Clinical trial results:
A Study to Evaluate the Safety and Efficacy of the CD40 Agonistic Antibody APX005M Administered in Combination with Nivolumab in Subjects with Non-small Cell Lung Cancer and Subjects with Metastatic Melanoma

Summary

EudraCT number	2018-003866-14
Trial protocol	ES FR
Global end of trial date	16 November 2020

Results information

Result version number	v1 (current)
This version publication date	19 January 2024
First version publication date	19 January 2024

Trial information

Trial identification

Sponsor protocol code	APX005M-002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03123783
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Pyxis Oncology, Inc.
Sponsor organisation address	321 Harrison Avenue, Boston, United States, MA 02118
Public contact	Clinical Operations, Pyxis Oncology, Inc., 1 (339) 545 8252, clinicaltrials@pyxisoncology.com
Scientific contact	Ken Kobayashi, Pyxis Oncology, Inc., 1 (816) 830-5408, kkobayashi@pyxisoncology.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	16 November 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 November 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Phase 1b:
•Determine the maximum tolerated dose (MTD) and the recommended Phase 2 dose (RP2D) of APX005M when given in combination with nivolumab.
Phase 2:
•Evaluate the objective response rate (ORR) by Response Evaluation Criteria In Solid Tumors (RECIST 1.1) in each cohort/group.

Protection of trial subjects:

Written informed consent was required from each participant prior to any testing under this protocol, including screening tests and evaluations. The informed consent form, as specified by the clinical site's institutional review board/independent ethics committee, followed the Protection of Human Subjects regulations listed in the Code of Federal Regulations, Title 21, Part 50.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 May 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Spain: 76
Country: Number of subjects enrolled	United States: 64
Worldwide total number of subjects	140
EEA total number of subjects	76

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0

Adults (18-64 years)	62
From 65 to 84 years	77
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

In Phase 1b dose-escalation portion of the study, a total of 10 participants were enrolled at 3 dose levels. Nine participants received at least one dose of both study drugs. 0.3 mg/kg was determined as the RP2D. The 3 participants treated in DL3 of Phase 1b are at the RP2D and are also included in Phase 2 results.

Pre-assignment

Screening details:

For the Phase 2 cohorts 1, 2, 3A, 3B, a total of 133 participants were enrolled in 4 cohorts to receive APX005M at 0.3 mg/kg (RP2D) plus nivolumab at 360 mg intravenously (IV). Three participants who were treated at the RP2D in the Phase 1b dose-escalation portion of the study were included in Phase 2 of the relevant disease-specific cohort.

Period 1

Period 1 title	Enrollment to Treatment
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	DL1 - APX005M 0.03 mg/kg + Nivolumab (Phase 1b)

Arm description:

Participants were to receive 0.03 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	DL2 - APX005M 0.1 mg/kg + Nivolumab (Phase 1b)

Arm description:

Participants were to receive 0.1 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	DL3 - APX005M 0.3 mg/kg + Nivolumab (Phase 1b)

Arm description:

Participants were to receive 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Cohort 1 (Arm)/ inNSCLC (Phase 2)

Arm description:

Participants with immunotherapy naïve metastatic or locally advanced non-small cell lung cancer (inNSCLC) were to receive 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV. One participant from DL3 was also included.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Cohort 2 (Arm)/ PD1-MM (Phase 2)

Arm description:

Participants with anti-programmed cell death protein 1 (PD-1) or anti-programmed death-ligand 1 (PD-L1) resistant or pretreated unresectable or metastatic melanoma (PD1-MM) were to receive 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV. Two participants from DL3 were also included.

Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Cohort 3A (Arm)/ PD1-NSCLC (Phase 2)

Arm description:

Participants with PD1 or PD-L1 resistant or pretreated-non-small cell lung cancer (PD1-NSCLC) metastatic or locally advanced NSCLC not amenable to curative treatment were to receive 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Arm type	No intervention
No investigational medicinal product assigned in this arm	
Arm title	Cohort 3B (Arm)/ PD1-NSCLC (Phase 2)

Arm description:

Participants with PD1-NSCLC metastatic or locally advanced NSCLC not amenable to curative treatment that progressed during prior treatment with anti-PD-1/ PD-L1 therapy were to receive 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Arm type	No intervention
No investigational medicinal product assigned in this arm	

Number of subjects in period 1	DL1 - APX005M 0.03 mg/kg + Nivolumab (Phase 1b)	DL2 - APX005M 0.1 mg/kg + Nivolumab (Phase 1b)	DL3 - APX005M 0.3 mg/kg + Nivolumab (Phase 1b)
Started	3	4	3
Completed	3	3	3
Not completed	0	1	0
Removed prior to APX005M administration	-	1	-

Number of subjects in period 1	Cohort 1 (Arm)/ inNSCLC (Phase 2)	Cohort 2 (Arm)/ PD1-MM (Phase 2)	Cohort 3A (Arm)/ PD1-NSCLC (Phase 2)
Started	53	38	14
Completed	53	38	14
Not completed	0	0	0
Removed prior to APX005M administration	-	-	-

Number of subjects in period 1	Cohort 3B (Arm)/ PD1-NSCLC (Phase 2)
Started	28
Completed	28
Not completed	0
Removed prior to APX005M administration	-

Period 2

Period 2 title	Treatment to End of Study
Is this the baseline period?	Yes[1]
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	No
Arm title	DL1 - APX005M 0.03 mg/kg + Nivolumab (Phase 1b)

Arm description:

Participants received 0.03 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Arm type	Experimental
Investigational medicinal product name	APX005M
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

APX005M was administered at the assigned dose as a 60-minute IV infusion on Day 1 of each 3-week treatment cycle approximately 30 minutes following nivolumab.

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

Dosage and administration details:

Nivolumab 360 mg was administered as a 30-minute IV infusion on Day 1 of each 3-week treatment cycle. It was not to be administered as an IV push or bolus injection.

Arm title	DL2 - APX005M 0.1 mg/kg + Nivolumab (Phase 1b)

Arm description:

Participants received 0.1 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Arm type	Experimental
Investigational medicinal product name	APX005M
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

APX005M was administered at the assigned dose as a 60-minute IV infusion on Day 1 of each 3-week treatment cycle approximately 30 minutes following nivolumab.

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

Dosage and administration details:

Nivolumab 360 mg was administered as a 30-minute IV infusion on Day 1 of each 3-week treatment cycle. It was not to be administered as an IV push or bolus injection.

Arm title	DL3 - APX005M 0.3 mg/kg + Nivolumab (Phase 1b)

Arm description:

Participants received 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab

360 mg IV.

Arm type	Experimental
Investigational medicinal product name	APX005M
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

APX005M was administered at the assigned dose as a 60-minute IV infusion on Day 1 of each 3-week treatment cycle approximately 30 minutes following nivolumab.

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

Dosage and administration details:

Nivolumab 360 mg was administered as a 30-minute IV infusion on Day 1 of each 3-week treatment cycle. It was not to be administered as an IV push or bolus injection.

Arm title	Cohort 1 (Arm)/ inNSCLC (Phase 2)

Arm description:

Participants with inNSCLC received 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV. One participant from DL3 was also included.

Arm type	Experimental
Investigational medicinal product name	APX005M
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

APX005M was administered at the assigned dose as a 60-minute IV infusion on Day 1 of each 3-week treatment cycle approximately 30 minutes following nivolumab.

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

Dosage and administration details:

Nivolumab 360 mg was administered as a 30-minute IV infusion on Day 1 of each 3-week treatment cycle. It was not to be administered as an IV push or bolus injection.

Arm title	Cohort 2 (Arm)/ PD1-MM (Phase 2)

Arm description:

Participants with PD-1 or anti-PD-L1 resistant or PD1-MM were to receive 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV. Two participants from DL3 were also included.

Arm type	Experimental
Investigational medicinal product name	APX005M
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

APX005M was administered at the assigned dose as a 60-minute IV infusion on Day 1 of each 3-week treatment cycle approximately 30 minutes following nivolumab.

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

Dosage and administration details:

Nivolumab 360 mg was administered as a 30-minute IV infusion on Day 1 of each 3-week treatment cycle. It was not to be administered as an IV push or bolus injection.

Arm title	Cohort 3A (Arm)/ PD1-NSCLC (Phase 2)

Arm description:

Participants with PD1-NSCLC metastatic or locally advanced NSCLC not amenable to curative treatment were to receive 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Arm type	Experimental
Investigational medicinal product name	APX005M
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

APX005M was administered at the assigned dose as a 60-minute IV infusion on Day 1 of each 3-week treatment cycle approximately 30 minutes following nivolumab.

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

Dosage and administration details:

Nivolumab 360 mg was administered as a 30-minute IV infusion on Day 1 of each 3-week treatment cycle. It was not to be administered as an IV push or bolus injection.

Arm title	Cohort 3B (Arm)/ PD1-NSCLC (Phase 2)

Arm description:

Participants with PD1-NSCLC metastatic or locally advanced NSCLC not amenable to curative treatment that progressed during prior treatment with anti-PD-1/PD-L1 therapy received 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Arm type	Experimental
Investigational medicinal product name	APX005M
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

APX005M was administered at the assigned dose as a 60-minute IV infusion on Day 1 of each 3-week treatment cycle approximately 30 minutes following nivolumab.

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

Dosage and administration details:

Nivolumab 360 mg was administered as a 30-minute IV infusion on Day 1 of each 3-week treatment cycle. It was not to be administered as an IV push or bolus injection.

Notes:
[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.
Justification: Baseline characteristics are presented for the Safety Population.

Number of subjects in period 2	DL1 - APX005M 0.03 mg/kg + Nivolumab (Phase 1b)	DL2 - APX005M 0.1 mg/kg + Nivolumab (Phase 1b)	DL3 - APX005M 0.3 mg/kg + Nivolumab (Phase 1b)
Started	3	3	3
Completed	3	3	3
Not completed	0	0	0
No post baseline tumor assessment	-	-	-
Prior systemic therapy not allowed	-	-	-

Number of subjects in period 2	Cohort 1 (Arm)/ inNSCLC (Phase 2)	Cohort 2 (Arm)/ PD1-MM (Phase 2)	Cohort 3A (Arm)/ PD1-NSCLC (Phase 2)
Started	53	38	14
Completed	48	33	12
Not completed	5	5	2
No post baseline tumor assessment	5	2	2
Prior systemic therapy not allowed	-	3	-

Number of subjects in period 2	Cohort 3B (Arm)/ PD1-NSCLC (Phase 2)
Started	28
Completed	25
Not completed	3
No post baseline tumor assessment	3
Prior systemic therapy not allowed	-

Baseline characteristics

Reporting groups[1]	
Reporting group title	Treatment to End of Study
Reporting group description:	
All participants in the safety population who received at least 1 dose of study drug.	

Notes:

[1] - The number of subjects reported to be in the baseline period is not equal to the worldwide number of subjects enrolled in the trial. It is expected that these numbers will be the same.
Justification: The 3 participants treated in DL3 of Phase 1b are at the RP2D and are also included in Phase 2 results. One participant was rolled over to Cohort 1 (Phase 2) and 2 participants were rolled over into Cohort 2 (Phase 2) to continue treatment.

Reporting group values	Treatment to End of Study	Total	
Number of subjects	139	139	
Age categorical Units: Subjects			
<=18 years	0	0	
Between 18 and 65 years	61	61	
>=65 years	78	78	
Gender categorical Units: Subjects			
Female	52	52	
Male	87	87	
Ethnicity Units: Subjects			
Hispanic or Latino	30	30	
Not Hispanic or Latino	109	109	
Unknown or Not Reported	0	0	
Race Units: Subjects			
American Indian or Alaska Native	1	1	
Asian	1	1	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	5	5	
White	132	132	
More than one race	0	0	
Unknown or Not Reported	0	0	
Region of Enrollment Units: Subjects			
United States	75	75	
Spain	64	64	
ECOG Performance Status			
Grade 0 - Normal activity, fully active, able to carry on all pre-disease performance without restriction. Grade 1 - Symptoms, but fully ambulatory, restricted in physically strenuous but ambulatory and able to carry out work of a light or sedentary nature (e.g., light housework, office work). Grade 0 is better than Grade 1.			
Units: Subjects			
ECOG Score 0	61	61	
ECOG Score 1	78	78	

End points

End points reporting groups

Reporting group title	DL1 - APX005M 0.03 mg/kg + Nivolumab (Phase 1b)
Reporting group description:	
Participants were to receive 0.03 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.	
Reporting group title	DL2 - APX005M 0.1 mg/kg + Nivolumab (Phase 1b)
Reporting group description:	
Participants were to receive 0.1 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.	
Reporting group title	DL3 - APX005M 0.3 mg/kg + Nivolumab (Phase 1b)
Reporting group description:	
Participants were to receive 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.	
Reporting group title	Cohort 1 (Arm)/ inNSCLC (Phase 2)
Reporting group description:	
Participants with immunotherapy naïve metastatic or locally advanced non-small cell lung cancer (inNSCLC) were to receive 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV. One participant from DL3 was also included.	
Reporting group title	Cohort 2 (Arm)/ PD1-MM (Phase 2)
Reporting group description:	
Participants with anti-programmed cell death protein 1 (PD-1) or anti-programmed death-ligand 1 (PD-L1) resistant or pretreated unresectable or metastatic melanoma (PD1-MM) were to receive 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV. Two participants from DL3 were also included.	
Reporting group title	Cohort 3A (Arm)/ PD1-NSCLC (Phase 2)
Reporting group description:	
Participants with PD1 or PD-L1 resistant or pretreated-non-small cell lung cancer (PD1-NSCLC) metastatic or locally advanced NSCLC not amenable to curative treatment were to receive 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.	
Reporting group title	Cohort 3B (Arm)/ PD1-NSCLC (Phase 2)
Reporting group description:	
Participants with PD1-NSCLC metastatic or locally advanced NSCLC not amenable to curative treatment that progressed during prior treatment with anti-PD-1/ PD-L1 therapy were to receive 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.	
Reporting group title	DL1 - APX005M 0.03 mg/kg + Nivolumab (Phase 1b)
Reporting group description:	
Participants received 0.03 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.	
Reporting group title	DL2 - APX005M 0.1 mg/kg + Nivolumab (Phase 1b)
Reporting group description:	
Participants received 0.1 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.	
Reporting group title	DL3 - APX005M 0.3 mg/kg + Nivolumab (Phase 1b)
Reporting group description:	
Participants received 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.	
Reporting group title	Cohort 1 (Arm)/ inNSCLC (Phase 2)
Reporting group description:	
Participants with inNSCLC received 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV. One participant from DL3 was also included.	
Reporting group title	Cohort 2 (Arm)/ PD1-MM (Phase 2)
Reporting group description:	
Participants with PD-1 or anti-PD-L1 resistant or PD1-MM were to receive 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV. Two participants from DL3 were	

also included.

Reporting group title	Cohort 3A (Arm)/ PD1-NSCLC (Phase 2)

Reporting group description:

Participants with PD1-NSCLC metastatic or locally advanced NSCLC not amenable to curative treatment were to receive 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Reporting group title	Cohort 3B (Arm)/ PD1-NSCLC (Phase 2)

Reporting group description:

Participants with PD1-NSCLC metastatic or locally advanced NSCLC not amenable to curative treatment that progressed during prior treatment with anti-PD-1/PD-L1 therapy received 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Subject analysis set title	Phase 1b Escalation
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received IV infusions of APX005M starting at DL 0.03, 0.1 or 0.3 mg/kg administered every 21 days in combination with nivolumab 360 mg IV.

Primary: Number of Participants Experiencing Dose-limiting Toxicities (DLTs)

End point title	Number of Participants Experiencing Dose-limiting Toxicities (DLTs)[1]

End point description:

All toxicities were graded according to the NCI-CTCAE version 4.03. DLT was defined as any of the following events attributed to APX005M and nivolumab combination:
- Grade 4 hematologic toxicity lasting ≥ 7 days (except asymptomatic lymphopenia)
- Grade 3 or 4 neutropenia with a single temperature of >38.3◦ C (101◦ F) or a sustained temperature of ≥38◦ C (100.4◦ F) for more than one hour
- Grade 4 thrombocytopenia or Grade ≥3 thrombocytopenia with signs or symptoms of bleeding or requiring platelet transfusion
- Grade 4 non-hematologic toxicity
- Grade 3 non-hematologic toxicity lasting >3 days despite optimal supportive care
- Any Grade ≥ 3 non-hematologic laboratory value if: medical intervention is required to treat the participant, abnormality leads to hospitalization, or abnormality persists for >1 week
- Failure to recover from a treatment-related adverse event to baseline or ≤ Grade 1 within 12 weeks of last dose of investigational product
- Grade 5 toxicity.

End point type	Primary

End point timeframe:

Up to 21 days following first dose of APX005M and nivolumab

Notes:

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

End point values	Phase 1b Escalation			
Subject group type	Subject analysis set			
Number of subjects analysed	9[2]			
Units: participants	0			

Notes:

[2] - All participants in the safety population who received at least 1 dose of study drug in Phase 1b.

Statistical analyses

No statistical analyses for this end point

Primary: MTD of APX005M + Nivolumab (Phase 1b)

End point title	MTD of APX005M + Nivolumab (Phase 1b)[3]

End point description:

Establish the MTD dose of APX005M combined with 360 mg of nivolumab for which < 33% of DLT-evaluable participants experience a DLT. In Phase 1b, the RP2D was based on the overall safety and tolerability of the combination of APX005M and nivolumab by testing increasing doses up to 0.3 mg/kg APX005M + nivolumab.

All participants in the safety population who received at least 1 dose of study drug in the escalation cohorts (APX005M 0.03 mg/kg + nivolumab; APX005M 0.1 mg/kg + nivolumab; APX005M 0.3 mg/kg + nivolumab). Values of "99999" indicate the MTD was formally not reached.

End point type	Primary

End point timeframe:

Up to 21 days following first dose of APX005M and nivolumab

Notes:

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

End point values	Phase 1b Escalation			
Subject group type	Subject analysis set			
Number of subjects analysed	9[4]			
Units: mg/kg				
number (not applicable)	99999			

Notes:

[4] - All participants in the safety population who received at least 1 dose of study drug in Phase 1b.

Statistical analyses

No statistical analyses for this end point

Primary: Evaluate the ORR by RECIST 1.1 and iRECIST in Each Cohort / Group (Phase 2)

End point title	Evaluate the ORR by RECIST 1.1 and iRECIST in Each Cohort / Group (Phase 2)[5][6]

End point description:

ORR defined as the rate of participants who show as best overall response; either a complete response (CR) or a partial response (PR). The ORR can be evaluated by RECIST v1.1 using computed tomography scans/magnetic resonance imaging. Per RECIST v1.1, for target lesions and assessed by imaging: CR, Disappearance of all target lesions and non-target (NT) lesions; PR, >30% decrease in the sum of the longest diameter of target lesions and no PD in NT lesions or new lesions; ORR = CR + PR.

Cohort 1: inNSCLC, Cohort 2: unresectable or MM that progressed during treatment with anti-PD-1/PD-L1 therapy and had confirmation of PD ≥4 weeks, Cohort 3: PD1-NSCLC metastatic or locally advanced NSCLC not amenable to curative treatment that progressed during prior treatment with anti-PD-1/PD-L1 therapy. Cohort 3A: best response of PD or with SD <16 weeks, Cohort 3B includes PD1-NSCLC with tumor response or with SD ≥ 16 weeks.

End point type	Primary

End point timeframe:

From start of the treatment (Day 1) until disease progression, withdrawal of consent, death, initiation of any anticancer therapy, lost to follow-up, or termination by the Sponsor, whichever comes first (for Phase 2: maximum up to 27 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: No additional statistical analyses were pre-specified for this endpoint.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: ORR analysis was pre-specified for Phase 2 only.

End point values	Cohort 1 (Arm)/ inNSCLC	Cohort 2 (Arm)/ PD1-MM (Phase 2)	Cohort 3A (Arm)/ PD1-NSCLC (Phase 2)	Cohort 3B (Arm)/ PD1-NSCLC (Phase 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	33	12	25
Units: percentage of participants				
number (confidence interval 90%)	16.67 (8.57 to 28.07)	15.15 (6.17 to 29.25)	0.00 (0.00 to 22.09)	0.00 (0.00 to 11.29)

Statistical analyses

No statistical analyses for this end point

Secondary: Safety of the APX005M and Nivolumab Combination (Phase 2)

End point title	Safety of the APX005M and Nivolumab Combination (Phase

End point description:

Number of participants with treatment emergent adverse events are reported. Any adverse event a participant has with 2 or more events in that category is counted only once.

End point type	Secondary

End point timeframe:

Day 1 up to 30 days (or 100 days for serious adverse events and adverse events with potential immunologic etiology) following the after the last dose of APX005M and/or nivolumab (from start of treatment up to 27 months)

Notes:

[7] - 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: Secondary safety analysis was pre-specified for Phase 2 only.

End point values	Cohort 1 (Arm)/ inNSCLC	Cohort 2 (Arm)/ PD1-MM (Phase 2)	Cohort 3A (Arm)/ PD1-NSCLC (Phase 2)	Cohort 3B (Arm)/ PD1-NSCLC (Phase 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	38	14	28
Units: participants	52	36	14	28

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) as Per RECIST 1.1 (Phase 2)

End point title	Duration of Response (DOR) as Per RECIST 1.1 (Phase 2)[8]

End point description:

Duration of Response is defined as the time from the first evidence of confirmed PR or better by per RECIST v1.1 to PD or death due to any cause; in participants alive without PD, DOR was censored on the date of the last tumor assessment. PD is defined using RECIST v1.1, as a 20% increase in the sum of the longest diameter of target lesions, or a measurable increase in a non-target lesion, or the appearance of new lesions. Four/Five participants in Cohort 2 had ongoing responses at the time of study closure.

Cohort 1: inNSCLC, Cohort 2: unresectable or MM that progressed during treatment with anti-PD-1/PD-L1 therapy and had confirmation of PD ≥4 week. Cohort 3A/PD1-NSCLC and Cohort 3B/PD1 NSCLC had no objective response and therefore DOR could not be assessed. Values of "9.9999" indicate the median duration of response not reached.

End point type	Secondary

End point timeframe:

Maximum up to 25 months

Notes:

[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: DOR analysis was pre-specified for Phase 2 only. Cohort 3A/PD1-NSCLC and Cohort 3B/PD1 NSCLC had no objective response and therefore DOR could not be assessed.

End point values	Cohort 1 (Arm)/ inNSCLC	Cohort 2 (Arm)/ PD1-MM (Phase 2)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	5		
Units: months				
median (full range (min-max))	9.9999 (3.9 to 21.4)	9.9999 (4.2 to 24.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Median Progression-free Survival (PFS) (Phase 2)

End point title	Median Progression-free Survival (PFS) (Phase 2)[9]

End point description:

PFS in each cohort, measured from first dose to the earlier of PD (by RECIST 1.1) or death due to any cause, whichever occurs first.

Cohort 1: inNSCLC, Cohort 2: unresectable or MM that progressed during treatment with anti-PD-1/PD-L1 therapy and had confirmation of PD ≥4 weeks, Cohort 3: PD1-NSCLC metastatic or locally advanced NSCLC not amenable to curative treatment that progressed during prior treatment with anti-PD-1/PD-L1 therapy. Cohort 3A: best response of PD or with SD <16 weeks, Cohort 3B includes PD1-NSCLC with tumor response or with SD ≥ 16 weeks.

End point type	Secondary

End point timeframe:

From start of treatment (Day 1) up to 27 months

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: PFS analysis was pre-specified for Phase 2 only.

End point values	Cohort 1 (Arm)/ inNSCLC	Cohort 2 (Arm)/ PD1-MM (Phase 2)	Cohort 3A (Arm)/ PD1-NSCLC (Phase 2)	Cohort 3B (Arm)/ PD1-NSCLC (Phase 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	33	12	25
Units: months				
median (confidence interval 90%)	4.11 (3.45 to 5.52)	1.97 (1.87 to 3.61)	3.43 (2.00 to 3.88)	3.65 (1.84 to 3.81)

Statistical analyses

No statistical analyses for this end point

Secondary: 6-month PFS Rate (Phase 2)

End point title	6-month PFS Rate (Phase 2)[10]

End point description:

PFS rate in each cohort, measured from first dose to the earlier of PD (by RECIST 1.1) or death due to any cause, whichever occurs first.

Cohort 1: inNSCLC, Cohort 2: unresectable or MM that progressed during treatment with anti-PD-1/PD-L1 therapy and had confirmation of PD ≥4 weeks, Cohort 3: PD1-NSCLC metastatic or locally advanced NSCLC not amenable to curative treatment that progressed during prior treatment with anti-PD-1/PD-L1 therapy. Cohort 3A: best response of PD or with SD <16 weeks, Cohort 3B includes PD1-NSCLC with tumor response or with SD ≥ 16 weeks.

End point type	Secondary

End point timeframe:

From start of treatment (Day 1) to 6 months

Notes:

[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: PFS analysis was pre-specified for Phase 2 only.

End point values	Cohort 1 (Arm)/ inNSCLC	Cohort 2 (Arm)/ PD1-MM (Phase 2)	Cohort 3A (Arm)/ PD1-NSCLC (Phase 2)	Cohort 3B (Arm)/ PD1-NSCLC (Phase 2)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	48	33	12	25
Units: percentage of participants				
number (confidence interval 90%)	33.10 (20.10 to 46.68)	21.21 (9.35 to 36.25)	25.00 (6.01 to 50.48)	12.92 (3.27 to 29.41)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Day 1 through 30 days (or 100 days for serious adverse events (SAEs) and adverse events (AEs) with potential immunologic etiology) after the last dose of study drug (up to 27 months)

Adverse event reporting additional description:

An AE considered "serious" if it results in any of the following outcomes:
- Death
- A life-threatening AE
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
- A congenital anomaly/birth defect.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.00

Reporting groups

Reporting group title	DL1 - APX005M 0.03 mg/kg + Nivolumab (Phase 1b escalation)

Reporting group description:

Participants received 0.03 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Reporting group title	DL2 - APX005M 0.1 mg/kg + Nivolumab (Phase 1b escalation)

Reporting group description:

Participants received 0.1 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Reporting group title	DL3 - APX005M 0.3 mg/kg + Nivolumab (Phase 1b escalation)

Reporting group description:

Participants received 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Note: The 3 participants in DL3 are at the RP2D and are also included in Phase 2 results. One participant was rolled over to Cohort 1 (Phase 2) and 2 participants were rolled over into Cohort 2 (Phase 2).

Reporting group title	Cohort 1 (Arm)/ inNSCLC (Phase 2)

Reporting group description:

Participants with inNSCLC received 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV. Includes data from 1 participant from DL3.

Reporting group title	Cohort 2 (Arm)/ PD1-MM (Phase 2)

Reporting group description:

Participants with PD-1 or anti-PD-L1 resistant or PD1-MM were to receive 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV. Two participants from DL3 were also included.

Reporting group title	Cohort 3A (Arm)/ PD1-NSCLC (Phase 2)

Reporting group description:

Participants with PD1-NSCLC metastatic or locally advanced NSCLC not amenable to curative treatment received 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Reporting group title	Cohort 3B (Arm)/ PD1-NSCLC (Phase 2)

Reporting group description:

Participants with PD1-NSCLC metastatic or locally advanced NSCLC not amenable to curative treatment that progressed during prior treatment with anti-PD-1/PD-L1 therapy received 0.3 mg/kg of APX005M administered every 21 days in combination with nivolumab 360 mg IV.

Serious adverse events	DL1 - APX005M 0.03 mg/kg + Nivolumab (Phase 1b escalation)	DL2 - APX005M 0.1 mg/kg + Nivolumab (Phase 1b escalation)	DL3 - APX005M 0.3 mg/kg + Nivolumab (Phase 1b escalation)
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 3 (0.00%)
number of deaths (all causes)	1	1	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone neoplasm			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Facial pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 physical health deterioration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Acute respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic respiratory failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 artery thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)
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 failure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fraction			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Acute coronary syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 myocardial infarction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 arrest			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis autoimmune			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Optic ischaemic neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (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
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Myositis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (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
Sepsis			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (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
Streptococcal bacteraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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			
Diabetic ketoacidosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
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 / 3 (0.00%)	0 / 3 (0.00%)
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	Cohort 1 (Arm)/ inNSCLC (Phase 2)	Cohort 2 (Arm)/ PD1-MM (Phase 2)	Cohort 3A (Arm)/ PD1-NSCLC (Phase 2)
Total subjects affected by serious adverse events			
subjects affected / exposed	25 / 53 (47.17%)	6 / 38 (15.79%)	6 / 14 (42.86%)
number of deaths (all causes)	18	4	4
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone neoplasm			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cancer pain			

subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Facial pain			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (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
General physical health deterioration			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (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
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	2 / 53 (3.77%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic respiratory failure			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	2 / 53 (3.77%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary artery thrombosis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	3 / 53 (5.66%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			

subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 53 (1.89%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood bilirubin increased			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fraction			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Toxicity to various agents			
subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	2 / 53 (3.77%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myocardial infarction			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardio-respiratory arrest			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	2 / 53 (3.77%)	0 / 38 (0.00%)	0 / 14 (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

Encephalitis autoimmune			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	2 / 53 (3.77%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Optic ischaemic neuropathy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	2 / 53 (3.77%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pancreatitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (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			
Acute kidney injury			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			

subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung infection			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	4 / 53 (7.55%)	0 / 38 (0.00%)	2 / 14 (14.29%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal bacteraemia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Diabetic ketoacidosis			

subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (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
Hypercalcaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Cohort 3B (Arm)/ PD1-NSCLC (Phase 2)		
Total subjects affected by serious adverse events			
subjects affected / exposed	13 / 28 (46.43%)		
number of deaths (all causes)	9		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Bone neoplasm			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cancer pain			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Facial pain			

subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	1 / 28 (3.57%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pain				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Cytokine release syndrome				
subjects affected / exposed	2 / 28 (7.14%)			
occurrences causally related to treatment / all	2 / 2			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Acute respiratory failure				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic obstructive pulmonary disease				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic respiratory failure				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Dyspnoea			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary artery thrombosis			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Respiratory failure			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Blood bilirubin increased			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Weight decreased				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Fall				
subjects affected / exposed	1 / 28 (3.57%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Femur fraction				
subjects affected / exposed	1 / 28 (3.57%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hip fracture				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radius fracture				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Toxicity to various agents				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Acute coronary syndrome				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute myocardial infarction				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Cardiac arrest				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardio-respiratory arrest				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pericardial effusion				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Brain oedema				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalitis autoimmune				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Eye disorders				

Optic ischaemic neuropathy			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Intestinal obstruction			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pancreatitis			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pancreatitis acute			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Myositis			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bacteraemia			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Bronchitis			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Influenza			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lung abscess			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Lung infection				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	2 / 28 (7.14%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	1 / 28 (3.57%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Streptococcal bacteraemia				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Diabetic ketoacidosis				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypercalcaemia				
subjects affected / exposed	1 / 28 (3.57%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
subjects affected / exposed	1 / 28 (3.57%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			

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

Non-serious adverse events	DL1 - APX005M 0.03 mg/kg + Nivolumab (Phase 1b escalation)	DL2 - APX005M 0.1 mg/kg + Nivolumab (Phase 1b escalation)	DL3 - APX005M 0.3 mg/kg + Nivolumab (Phase 1b escalation)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	3 / 3 (100.00%)	3 / 3 (100.00%)
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypertention			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	3 / 3 (100.00%)
occurrences (all)	0	3	5
Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	3 / 3 (100.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	4	8	0
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	2

Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	0	4	0
Pain			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Performance status decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	2 / 3 (66.67%)
occurrences (all)	0	3	4
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cough			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	1	1	1
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dyspnoea at rest			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lung infiltration			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Pleural effusion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pneumonitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	6	0	0
Productive cough			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	4	0	0
Pulmonary embolism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Upper-airway cough syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Confusional state			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depressive symptom			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Disorientation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Amylase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			

subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	5	0
Blood alkaline phosphatase			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Blood bilirubin increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Blood cortisol decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood glucose increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemoglobin			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lipase increased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	2	0
Monocyte count decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Weight increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Fall			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Palpitations			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dysgeusia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Headache			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	1	2	1
Hypoaesthesia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Lethargy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Tremor			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vocal cord paralysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Lymph node pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retinal exudates			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	2 / 3 (66.67%)
occurrences (all)	0	1	3
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	3 / 3 (100.00%)
occurrences (all)	1	7	5
Odynophagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Vomiting			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	3 / 3 (100.00%)
occurrences (all)	1	3	4
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	2 / 3 (66.67%)	1 / 3 (33.33%)
occurrences (all)	0	3	1
Hyperhidrosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	1	1
Lichenoid keratosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Pruritus generalised			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	3 / 3 (100.00%)
occurrences (all)	0	1	3
Rash			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	2 / 3 (66.67%)
occurrences (all)	2	1	3
Rash maculo-papular			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Skin hypopigmentation			

subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	3	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	1	1	5
Back pain			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	1	1	0
Bone pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Flank pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 3 (33.33%)
occurrences (all)	0	2	1
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ostenonecrosis of jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle rigidity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Infections and infestations			
Anorectal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Fungal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Gingivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Localised infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Lung infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 3 (33.33%)	2 / 3 (66.67%)	1 / 3 (33.33%)
occurrences (all)	1	9	2
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypercalcaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Cohort 1 (Arm)/ inNSCLC (Phase 2)	Cohort 2 (Arm)/ PD1-MM (Phase 2)	Cohort 3A (Arm)/ PD1-NSCLC (Phase 2)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	52 / 53 (98.11%)	36 / 38 (94.74%)	14 / 14 (100.00%)
Vascular disorders			
Flushing			
subjects affected / exposed	6 / 53 (11.32%)	3 / 38 (7.89%)	0 / 14 (0.00%)
occurrences (all)	8	3	0
Hypertention			
subjects affected / exposed	11 / 53 (20.75%)	2 / 38 (5.26%)	0 / 14 (0.00%)
occurrences (all)	16	2	0

Hypotension			
subjects affected / exposed	10 / 53 (18.87%)	4 / 38 (10.53%)	1 / 14 (7.14%)
occurrences (all)	16	5	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	7 / 53 (13.21%)	6 / 38 (15.79%)	4 / 14 (28.57%)
occurrences (all)	8	10	6
Chest discomfort			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Chest pain			
subjects affected / exposed	2 / 53 (3.77%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	2	1	0
Chills			
subjects affected / exposed	30 / 53 (56.60%)	19 / 38 (50.00%)	5 / 14 (35.71%)
occurrences (all)	65	51	14
Discomfort			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	18 / 53 (33.96%)	15 / 38 (39.47%)	5 / 14 (35.71%)
occurrences (all)	41	36	12
Influenza like illness			
subjects affected / exposed	2 / 53 (3.77%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	2	1	0
Malaise			
subjects affected / exposed	2 / 53 (3.77%)	4 / 38 (10.53%)	3 / 14 (21.43%)
occurrences (all)	2	4	3
Non-cardiac chest pain			
subjects affected / exposed	5 / 53 (9.43%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	5	0	0
Oedema peripheral			
subjects affected / exposed	4 / 53 (7.55%)	3 / 38 (7.89%)	3 / 14 (21.43%)
occurrences (all)	7	3	3
Pain			

subjects affected / exposed	5 / 53 (9.43%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	6	1	0
Performance status decreased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	28 / 53 (52.83%)	26 / 38 (68.42%)	7 / 14 (50.00%)
occurrences (all)	56	57	34
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	3 / 53 (5.66%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	4	0	0
Hypersensitivity			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	3 / 53 (5.66%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	7	0	0
Cough			
subjects affected / exposed	13 / 53 (24.53%)	3 / 38 (7.89%)	3 / 14 (21.43%)
occurrences (all)	16	4	3
Dysphonia			
subjects affected / exposed	2 / 53 (3.77%)	2 / 38 (5.26%)	0 / 14 (0.00%)
occurrences (all)	2	2	0
Dyspnoea			
subjects affected / exposed	21 / 53 (39.62%)	3 / 38 (7.89%)	6 / 14 (42.86%)
occurrences (all)	30	3	8
Dyspnoea at rest			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	3 / 53 (5.66%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Epistaxis			

subjects affected / exposed	2 / 53 (3.77%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Haemoptysis			
subjects affected / exposed	3 / 53 (5.66%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	3	0	3
Hypoxia			
subjects affected / exposed	2 / 53 (3.77%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Lung infiltration			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 53 (1.89%)	2 / 38 (5.26%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
Pleural effusion			
subjects affected / exposed	4 / 53 (7.55%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	4	1	0
Pneumonitis			
subjects affected / exposed	0 / 53 (0.00%)	2 / 38 (5.26%)	0 / 14 (0.00%)
occurrences (all)	0	4	0
Productive cough			
subjects affected / exposed	2 / 53 (3.77%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Pulmonary embolism			
subjects affected / exposed	3 / 53 (5.66%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Rhinorrhoea			
subjects affected / exposed	2 / 53 (3.77%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Wheezing			
subjects affected / exposed	5 / 53 (9.43%)	1 / 38 (2.63%)	1 / 14 (7.14%)
occurrences (all)	5	1	1
Psychiatric disorders			

Anxiety			
subjects affected / exposed	5 / 53 (9.43%)	1 / 38 (2.63%)	1 / 14 (7.14%)
occurrences (all)	5	1	1
Confusional state			
subjects affected / exposed	3 / 53 (5.66%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	4	0	0
Depression			
subjects affected / exposed	3 / 53 (5.66%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	3	1	0
Depressive symptom			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Disorientation			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	13 / 53 (24.53%)	1 / 38 (2.63%)	1 / 14 (7.14%)
occurrences (all)	14	1	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	11 / 53 (20.75%)	11 / 38 (28.95%)	4 / 14 (28.57%)
occurrences (all)	33	19	6
Amylase increased			
subjects affected / exposed	3 / 53 (5.66%)	2 / 38 (5.26%)	1 / 14 (7.14%)
occurrences (all)	5	4	2
Aspartate aminotransferase increased			
subjects affected / exposed	12 / 53 (22.64%)	9 / 38 (23.68%)	4 / 14 (28.57%)
occurrences (all)	23	16	5
Blood alkaline phosphatase			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Blood alkaline phosphatase increased			
subjects affected / exposed	9 / 53 (16.98%)	7 / 38 (18.42%)	1 / 14 (7.14%)
occurrences (all)	34	12	1
Blood bilirubin increased			

subjects affected / exposed	3 / 53 (5.66%)	3 / 38 (7.89%)	0 / 14 (0.00%)
occurrences (all)	4	5	0
Blood cortisol decreased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Blood creatinine increased			
subjects affected / exposed	5 / 53 (9.43%)	1 / 38 (2.63%)	1 / 14 (7.14%)
occurrences (all)	8	5	2
Blood glucose increased			
subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	1 / 14 (7.14%)
occurrences (all)	0	2	2
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 53 (0.00%)	3 / 38 (7.89%)	0 / 14 (0.00%)
occurrences (all)	0	3	0
Blood urea increased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	8 / 53 (15.09%)	7 / 38 (18.42%)	4 / 14 (28.57%)
occurrences (all)	19	18	10
Haemoglobin			
subjects affected / exposed	1 / 53 (1.89%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	1	7	0
Lipase increased			
subjects affected / exposed	5 / 53 (9.43%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	9	2	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Monocyte count decreased			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			

subjects affected / exposed	4 / 53 (7.55%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	10	1	0
Weight decreased			
subjects affected / exposed	14 / 53 (26.42%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	21	0	1
Weight increased			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	4 / 53 (7.55%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	6	0	0
Infusion related reaction			
subjects affected / exposed	5 / 53 (9.43%)	3 / 38 (7.89%)	2 / 14 (14.29%)
occurrences (all)	6	4	2
Ligament sprain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	2 / 53 (3.77%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Palpitations			
subjects affected / exposed	1 / 53 (1.89%)	2 / 38 (5.26%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
Pericardial effusion			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Sinus tachycardia			
subjects affected / exposed	3 / 53 (5.66%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	3	1	0
Tachycardia			

subjects affected / exposed	7 / 53 (13.21%)	2 / 38 (5.26%)	1 / 14 (7.14%)
occurrences (all)	7	2	1
Nervous system disorders			
Dizziness			
subjects affected / exposed	3 / 53 (5.66%)	2 / 38 (5.26%)	1 / 14 (7.14%)
occurrences (all)	3	2	1
Dysgeusia			
subjects affected / exposed	3 / 53 (5.66%)	2 / 38 (5.26%)	1 / 14 (7.14%)
occurrences (all)	4	2	1
Headache			
subjects affected / exposed	8 / 53 (15.09%)	8 / 38 (21.05%)	2 / 14 (14.29%)
occurrences (all)	13	20	4
Hypoaesthesia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Lethargy			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Somnolence			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	2 / 14 (14.29%)
occurrences (all)	0	0	2
Tremor			
subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Vocal cord paralysis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	13 / 53 (24.53%)	4 / 38 (10.53%)	0 / 14 (0.00%)
occurrences (all)	31	8	0
Lymph node pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	1 / 53 (1.89%)	2 / 38 (5.26%)	0 / 14 (0.00%)
occurrences (all)	1	2	0
Vertigo			
subjects affected / exposed	0 / 53 (0.00%)	2 / 38 (5.26%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Dry eye			
subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Eye pain			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Retinal exudates			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	2 / 53 (3.77%)	1 / 38 (2.63%)	1 / 14 (7.14%)
occurrences (all)	2	1	1
Vitreous floaters			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 53 (5.66%)	2 / 38 (5.26%)	2 / 14 (14.29%)
occurrences (all)	7	2	3
Abdominal pain upper			

subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	3 / 14 (21.43%)
occurrences (all)	0	3	3
Constipation			
subjects affected / exposed	10 / 53 (18.87%)	5 / 38 (13.16%)	3 / 14 (21.43%)
occurrences (all)	15	5	3
Diarrhoea			
subjects affected / exposed	12 / 53 (22.64%)	6 / 38 (15.79%)	2 / 14 (14.29%)
occurrences (all)	37	8	8
Dry mouth			
subjects affected / exposed	6 / 53 (11.32%)	2 / 38 (5.26%)	2 / 14 (14.29%)
occurrences (all)	6	2	2
Dyspepsia			
subjects affected / exposed	0 / 53 (0.00%)	2 / 38 (5.26%)	0 / 14 (0.00%)
occurrences (all)	0	3	0
Dysphagia			
subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	24 / 53 (45.28%)	18 / 38 (47.37%)	7 / 14 (50.00%)
occurrences (all)	54	22	13
Odynophagia			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	4 / 53 (7.55%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	5	0	0
Toothache			
subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	1 / 14 (7.14%)
occurrences (all)	0	1	1
Vomiting			
subjects affected / exposed	18 / 53 (33.96%)	10 / 38 (26.32%)	2 / 14 (14.29%)
occurrences (all)	46	19	3
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0

Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	2 / 53 (3.77%)	2 / 38 (5.26%)	0 / 14 (0.00%)
occurrences (all)	2	2	0
Hyperhidrosis			
subjects affected / exposed	3 / 53 (5.66%)	0 / 38 (0.00%)	2 / 14 (14.29%)
occurrences (all)	3	0	3
Lichenoid keratosis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Night sweats			
subjects affected / exposed	2 / 53 (3.77%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	1
Pruritus generalised			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Pruritus			
subjects affected / exposed	16 / 53 (30.19%)	13 / 38 (34.21%)	4 / 14 (28.57%)
occurrences (all)	34	15	7
Rash			
subjects affected / exposed	9 / 53 (16.98%)	10 / 38 (26.32%)	1 / 14 (7.14%)
occurrences (all)	13	13	3
Rash maculo-papular			
subjects affected / exposed	4 / 53 (7.55%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	9	1	0
Skin hypopigmentation			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Urticaria			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	1	0	1
Renal and urinary disorders			

Chromaturia			
subjects affected / exposed	0 / 53 (0.00%)	2 / 38 (5.26%)	0 / 14 (0.00%)
occurrences (all)	0	7	0
Dysuria			
subjects affected / exposed	0 / 53 (0.00%)	2 / 38 (5.26%)	0 / 14 (0.00%)
occurrences (all)	0	2	0
Haematuria			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	4 / 53 (7.55%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	4	1	0
Hypothyroidism			
subjects affected / exposed	5 / 53 (9.43%)	2 / 38 (5.26%)	1 / 14 (7.14%)
occurrences (all)	5	2	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	12 / 53 (22.64%)	6 / 38 (15.79%)	3 / 14 (21.43%)
occurrences (all)	23	16	3
Back pain			
subjects affected / exposed	8 / 53 (15.09%)	4 / 38 (10.53%)	1 / 14 (7.14%)
occurrences (all)	11	6	1
Bone pain			
subjects affected / exposed	3 / 53 (5.66%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Flank pain			
subjects affected / exposed	3 / 53 (5.66%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Muscular weakness			
subjects affected / exposed	4 / 53 (7.55%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	4	0	0
Musculoskeletal chest pain			

subjects affected / exposed	2 / 53 (3.77%)	2 / 38 (5.26%)	1 / 14 (7.14%)
occurrences (all)	2	2	1
Musculoskeletal pain			
subjects affected / exposed	2 / 53 (3.77%)	1 / 38 (2.63%)	2 / 14 (14.29%)
occurrences (all)	4	1	2
Myalgia			
subjects affected / exposed	4 / 53 (7.55%)	6 / 38 (15.79%)	1 / 14 (7.14%)
occurrences (all)	4	10	2
Neck pain			
subjects affected / exposed	2 / 53 (3.77%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	3	0	1
Ostenonecrosis of jaw			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	2 / 53 (3.77%)	3 / 38 (7.89%)	0 / 14 (0.00%)
occurrences (all)	3	6	0
Pain in jaw			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	1
Muscle rigidity			
subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Anorectal infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Candida infection			
subjects affected / exposed	2 / 53 (3.77%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	1
Fungal infection			
subjects affected / exposed	0 / 53 (0.00%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	0	1	0
Gingivitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1

Herpes zoster			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	2	0	1
Localised infection			
subjects affected / exposed	1 / 53 (1.89%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	1	1	0
Lung infection			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	3 / 53 (5.66%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	3	1	0
Pharyngitis			
subjects affected / exposed	0 / 53 (0.00%)	0 / 38 (0.00%)	1 / 14 (7.14%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	6 / 53 (11.32%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	8	0	0
Respiratory tract infection			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Skin infection			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	2	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 53 (3.77%)	4 / 38 (10.53%)	2 / 14 (14.29%)
occurrences (all)	3	4	2
Urinary tract infection			
subjects affected / exposed	2 / 53 (3.77%)	2 / 38 (5.26%)	0 / 14 (0.00%)
occurrences (all)	2	2	0
Metabolism and nutrition disorders			
Decreased appetite			

subjects affected / exposed	14 / 53 (26.42%)	4 / 38 (10.53%)	4 / 14 (28.57%)
occurrences (all)	15	4	5
Dehydration			
subjects affected / exposed	5 / 53 (9.43%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	10	0	0
Hypercalcaemia			
subjects affected / exposed	1 / 53 (1.89%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	4 / 53 (7.55%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	4	1	0
Hypokalaemia			
subjects affected / exposed	4 / 53 (7.55%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	4	0	0
Hypomagnesaemia			
subjects affected / exposed	3 / 53 (5.66%)	0 / 38 (0.00%)	0 / 14 (0.00%)
occurrences (all)	3	0	0
Hyponatraemia			
subjects affected / exposed	4 / 53 (7.55%)	1 / 38 (2.63%)	0 / 14 (0.00%)
occurrences (all)	6	1	0

Non-serious adverse events	Cohort 3B (Arm)/ PD1-NSCLC (Phase 2)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 28 (100.00%)		
Vascular disorders			
Flushing			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	2		
Hypertention			
subjects affected / exposed	3 / 28 (10.71%)		
occurrences (all)	5		
Hypotension			
subjects affected / exposed	3 / 28 (10.71%)		
occurrences (all)	4		
General disorders and administration site conditions			

Asthenia				
subjects affected / exposed	12 / 28 (42.86%)			
occurrences (all)	17			
Chest discomfort				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences (all)	0			
Chest pain				
subjects affected / exposed	5 / 28 (17.86%)			
occurrences (all)	8			
Chills				
subjects affected / exposed	13 / 28 (46.43%)			
occurrences (all)	24			
Discomfort				
subjects affected / exposed	1 / 28 (3.57%)			
occurrences (all)	1			
Fatigue				
subjects affected / exposed	4 / 28 (14.29%)			
occurrences (all)	4			
Influenza like illness				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences (all)	0			
Malaise				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences (all)	0			
Non-cardiac chest pain				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences (all)	0			
Oedema peripheral				
subjects affected / exposed	2 / 28 (7.14%)			
occurrences (all)	2			
Pain				
subjects affected / exposed	1 / 28 (3.57%)			
occurrences (all)	1			
Performance status decreased				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences (all)	0			

Pyrexia			
subjects affected / exposed	12 / 28 (42.86%)		
occurrences (all)	24		
Immune system disorders			
Cytokine release syndrome			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Hypersensitivity			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Cough			
subjects affected / exposed	10 / 28 (35.71%)		
occurrences (all)	13		
Dysphonia			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Dyspnoea			
subjects affected / exposed	8 / 28 (28.57%)		
occurrences (all)	9		
Dyspnoea at rest			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Dyspnoea exertional			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	3		
Haemoptysis			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Hypoxia			

subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Lung infiltration			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Pleural effusion			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Pneumonitis			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	2		
Productive cough			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Pulmonary embolism			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Upper-airway cough syndrome			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	2		
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Confusional state			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		

Depression			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Depressive symptom			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Disorientation			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Insomnia			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	8 / 28 (28.57%)		
occurrences (all)	34		
Amylase increased			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	3		
Aspartate aminotransferase increased			
subjects affected / exposed	8 / 28 (28.57%)		
occurrences (all)	17		
Blood alkaline phosphatase			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Blood alkaline phosphatase increased			
subjects affected / exposed	3 / 28 (10.71%)		
occurrences (all)	5		
Blood bilirubin increased			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	4		
Blood cortisol decreased			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			

subjects affected / exposed	1 / 28 (3.57%)			
occurrences (all)	1			
Blood glucose increased				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences (all)	0			
Blood lactate dehydrogenase increased				
subjects affected / exposed	1 / 28 (3.57%)			
occurrences (all)	2			
Blood urea increased				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences (all)	0			
Gamma-glutamyltransferase increased				
subjects affected / exposed	5 / 28 (17.86%)			
occurrences (all)	15			
Haemoglobin				
subjects affected / exposed	3 / 28 (10.71%)			
occurrences (all)	3			
Lipase increased				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences (all)	0			
Lymphocyte count decreased				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences (all)	0			
Monocyte count decreased				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences (all)	0			
Platelet count decreased				
subjects affected / exposed	0 / 28 (0.00%)			
occurrences (all)	0			
Weight decreased				
subjects affected / exposed	3 / 28 (10.71%)			
occurrences (all)	3			
Weight increased				

subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Infusion related reaction			
subjects affected / exposed	3 / 28 (10.71%)		
occurrences (all)	6		
Ligament sprain			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Palpitations			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Pericardial effusion			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Tachycardia			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	2		
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Dysgeusia			

subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	4 / 28 (14.29%)		
occurrences (all)	4		
Hypoaesthesia			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Lethargy			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Neuralgia			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Presyncope			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Somnolence			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Vocal cord paralysis			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 28 (21.43%)		
occurrences (all)	10		
Lymph node pain			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear pain			

subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Dry eye			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Eye pain			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Retinal exudates			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Vitreous floaters			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Constipation			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Diarrhoea			

subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	2		
Dry mouth			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Dyspepsia			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Dysphagia			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	2		
Nausea			
subjects affected / exposed	8 / 28 (28.57%)		
occurrences (all)	13		
Odynophagia			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	2		
Stomatitis			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	5 / 28 (17.86%)		
occurrences (all)	8		
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Blister			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Dry skin			

subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	3		
Lichenoid keratosis			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Night sweats			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Pruritus generalised			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	4 / 28 (14.29%)		
occurrences (all)	7		
Rash			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Rash maculo-papular			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Skin hypopigmentation			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Urticaria			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Chromaturia			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Dysuria			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		

Haematuria			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Pollakiuria			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Hypothyroidism			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 28 (17.86%)		
occurrences (all)	6		
Back pain			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	2		
Bone pain			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	3		
Flank pain			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	2		
Muscular weakness			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Musculoskeletal chest pain			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Musculoskeletal pain			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	2		
Myalgia			

subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Neck pain			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	2		
Ostenonecrosis of jaw			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Pain in extremity			
subjects affected / exposed	5 / 28 (17.86%)		
occurrences (all)	5		
Pain in jaw			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Muscle rigidity			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Anorectal infection			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Candida infection			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Fungal infection			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Gingivitis			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Herpes zoster			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		
Localised infection			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		

Lung infection subjects affected / exposed occurrences (all)	0 / 28 (0.00%) 0		
Nasopharyngitis subjects affected / exposed occurrences (all)	2 / 28 (7.14%) 2		
Pharyngitis subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Pneumonia subjects affected / exposed occurrences (all)	0 / 28 (0.00%) 0		
Respiratory tract infection subjects affected / exposed occurrences (all)	4 / 28 (14.29%) 4		
Sinusitis subjects affected / exposed occurrences (all)	2 / 28 (7.14%) 2		
Skin infection subjects affected / exposed occurrences (all)	0 / 28 (0.00%) 0		
Upper respiratory tract infection subjects affected / exposed occurrences (all)	0 / 28 (0.00%) 0		
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 28 (0.00%) 0		
Metabolism and nutrition disorders Decreased appetite subjects affected / exposed occurrences (all)	7 / 28 (25.00%) 8		
Dehydration subjects affected / exposed occurrences (all)	1 / 28 (3.57%) 1		
Hypercalcaemia			

subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	3		
Hyperglycaemia			
subjects affected / exposed	0 / 28 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	2 / 28 (7.14%)		
occurrences (all)	5		
Hypomagnesaemia			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	3		
Hyponatraemia			
subjects affected / exposed	1 / 28 (3.57%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 October 2019	- Provide clarification regarding optional biopsies. - Provide clarification regarding confirm. - Regroup the Eligibility Criteria for easier reference. - Relax the requirement to discuss minor study treatment delays with the Medical Monitor. - Provide additional guidance regarding the infusion rate following infusion-related reactions and premedication regimen. - Modify the supportive care guidelines related to elevated liver function tests and cytokine release syndrome. - Add supportive care guidelines for myocarditis toxicity. - Add definition of correlative laboratory testing. - Specify that the dose modification regarding neutropenia related to Grade 3-4 and not Grades 2 to 4. - Remove summary of changes appendices as redline tracked changes versions of the amendment will be provided. - Remove summary of changes appendices as redline versions will be provided.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported