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 1.

Arm title	Phase 1, Dose Escalation: TAK-981 15 mg BIW

Arm description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 15 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 15 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 1.

Arm title	Phase 1, Dose Escalation: TAK-981 25 mg BIW

Arm description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 25 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 25 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 1.

Arm title	Phase 1, Dose Escalation: TAK-981 40 mg BIW

Arm description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 40 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 40 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 1.

Arm title	Phase 1, Dose Escalation: TAK-981 60 mg BIW

Arm description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 60 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 60 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 1.

Arm title	Phase 1, Dose Escalation: TAK-981 60 mg QW

Arm description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 60 mg, infusion, intravenously, once weekly (QW) on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 60 mg, infusion, intravenously, on Days 1 and 8 in a 21-day treatment cycle in Phase 1.

Arm title	Phase 1, Dose Escalation: TAK-981 75 mg BIW

Arm description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 75 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 75 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 1.

Arm title	Phase 1, Dose Escalation: TAK-981 75 mg QW

Arm description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 75 mg, infusion, intravenously, QW on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Arm type	Experimental

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

Dosage and administration details:

TAK-981 was administered as 75 mg, infusion, intravenously, on Days 1 and 8 in a 21-day treatment cycle in Phase 1.

Arm title	Phase 1, Dose Escalation: TAK-981 90 mg BIW

Arm description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 90 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 1.

Arm title	Phase 1, Dose Escalation: TAK-981 90 mg QW

Arm description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 90 mg, infusion, intravenously, QW on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 90 mg, infusion, intravenously, on Days 1 and 8 in a 21-day treatment cycle in Phase 1.

Arm title	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15

Arm description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 90 mg, infusion, intravenously, QW on Days 1, 8 and 15 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 90 mg, infusion, intravenously, on Days 1, 8 and 15 in a 21-day treatment cycle in Phase 1.

Arm title	Phase 1, Dose Escalation: TAK-981 120 mg BIW

Arm description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 120 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 120 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 1.

Arm title	Phase 1, Dose Escalation: TAK-981 120 mg QW

Arm description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 120 mg, infusion, intravenously, QW on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 120 mg, infusion, intravenously, on Days 1 and 8 in a 21-day treatment cycle in Phase 1.

Arm title	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW

Arm description:

Participants with non-squamous non-small cell lung cancer (NSCLC) received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 90 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 2.

Arm title	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW

Arm description:

Participants with cervical cancer received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 90 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 2.

Arm title	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW

Arm description:

Participants with microsatellite-stable colorectal cancer (MSS-CRC) received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 90 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 2.

Arm title	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW

Arm description:

Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) progressed or relapsed after chimeric antigen receptor (CAR) T-cell therapy received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 90 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 2.

Arm title	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW

Arm description:

Participants with relapsed/refractory DLBCL that have not received prior cellular therapy received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 90 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 2.

Arm title	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW

Arm description:

Participants with relapsed/refractory follicular lymphoma received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease

progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

Dosage and administration details:

TAK-981 was administered as 90 mg, infusion, intravenously, on Days 1, 4, 8 and 11 in a 21-day treatment cycle in Phase 2.

Number of subjects in period 1	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW
Started	5	3	4
Completed	1	0	0
Not completed	4	3	4
Consent withdrawn by subject	2	-	-
Start of a New Systemic Treatment	-	-	-
Progressive Disease	2	3	4
Unspecified	-	-	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Phase 1, Dose Escalation: TAK-981 15 mg BIW	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW
Started	3	4	4
Completed	0	1	1
Not completed	3	3	3
Consent withdrawn by subject	-	-	1
Start of a New Systemic Treatment	-	-	-
Progressive Disease	3	2	2
Unspecified	-	1	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW	Phase 1, Dose Escalation: TAK-981 75 mg BIW
Started	7	6	6
Completed	2	1	1
Not completed	5	5	5
Consent withdrawn by subject	2	-	-
Start of a New Systemic Treatment	-	2	-
Progressive Disease	3	3	5
Unspecified	-	-	-

Lost to follow-up	-	-	-

Number of subjects in period 1	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Started	6	8	7
Completed	1	2	2
Not completed	5	6	5
Consent withdrawn by subject	-	2	-
Start of a New Systemic Treatment	-	1	-
Progressive Disease	5	2	3
Unspecified	-	1	2
Lost to follow-up	-	-	-

Number of subjects in period 1	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW
Started	7	8	6
Completed	1	1	0
Not completed	6	7	6
Consent withdrawn by subject	2	-	-
Start of a New Systemic Treatment	-	-	-
Progressive Disease	3	3	6
Unspecified	1	3	-
Lost to follow-up	-	1	-

Number of subjects in period 1	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW
Started	7	3	7
Completed	1	1	1
Not completed	6	2	6
Consent withdrawn by subject	-	1	-
Start of a New Systemic Treatment	-	-	-
Progressive Disease	-	-	-
Unspecified	5	1	5
Lost to follow-up	1	-	1

Number of subjects in period 1	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW
Started	4	3	1
Completed	4	2	1
Not completed	0	1	0
Consent withdrawn by subject	-	-	-
Start of a New Systemic Treatment	-	-	-

Progressive Disease	-	-	-
Unspecified	-	1	-
Lost to follow-up	-	-	-

Baseline characteristics

Reporting groups

Reporting group title	Phase 1, Dose Escalation: TAK-981 3 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 3 milligram (mg), infusion, intravenously, twice weekly (BIW) on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 6 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 6 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 10 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 10 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 15 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 15 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 25 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 25 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 40 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 40 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 60 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 60 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 60 mg QW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 60 mg, infusion, intravenously, once weekly (QW) on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 75 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 75 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 75 mg QW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 75 mg, infusion, intravenously, QW on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 90 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 90 mg QW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 90 mg, infusion, intravenously, QW on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 90 mg, infusion, intravenously, QW on Days 1, 8 and 15 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 120 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 120 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 120 mg QW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 120 mg, infusion, intravenously, QW on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW

Reporting group description:

Participants with non-squamous non-small cell lung cancer (NSCLC) received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW

Reporting group description:

Participants with cervical cancer received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW

Reporting group description:

Participants with microsatellite-stable colorectal cancer (MSS-CRC) received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW

Reporting group description:

Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) progressed or relapsed after chimeric antigen receptor (CAR) T-cell therapy received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW

Reporting group description:

Participants with relapsed/refractory DLBCL that have not received prior cellular therapy received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW

Reporting group description:

Participants with relapsed/refractory follicular lymphoma received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW
Number of subjects	5	3	4
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	59.8	61.0	52.0
standard deviation	± 9.78	± 14.73	± 11.05
Gender categorical Units: Subjects			
Female	4	2	2
Male	1	1	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	5	3	4
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	5	3	4
Unknown or Not Reported	0	0	0

Reporting group values	Phase 1, Dose Escalation: TAK-981 15 mg BIW	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW
Number of subjects	3	4	4
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	66.7	59.5	65.0

standard deviation	± 10.69	± 5.80	± 4.69

Gender categorical Units: Subjects			
Female	2	2	2
Male	1	2	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	3	3	4
More than one race	0	0	0
Unknown or Not Reported	0	1	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	2	3	4
Unknown or Not Reported	1	0	0

Reporting group values	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW	Phase 1, Dose Escalation: TAK-981 75 mg BIW
Number of subjects	7	6	6
Age Categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	59.3	62.5	60.8
standard deviation	± 10.21	± 9.07	± 10.87
Gender categorical Units: Subjects			
Female	3	2	4
Male	4	4	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	2	2
White	4	4	4
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	7	6	6

Unknown or Not Reported	0	0	0

Reporting group values	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Number of subjects	6	8	7
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	62.3	60.5	62.4
standard deviation	± 10.97	± 9.56	± 14.21
Gender categorical Units: Subjects			
Female	4	3	5
Male	2	5	2
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	6	7	6
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	6	6	6
Unknown or Not Reported	0	1	1

Reporting group values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW
Number of subjects	7	8	6
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	64.4	59.4	57.8
standard deviation	± 7.93	± 11.02	± 8.33
Gender categorical Units: Subjects			
Female	4	3	5
Male	3	5	1

Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	7	5	5
More than one race	0	0	0
Unknown or Not Reported	0	2	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	6	6	5
Unknown or Not Reported	1	1	1

Reporting group values	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW
Number of subjects	7	3	7
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	64.0	53.3	51.6
standard deviation	± 6.98	± 2.08	± 13.02
Gender categorical Units: Subjects			
Female	1	3	3
Male	6	0	4
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	1
White	7	3	2
More than one race	0	0	1
Unknown or Not Reported	0	0	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	7	3	7
Unknown or Not Reported	0	0	0

Reporting group values	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW
Number of subjects	4	3	1

Age Categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean	56.3	71.7	53.0
standard deviation	± 18.06	± 5.51	± 99999
Gender categorical Units: Subjects			
Female	0	3	1
Male	4	0	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	4	2	0
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	4	3	1
Unknown or Not Reported	0	0	0

Reporting group values	Total		
Number of subjects	109		
Age Categorical Units: Subjects			

Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	58		
Male	51		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	6		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	9		
White	88		
More than one race	1		
Unknown or Not Reported	5		
Ethnicity (NIH/OMB) Units: Subjects			

Hispanic or Latino	3		
Not Hispanic or Latino	100		
Unknown or Not Reported	6		

End points

End points reporting groups

Reporting group title	Phase 1, Dose Escalation: TAK-981 3 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 3 milligram (mg), infusion, intravenously, twice weekly (BIW) on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 6 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 6 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 10 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 10 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 15 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 15 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 25 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 25 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 40 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 40 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 60 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 60 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 60 mg QW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 60 mg, infusion, intravenously, once weekly (QW) on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 75 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 75 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 75 mg QW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 75 mg, infusion, intravenously, QW on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 90 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 90 mg QW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 90 mg, infusion, intravenously, QW on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 90 mg, infusion, intravenously, QW on Days 1, 8 and 15 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 120 mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 120 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1, Dose Escalation: TAK-981 120 mg QW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 120 mg, infusion, intravenously, QW on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW

Reporting group description:

Participants with non-squamous non-small cell lung cancer (NSCLC) received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW

Reporting group description:

Participants with cervical cancer received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW

Reporting group description:

Participants with microsatellite-stable colorectal cancer (MSS-CRC) received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW

Reporting group description:

Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) progressed or relapsed after chimeric antigen receptor (CAR) T-cell therapy received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW

Reporting group description:

Participants with relapsed/refractory DLBCL that have not received prior cellular therapy received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW

Reporting group description:

Participants with relapsed/refractory follicular lymphoma received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

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

End point title	Phase 1: Number of Participants Reporting one or More Treatment Emergent Adverse Events (TEAEs)[1][2]

End point description:

TEAEs were adverse events (AEs) that occurred after administration of the first dose of any study drug and through 30 days after the last dose of any study drug. 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. Any abnormal laboratory results were considered as TEAEs. Safety analysis set consisted of participants who received at least 1 dose, even if incomplete, of study drug.

End point type	Primary

End point timeframe:

From the first dose of study drug through 30 days after the last dose of study drug (up to 35.3 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 data was planned to be analysed for this endpoint.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	4	3
Units: participants	4	3	4	3

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	6
Units: participants	4	4	6	6

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	8	7
Units: participants	5	6	8	7

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	8	6	
Units: participants	7	8	6	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Number of Participants With Grade 3 or Higher TEAEs

End point title	Phase 1: Number of Participants With Grade 3 or Higher

End point description:

The severity grade was evaluated as per the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) Version 5.0, except for Cytokine Release Syndrome (CRS), which was assessed by American Society for Transplantation and Cellular Therapy (ASTCT) consensus grading. Where Grade 3 was severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care activities of daily living (ADL), Grade 4 was life-threatening consequences; urgent intervention indicated, and Grade 5 was death related to AE. TEAEs were AEs that occurred after administration of the first dose of any study drug and through 30 days after the last dose of any study drug. Safety analysis set consisted of participants who received at least 1 dose, even if incomplete, of study drug.

End point type	Primary

End point timeframe:

From the first dose of study drug through 30 days after the last dose of study drug (up to 35.3 months)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this endpoint.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	4	3
Units: participants	2	2	3	1

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	6
Units: participants	2	2	4	3

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	8	7
Units: participants	4	0	6	5

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	8	6	
Units: participants	4	7	3	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 1: Duration of TEAEs

End point title	Phase 1: Duration of TEAEs[5][6]

End point description:

TEAEs were AEs that occurred after administration of the first dose of any study drug and through 30 days after the last dose of any study drug. 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. Safety analysis set consisted of participants who received at least 1 dose, even if incomplete, of study drug.

End point type	Primary

End point timeframe:

From the first dose of study drug through 30 days after the last dose of study drug (up to 35.3 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 data was planned to be analysed for this endpoint.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	4	3
Units: days				
median (full range (min-max))	3.0 (1 to 37)	4.0 (1 to 21)	1.0 (1 to 33)	3.0 (1 to 5)

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	6
Units: days				
median (full range (min-max))	4.0 (1 to 39)	9.5 (1 to 36)	4.0 (1 to 42)	3 (1 to 47)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	8	7
Units: days				
median (full range (min-max))	8.0 (1 to 82)	2.0 (1 to 58)	4.5 (1 to 188)	5.0 (1 to 37)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	8	6	
Units: days				
median (full range (min-max))	2.0 (1 to 80)	3.0 (1 to 131)	4.0 (1 to 64)	

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)[7][8]

End point description:

DLTs were evaluated according to NCI CTCAE version 5.0. Grade 5 AE. Hematologic toxicity: Nonfebrile Grade 4 neutropenia/Grade greater than or equal to (>=) 3 febrile neutropenia; Significant Grade 3 thrombocytopenia; Grade 4 thrombocytopenia. Nonhematologic Grade 3 or higher toxicities; Grade 2 nonhematologic toxicities that were considered by the investigator to be related to study drug and dose-limiting. DLT-evaluable analysis set consisted of participants in dose escalation who received all Cycle 1 doses of TAK-981 without experiencing a DLT or who had a DLT during Cycle 1 of the study.

End point type	Primary

End point timeframe:

Cycle 1 (Cycle length is equal to [=] 21 days)

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 data was planned to be analysed for this endpoint.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	3
Units: participants	0	0	0	0

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	6	5
Units: participants	0	0	1	0

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	6	6
Units: participants	0	0	1	0

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	

Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	6	6	
Units: participants	0	2	0	

Statistical analyses

No statistical analyses for this end point

Primary: Phase 2: Overall Response Rate (ORR)

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

End point description:

ORR was defined as percentage of participants who achieved complete response (CR) or partial response (PR) during the study as determined by the investigator according to response assessments based on Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST V1.1) for solid tumors or Lugano classification for lymphoma. Tumor response-evaluable analysis set consisted of participants who received at least 1 dose of study drug, had sites of measurable disease at baseline, and 1 postbaseline disease assessment, or was discontinued due to symptomatic deterioration or death before a postbaseline evaluation happened.

End point type	Primary

End point timeframe:

From the first dose of study drug until first disease progression (PD) or death, whichever occurred first (up to 11.2 months)

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be analysed for this endpoint.

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	6	4
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 40.96)	0.0 (0.0 to 70.76)	0.0 (0.0 to 45.93)	0.0 (0.0 to 60.24)

End point values	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	1		
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 70.76)	100.0 (2.50 to 100.0)		

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[11]

End point description:

Cmax for TAK-981 was reported. PK analysis set consisted of participants with sufficient dosing and PK data to reliably estimate 1 or more PK parameters. Here "number of subjects analyzed" "N" signifies participants who were evaluable for this endpoint and "number analyzed" signifies participants evaluable at specified time-points. As planned, this endpoint was analyzed in Phase 1 only. Here, "99999" indicates that no subjects were analyzed for Phase 1, Dose Escalation: TAK-981 3 mg BIW at Cycle 1 Day 8 because concentrations were below the lower limit of quantitation (LLOQ) after dosing. As planned, this endpoint was analyzed in Phase 1 only. Here "C" refers to cycle, "D" refers to day.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1: pre-dose and at multiple timepoints (up to 48 hours) post-dose; Cycle 1 Day 8: pre-dose and at multiple timepoints (up to 24 hours) post-dose (Cycle length = 21 days)

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	4	3
Units: nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,7,8,5	14.0 (± 74.6)	22.5 (± 19.7)	46.1 (± 45.3)	61.0 (± 69.0)
C1D8:n=0,2,4,3,3,4,6,5,5,6,6,6,6,6,5	99999 (± 99999)	22.5 (± 22.8)	33.8 (± 35.7)	114 (± 103.6)

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	6
Units: nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,7,8,5	124 (± 80.9)	314 (± 37.8)	417 (± 33.4)	446 (± 27.4)

C1D8:n=0,2,4,3,3,4,6,5,5,6,6,6,6,5	108 (± 39.2)	428 (± 49.9)	343 (± 26.6)	405 (± 35.6)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	7	7
Units: nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,7,8,5	738 (± 37.1)	685 (± 30.4)	773 (± 49.3)	887 (± 54.5)
C1D8:n=0,2,4,3,3,4,6,5,5,6,6,6,6,5	846 (± 33.3)	923 (± 69.0)	654 (± 57.5)	852 (± 66.2)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	8	5	
Units: nanograms per milliliter (ng/mL)				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,7,8,5	668 (± 32.9)	1410 (± 46.8)	1100 (± 36.4)	
C1D8:n=0,2,4,3,3,4,6,5,5,6,6,6,6,5	653 (± 69.6)	1460 (± 65.7)	825 (± 22.3)	

Statistical analyses

No statistical analyses for this end point

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

End point title	Phase 1, Tmax: Time to Reach the Maximum Observed Plasma Concentration (Cmax) for TAK-981[12]

End point description:

Tmax for TAK-981 was reported. PK analysis set consisted of participants with sufficient dosing and PK data to reliably estimate 1 or more PK parameters. Here "number of subjects analyzed" "N" signifies participants who were evaluable for this endpoint and "number analyzed" signifies participants evaluable at specified time-points. As planned, this endpoint was analyzed in Phase 1 only. Here, "99999" indicates that no subjects were analyzed for Phase 1, Dose Escalation: TAK-981 3 mg BIW at Cycle 1 Day 8 because concentrations were below the lower limit of quantitation (LLOQ) after dosing. As planned, this endpoint was analyzed in Phase 1 only. Here "C" refers to cycle, "D" refers to day.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1: pre-dose and at multiple timepoints (up to 48 hours) post-dose; Cycle 1 Day 8: pre-dose and at multiple timepoints (up to 24 hours) post-dose (Cycle length = 21 days)

Notes:

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

Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	4	3
Units: hours				
median (full range (min-max))				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,7,8,5	1.17 (1.08 to 1.62)	1.22 (1.03 to 1.33)	1.03 (0.93 to 1.08)	1.08 (1.07 to 1.65)
C1D8:n=0,2,4,3,3,4,6,5,5,6,6,6,6,6,5	99999 (99999 to 99999)	1.19 (1.13 to 1.25)	1.17 (1.07 to 2.08)	1.03 (1.00 to 1.05)

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	6
Units: hours				
median (full range (min-max))				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,7,8,5	1.08 (1.07 to 1.57)	1.18 (1.05 to 2.13)	1.12 (1.00 to 1.68)	1.08 (1.00 to 1.40)
C1D8:n=0,2,4,3,3,4,6,5,5,6,6,6,6,6,5	1.10 (1.03 to 1.42)	1.09 (1.00 to 1.23)	1.09 (1.03 to 1.13)	1.13 (1.00 to 1.25)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	7	7
Units: hours				
median (full range (min-max))				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,7,8,5	1.02 (0.97 to 1.20)	1.17 (1.08 to 1.22)	1.03 (1.00 to 1.13)	1.12 (1.05 to 1.25)
C1D8:n=0,2,4,3,3,4,6,5,5,6,6,6,6,6,5	1.05 (1.00 to 1.17)	1.05 (0.95 to 1.35)	1.03 (1.00 to 1.12)	1.12 (1.10 to 1.75)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	

Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	8	5	
Units: hours				
median (full range (min-max))				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,7,8,5	1.17 (1.03 to 1.25)	1.11 (1.07 to 1.27)	1.05 (1.02 to 1.17)	
C1D8:n=0,2,4,3,3,4,6,5,5,6,6,6,6,6,5	1.15 (0.98 to 3.08)	1.08 (1.00 to 1.22)	1.13 (1.08 to 1.17)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1, AUC0-last: Area Under the Plasma Concentration-time Curve From Time 0 to the Time of the Last Quantifiable Concentration for TAK-981

End point title	Phase 1, AUC0-last: Area Under the Plasma Concentration-time Curve From Time 0 to the Time of the Last Quantifiable Concentration for TAK-981[13]

End point description:

AUC0-last for TAK-981 was reported. PK analysis set consisted of participants with sufficient dosing and PK data to reliably estimate 1 or more PK parameters. Here "number of subjects analyzed" "N" signifies participants who were evaluable for this endpoint and "number analyzed" signifies participants evaluable at specified time-points. As planned, this endpoint was analyzed in Phase 1 only. Here, "99999" indicates that no subjects were analyzed for Phase 1, Dose Escalation: TAK-981 3 mg BIW at Cycle 1 Day 8 because concentrations were below the lower limit of quantitation (LLOQ) after dosing. As planned, this endpoint was analyzed in Phase 1 only. Here "C" refers to cycle, "D" refers to day.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1: pre-dose and at multiple timepoints (up to 48 hours) post-dose; Cycle 1 Day 8: pre-dose and at multiple timepoints (up to 24 hours) post-dose (Cycle length = 21 days)

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	4	3
Units: hours*nanograms per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,7,8,5	50.1 (± 35.0)	98.4 (± 15.5)	178 (± 19.6)	289 (± 40.6)
C1D8:n=0,2,4,3,3,4,6,5,5,6,6,6,6,6,5	99999 (± 99999)	98.6 (± 13.5)	174 (± 23.0)	364 (± 58.0)

End point values	Phase 1, Dose Escalation: TAK-981 25	Phase 1, Dose Escalation: TAK-981 40	Phase 1, Dose Escalation: TAK-981 60	Phase 1, Dose Escalation: TAK-981 60

	mg BIW	mg BIW	mg BIW	mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	6
Units: hours*nanograms per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,7,8,5	438 (± 34.5)	939 (± 20.7)	1070 (± 28.2)	1020 (± 25.8)
C1D8:n=0,2,4,3,3,4,6,5,5,6,6,6,6,6,5	405 (± 20.3)	1020 (± 31.1)	906 (± 30.6)	931 (± 19.5)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	7	7
Units: hours*nanograms per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,7,8,5	1310 (± 16.9)	1330 (± 15.7)	1460 (± 31.0)	1670 (± 31.9)
C1D8:n=0,2,4,3,3,4,6,5,5,6,6,6,6,6,5	1220 (± 19.1)	1310 (± 33.0)	1230 (± 31.1)	1650 (± 47.6)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	8	5	
Units: hours*nanograms per milliliter (h*ng/mL)				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,7,8,5	1410 (± 31.8)	2510 (± 30.1)	1890 (± 39.7)	
C1D8:n=0,2,4,3,3,4,6,5,5,6,6,6,6,6,5	1300 (± 59.2)	3050 (± 81.2)	1620 (± 23.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1, AUC0-inf: Area Under the Plasma Concentration-time Curve from Time 0 to Infinity for TAK-981

End point title	Phase 1, AUC0-inf: Area Under the Plasma Concentration-time Curve from Time 0 to Infinity for TAK-981[14]

End point description:

AUC0-inf for TAK-981 was reported. PK analysis set consisted of participants with sufficient dosing and PK data to reliably estimate 1 or more PK parameters. Here “number of subjects analyzed” "N" signifies participants who were evaluable for this endpoint and “number analyzed” signifies participants evaluable

at specified time-points. As planned, this endpoint was analyzed in Phase 1 only. Here, "99999" indicates that no subjects were analyzed for Phase 1, Dose Escalation: TAK-981 3 mg BIW at Cycle 1 Day 8 because concentrations were below the lower limit of quantitation (LLOQ) after dosing. As planned, this endpoint was analyzed in Phase 1 only.Here "C" refers to cycle, "D" refers to day.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1: pre-dose and at multiple timepoints (up to 48 hours) post-dose; Cycle 1 Day 8: pre-dose and at multiple timepoints (up to 24 hours) post-dose (Cycle length = 21 days)

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	4	3
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,3,4,4,7,6,6,6,7,7,6,7,3	53.5 (± 31.1)	100 (± 14.7)	181 (± 19.5)	294 (± 39.2)
C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	99999 (± 99999)	103 (± 12.8)	183 (± 21.9)	382 (± 53.5)

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	6
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,3,4,4,7,6,6,6,7,7,6,7,3	443 (± 34.7)	949 (± 20.2)	1090 (± 28.0)	1040 (± 26.1)
C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	438 (± 16.2)	1050 (± 29.9)	897 (± 30.7)	967 (± 20.6)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	7	7
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,3,4,4,7,6,6,6,7,7,6,7,3	1330 (± 17.0)	1350 (± 15.5)	1480 (± 31.6)	1700 (± 31.7)
C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	1260 (± 21.9)	1410 (± 31.4)	1310 (± 28.3)	1710 (± 46.8)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	7	5	
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,6,7,3	1360 (± 32.3)	2540 (± 33.3)	2280 (± 5.6)	
C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	1190 (± 40.8)	2590 (± 60.2)	1710 (± 24.4)	

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[15]

End point description:

t1/2z for TAK-981 was reported. PK analysis set consisted of participants with sufficient dosing and PK data to reliably estimate 1 or more PK parameters. Here "number of subjects analyzed" "N" signifies participants who were evaluable for this endpoint and "number analyzed" signifies participants evaluable at specified time-points. As planned, this endpoint was analyzed in Phase 1 only. Here, "99999" indicates that no subjects were analyzed for Phase 1, Dose Escalation: TAK-981 3 mg BIW at Cycle 1 Day 8 because concentrations were below the lower limit of quantitation (LLOQ) after dosing. As planned, this endpoint was analyzed in Phase 1 only. Here "C" refers to cycle, "D" refers to day.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1: pre-dose and at multiple timepoints (up to 48 hours) post-dose; Cycle 1 Day 8: pre-dose and at multiple timepoints (up to 24 hours) post-dose (Cycle length = 21 days)

Notes:

[15] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	4	3
Units: hours				
median (full range (min-max))				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,6,7,3	5.41 (2.92 to 6.40)	7.37 (4.90 to 9.90)	7.60 (6.92 to 8.49)	7.88 (5.81 to 10.32)
C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	99999 (-99999 to 99999)	5.74 (5.65 to 5.83)	6.02 (4.53 to 6.74)	6.08 (4.51 to 7.45)

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	6
Units: hours				
median (full range (min-max))				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,6,7,3	7.87 (7.30 to 9.78)	8.12 (6.77 to 9.19)	9.18 (8.05 to 10.95)	8.89 (6.56 to 11.81)
C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	6.38 (6.12 to 10.33)	5.73 (5.03 to 6.14)	6.47 (5.15 to 6.59)	6.16 (5.26 to 7.36)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	7	7
Units: hours				
median (full range (min-max))				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,6,7,3	9.44 (7.58 to 10.23)	9.62 (7.30 to 10.48)	8.01 (5.39 to 9.90)	8.32 (7.06 to 13.77)
C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	4.64 (3.12 to 6.81)	2.95 (2.32 to 7.30)	5.45 (3.02 to 6.13)	6.54 (5.40 to 7.02)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	7	5	
Units: hours				
median (full range (min-max))				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,6,7,3	8.38 (7.01 to 10.74)	8.99 (7.38 to 11.67)	8.61 (7.01 to 9.74)	
C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	5.43 (3.00 to 6.20)	6.20 (6.03 to 16.02)	6.36 (3.12 to 7.16)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1, CL: Total Clearance for TAK-981

End point title	Phase 1, CL: Total Clearance for TAK-981[16]

End point description:

CL for TAK-981 was reported. PK analysis set consisted of participants with sufficient dosing and PK data to reliably estimate 1 or more PK parameters. Here "number of subjects analyzed" "N" signifies participants who were evaluable for this endpoint and "number analyzed" signifies participants evaluable at specified time-points. As planned, this endpoint was analyzed in Phase 1 only. Here, "99999" indicates that no subjects were analyzed for Phase 1, Dose Escalation: TAK-981 3 mg BIW at Cycle 1 Day 8 because concentrations were below the lower limit of quantitation (LLOQ) after dosing. As planned, this endpoint was analyzed in Phase 1 only. Here "C" refers to cycle, "D" refers to day.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1: pre-dose and at multiple timepoints (up to 48 hours) post-dose; Cycle 1 Day 8: pre-dose and at multiple timepoints (up to 24 hours) post-dose (Cycle length = 21 days)

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	4	3
Units: liter per hour (L/h)				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,6,7,3	56.1 (± 31.1)	59.8 (± 14.7)	55.3 (± 19.5)	51.0 (± 39.2)
C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	99999 (± 99999)	58.3 (± 12.8)	54.7 (± 21.9)	39.3 (± 53.5)

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	6
Units: liter per hour (L/h)				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,6,7,3	56.4 (± 34.7)	42.2 (± 20.2)	55.3 (± 28.0)	57.8 (± 26.1)
C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	57.1 (± 16.2)	38.1 (± 29.9)	66.9 (± 30.7)	62.0 (± 20.6)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	7	7
Units: liter per hour (L/h)				
geometric mean (geometric coefficient of variation)				

C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,6,7,3	56.3 (± 17.0)	55.7 (± 15.5)	60.7 (± 31.6)	52.9 (± 31.7)
C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	59.4 (± 21.9)	53.1 (± 31.4)	68.8 (± 28.3)	52.8 (± 46.8)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	7	5	
Units: liter per hour (L/h)				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,6,7,3	66.0 (± 32.3)	47.3 (± 33.3)	52.6 (± 5.6)	
C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	75.6 (± 40.8)	46.4 (± 60.2)	70.3 (± 24.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1, Vss: Volume of Distribution at Steady State for TAK-981

End point title	Phase 1, Vss: Volume of Distribution at Steady State for TAK-981[17]

End point description:

Vss for TAK-981 was reported. PK analysis set consisted of participants with sufficient dosing and PK data to reliably estimate 1 or more PK parameters. Here "number of subjects analyzed" "N" signifies participants who were evaluable for this endpoint and "number analyzed" signifies participants evaluable at specified time-points. As planned, this endpoint was analyzed in Phase 1 only. Here, "99999" indicates that no subjects were analyzed for Phase 1, Dose Escalation: TAK-981 3 mg BIW at Cycle 1 Day 8 because concentrations were below the lower limit of quantitation (LLOQ) after dosing. As planned, this endpoint was analyzed in Phase 1 only. Here "C" refers to cycle, "D" refers to day.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1: pre-dose and at multiple timepoints (up to 48 hours) post-dose; Cycle 1 Day 8: pre-dose and at multiple timepoints (up to 24 hours) post-dose (Cycle length = 21 days)

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	4	3
Units: liters				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,6,7,3	332 (± 37.9)	437 (± 18.2)	443 (± 28.9)	411 (± 72.8)

C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	99999 (± 99999)	385 (± 12.9)	390 (± 32.0)	233 (± 119.7)

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	6
Units: liters				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,6,7,3	392 (± 39.9)	234 (± 36.0)	359 (± 33.5)	367 (± 19.2)
C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	441 (± 41.0)	173 (± 51.7)	400 (± 32.2)	334 (± 21.2)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	7	7
Units: liters				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,6,7,3	311 (± 24.0)	345 (± 29.1)	314 (± 46.3)	290 (± 59.4)
C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	185 (± 48.8)	144 (± 84.8)	285 (± 39.3)	241 (± 76.2)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	7	5	
Units: liters				
geometric mean (geometric coefficient of variation)				
C1D1:n=5,3,4,3,4,4,7,6,6,6,7,7,6,7,3	396 (± 25.8)	271 (± 31.3)	288 (± 27.6)	
C1D8:n=0,2,4,3,3,4,5,5,4,6,6,6,5,5,5	307 (± 60.6)	255 (± 36.6)	322 (± 32.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: ORR

End point title	Phase 1: ORR[18]

End point description:

ORR was defined as percentage of participants who achieved CR or PR during the study as determined by the investigator according to response assessments based on RECIST v1.1 for solid tumors or Lugano classification for lymphoma. Tumor response-evaluable analysis set consisted of participants who received at least 1 dose of study drug, had sites of measurable disease at baseline, and 1 postbaseline disease assessment, or was discontinued due to symptomatic deterioration or death before a postbaseline evaluation happened.

End point type	Secondary

End point timeframe:

From the first dose of study drug until first disease progression (PD) or death, whichever occurred first (up to 34.3 months)

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	3
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.00 to 60.24)	0.0 (0.00 to 70.76)	0.0 (0.00 to 60.24)	0.0 (0.00 to 70.76)

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	6	6
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.00 to 60.24)	33.3 (0.84 to 90.57)	0.0 (0.00 to 45.93)	0.0 (0.00 to 45.93)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	7	6
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 45.93)	0.0 (0.0 to 45.93)	0.0 (0.0 to 40.96)	16.7 (0.42 to 64.12)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	

	Days 1, 8, 15			
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	5	7	5	
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 52.18)	14.3 (0.36 to 57.87)	0.0 (0.00 to 52.18)	

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

DCR was defined as the percentage of participants who achieved stable disease (SD) (greater than [>] 6 weeks) or better as determined by the investigator according to RECIST v1.1 for solid tumors or Lugano classification for lymphoma. Tumor response-evaluable analysis set consisted of participants who received at least 1 dose of study drug, had sites of measurable disease at baseline, and 1 postbaseline disease assessment, or was discontinued due to symptomatic deterioration or death before a postbaseline evaluation happened.

End point type	Secondary

End point timeframe:

From first dose of study drug up to 34.3 months (for Phase 1) and up to 11.2 months (for Phase 2)

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	3
Units: percentage of participants				
number (confidence interval 95%)	0.0 (0.0 to 60.24)	0.0 (0.0 to 70.76)	25.0 (0.63 to 80.59)	33.3 (0.84 to 90.57)

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	6	6
Units: percentage of participants				
number (confidence interval 95%)	75.0 (19.41 to 99.37)	66.7 (9.43 to 99.16)	0.0 (0.0 to 45.93)	66.7 (22.28 to 95.67)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	7	6
Units: percentage of participants				
number (confidence interval 95%)	16.7 (0.42 to 64.12)	66.7 (22.28 to 95.67)	42.9 (9.90 to 81.59)	50.0 (11.81 to 88.19)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	7	5	7
Units: percentage of participants				
number (confidence interval 95%)	60.0 (14.66 to 94.73)	42.9 (9.90 to 81.59)	20.0 (0.51 to 71.64)	71.4 (29.04 to 96.33)

End point values	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	6	4	3
Units: percentage of participants				
number (confidence interval 95%)	66.7 (9.43 to 99.16)	33.3 (4.33 to 77.72)	0.0 (0.0 to 60.24)	0.0 (0.0 to 70.76)

End point values	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: percentage of participants				
number (confidence interval 95%)	100.0 (2.50 to 100.0)			

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

DOR was defined as the time from the date of first documentation of a PR or better to the date of first documentation of PD for responders (PR or better) and determined by the investigator according to RECIST v1.1 with solid tumors or Lugano classification for lymphoma. Tumor response-evaluable analysis set consisted of participants who received at least 1 dose of study drug, had sites of measurable disease at baseline, and 1 postbaseline disease assessment, or was discontinued due to symptomatic deterioration or death before a postbaseline evaluation happened. Here, "number of subjects analyzed" signifies participants who had CR or PR and "99999" indicates median, upper or lower limit of 95% CI could not be estimated due to insufficient number of participants with events.

End point type	Secondary

End point timeframe:

From first documented confirmed CR or PR until first documentation of PD up to 34.3 months (for Phase 1) and up to 11.2 months (for Phase 2)

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[19]	0[20]	0[21]	0[22]
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[19] - No participants with complete response or partial response were observed here.

[20] - No participants with complete response or partial response were observed here.

[21] - No participants with complete response or partial response were observed here.

[22] - No participants with complete response or partial response were observed here.

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[23]	1	0[24]	0[25]
Units: months				
median (confidence interval 95%)	(to)	6.93 (-99999 to 99999)	(to)	(to)

Notes:

[23] - No participants with complete response or partial response were observed here.

[24] - No participants with complete response or partial response were observed here.

[25] - No participants with complete response or partial response were observed here.

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[26]	0[27]	0[28]	1
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	1.41 (-99999 to 99999)

Notes:

[26] - No participants with complete response or partial response were observed here.

[27] - No participants with complete response or partial response were observed here.

[28] - No participants with complete response or partial response were observed here.

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[29]	1	0[30]	0[31]
Units: months				
median (confidence interval 95%)	(to)	99999 (-99999 to 99999)	(to)	(to)

Notes:

[29] - No participants with complete response or partial response were observed here.

[30] - No participants with complete response or partial response were observed here.

[31] - No participants with complete response or partial response were observed here.

End point values	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[32]	0[33]	0[34]	0[35]
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[32] - No participants with complete response or partial response were observed here.

[33] - No participants with complete response or partial response were observed here.

[34] - No participants with complete response or partial response were observed here.

[35] - No participants with complete response or partial response were observed here.

End point values	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: months				
median (confidence interval 95%)	5.55 (-99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

TTP was defined as the time from the date of the first dose administration to the date of first

documented PD as determined by the investigator according to RECIST v1.1 for solid tumors or Lugano classification for lymphoma. Tumor response-evaluable analysis set consisted of participants who received at least 1 dose of study drug, had sites of measurable disease at baseline, and 1 postbaseline disease assessment, or was discontinued due to symptomatic deterioration or death before a postbaseline evaluation happened. Here "99999" indicates median, upper or lower limit of 95% CI could not be estimated due to insufficient number of participants with events.

End point type	Secondary

End point timeframe:

From first dose of study drug to the date of the first documentation of PD up to 34.3 months (for Phase 1) and up to 11.2 months (for Phase 2)

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	4	3
Units: months				
median (confidence interval 95%)	1.18 (0.72 to 99999)	0.79 (0.76 to 99999)	1.38 (0.59 to 99999)	1.25 (1.18 to 99999)

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	6
Units: months				
median (confidence interval 95%)	2.10 (1.38 to 99999)	5.49 (1.25 to 99999)	1.21 (0.46 to 99999)	3.75 (0.72 to 99999)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	8	7
Units: months				
median (confidence interval 95%)	1.28 (1.22 to 99999)	2.71 (1.35 to 8.08)	6.97 (2.66 to 99999)	3.94 (1.18 to 99999)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	7
Units: months				
median (confidence interval 95%)	2.79 (1.25 to 99999)	99999 (1.38 to 99999)	1.97 (1.74 to 2.04)	6.06 (2.07 to 99999)

End point values	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	7	4	3
Units: months				
median (confidence interval 95%)	3.78 (0.99 to 99999)	1.18 (0.92 to 99999)	1.04 (0.59 to 99999)	1.09 (0.43 to 99999)

End point values	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: months				
median (confidence interval 95%)	11.17 (-99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

TTR was defined as the time from the date of first study drug administration to the date of first documented PR or better by the investigator for responders according to RECIST v1.1 for solid tumors or Lugano classification for lymphoma. Tumor response-evaluable analysis set consisted of participants who received at least 1 dose of study drug, had sites of measurable disease at baseline, and 1 postbaseline disease assessment, or was discontinued due to symptomatic deterioration or death before a postbaseline evaluation happened. Here, "number of subjects analyzed" "N" signifies participants who had CR or PR. Here "99999" indicates median, upper or lower limit of 95% CI could not be estimated due to insufficient number of participants with events.

End point type	Secondary

End point timeframe:

From first dose of study drug to the date of the first documentation of PR or better, whichever occurred first up to 34.3 months (for Phase 1) and up to 11.2 months (for Phase 2)

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[36]	0[37]	0[38]	0[39]
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[36] - No participants with complete or partial response were observed here.

[37] - No participants with complete or partial response were observed here.

[38] - No participants with complete or partial response were observed here.

[39] - No participants with complete or partial response were observed here.

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[40]	1	0[41]	0[42]
Units: months				
median (confidence interval 95%)	(to)	99999 (1.38 to 99999)	(to)	(to)

Notes:

[40] - No participants with complete or partial response were observed here.

[41] - No participants with complete or partial response were observed here.

[42] - No participants with complete or partial response were observed here.

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[43]	0[44]	0[45]	1
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	99999 (3.91 to 99999)

Notes:

[43] - No participants with complete or partial response were observed here.

[44] - No participants with complete or partial response were observed here.

[45] - No participants with complete or partial response were observed here.

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[46]	1	0[47]	0[48]
Units: months				
median (confidence interval 95%)	(to)	99999 (1.74 to 99999)	(to)	(to)

Notes:

[46] - No participants with complete or partial response were observed here.

[47] - No participants with complete or partial response were observed here.

[48] - No participants with complete or partial response were observed here.

End point values	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[49]	0[50]	0[51]	0[52]
Units: months				
median (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[49] - No participants with complete or partial response were observed here.

[50] - No participants with complete or partial response were observed here.

[51] - No participants with complete or partial response were observed here.

[52] - No participants with complete or partial response were observed here.

End point values	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: months				
median (confidence interval 95%)	5.65 (-99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

PFS was defined as the 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 as determined by the investigator according to RECIST v1.1 for solid tumors or Lugano classification for lymphoma. Safety analysis set consisted of participants who received at least 1 dose, even if incomplete, of study drug. Here "99999" indicates upper or lower limit of 95% CI could not be estimated due to insufficient number of participants with events.

End point type	Secondary

End point timeframe:

From the first dose of study drug to date of PD or death, whichever occurred first up to 34.3 months (for Phase 1) and up to 11.2 months (for Phase 2)

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	4	3
Units: months				
median (confidence interval 95%)	0.95 (0.46 to 99999)	0.79 (0.76 to 99999)	1.38 (0.59 to 99999)	1.25 (1.18 to 99999)

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	6
Units: months				
median (confidence interval 95%)	2.10 (1.38 to 99999)	5.49 (1.25 to 99999)	1.18 (0.46 to 99999)	2.53 (1.02 to 99999)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	8	7
Units: months				
median (confidence interval 95%)	1.27 (1.22 to 1.54)	2.71 (1.35 to 8.08)	2.66 (0.82 to 99999)	3.94 (1.18 to 99999)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	7
Units: months				
median (confidence interval 95%)	2.79 (1.25 to 99999)	3.32 (1.38 to 99999)	1.97 (1.74 to 2.04)	6.06 (2.07 to 99999)

End point values	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	7	4	3
Units: months				
median (confidence interval 95%)	3.78 (0.99 to 99999)	1.18 (0.92 to 99999)	1.38 (0.59 to 99999)	1.09 (0.43 to 99999)

End point values	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: months				
median (confidence interval 95%)	11.17 (-99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1 and 2: Overall Survival (OS)

End point title	Phase 1 and 2: Overall Survival (OS)

End point description:

OS was defined as the time from the date of the first dose administration to the date of death. Safety analysis set consisted of participants who received at least 1 dose, even if incomplete, of study drug. Here, "99999" indicates median, upper limit or lower limit of 95% CI could not be estimated due to insufficient number of participants with events.

End point type	Secondary

End point timeframe:

From date of first dose of study drug up to death up to 34.3 months (for Phase 1) and up to 11.2 months (for Phase 2)

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	4	3
Units: months				
median (confidence interval 95%)	99999 (0.46 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Phase 1, Dose Escalation: TAK-981 25	Phase 1, Dose Escalation: TAK-981 40	Phase 1, Dose Escalation: TAK-981 60	Phase 1, Dose Escalation: TAK-981 60

	mg BIW	mg BIW	mg BIW	mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	6
Units: months				
median (confidence interval 95%)	99999 (3.02 to 99999)	99999 (1.48 to 99999)	99999 (1.25 to 99999)	99999 (99999 to 99999)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	8	7
Units: months				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (0.82 to 99999)	5.49 (5.49 to 99999)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	8	6	7
Units: months				
median (confidence interval 95%)	99999 (1.77 to 99999)	99999 (5.22 to 99999)	99999 (99999 to 99999)	99999 (1.87 to 99999)

End point values	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	7	4	3
Units: months				
median (confidence interval 95%)	99999 (3.29 to 99999)	99999 (1.87 to 99999)	2.43 (1.28 to 99999)	6.14 (1.58 to 99999)

End point values	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: months				

median (confidence interval 95%)	99999 (99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Fold Change from Baseline in Levels of TAK-981 Small Ubiquitin-like Modifier (SUMO) Adduct Formation in Blood Lymphocytes

End point title	Phase 1: Fold Change from Baseline in Levels of TAK-981 Small Ubiquitin-like Modifier (SUMO) Adduct Formation in Blood Lymphocytes[53]

End point description:

TAK-981-SUMO adduct formation in peripheral blood lymphocytes was tested by flow cytometry with antibody recognizing TAK-981-SUMO adduct formation during inhibition of SUMO-activating enzyme by TAK-981.Pharmacodynamic analysis set consisted of participants who provided evaluable blood samples(Cycle 1 Day 1 pre-dose sample and at least 1 post-dose sample).Here "number of subjects analyzed" "N" and number analyzed "n"= subjects evaluable for this endpoint at specified time-points, "99999" = no data as "n" was zero at specified time-points for specific arms.Cycle 1 Day 1,1 hour post-dose:n=3,3,4,3,3,4,7,6,6,6,8,7,7,8,6;Cycle 1 Day 1,4 hour post-dose:n=4,3,4,3,3,4,7,6,6,6,8,7,7,8,6;Cycle 1 Day 1,8 hour post-dose:n=4,3,4,3,3,4,7,5,6,6,8,7,7,8,6;Cycle 1 Day 8,Pre-dose:n=0,2,4,3,3,4,7,5,6,6,6,6,7,5,4;Cycle 1 Day 8,1 hour post-dose:n=0,2,4,3,3,4,6,5,6,6,6,6,7,4,4;Cycle 1 Day 8,4 hour post-dose:n=0,2,4,3,3,4,6,5,6,6,6,6,7,4,5;Cycle 1 Day 8,8 hour post-dose:n=0,2,4,3,3,4,6,4,6,6,6,6,6,4,5.

End point type	Secondary

End point timeframe:

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

Notes:

[53] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	3
Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 1: 1 hour post-dose	1.8 (± 0.21)	2.3 (± 0.16)	2.9 (± 1.38)	5.9 (± 0.83)
Cycle 1 Day 1: 4 hour post-dose	1.6 (± 0.19)	2.1 (± 0.04)	2.6 (± 1.64)	4.8 (± 0.70)
Cycle 1 Day 1: 8 hour post-dose	1.5 (± 0.23)	1.9 (± 0.08)	2.7 (± 1.36)	4.3 (± 0.85)
Cycle 1 Day 8: Pre-dose	99999 (± 99999)	1.8 (± 0.27)	2.0 (± 0.80)	3.6 (± 0.92)
Cycle 1 Day 8: 1 hour post-dose	99999 (± 99999)	3.2 (± 0.72)	3.8 (± 1.73)	8.0 (± 3.03)
Cycle 1 Day 8: 4 hour post-dose	99999 (± 99999)	2.9 (± 0.62)	3.4 (± 1.55)	7.1 (± 2.38)
Cycle 1 Day 8: 8 hour post-dose	99999 (± 99999)	2.9 (± 0.65)	3.2 (± 1.53)	6.7 (± 1.98)

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	7	6
Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 1: 1 hour post-dose	5.9 (± 1.07)	8.4 (± 1.25)	7.5 (± 2.57)	6.5 (± 2.27)
Cycle 1 Day 1: 4 hour post-dose	5.1 (± 0.74)	5.8 (± 0.44)	6.2 (± 2.15)	4.7 (± 1.57)
Cycle 1 Day 1: 8 hour post-dose	4.6 (± 0.77)	4.9 (± 0.10)	4.3 (± 2.05)	3.3 (± 1.02)
Cycle 1 Day 8: Pre-dose	3.3 (± 0.31)	2.9 (± 0.87)	2.9 (± 1.20)	2.1 (± 0.30)
Cycle 1 Day 8: 1 hour post-dose	7.9 (± 2.00)	8.4 (± 2.20)	9.6 (± 3.94)	6.9 (± 0.89)
Cycle 1 Day 8: 4 hour post-dose	7.2 (± 1.84)	6.3 (± 2.01)	7.3 (± 3.17)	5.3 (± 0.55)
Cycle 1 Day 8: 8 hour post-dose	6.0 (± 1.42)	6.1 (± 2.45)	6.3 (± 2.63)	4.3 (± 0.59)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	8	7
Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 1: 1 hour post-dose	7.8 (± 1.59)	7.0 (± 2.03)	8.5 (± 1.10)	8.8 (± 1.46)
Cycle 1 Day 1: 4 hour post-dose	5.8 (± 0.86)	5.8 (± 1.05)	6.0 (± 1.05)	6.2 (± 1.10)
Cycle 1 Day 1: 8 hour post-dose	5.2 (± 1.49)	4.8 (± 1.10)	4.7 (± 1.02)	5.5 (± 1.32)
Cycle 1 Day 8: Pre-dose	3.9 (± 0.75)	2.1 (± 0.66)	2.6 (± 0.92)	2.4 (± 0.53)
Cycle 1 Day 8: 1 hour post-dose	8.7 (± 2.91)	7.4 (± 2.95)	7.5 (± 2.18)	9.6 (± 1.74)
Cycle 1 Day 8: 4 hour post-dose	7.1 (± 1.47)	5.9 (± 2.37)	6.9 (± 0.85)	6.9 (± 1.58)
Cycle 1 Day 8: 8 hour post-dose	6.6 (± 1.68)	5.2 (± 2.05)	5.8 (± 1.19)	5.7 (± 1.05)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	8	6	
Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 1: 1 hour post-dose	8.1 (± 2.12)	8.5 (± 2.12)	8.1 (± 1.41)	
Cycle 1 Day 1: 4 hour post-dose	5.9 (± 1.42)	6.2 (± 1.32)	5.8 (± 1.22)	
Cycle 1 Day 1: 8 hour post-dose	4.9 (± 1.20)	5.0 (± 0.94)	4.0 (± 1.21)	
Cycle 1 Day 8: Pre-dose	2.4 (± 0.62)	3.7 (± 1.06)	2.3 (± 0.38)	
Cycle 1 Day 8: 1 hour post-dose	8.4 (± 2.68)	9.2 (± 1.79)	8.2 (± 1.94)	

Cycle 1 Day 8: 4 hour post-dose	6.2 (± 1.81)	7.9 (± 1.90)	6.1 (± 1.30)	
Cycle 1 Day 8: 8 hour post-dose	5.8 (± 2.04)	5.9 (± 0.83)	5.2 (± 1.06)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Fold Change from Baseline in Levels of TAK-981 SUMO Adduct Formation in Skin

End point title	Phase 1: Fold Change from Baseline in Levels of TAK-981 SUMO Adduct Formation in Skin[54]

End point description:

TAK-981-SUMO adduct formation in skin was tested by flow cytometry with an antibody recognizing the TAK-981-SUMO adduct formation during the inhibition of the SUMO-activating enzyme by TAK-981. Pharmacodynamic analysis set consisted of participants who provided evaluable skin biopsies (screening sample and at least 1 on-treatment sample). Here "number of subjects analyzed" "N" signifies participants who were evaluable for this endpoint. Here "99999" indicates standard deviation could not be estimated due to insufficient number of participants available for analysis.

End point type	Secondary

End point timeframe:

Cycle 1 Day 8 (Cycle length = 21 days)

Notes:

[54] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[55]	0[56]	1	0[57]
Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 8	()	()	115.57 (± 99999)	()

Notes:

[55] - No participants were observed in this arm.

[56] - No participants were observed in this arm.

[57] - No participants were observed in this arm.

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[58]	0[59]	0[60]	0[61]
Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 8	()	()	()	()

Notes:

[58] - No participants were observed in this arm.

[59] - No participants were observed in this arm.

[60] - No participants were observed in this arm.

[61] - No participants were observed in this arm.

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[62]	0[63]	0[64]	1
Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 8	()	()	()	1343.23 (± 99999)

Notes:

[62] - No participants were observed in this arm.

[63] - No participants were observed in this arm.

[64] - No participants were observed in this arm.

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[65]	0[66]	0[67]	
Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 8	()	()	()	

Notes:

[65] - No participants were observed in this arm.

[66] - No participants were observed in this arm.

[67] - No participants were observed in this arm.

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Fold Change from Baseline in SUMO Pathway Inhibition in Blood Lymphocytes

End point title	Phase 1: Fold Change from Baseline in SUMO Pathway Inhibition in Blood Lymphocytes[68]

End point description:

SUMO pathway inhibition in peripheral blood lymphocytes was tested by flow cytometry with antibody recognizing SUMO-2/3 chains. Pharmacodynamic analysis set consisted of participants who provided evaluable blood samples (Cycle 1 Day 1 pre-dose sample and at least 1 post-dose sample). Here "number of subjects analyzed" "N" signifies participants who were evaluable for this endpoint, number analyzed "n" signifies subjects evaluable at specified time-points, "99999" indicates no data was available as "n" was zero at specified time-points for specific arms.Cycle 1 Day 1,1 hour post-dose:n=3,3,4,3,3,4,7,6,6,6,8,7,7,8,6; Cycle 1 Day 1,4 hour post-dose:n=4,3,4,3,3,4,7,6,6,6,8,7,7,8,6;Cycle 1 Day 1,8 hour post-dose:n=4,3,4,3,3,4,7,5,6,6,8,7,7,8,6;Cycle 1 Day 8,Pre-dose:n=0,2,4,3,3,4,7,5,6,6,6,6,7,5,4;Cycle 1 Day 8,1 hour post-dose:n =0,2,4,3,3,4,6,5,6,6,6,6,7,4,4;Cycle 1 Day 8,4 hour post-dose:n=0,2,4,3,3,4,6,5,6,6,6,6,7,4,5;Cycle 1 Day 8,8 hour post-dose:n=0,2,4,3,3,4,6,4,6,6,6,6,6,4,5..

End point type	Secondary

End point timeframe:

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

Notes:

[68] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	3
Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 1: 1 hour post-dose	1.0 (± 0.04)	1.0 (± 0.05)	0.9 (± 0.11)	0.9 (± 0.04)
Cycle 1 Day 1: 4 hour post-dose	0.9 (± 0.15)	1.0 (± 0.07)	1.0 (± 0.07)	0.9 (± 0.05)
Cycle 1 Day 1: 8 hour post-dose	1.0 (± 0.20)	1.0 (± 0.12)	1.0 (± 0.19)	1.0 (± 0.07)
Cycle 1 Day 8: Pre-dose	99999 (± 99999)	1.0 (± 0.17)	1.0 (± 0.15)	1.1 (± 0.16)
Cycle 1 Day 8: 1 hour post-dose	99999 (± 99999)	1.0 (± 0.16)	1.0 (± 0.14)	0.9 (± 0.10)
Cycle 1 Day 8: 4 hour post-dose	99999 (± 99999)	1.0 (± 0.15)	1.0 (± 0.15)	1.0 (± 0.08)
Cycle 1 Day 8: 8 hour post-dose	99999 (± 99999)	1.1 (± 0.10)	1.0 (± 0.23)	0.9 (± 0.11)

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	4	7	6
Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 1: 1 hour post-dose	0.9 (± 0.06)	4.7 (± 7.88)	0.8 (± 0.13)	0.7 (± 0.13)
Cycle 1 Day 1: 4 hour post-dose	1.0 (± 0.09)	4.1 (± 6.38)	2.3 (± 4.03)	0.9 (± 0.41)
Cycle 1 Day 1: 8 hour post-dose	0.9 (± 0.18)	4.0 (± 6.19)	0.7 (± 0.18)	0.7 (± 0.25)
Cycle 1 Day 8: Pre-dose	1.7 (± 0.82)	5.5 (± 9.42)	2.1 (± 3.57)	1.5 (± 0.66)
Cycle 1 Day 8: 1 hour post-dose	1.6 (± 0.68)	4.6 (± 8.08)	0.6 (± 0.35)	0.9 (± 0.41)
Cycle 1 Day 8: 4 hour post-dose	1.7 (± 0.77)	4.6 (± 7.98)	0.7 (± 0.31)	1.0 (± 0.51)
Cycle 1 Day 8: 8 hour post-dose	1.7 (± 0.65)	4.6 (± 8.20)	0.7 (± 0.30)	1.0 (± 0.76)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	8	7

Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 1: 1 hour post-dose	0.6 (± 0.14)	0.6 (± 0.11)	0.6 (± 0.11)	0.6 (± 0.12)
Cycle 1 Day 1: 4 hour post-dose	0.5 (± 0.20)	2.5 (± 4.74)	0.6 (± 0.13)	0.6 (± 0.18)
Cycle 1 Day 1: 8 hour post-dose	0.6 (± 0.26)	2.5 (± 4.49)	0.6 (± 0.17)	0.7 (± 0.13)
Cycle 1 Day 8: Pre-dose	1.0 (± 0.24)	1.0 (± 0.16)	0.8 (± 0.43)	1.1 (± 0.27)
Cycle 1 Day 8: 1 hour post-dose	0.5 (± 0.24)	0.6 (± 0.22)	0.5 (± 0.23)	0.7 (± 0.19)
Cycle 1 Day 8: 4 hour post-dose	0.6 (± 0.22)	1.8 (± 3.05)	0.7 (± 0.16)	0.7 (± 0.19)
Cycle 1 Day 8: 8 hour post-dose	0.6 (± 0.18)	1.9 (± 3.06)	0.8 (± 0.19)	0.7 (± 0.20)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	7	8	6	
Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 1: 1 hour post-dose	0.6 (± 0.09)	0.5 (± 0.07)	0.6 (± 0.22)	
Cycle 1 Day 1: 4 hour post-dose	0.6 (± 0.11)	0.5 (± 0.14)	0.6 (± 0.36)	
Cycle 1 Day 1: 8 hour post-dose	0.6 (± 0.11)	0.6 (± 0.23)	0.6 (± 0.35)	
Cycle 1 Day 8: Pre-dose	1.0 (± 0.18)	1.1 (± 0.21)	2.8 (± 3.74)	
Cycle 1 Day 8: 1 hour post-dose	0.5 (± 0.09)	0.6 (± 0.17)	1.5 (± 2.00)	
Cycle 1 Day 8: 4 hour post-dose	0.6 (± 0.14)	0.7 (± 0.19)	1.5 (± 1.87)	
Cycle 1 Day 8: 8 hour post-dose	0.6 (± 0.21)	0.6 (± 0.18)	1.5 (± 2.14)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 1: Fold Change from Baseline in SUMO Pathway Inhibition in Skin

End point title	Phase 1: Fold Change from Baseline in SUMO Pathway Inhibition in Skin[69]

End point description:

SUMO pathway inhibition in skin was tested by flow cytometry with an antibody recognizing SUMO-2/3 chains. Pharmacodynamic analysis set consisted of participants who provided evaluable skin biopsies (screening sample and at least 1 on-treatment sample). Here "number of subjects analyzed" "N" signifies participants who were evaluable for this endpoint.

End point type	Secondary

End point timeframe:

Cycle 1 Day 8 (Cycle length = 21 days)

Notes:

[69] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 1, Dose Escalation: TAK-981 3 mg BIW	Phase 1, Dose Escalation: TAK-981 6 mg BIW	Phase 1, Dose Escalation: TAK-981 10 mg BIW	Phase 1, Dose Escalation: TAK-981 15 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	4	3
Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 8	1.01 (± 0.067)	0.71 (± 0.398)	0.82 (± 0.088)	0.91 (± 0.233)

End point values	Phase 1, Dose Escalation: TAK-981 25 mg BIW	Phase 1, Dose Escalation: TAK-981 40 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg BIW	Phase 1, Dose Escalation: TAK-981 60 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	5
Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 8	1.05 (± 0.122)	0.86 (± 0.146)	0.72 (± 0.276)	0.73 (± 0.298)

End point values	Phase 1, Dose Escalation: TAK-981 75 mg BIW	Phase 1, Dose Escalation: TAK-981 75 mg QW	Phase 1, Dose Escalation: TAK-981 90 mg BIW	Phase 1, Dose Escalation: TAK-981 90 mg QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	6	6	6
Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 8	0.64 (± 0.156)	0.71 (± 0.224)	0.56 (± 0.136)	0.65 (± 0.298)

End point values	Phase 1, Dose Escalation: TAK-981 90 mg QW on Days 1, 8, 15	Phase 1, Dose Escalation: TAK-981 120 mg BIW	Phase 1, Dose Escalation: TAK-981 120 mg QW	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	6	6	6	
Units: fold change				
arithmetic mean (standard deviation)				
Cycle 1 Day 8	0.78 (± 0.123)	0.42 (± 0.376)	0.44 (± 0.210)	

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Participants Reporting one or More TEAEs

End point title	Phase 2: Number of Participants Reporting one or More

End point description:

TEAEs were AEs that occurred after administration of the first dose of any study drug and through 30 days after the last dose of any study drug. 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. Any abnormal laboratory results were considered as TEAEs. Safety analysis set consisted of participants who received at least 1 dose, even if incomplete, of study drug.

End point type	Secondary

End point timeframe:

From the first dose of study drug through 30 days after the last dose of study drug (up to 12.2 months)

Notes:

[70] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	7	4
Units: participants	6	3	7	4

End point values	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	1		
Units: participants	3	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Number of Participants With Grade 3 or Higher TEAEs

End point title	Phase 2: Number of Participants With Grade 3 or Higher

End point description:

The severity grade was evaluated as per the CTCAE Version 5.0, except for CRS, which was assessed by ASTCT consensus grading. Where Grade 3 was severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL, Grade 4 was 4 Life-threatening consequences; urgent intervention indicated. and Grade 5 was death related to AE. TEAEs were AEs that occurred after administration of the first dose of any study drug and through 30 days after the last dose of any study drug. Safety analysis set consisted of participants who received at least 1 dose, even if incomplete, of study drug.

End point type	Secondary

End point timeframe:

From the first dose of study drug through 30 days after the last dose of study drug (up to 12.2 months)

Notes:

[71] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	7	4
Units: participants	4	1	6	3

End point values	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	1		
Units: participants	3	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Phase 2: Duration of TEAEs

End point title	Phase 2: Duration of TEAEs[72]

End point description:

TEAEs were AEs that occurred after administration of the first dose of any study drug and through 30 days after the last dose of any study drug. 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. Safety analysis set consisted of participants who received at least 1 dose, even if incomplete, of study drug.

End point type	Secondary

End point timeframe:

From the first dose of study drug through 30 days after the last dose of study drug (up to 12.2 months)

Notes:

[72] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only descriptive data was planned to be analysed for this endpoint.

End point values	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	3	7	4
Units: days				
median (full range (min-max))	8.5 (1 to 336)	4.0 (1 to 45)	5.0 (1 to 72)	5.0 (1 to 26)

End point values	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	3	1		
Units: days				
median (full range (min-max))	3.0 (1 to 19)	1.0 (1 to 56)		

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Serious/Non-serious AEs: From first dose of study drug to 30 days after last dose up to 35.3 months (Phase 1) up to 12.2 months (Phase 2); All fatalities: From first dose up to death due to any cause up to 34.3 months (Phase 1) up to 12.2 months (Phase 2)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Phase 1: TAK-981 25mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 25 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1: TAK-981 15mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 15 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1: TAK-981 10mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 10 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1: TAK-981 6mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 6 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1: TAK-981 3mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 3 milligram (mg), infusion, intravenously, twice weekly (BIW) on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1: TAK-981 75mg QW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 75 mg, infusion, intravenously, QW on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1: TAK-981 75mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 75 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1: TAK-981 60mg QW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-

981 60 mg, infusion, intravenously, once weekly (QW) on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1: TAK-981 60mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 60 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1: TAK-981 40mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 40 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1: TAK-981 90mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW

Reporting group description:

Participants with microsatellite-stable colorectal cancer (MSS-CRC) received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW

Reporting group description:

Participants with cervical cancer received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1: TAK-981 90mg QW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 90 mg, infusion, intravenously, QW on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1: TAK-981 90mg Days 1,8,15

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 90 mg, infusion, intravenously, QW on Days 1, 8 and 15 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1: TAK-981 120mg BIW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 120 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 1: TAK-981 120mg QW

Reporting group description:

Participants with relapsed/refractory advanced or metastatic solid tumors or lymphoma received TAK-981 120 mg, infusion, intravenously, QW on Days 1 and 8 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW

Reporting group description:

Participants with non-squamous non-small cell lung cancer (NSCLC) received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease

progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW

Reporting group description:

Participants with relapsed/refractory diffuse large B-cell lymphoma (DLBCL) progressed or relapsed after chimeric antigen receptor (CAR) T-cell therapy received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW

Reporting group description:

Participants with relapsed/refractory DLBCL that have not received prior cellular therapy received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Reporting group title	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW

Reporting group description:

Participants with relapsed/refractory follicular lymphoma received TAK-981 90 mg, infusion, intravenously, BIW on Days 1, 4, 8 and 11 in a 21-day treatment cycle until confirmed disease progression, unacceptable toxicity, or any criterion for withdrawal from the study or discontinuation of study drug occurred.

Serious adverse events	Phase 1: TAK-981 25mg BIW	Phase 1: TAK-981 15mg BIW	Phase 1: TAK-981 10mg BIW
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	1 / 3 (33.33%)	3 / 4 (75.00%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
Pancreatic carcinoma			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Prostate cancer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Rectal adenocarcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 cell lung cancer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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			

Cytokine release syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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			
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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			
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	0 / 3 (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
Lumbar vertebral fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Subdural haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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			
Sinus bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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			
Cognitive disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Dizziness postural			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Glossodynia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Rectal obstruction			

subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (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
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 / 4 (0.00%)	1 / 3 (33.33%)	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
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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 failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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			
Dermatitis acneiform			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (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
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Acute kidney injury			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (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

Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Cystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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	0 / 4 (0.00%)	0 / 3 (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			
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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

Serious adverse events	Phase 1: TAK-981 6mg BIW	Phase 1: TAK-981 3mg BIW	Phase 1: TAK-981 75mg QW
Total subjects affected by serious adverse events			

subjects affected / exposed	2 / 3 (66.67%)	3 / 5 (60.00%)	1 / 6 (16.67%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events	0	1	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	1 / 5 (20.00%)	0 / 6 (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
Pancreatic carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 cell lung cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 6 (0.00%)
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 / 5 (0.00%)	0 / 6 (0.00%)
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			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	1 / 5 (20.00%)	0 / 6 (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			
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Subdural haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Cognitive disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness postural			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 6 (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			
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glossodynia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 mass			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 6 (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
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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%)	1 / 5 (20.00%)	0 / 6 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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			
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 6 (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
COVID-19			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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 / 3 (33.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
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	Phase 1: TAK-981 75mg BIW	Phase 1: TAK-981 60mg QW	Phase 1: TAK-981 60mg BIW
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 6 (50.00%)	1 / 6 (16.67%)	3 / 7 (42.86%)
number of deaths (all causes)	1	1	2
number of deaths resulting from adverse events	1	1	2
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Small cell lung cancer			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
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 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
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	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 7 (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
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Sinus bradycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cognitive disorder			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness postural			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glossodynia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal mass			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 1: TAK-981 40mg BIW	Phase 1: TAK-981 90mg BIW	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	5 / 8 (62.50%)	4 / 7 (57.14%)
number of deaths (all causes)	1	2	1
number of deaths resulting from adverse events	1	2	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Colorectal cancer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Malignant neoplasm progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Prostate cancer			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell lung cancer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (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
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			

subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Sinus bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cognitive disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness postural			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glossodynia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW	Phase 1: TAK-981 90mg QW	Phase 1: TAK-981 90mg Days 1,8,15
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	2 / 7 (28.57%)

number of deaths (all causes)	1	2	1
number of deaths resulting from adverse events	0	0	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell lung cancer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Subdural haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cognitive disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness postural			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glossodynia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 1: TAK-981 120mg BIW	Phase 1: TAK-981 120mg QW	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 8 (62.50%)	2 / 6 (33.33%)	2 / 7 (28.57%)
number of deaths (all causes)	1	0	1
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell lung cancer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			

subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences causally related to treatment / all	1 / 1	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 7 (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
Pulmonary embolism			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Investigations			
Blood bilirubin increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardiac disorders			
Sinus bradycardia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (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
Nervous system disorders			
Cognitive disorder			

subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (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
Presyncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness postural			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Glossodynia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal mass			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	2 / 3 (66.67%)	0 / 1 (0.00%)
number of deaths (all causes)	4	2	0
number of deaths resulting from adverse events	1	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Adenocarcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colorectal cancer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic carcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small cell lung cancer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of the tongue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar vertebral fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Sinus bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cognitive disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness postural			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (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
Glossodynia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Incarcerated umbilical hernia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis acneiform			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Phase 1: TAK-981 25mg BIW	Phase 1: TAK-981 15mg BIW	Phase 1: TAK-981 10mg BIW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	2 / 3 (66.67%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Colorectal cancer metastatic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metastases to lung			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypotension			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Complication associated with device			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 4 (50.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	2	0	2
Face oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion site bruising			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	2	1
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Thirst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Performance status decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Bronchospasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Orthopnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Sinus congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hallucination, visual			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Middle insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			

subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
Ammonia increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood antidiuretic hormone increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Interferon alpha level increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Interferon gamma level increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Interleukin level increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural fluid analysis abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Prothrombin level increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary occult blood			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Foot fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stoma prolapse			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Cardiac disorders			
Atrial tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Neuropathy peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Anisocoria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry eye			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Eyelid ptosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	2 / 4 (50.00%)
occurrences (all)	1	1	2
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2

Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Faeces pale			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip blister			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lip scab			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	2	1

Pancreatic failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 4 (25.00%)
occurrences (all)	0	1	2
Umbilical hernia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Biliary obstruction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hair texture abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Scab			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Bladder spasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haematuria			

subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Coccydynia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Osteolysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spondylitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Spinal pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
COVID-19 pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	2
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 1: TAK-981 6mg BIW	Phase 1: TAK-981 3mg BIW	Phase 1: TAK-981 75mg QW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	4 / 5 (80.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Abdominal neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Colorectal cancer metastatic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Metastases to lung			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Phlebitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	4 / 6 (66.67%)
occurrences (all)	0	0	86
Chest pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Complication associated with device			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	1 / 5 (20.00%)	4 / 6 (66.67%)
occurrences (all)	1	2	7
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infusion site bruising			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infusion site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Injection site bruising			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Thirst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pyrexia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	3 / 6 (50.00%)
occurrences (all)	0	0	5
Performance status decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Cough			

subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	2 / 6 (33.33%)
occurrences (all)	0	1	2
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	3
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Orthopnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Rhinorrhoea			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hallucination, visual			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Middle insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Product issues			
Device dislocation			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Investigations			
Ammonia increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Blood creatine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood antidiuretic hormone increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Interferon alpha level increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Interferon gamma level increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Interleukin level increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pleural fluid analysis abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Prothrombin level increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary occult blood			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural			

complications			
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stoma prolapse			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	2 / 5 (40.00%)	2 / 6 (33.33%)
occurrences (all)	0	2	2
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 3 (66.67%)	2 / 5 (40.00%)	5 / 6 (83.33%)
occurrences (all)	2	2	88
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2

Ophthalmic migraine			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Radiculopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Anisocoria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Eye pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vision blurred			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Abdominal distension			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 3 (33.33%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	1	1	1
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	2 / 5 (40.00%)	4 / 6 (66.67%)
occurrences (all)	0	4	5
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Gastrointestinal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Faeces pale			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Lip blister			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lip scab			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	2 / 5 (40.00%)	6 / 6 (100.00%)
occurrences (all)	1	2	13
Pancreatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Proctalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	3 / 6 (50.00%)
occurrences (all)	0	1	5
Umbilical hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Biliary obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hair texture abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	2
Onycholysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Scab			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bladder spasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pollakiuria			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Back pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Flank pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Gouty arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	1 / 6 (16.67%)
occurrences (all)	0	1	1
Muscle spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	2 / 6 (33.33%)
occurrences (all)	0	0	2
Osteolysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spondylitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			

Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
COVID-19 pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Parotitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Tooth abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	4
Vaginal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 5 (20.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hyperlipidaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
Hyponatraemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 5 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Metabolic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 5 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 1: TAK-981 75mg BIW	Phase 1: TAK-981 60mg QW	Phase 1: TAK-981 60mg BIW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 6 (83.33%)	6 / 6 (100.00%)	6 / 7 (85.71%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cancer pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Colorectal cancer metastatic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metastases to lung			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Deep vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Axillary pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	3	25	0
Chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Complication associated with device			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	4 / 6 (66.67%)	5 / 6 (83.33%)	4 / 7 (57.14%)
occurrences (all)	9	6	4
Face oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Infusion site bruising			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Infusion site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Oedema peripheral			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Thirst			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	3 / 6 (50.00%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	6	5	2
Performance status decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Vessel puncture site bruise			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	2
Reproductive system and breast disorders			
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Prostatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal inflammation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

Dyspnoea exertional			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	3 / 7 (42.86%)
occurrences (all)	1	1	3
Epistaxis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	1	1	2
Orthopnoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Stridor			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hallucination, visual			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Delirium			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Middle insomnia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	3 / 6 (50.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Ammonia increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			

subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	6	1
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	2	10	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	5	2
Blood creatine increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Blood antidiuretic hormone increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	3	0	3
Blood creatinine increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	3	1
Body temperature increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Interferon alpha level increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Interferon gamma level increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Interleukin level increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	4	0	0
Pleural fluid analysis abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Prothrombin level increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary occult blood			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Skin laceration			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stoma prolapse			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	2 / 6 (33.33%)	2 / 7 (28.57%)
occurrences (all)	0	4	2

Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	1 / 6 (16.67%)	2 / 6 (33.33%)	0 / 7 (0.00%)
occurrences (all)	1	33	0
Lethargy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Radiculopathy			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Tremor			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Anaemia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Leukopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pancytopenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Anisocoria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			

subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Abdominal pain lower			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Abdominal pain upper			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 6 (33.33%)	1 / 6 (16.67%)	3 / 7 (42.86%)
occurrences (all)	2	1	4
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Faeces pale			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Haemorrhoids			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip blister			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip scab			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	2 / 6 (33.33%)	2 / 6 (33.33%)	2 / 7 (28.57%)
occurrences (all)	3	11	2
Pancreatic failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Retching			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Umbilical hernia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Biliary obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hair texture abnormal			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Onycholysis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rash pruritic			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Scab			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Skin ulcer			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bladder spasm			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Micturition urgency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Urinary retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Back pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	3	0	2
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Coccydynia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Muscle spasms			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Osteolysis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Spondylitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
COVID-19 pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Clostridium difficile colitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Tooth abscess			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Vaginal infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 6 (33.33%)	2 / 6 (33.33%)	2 / 7 (28.57%)
occurrences (all)	3	3	2
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dehydration			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			

subjects affected / exposed	3 / 6 (50.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	3	0	3
Hyponatraemia			
subjects affected / exposed	2 / 6 (33.33%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	2	0	2
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 6 (16.67%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	2	1	2
Metabolic acidosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Phase 1: TAK-981 40mg BIW	Phase 1: TAK-981 90mg BIW	Phase 2, Dose Expansion, Cohort C: TAK-981 90 mg BIW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	7 / 8 (87.50%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Colorectal cancer metastatic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metastases to lung			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Tumour pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	4 / 8 (50.00%)	6 / 7 (85.71%)
occurrences (all)	0	4	9
Chest pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Complication associated with device			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	2 / 4 (50.00%)	5 / 8 (62.50%)	4 / 7 (57.14%)
occurrences (all)	2	7	4
Face oedema			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion site bruising			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Oedema peripheral			
subjects affected / exposed	1 / 4 (25.00%)	2 / 8 (25.00%)	2 / 7 (28.57%)
occurrences (all)	1	2	4
Thirst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pyrexia			
subjects affected / exposed	1 / 4 (25.00%)	4 / 8 (50.00%)	5 / 7 (71.43%)
occurrences (all)	1	5	7
Performance status decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	11	0
Reproductive system and breast disorders			
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Erectile dysfunction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Vaginal discharge			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	1 / 4 (25.00%)	4 / 8 (50.00%)	2 / 7 (28.57%)
occurrences (all)	1	6	2
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Haemoptysis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Orthopnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0

Confusional state			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	1	2	0
Hallucination			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hallucination, visual			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Middle insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	2 / 7 (28.57%)
occurrences (all)	0	2	2
Product issues			
Device dislocation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Ammonia increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Blood creatine increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood antidiuretic hormone increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Body temperature increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Interferon alpha level increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Interferon gamma level increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Interleukin level increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pleural fluid analysis abnormal			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Prothrombin level increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary occult blood			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Fall			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Skin laceration			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Foot fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stoma prolapse			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	3 / 7 (42.86%)
occurrences (all)	0	0	4
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Memory impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	4 / 8 (50.00%)	4 / 7 (57.14%)
occurrences (all)	0	4	5
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	4 / 7 (57.14%)
occurrences (all)	0	3	7
Leukopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pancytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Eye disorders			
Anisocoria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Abdominal distension			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	1 / 4 (25.00%)	4 / 8 (50.00%)	2 / 7 (28.57%)
occurrences (all)	1	4	2
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	1	0	3
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	2 / 7 (28.57%)
occurrences (all)	0	1	2
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 4 (50.00%)	4 / 8 (50.00%)	4 / 7 (57.14%)
occurrences (all)	2	5	7
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Gastrointestinal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Faeces pale			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip blister			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Lip scab			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Mouth ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	6 / 8 (75.00%)	1 / 7 (14.29%)
occurrences (all)	0	7	2
Pancreatic failure			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Proctalgia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	2 / 4 (50.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Retching			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting			

subjects affected / exposed	0 / 4 (0.00%)	4 / 8 (50.00%)	1 / 7 (14.29%)
occurrences (all)	0	5	1
Umbilical hernia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Biliary obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	3
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erythema			

subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hair texture abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Onycholysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Scab			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Bladder spasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Chromaturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Haematuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	3
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Micturition urgency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Leukocyturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Urinary tract obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	1	2	3
Back pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	0	1	2
Osteolysis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Spondylitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
COVID-19 pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Clostridium difficile colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	2	0

Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 4 (25.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	3	1	1
Vaginal infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 4 (0.00%)	5 / 8 (62.50%)	3 / 7 (42.86%)
occurrences (all)	0	6	4
Hyperglycaemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	3 / 8 (37.50%)	1 / 7 (14.29%)
occurrences (all)	0	5	1
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyperlipidaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	3 / 8 (37.50%)	1 / 7 (14.29%)
occurrences (all)	0	5	1
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia			

subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	1 / 7 (14.29%)
occurrences (all)	0	2	2
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences (all)	0	4	0
Metabolic acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 2, Dose Expansion, Cohort B: TAK-981 90 mg BIW	Phase 1: TAK-981 90mg QW	Phase 1: TAK-981 90mg Days 1,8,15
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	7 / 7 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Cancer pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Colorectal cancer metastatic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metastases to lung			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	3
Phlebitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Axillary pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	3 / 7 (42.86%)
occurrences (all)	1	1	12
Chest pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Complication associated with device			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Discomfort			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	5 / 7 (71.43%)
occurrences (all)	0	2	5
Face oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion site bruising			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gait disturbance			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	3 / 7 (42.86%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Thirst			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	2 / 7 (28.57%)
occurrences (all)	1	2	3
Performance status decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	0 / 7 (0.00%)
occurrences (all)	1	8	0
Reproductive system and breast disorders			
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			

subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vaginal haemorrhage			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	2 / 7 (28.57%)
occurrences (all)	0	2	2
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			

subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Orthopnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1

Hallucination, visual			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Middle insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Product issues			
Device dislocation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Investigations			
Ammonia increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood antidiuretic hormone increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Body temperature increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Interferon alpha level increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	3	0
Interferon gamma level increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Interleukin level increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural fluid analysis abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Prothrombin level increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary occult blood			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Foot fracture			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Stoma prolapse			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac ventricular thrombosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	1	2
Encephalopathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Memory impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 3 (33.33%)	4 / 7 (57.14%)	4 / 7 (57.14%)
occurrences (all)	2	4	13
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukocytosis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	2 / 7 (28.57%)
occurrences (all)	0	5	3
Leukopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Ear discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Anisocoria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	3 / 7 (42.86%)	1 / 7 (14.29%)
occurrences (all)	0	3	1
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	1 / 7 (14.29%)
occurrences (all)	0	2	2
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2

Constipation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	3 / 7 (42.86%)	3 / 7 (42.86%)
occurrences (all)	0	3	3
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	3
Gastrointestinal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Faeces pale			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip blister			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip scab			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Mouth ulceration			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Oesophagitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	2 / 3 (66.67%)	5 / 7 (71.43%)	5 / 7 (71.43%)
occurrences (all)	3	7	16
Pancreatic failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Retching			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	3 / 7 (42.86%)	4 / 7 (57.14%)
occurrences (all)	0	3	7
Umbilical hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic function abnormal			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cholestasis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hepatic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Biliary obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dermatitis acneiform			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hair texture abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	3
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Scab			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Bladder pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bladder spasm			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Micturition urgency			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Urinary incontinence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 7 (28.57%)	1 / 7 (14.29%)
occurrences (all)	1	2	1
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	2 / 7 (28.57%)
occurrences (all)	0	2	2
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Muscle spasms			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Osteolysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spondylitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spinal pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
COVID-19 pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Otitis media			

subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 3 (33.33%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Vaginal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	2 / 7 (28.57%)
occurrences (all)	0	1	3
Hyperglycaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Fluid retention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypocalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	2 / 7 (28.57%)
occurrences (all)	0	2	2
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 7 (28.57%)	1 / 7 (14.29%)
occurrences (all)	0	2	1
Hypophosphataemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 7 (14.29%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

Metabolic acidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 7 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 1: TAK-981 120mg BIW	Phase 1: TAK-981 120mg QW	Phase 2, Dose Expansion, Cohort A: TAK-981 90 mg BIW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 8 (100.00%)	6 / 6 (100.00%)	6 / 7 (85.71%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Colorectal cancer metastatic			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Metastases to lung			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hot flush			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Hypotension			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Axillary pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Catheter site inflammation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	3 / 8 (37.50%)	2 / 6 (33.33%)	1 / 7 (14.29%)
occurrences (all)	21	3	2
Chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Complication associated with device			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	3 / 8 (37.50%)	2 / 6 (33.33%)	3 / 7 (42.86%)
occurrences (all)	7	2	8
Face oedema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Infusion site bruising			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion site pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Injection site pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Mucosal inflammation			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			

subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	3	1	0
Thirst			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	6 / 8 (75.00%)	3 / 6 (50.00%)	2 / 7 (28.57%)
occurrences (all)	8	3	5
Performance status decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	2 / 8 (25.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	5	0	0
Reproductive system and breast disorders			
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal inflammation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 8 (12.50%)	2 / 6 (33.33%)	1 / 7 (14.29%)
occurrences (all)	1	2	1
Dysphonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	2 / 8 (25.00%)	2 / 6 (33.33%)	1 / 7 (14.29%)
occurrences (all)	3	3	1
Epistaxis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hiccups			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoxia			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Orthopnoea			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Sinus congestion			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Productive cough			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Stridor			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hallucination			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hallucination, visual			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Delirium			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Middle insomnia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Investigations			
Ammonia increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blood creatine increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood antidiuretic hormone increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Body temperature increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Interferon alpha level increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Interferon gamma level increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Interleukin level increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pleural fluid analysis abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Prothrombin level increased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary occult blood			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			

subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 8 (12.50%)	2 / 6 (33.33%)	0 / 7 (0.00%)
occurrences (all)	2	2	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Skin laceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 8 (0.00%)	2 / 6 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Foot fracture			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stoma prolapse			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac ventricular thrombosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mitral valve incompetence			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Supraventricular tachycardia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	2	2	0
Dysgeusia			
subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	3	1	1
Encephalopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Headache			
subjects affected / exposed	1 / 8 (12.50%)	3 / 6 (50.00%)	2 / 7 (28.57%)
occurrences (all)	1	3	4
Lethargy			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Anaemia			

subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	2	3	2
Leukopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	3
Lymphopenia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pancytopenia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Thrombocytopenia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Anisocoria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Blepharitis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Diplopia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vision blurred			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	2 / 8 (25.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	2	1	0

Dry mouth			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	2 / 8 (25.00%)	2 / 6 (33.33%)	3 / 7 (42.86%)
occurrences (all)	2	2	4
Dysphagia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Gastrointestinal pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Gastritis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Faeces pale			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Lip blister			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lip scab			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Oesophagitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	5 / 8 (62.50%)	3 / 6 (50.00%)	1 / 7 (14.29%)
occurrences (all)	6	4	1
Pancreatic failure			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	3 / 8 (37.50%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	1
Retching			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	4 / 8 (50.00%)	3 / 6 (50.00%)	0 / 7 (0.00%)
occurrences (all)	6	3	0
Umbilical hernia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cholestasis			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Biliary obstruction			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	3
Erythema			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hair texture abnormal			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Night sweats			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Pruritus			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Onycholysis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	1 / 8 (12.50%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	2	1	3
Scab			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Bladder spasm			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Chromaturia			

subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dysuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Pollakiuria			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Micturition urgency			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Urinary retention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 8 (0.00%)	2 / 6 (33.33%)	0 / 7 (0.00%)
occurrences (all)	0	2	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	2	1	3
Back pain			

subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	0	1	4
Bone pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Coccydynia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	2 / 7 (28.57%)
occurrences (all)	0	2	5
Muscle spasms			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Osteolysis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Spondylitis			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Spinal pain			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
COVID-19 pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Herpes simplex reactivation			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Paronychia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Vaginal infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	4 / 8 (50.00%)	3 / 6 (50.00%)	2 / 7 (28.57%)
occurrences (all)	7	3	2
Hyperglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 8 (0.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dehydration			

subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperkalaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 8 (12.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	3 / 8 (37.50%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	8	0	0
Hyponatraemia			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	2 / 8 (25.00%)	1 / 6 (16.67%)	0 / 7 (0.00%)
occurrences (all)	3	3	0
Hypophosphataemia			
subjects affected / exposed	2 / 8 (25.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 8 (0.00%)	0 / 6 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Phase 2, Dose Expansion, Cohort D: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort E: TAK-981 90 mg BIW	Phase 2, Dose Expansion, Cohort F: TAK-981 90 mg BIW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	3 / 3 (100.00%)	1 / 1 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Abdominal neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cancer pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Colorectal cancer metastatic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Malignant peritoneal neoplasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metastases to lung			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0

Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Phlebitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Axillary pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Catheter site inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Complication associated with device			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Discomfort			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Face oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infusion site bruising			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gait disturbance			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infusion site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injection site bruising			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Injection site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Thirst			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	1	4	51
Performance status decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vessel puncture site bruise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Postmenopausal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Erectile dysfunction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Prostatitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Bronchospasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Orthopnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Sinus congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Stridor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hallucination, visual			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Delirium			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Middle insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Insomnia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Investigations			
Ammonia increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood creatine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood antidiuretic hormone increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Body temperature increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Interferon alpha level increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Interferon gamma level increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Interleukin level increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	0	2	6
Neutrophil count decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	0	4	2
Platelet count decreased			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	5	1	1
Pleural fluid analysis abnormal			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Prothrombin level increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Urinary occult blood			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
White blood cell count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	0	4	3
Weight decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Foot fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Stoma prolapse			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Cardiac ventricular thrombosis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tachycardia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Supraventricular tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Supraventricular extrasystoles			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Ataxia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Encephalopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Neuropathy peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ophthalmic migraine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Radiculopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	2 / 3 (66.67%)	0 / 1 (0.00%)
occurrences (all)	0	2	0
Leukopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Neutropenia			

subjects affected / exposed	2 / 4 (50.00%)	2 / 3 (66.67%)	0 / 1 (0.00%)
occurrences (all)	2	3	0
Lymphopenia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	2	0	0
Pancytopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Anisocoria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eye pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Blepharitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Diplopia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Dry eye			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eyelid ptosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 4 (25.00%)	2 / 3 (66.67%)	0 / 1 (0.00%)
occurrences (all)	1	2	0

Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Faeces pale			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lip blister			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Lip scab			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Mouth ulceration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oesophagitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Pancreatic failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Proctalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Retching			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Umbilical hernia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hepatic function abnormal			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	0	1	0
Cholestasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hepatic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Biliary obstruction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermatitis contact			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dry skin			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hair texture abnormal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Onycholysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash pruritic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Scab			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Skin exfoliation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bladder pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bladder spasm			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Haematuria			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 3 (33.33%)	0 / 1 (0.00%)
occurrences (all)	2	1	0
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Coccydynia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Gouty arthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Osteolysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Rotator cuff syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Spondylitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Spinal pain			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	2 / 4 (50.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	2	0	2
COVID-19 pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	1
Herpes simplex reactivation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile colitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Parotitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Tooth abscess			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Fluid retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hyperlipidaemia			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 1 (100.00%)
occurrences (all)	0	0	5
Hyperuricaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	1 / 1 (100.00%)
occurrences (all)	0	1	1
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0
Metabolic acidosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 1 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 July 2018	Protocol Amendment 1: The primary reason for this amendment is to incorporate changes requested by the Food and Drug Administration (FDA) during review of the protocol.
26 March 2019	Protocol Amendment 2: The primary reasons for this amendment are to modify the lymphopenia limit inclusion criteria and to clarify how and when various tests and procedures should be performed.
31 March 2020	Protocol Amendment 3: The primary reason for this amendment was to explore the potential of TAK-981 to control severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) infection in participants with cancer by modulating type I interferon (IFN) response. The amendment also addresses study conduct during the Coronavirus disease (COVID-19) pandemic.
10 April 2020	Protocol Amendment 4: The primary reason for this amendment was to incorporate changes requested by the FDA during the review of protocol incorporating amendment 03 that intended to explore potential of TAK-981 to control SARS-CoV-2 infection in patients with cancer by modulating type I interferon (IFN) response.
28 August 2020	Protocol Amendment 5: The primary reason for this amendment was to incorporate a phase 2 portion to assess the preliminary efficacy of TAK-981 in select tumor types and indications in the clinical study design.
14 December 2020	Protocol Amendment 6: The primary reason for this amendment was to address the FDA request to remove COVID-19 expansion cohort.
09 November 2021	Protocol Amendment 7: The primary reason for this amendment was to incorporate updated language around pregnancy and lactation to align with the investigator brochure (IB).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

The study was terminated early due to enrollment challenges.

Notes: