Clinical trial results:
A Phase 2 Study of INCMGA00012 (PD-1 Inhibitor) in Participants With Selected Solid Tumors (POD1UM-203)

Summary

EudraCT number	2018-002941-12
Trial protocol	AT HU PL ES IT RO
Global end of trial date	28 June 2022

Results information

Result version number	v1 (current)
This version publication date	12 July 2023
First version publication date	12 July 2023

Trial information

Trial identification

Sponsor protocol code	INCMGA 0012-203

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03679767
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Incyte Corporation
Sponsor organisation address	1801 Augustine Cutoff Drive, Wilmington, United States, 19803
Public contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.com
Scientific contact	Study Director, Incyte Corporation, 1 8554633463, medinfo@incyte.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	28 June 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	28 June 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This trial was conducted to assess the efficacy of INCMGA00012 in terms of the overall response rate (ORR) in tumor types of interest.

Protection of trial subjects:

This study was to be performed in accordance with ethical principles that have their origin in the Declaration of Helsinki and conducted in adherence to the study Protocol, applicable Good Clinical Practices, and applicable laws and country-specific regulations in which the study was being conducted.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	09 January 2019
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	Austria: 8
Country: Number of subjects enrolled	Spain: 11
Country: Number of subjects enrolled	France: 23
Country: Number of subjects enrolled	Hungary: 10
Country: Number of subjects enrolled	Italy: 19
Country: Number of subjects enrolled	Poland: 9
Country: Number of subjects enrolled	Romania: 24
Country: Number of subjects enrolled	United States: 17
Worldwide total number of subjects	121
EEA total number of subjects	104

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)	44
From 65 to 84 years	69
85 years and over	8

Subject disposition

Recruitment

Recruitment details:

This study was conducted at 34 study centers in Austria, Spain, France, Hungary, Italy, Poland, Romania, and the United States.

Pre-assignment

Screening details:

A total of 121 participants with advanced solid tumors (melanoma, non-small cell lung cancer, urethelial carcinoma, and renal cell carcinoma) were enrolled in the study and treated with retifanlimab.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Melanoma

Arm description:

Participants with melanoma received retifanlimab 500 milligrams (mg), administered by intravenous (IV) infusion over 30 minutes on Day 1 of each 28-day cycle (Q4W).

Arm type	Experimental
Investigational medicinal product name	Retifanlimab
Investigational medicinal product code	INCMGA00012
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

500 mg Q4W

Arm title	Non-small Cell Lung Cancer

Arm description:

Participants with non-small cell lung cancer received retifanlimab 500 mg, administered by IV infusion over 30 minutes on Day 1 Q4W.

Arm type	Experimental
Investigational medicinal product name	Retifanlimab
Investigational medicinal product code	INCMGA00012
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

500 mg Q4W

Arm title	Urethelial Carcinoma

Arm description:

Participants with urethelial carcinoma received retifanlimab 500 mg, administered by IV infusion over 30 minutes on Day 1 Q4W.

Arm type	Experimental

Investigational medicinal product name	Retifanlimab
Investigational medicinal product code	INCMGA00012
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

500 mg Q4W

Arm title	Renal Cell Carcinoma

Arm description:

Participants with renal cell carcinoma received retifanlimab 500 mg, administered by IV infusion over 30 minutes on Day 1 Q4W.

Arm type	Experimental
Investigational medicinal product name	Retifanlimab
Investigational medicinal product code	INCMGA00012
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

500 mg Q4W

Number of subjects in period 1	Melanoma	Non-small Cell Lung Cancer	Urethelial Carcinoma
Started	35	23	29
Completed	0	0	0
Not completed	35	23	29
Adverse event, serious fatal	16	11	17
Consent withdrawn by subject	-	-	-
Follow-up Completed	18	11	11
Progressive Disease	-	-	-
Lost to follow-up	1	1	1
Entered Hospice Care	-	-	-

Number of subjects in period 1	Renal Cell Carcinoma
Started	34
Completed	0
Not completed	34
Adverse event, serious fatal	10
Consent withdrawn by subject	1
Follow-up Completed	20
Progressive Disease	1
Lost to follow-up	1
Entered Hospice Care	1

Baseline characteristics

Reporting groups	
Reporting group title	Melanoma
Reporting group description:	
Participants with melanoma received retifanlimab 500 milligrams (mg), administered by intravenous (IV) infusion over 30 minutes on Day 1 of each 28-day cycle (Q4W).	
Reporting group title	Non-small Cell Lung Cancer
Reporting group description:	
Participants with non-small cell lung cancer received retifanlimab 500 mg, administered by IV infusion over 30 minutes on Day 1 Q4W.	
Reporting group title	Urethelial Carcinoma
Reporting group description:	
Participants with urethelial carcinoma received retifanlimab 500 mg, administered by IV infusion over 30 minutes on Day 1 Q4W.	
Reporting group title	Renal Cell Carcinoma
Reporting group description:	
Participants with renal cell carcinoma received retifanlimab 500 mg, administered by IV infusion over 30 minutes on Day 1 Q4W.	

Reporting group values	Melanoma	Non-small Cell Lung Cancer	Urethelial Carcinoma
Number of subjects	35	23	29
Age categorical Units: Subjects			
Adults (18-64 years)	14	9	6
From 65-84 years	16	13	22
85 years and over	5	1	1
Age Continuous Units: Years			
arithmetic mean	67.2	67.8	72.0
standard deviation	± 15.24	± 8.68	± 8.23
Sex: Female, Male Units:			
Female	20	7	4
Male	15	16	25
Race, Customized Units: Subjects			
White/Caucasian	35	22	20
Asian	0	1	0
Not Reported	0	0	9
Ethnicity, Customized Units: Subjects			
Hispanic or Latino	4	0	1
Not Hispanic or Latino	30	22	12
Not Reported	1	1	16

Reporting group values	Renal Cell Carcinoma	Total	
Number of subjects	34	121	

Age categorical Units: Subjects			
Adults (18-64 years)	15	44	
From 65-84 years	18	69	
85 years and over	1	8	
Age Continuous Units: Years			
arithmetic mean	66.6		
standard deviation	± 10.28	-	
Sex: Female, Male Units:			
Female	10	41	
Male	24	80	
Race, Customized Units: Subjects			
White/Caucasian	33	110	
Asian	0	1	
Not Reported	1	10	
Ethnicity, Customized Units: Subjects			
Hispanic or Latino	0	5	
Not Hispanic or Latino	29	93	
Not Reported	5	23	

End points

End points reporting groups

Reporting group title	Melanoma
Reporting group description:	
Participants with melanoma received retifanlimab 500 milligrams (mg), administered by intravenous (IV) infusion over 30 minutes on Day 1 of each 28-day cycle (Q4W).	
Reporting group title	Non-small Cell Lung Cancer
Reporting group description:	
Participants with non-small cell lung cancer received retifanlimab 500 mg, administered by IV infusion over 30 minutes on Day 1 Q4W.	
Reporting group title	Urethelial Carcinoma
Reporting group description:	
Participants with urethelial carcinoma received retifanlimab 500 mg, administered by IV infusion over 30 minutes on Day 1 Q4W.	
Reporting group title	Renal Cell Carcinoma
Reporting group description:	
Participants with renal cell carcinoma received retifanlimab 500 mg, administered by IV infusion over 30 minutes on Day 1 Q4W.	
Subject analysis set title	All Participants
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants with melanoma, non-small cell lung cancer, urethelial carcinoma, and renal cell carcinoma received retifanlimab 500 mg, administered by IV infusion over 30 minutes on Day 1 Q4W. Participants received at least 1 dose of study drug and provided a Baseline and at least 1 postdose pharmacokinetic sample.	

Primary: Overall response rate (ORR)

End point title	Overall response rate (ORR)[1]
End point description:	
ORR was defined as the percentage of participants with a best overall response of complete response (CR) or partial response (PR), per Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 (v1.1), as determined by the investigator, at any post-Baseline visit until new anti-cancer therapy or first Progressive Disease. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 millimeters (mm). PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. Participants were to be analyzed based on disease-specific diagnosis. Confidence intervals were calculated based on the exact method for binomial distributions.	
End point type	Primary
End point timeframe:	
up to 25.9 months	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Statistical analysis was not conducted for this endpoint.

End point values	Melanoma	Non-small Cell Lung Cancer	Urethelial Carcinoma	Renal Cell Carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	23	29	34
Units: percentage of participants				
number (confidence interval 95%)	40.0 (23.9 to 57.9)	34.8 (16.4 to 57.3)	37.9 (20.7 to 57.7)	23.5 (10.7 to 41.2)

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response (DOR)

End point title	Duration of response (DOR)

End point description:

DOR was defined as the time from initial objective response (CR or PR) per RECIST v1.1 until the first observation of documented disease progression (PD), as determined by the investigator, or death due to any cause. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. PD: progression of a target or non-target lesion or presence of a new lesion. The 95% confidence interval was calculated using the Brookmeyer and Crowley's method and Klein and Moeschberger's method with log-log transformation. 9999=The median and upper limit of the confidence interval were not estimable because too few participants had disease progression or died.

End point type	Secondary

End point timeframe:

up to 24.0 months

End point values	Melanoma	Non-small Cell Lung Cancer	Urethelial Carcinoma	Renal Cell Carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	14[2]	8[3]	11[4]	8[5]
Units: months				
median (confidence interval 95%)	9999 (9.2 to 9999)	18.2 (1.9 to 9999)	11.5 (2.2 to 9999)	9999 (2.8 to 9999)

Notes:

[2] - Only those participants with a CR or PR were included in the analysis.

[3] - Only those participants with a CR or PR were included in the analysis.

[4] - Only those participants with a CR or PR were included in the analysis.

[5] - Only those participants with a CR or PR were included in the analysis.

Statistical analyses

No statistical analyses for this end point

Secondary: Disease control rate (DCR)

End point title	Disease control rate (DCR)

End point description:

DCR was defined as the proportion of participants with an overall response of CR, PR, or stable disease (SD), per RECIST v1.1. CR: disappearance of all target and non-target lesions and no appearance of any new lesions. Any pathological lymph nodes (whether target or non-target) must have a reduction in the short axis to <10 mm. PR: complete disappearance or at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference the baseline sum diameters, no new lesions, and no progression of non-target lesions. PD: progression of a target or non-target lesion or presence of a new

lesion. SD: no change in target lesions to qualify for CR, PR, or PD. Confidence intervals were calculated based on the exact method for binomial distributions.

End point type	Secondary

End point timeframe:

up to 25.9 months

End point values	Melanoma	Non-small Cell Lung Cancer	Urethelial Carcinoma	Renal Cell Carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	23	29	34
Units: percentage of participants				
number (confidence interval 95%)	54.3 (36.6 to 71.2)	65.2 (42.7 to 83.6)	55.2 (35.7 to 73.6)	64.7 (46.5 to 80.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free survival (PFS)

End point title	Progression-free survival (PFS)

End point description:

According to RECIST 1.1, PFS was defined as the length of time from the initial infusion of study drug until the earliest date of disease progression, determined by investigator assessment, or death due to any cause, if occurring sooner than progression. Median PFS was estimated using the Kaplan-Meier method. The confidence interval for median PFS was calculated using the method of Brookmeyer and Crowley. 9999=The upper limit of the confidence interval was not estimable because too few participants had events of disease progression or death.

End point type	Secondary

End point timeframe:

up to 25.9 months

End point values	Melanoma	Non-small Cell Lung Cancer	Urethelial Carcinoma	Renal Cell Carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	23	29	34
Units: months				
median (confidence interval 95%)	3.6 (1.8 to 9999)	4.4 (1.8 to 21.9)	5.7 (1.8 to 13.6)	5.4 (2.3 to 11.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with treatment-emergent adverse events

(TEAEs)	
End point title	Number of participants with treatment-emergent adverse events (TEAEs)

End point description:

An adverse event (AE) was defined as any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug-related. An AE could therefore have been any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of study drug. A TEAE was defined as any AE either reported for the first time or the worsening of a pre-existing event after the first dose of retifanlimab and until the earlier of 90 days of the last administration of retifanlimab and new anti-cancer therapy start if any, are reported.

End point type	Secondary

End point timeframe:

up to approximately 2.3 years

End point values	Melanoma	Non-small Cell Lung Cancer	Urethelial Carcinoma	Renal Cell Carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	23	29	34
Units: participants				
number (not applicable)	32	21	28	32

Statistical analyses

No statistical analyses for this end point

Secondary: Overall survival	
End point title	Overall survival

End point description:

Overall survival was defined as the time in months between the first dose date (Day 1) and the date of death due to any cause. Median survival time in months was estimated using the Kaplan-Meier method. The confidence interval for median survival time was calculated using the method of Brookmeyer and Crowley. -9999, 9999=The median and the upper and lower limits of the confidence interval were not estimable because too few participants had events of death.

End point type	Secondary

End point timeframe:

up to 28.2 months

End point values	Melanoma	Non-small Cell Lung Cancer	Urethelial Carcinoma	Renal Cell Carcinoma
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	23	29	34
Units: months				
median (confidence interval 95%)	9999 (8.7 to 9999)	21.9 (5.2 to 9999)	15.2 (7.7 to 9999)	9999 (-9999 to 9999)

Statistical analyses

No statistical analyses for this end point

Secondary: First-dose tmax of retifanlimab

End point title	First-dose tmax of retifanlimab

End point description:

tmax was defined as the time to the maximum concentration of retifanlimab.

End point type	Secondary

End point timeframe:

preinfusion and 10 minutes postinfusion (± 10 minutes) on Day 1 of Cycle 1

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	121			
Units: hours				
median (full range (min-max))	0.500 (0.500 to 1.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: First-dose Cmax of retifanlimab

End point title	First-dose Cmax of retifanlimab

End point description:

Cmax was defined as the maximum observed plasma or serum concentration of retifanlimab.

End point type	Secondary

End point timeframe:

preinfusion and 10 minutes postinfusion (± 10 minutes) on Day 1 of Cycle 1

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	121			
Units: milligrams per Liter (mg/L)				
arithmetic mean (standard deviation)	143 (± 30.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax of retifanlimab at steady-state

End point title	Cmax of retifanlimab at steady-state

End point description:

Cmax was defined as the maximum observed plasma or serum concentration of retifanlimab.

End point type	Secondary

End point timeframe:

preinfusion and 10 minutes postinfusion (± 10 minutes) on Day 1 of Cycles 1, 2, 4, and 6 (up to approximately 168 days; each cycle was 28 days)

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	121			
Units: mg/L				
arithmetic mean (standard deviation)	181 (± 39.4)			

Statistical analyses

No statistical analyses for this end point

Secondary: tmax of retifanlimab at steady-state

End point title	tmax of retifanlimab at steady-state

End point description:

tmax was defined as the time to the maximum concentration of retifanlimab.

End point type	Secondary

End point timeframe:

preinfusion and 10 minutes postinfusion (± 10 minutes) on Day 1 of Cycles 1, 2, 4, and 6 (up to approximately 168 days; each cycle was 28 days)

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	121			
Units: hours				
median (full range (min-max))	0.500 (0.500 to 1.00)			

Statistical analyses

No statistical analyses for this end point

Secondary: AUC0-t of retifanlimab at steady-state

End point title	AUC0-t of retifanlimab at steady-state

End point description:

AUC0-t was defined as the area under the plasma or serum concentration-time curve from time = 0 to the last measurable concentration at time = t of retifanlimab.

End point type	Secondary

End point timeframe:

preinfusion and 10 minutes postinfusion (± 10 minutes) on Day 1 of Cycles 1, 2, 4, and 6 (up to approximately 168 days; each cycle was 28 days)

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	121			
Units: day*mg/L				
arithmetic mean (standard deviation)	2030 (± 566)			

Statistical analyses

No statistical analyses for this end point

Secondary: Cmin of retifanlimabv at steady-state

End point title	Cmin of retifanlimabv at steady-state

End point description:

Cmin was defined as the minimum observed plasma or serum concentration over the dose interval of retifanlimab.

End point type	Secondary

End point timeframe:

preinfusion and 10 minutes postinfusion (± 10 minutes) on Day 1 of Cycles 1, 2, 4, and 6 (up to approximately 168 days; each cycle was 28 days)

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	121			
Units: mg/L				
arithmetic mean (standard deviation)	38.2 (± 16.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: First-dose Cmin of retifanlimab

End point title	First-dose Cmin of retifanlimab

End point description:

Cmin was defined as the minimum observed plasma or serum concentration over the dose interval of retifanlimab.

End point type	Secondary

End point timeframe:

preinfusion and 10 minutes postinfusion (± 10 minutes) on Day 1 of Cycle 1

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	121			
Units: mg/L				
arithmetic mean (standard deviation)	18.0 (± 7.52)			

Statistical analyses

No statistical analyses for this end point

Secondary: First-dose AUC0-t of retifanlimab

End point title	First-dose AUC0-t of retifanlimab

End point description:

AUC0-t was defined as the area under the plasma or serum concentration-time curve from time = 0 to the last measurable concentration at time = t of retifanlimab.

End point type	Secondary

End point timeframe:

preinfusion and 10 minutes postinfusion (± 10 minutes) on Day 1 of Cycle 1

End point values	All Participants			
Subject group type	Subject analysis set			
Number of subjects analysed	121			
Units: day*mg/L				
arithmetic mean (standard deviation)	1620 (± 506)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

up to approximately 2.3 years

Adverse event reporting additional description:

Treatment-emergent adverse events, defined as any adverse events either reported for the first time or the worsening of pre-existing events after the first dose of retifanlimab and until the earlier of 90 days of the last administration of retifanlimab and new anti-cancer therapy start if any, are reported.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups

Reporting group title	Melanoma

Reporting group description:

Participants with melanoma received retifanlimab 500 milligrams (mg), administered by intravenous (IV) infusion over 30 minutes on Day 1 of each 28-day cycle (Q4W).

Reporting group title	Non-small Cell Lung Cancer

Reporting group description:

Participants with non-small cell lung cancer received retifanlimab 500 mg, administered by IV infusion over 30 minutes on Day 1 Q4W.

Reporting group title	Total

Reporting group description:

Total

Reporting group title	Renal Cell Carcinoma

Reporting group description:

Participants with renal cell carcinoma received retifanlimab 500 mg, administered by IV infusion over 30 minutes on Day 1 Q4W.

Reporting group title	Urothelial Cancer

Reporting group description:

Participants with urethelial carcinoma received retifanlimab 500 mg, administered by IV infusion over 30 minutes on Day 1 Q4W.

Serious adverse events	Melanoma	Non-small Cell Lung Cancer	Total
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 35 (22.86%)	9 / 23 (39.13%)	40 / 121 (33.06%)
number of deaths (all causes)	16	11	54
number of deaths resulting from adverse events	2	1	7
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			

subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal adenocarcinoma			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour associated fever			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
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			
Arterial occlusive disease			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hypertensive crisis			
subjects affected / exposed	1 / 35 (2.86%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava syndrome			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vena cava thrombosis			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	1 / 35 (2.86%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
General physical health deterioration			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hyperthermia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Bronchial obstruction			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Chronic obstructive pulmonary disease			
subjects affected / exposed	2 / 35 (5.71%)	2 / 23 (8.70%)	4 / 121 (3.31%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	2 / 121 (1.65%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paroxysmal atrioventricular block			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Right ventricular failure			

subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cognitive disorder			
subjects affected / exposed	1 / 35 (2.86%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extrapyramidal disorder			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukocytosis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rectal haemorrhage			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hepatocellular injury			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	2 / 121 (1.65%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 35 (2.86%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypophysitis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Bone lesion			

subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	1 / 35 (2.86%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	1 / 35 (2.86%)	1 / 23 (4.35%)	2 / 121 (1.65%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 1
Gastroenteritis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orchitis			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			

subjects affected / exposed	0 / 35 (0.00%)	3 / 23 (13.04%)	6 / 121 (4.96%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 35 (2.86%)	1 / 23 (4.35%)	3 / 121 (2.48%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Urinary tract infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	1 / 35 (2.86%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	1 / 121 (0.83%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Renal Cell Carcinoma	Urothelial Cancer	
Total subjects affected by serious adverse events			
subjects affected / exposed	11 / 34 (32.35%)	12 / 29 (41.38%)	
number of deaths (all causes)	10	17	
number of deaths resulting from adverse events	2	2	

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant melanoma in situ			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myelodysplastic syndrome			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal adenocarcinoma			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour associated fever			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Arterial occlusive disease			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypertensive crisis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superior vena cava syndrome			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Vena cava thrombosis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chills			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hyperthermia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Respiratory, thoracic and mediastinal disorders			
Bronchial obstruction			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paroxysmal atrioventricular block			

subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cognitive disorder			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extrapyramidal disorder			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain lower			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Gastric ulcer			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hepatocellular injury			
subjects affected / exposed	0 / 34 (0.00%)	2 / 29 (6.90%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hypophysitis			

subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Bone lesion			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Orchitis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	3 / 34 (8.82%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Melanoma	Non-small Cell Lung Cancer	Total
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 35 (85.71%)	19 / 23 (82.61%)	104 / 121 (85.95%)
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	6 / 121 (4.96%)
occurrences (all)	0	2	8
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	7 / 35 (20.00%)	2 / 23 (8.70%)	24 / 121 (19.83%)
occurrences (all)	11	2	31
Chills			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	3 / 121 (2.48%)
occurrences (all)	0	0	3
Fatigue			
subjects affected / exposed	6 / 35 (17.14%)	2 / 23 (8.70%)	12 / 121 (9.92%)
occurrences (all)	7	2	13
Malaise			
subjects affected / exposed	2 / 35 (5.71%)	0 / 23 (0.00%)	3 / 121 (2.48%)
occurrences (all)	2	0	3
Oedema peripheral			
subjects affected / exposed	1 / 35 (2.86%)	1 / 23 (4.35%)	10 / 121 (8.26%)
occurrences (all)	1	1	11
Pain			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	3 / 121 (2.48%)
occurrences (all)	0	0	3
Pyrexia			
subjects affected / exposed	3 / 35 (8.57%)	2 / 23 (8.70%)	13 / 121 (10.74%)
occurrences (all)	6	2	23
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	2 / 121 (1.65%)
occurrences (all)	0	0	2

Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 35 (11.43%)	0 / 23 (0.00%)	9 / 121 (7.44%)
occurrences (all)	5	0	13
Dyspnoea			
subjects affected / exposed	2 / 35 (5.71%)	3 / 23 (13.04%)	12 / 121 (9.92%)
occurrences (all)	4	3	14
Dyspnoea exertional			
subjects affected / exposed	3 / 35 (8.57%)	0 / 23 (0.00%)	3 / 121 (2.48%)
occurrences (all)	3	0	3
Haemoptysis			
subjects affected / exposed	0 / 35 (0.00%)	2 / 23 (8.70%)	3 / 121 (2.48%)
occurrences (all)	0	2	3
Rhinorrhoea			
subjects affected / exposed	2 / 35 (5.71%)	0 / 23 (0.00%)	3 / 121 (2.48%)
occurrences (all)	2	0	3
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 35 (5.71%)	2 / 23 (8.70%)	5 / 121 (4.13%)
occurrences (all)	3	2	6
Confusional state			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	3 / 121 (2.48%)
occurrences (all)	0	0	4
Insomnia			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	5 / 121 (4.13%)
occurrences (all)	0	1	5
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 35 (2.86%)	3 / 23 (13.04%)	7 / 121 (5.79%)
occurrences (all)	1	4	8
Amylase increased			
subjects affected / exposed	1 / 35 (2.86%)	2 / 23 (8.70%)	3 / 121 (2.48%)
occurrences (all)	1	2	3
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 35 (0.00%)	3 / 23 (13.04%)	4 / 121 (3.31%)
occurrences (all)	0	3	4

Blood creatinine increased			
subjects affected / exposed	1 / 35 (2.86%)	1 / 23 (4.35%)	9 / 121 (7.44%)
occurrences (all)	1	1	10
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	2 / 121 (1.65%)
occurrences (all)	0	0	2
Lipase increased			
subjects affected / exposed	1 / 35 (2.86%)	0 / 23 (0.00%)	3 / 121 (2.48%)
occurrences (all)	1	0	4
Weight decreased			
subjects affected / exposed	1 / 35 (2.86%)	0 / 23 (0.00%)	4 / 121 (3.31%)
occurrences (all)	1	0	4
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 35 (20.00%)	1 / 23 (4.35%)	9 / 121 (7.44%)
occurrences (all)	7	2	10
Paraesthesia			
subjects affected / exposed	3 / 35 (8.57%)	0 / 23 (0.00%)	8 / 121 (6.61%)
occurrences (all)	3	0	8
Somnolence			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	3 / 121 (2.48%)
occurrences (all)	0	1	3
Sciatica			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	3 / 121 (2.48%)
occurrences (all)	0	0	5
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 35 (5.71%)	1 / 23 (4.35%)	17 / 121 (14.05%)
occurrences (all)	2	1	17
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	3 / 121 (2.48%)
occurrences (all)	0	0	3
Gastrointestinal disorders			
Abdominal pain upper			

subjects affected / exposed	4 / 35 (11.43%)	0 / 23 (0.00%)	6 / 121 (4.96%)
occurrences (all)	4	0	6
Abdominal pain			
subjects affected / exposed	1 / 35 (2.86%)	0 / 23 (0.00%)	5 / 121 (4.13%)
occurrences (all)	1	0	6
Constipation			
subjects affected / exposed	1 / 35 (2.86%)	2 / 23 (8.70%)	14 / 121 (11.57%)
occurrences (all)	1	2	17
Dry mouth			
subjects affected / exposed	1 / 35 (2.86%)	0 / 23 (0.00%)	5 / 121 (4.13%)
occurrences (all)	1	0	5
Diarrhoea			
subjects affected / exposed	7 / 35 (20.00%)	3 / 23 (13.04%)	19 / 121 (15.70%)
occurrences (all)	22	3	38
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 35 (5.71%)	0 / 23 (0.00%)	4 / 121 (3.31%)
occurrences (all)	2	0	4
Nausea			
subjects affected / exposed	5 / 35 (14.29%)	0 / 23 (0.00%)	12 / 121 (9.92%)
occurrences (all)	5	0	12
Toothache			
subjects affected / exposed	2 / 35 (5.71%)	0 / 23 (0.00%)	2 / 121 (1.65%)
occurrences (all)	2	0	2
Vomiting			
subjects affected / exposed	2 / 35 (5.71%)	1 / 23 (4.35%)	6 / 121 (4.96%)
occurrences (all)	3	1	9
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	3 / 35 (8.57%)	1 / 23 (4.35%)	10 / 121 (8.26%)
occurrences (all)	3	1	12
Erythema			
subjects affected / exposed	0 / 35 (0.00%)	3 / 23 (13.04%)	5 / 121 (4.13%)
occurrences (all)	0	3	8
Skin toxicity			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	3 / 121 (2.48%)
occurrences (all)	0	0	3

Pruritus			
subjects affected / exposed	9 / 35 (25.71%)	3 / 23 (13.04%)	21 / 121 (17.36%)
occurrences (all)	12	3	25
Rash			
subjects affected / exposed	5 / 35 (14.29%)	2 / 23 (8.70%)	15 / 121 (12.40%)
occurrences (all)	12	2	22
Rash macular			
subjects affected / exposed	2 / 35 (5.71%)	0 / 23 (0.00%)	3 / 121 (2.48%)
occurrences (all)	2	0	3
Vitiligo			
subjects affected / exposed	2 / 35 (5.71%)	0 / 23 (0.00%)	2 / 121 (1.65%)
occurrences (all)	2	0	2
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	2 / 121 (1.65%)
occurrences (all)	0	0	2
Dysuria			
subjects affected / exposed	2 / 35 (5.71%)	0 / 23 (0.00%)	5 / 121 (4.13%)
occurrences (all)	2	0	5
Haematuria			
subjects affected / exposed	1 / 35 (2.86%)	0 / 23 (0.00%)	3 / 121 (2.48%)
occurrences (all)	1	0	3
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 35 (0.00%)	1 / 23 (4.35%)	3 / 121 (2.48%)
occurrences (all)	0	1	3
Hypothyroidism			
subjects affected / exposed	5 / 35 (14.29%)	1 / 23 (4.35%)	11 / 121 (9.09%)
occurrences (all)	5	1	11
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	3 / 35 (8.57%)	1 / 23 (4.35%)	10 / 121 (8.26%)
occurrences (all)	3	1	11
Arthralgia			
subjects affected / exposed	8 / 35 (22.86%)	0 / 23 (0.00%)	21 / 121 (17.36%)
occurrences (all)	10	0	38

Groin pain			
subjects affected / exposed	1 / 35 (2.86%)	0 / 23 (0.00%)	3 / 121 (2.48%)
occurrences (all)	1	0	3
Muscular weakness			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	2 / 121 (1.65%)
occurrences (all)	0	0	2
Myalgia			
subjects affected / exposed	2 / 35 (5.71%)	1 / 23 (4.35%)	6 / 121 (4.96%)
occurrences (all)	2	1	6
Neck pain			
subjects affected / exposed	1 / 35 (2.86%)	0 / 23 (0.00%)	3 / 121 (2.48%)
occurrences (all)	1	0	4
Pain in extremity			
subjects affected / exposed	2 / 35 (5.71%)	1 / 23 (4.35%)	8 / 121 (6.61%)
occurrences (all)	2	1	10
Infections and infestations			
COVID-19			
subjects affected / exposed	2 / 35 (5.71%)	0 / 23 (0.00%)	2 / 121 (1.65%)
occurrences (all)	2	0	2
Nasopharyngitis			
subjects affected / exposed	1 / 35 (2.86%)	0 / 23 (0.00%)	3 / 121 (2.48%)
occurrences (all)	1	0	3
Skin infection			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	2 / 121 (1.65%)
occurrences (all)	0	0	3
Pneumonia			
subjects affected / exposed	1 / 35 (2.86%)	2 / 23 (8.70%)	7 / 121 (5.79%)
occurrences (all)	1	2	9
Rash pustular			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	2 / 121 (1.65%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	3 / 35 (8.57%)	5 / 23 (21.74%)	17 / 121 (14.05%)
occurrences (all)	4	6	21
Metabolism and nutrition disorders			

Decreased appetite			
subjects affected / exposed	4 / 35 (11.43%)	5 / 23 (21.74%)	19 / 121 (15.70%)
occurrences (all)	4	5	20
Hyperglycaemia			
subjects affected / exposed	1 / 35 (2.86%)	1 / 23 (4.35%)	5 / 121 (4.13%)
occurrences (all)	1	1	6
Hypercalcaemia			
subjects affected / exposed	0 / 35 (0.00%)	0 / 23 (0.00%)	4 / 121 (3.31%)
occurrences (all)	0	0	4
Hypokalaemia			
subjects affected / exposed	1 / 35 (2.86%)	2 / 23 (8.70%)	6 / 121 (4.96%)
occurrences (all)	1	2	6

Non-serious adverse events	Renal Cell Carcinoma	Urothelial Cancer	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 34 (88.24%)	25 / 29 (86.21%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 34 (5.88%)	3 / 29 (10.34%)	
occurrences (all)	2	4	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	6 / 34 (17.65%)	9 / 29 (31.03%)	
occurrences (all)	7	11	
Chills			
subjects affected / exposed	1 / 34 (2.94%)	2 / 29 (6.90%)	
occurrences (all)	1	2	
Fatigue			
subjects affected / exposed	2 / 34 (5.88%)	2 / 29 (6.90%)	
occurrences (all)	2	2	
Malaise			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Oedema peripheral			
subjects affected / exposed	3 / 34 (8.82%)	5 / 29 (17.24%)	
occurrences (all)	4	5	

Pain			
subjects affected / exposed	2 / 34 (5.88%)	1 / 29 (3.45%)	
occurrences (all)	2	1	
Pyrexia			
subjects affected / exposed	4 / 34 (11.76%)	4 / 29 (13.79%)	
occurrences (all)	8	7	
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 34 (0.00%)	2 / 29 (6.90%)	
occurrences (all)	0	2	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 34 (11.76%)	1 / 29 (3.45%)	
occurrences (all)	4	4	
Dyspnoea			
subjects affected / exposed	6 / 34 (17.65%)	1 / 29 (3.45%)	
occurrences (all)	6	1	
Dyspnoea exertional			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Haemoptysis			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Rhinorrhoea			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Confusional state			
subjects affected / exposed	0 / 34 (0.00%)	3 / 29 (10.34%)	
occurrences (all)	0	4	
Insomnia			
subjects affected / exposed	3 / 34 (8.82%)	1 / 29 (3.45%)	
occurrences (all)	3	1	

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 34 (5.88%)	1 / 29 (3.45%)	
occurrences (all)	2	1	
Amylase increased			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Blood creatinine increased			
subjects affected / exposed	2 / 34 (5.88%)	5 / 29 (17.24%)	
occurrences (all)	3	5	
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 34 (0.00%)	2 / 29 (6.90%)	
occurrences (all)	0	2	
Lipase increased			
subjects affected / exposed	2 / 34 (5.88%)	0 / 29 (0.00%)	
occurrences (all)	3	0	
Weight decreased			
subjects affected / exposed	2 / 34 (5.88%)	1 / 29 (3.45%)	
occurrences (all)	2	1	
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 34 (0.00%)	1 / 29 (3.45%)	
occurrences (all)	0	1	
Paraesthesia			
subjects affected / exposed	4 / 34 (11.76%)	1 / 29 (3.45%)	
occurrences (all)	4	1	
Somnolence			
subjects affected / exposed	2 / 34 (5.88%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Sciatica			
subjects affected / exposed	1 / 34 (2.94%)	2 / 29 (6.90%)	
occurrences (all)	1	4	
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	5 / 34 (14.71%)	9 / 29 (31.03%)	
occurrences (all)	5	9	
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 34 (2.94%)	2 / 29 (6.90%)	
occurrences (all)	1	2	
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	1 / 34 (2.94%)	1 / 29 (3.45%)	
occurrences (all)	1	1	
Abdominal pain			
subjects affected / exposed	1 / 34 (2.94%)	3 / 29 (10.34%)	
occurrences (all)	2	3	
Constipation			
subjects affected / exposed	5 / 34 (14.71%)	6 / 29 (20.69%)	
occurrences (all)	5	9	
Dry mouth			
subjects affected / exposed	3 / 34 (8.82%)	1 / 29 (3.45%)	
occurrences (all)	3	1	
Diarrhoea			
subjects affected / exposed	4 / 34 (11.76%)	5 / 29 (17.24%)	
occurrences (all)	7	6	
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 34 (5.88%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Nausea			
subjects affected / exposed	3 / 34 (8.82%)	4 / 29 (13.79%)	
occurrences (all)	3	4	
Toothache			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	1 / 34 (2.94%)	2 / 29 (6.90%)	
occurrences (all)	1	4	
Skin and subcutaneous tissue disorders			

Dry skin			
subjects affected / exposed	4 / 34 (11.76%)	2 / 29 (6.90%)	
occurrences (all)	5	3	
Erythema			
subjects affected / exposed	1 / 34 (2.94%)	1 / 29 (3.45%)	
occurrences (all)	4	1	
Skin toxicity			
subjects affected / exposed	1 / 34 (2.94%)	2 / 29 (6.90%)	
occurrences (all)	1	2	
Pruritus			
subjects affected / exposed	5 / 34 (14.71%)	4 / 29 (13.79%)	
occurrences (all)	5	5	
Rash			
subjects affected / exposed	5 / 34 (14.71%)	3 / 29 (10.34%)	
occurrences (all)	5	3	
Rash macular			
subjects affected / exposed	1 / 34 (2.94%)	0 / 29 (0.00%)	
occurrences (all)	1	0	
Vitiligo			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Azotaemia			
subjects affected / exposed	2 / 34 (5.88%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Dysuria			
subjects affected / exposed	1 / 34 (2.94%)	2 / 29 (6.90%)	
occurrences (all)	1	2	
Haematuria			
subjects affected / exposed	0 / 34 (0.00%)	2 / 29 (6.90%)	
occurrences (all)	0	2	
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	2 / 34 (5.88%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Hypothyroidism			

subjects affected / exposed	3 / 34 (8.82%)	2 / 29 (6.90%)	
occurrences (all)	3	2	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	2 / 34 (5.88%)	4 / 29 (13.79%)	
occurrences (all)	3	4	
Arthralgia			
subjects affected / exposed	5 / 34 (14.71%)	8 / 29 (27.59%)	
occurrences (all)	13	15	
Groin pain			
subjects affected / exposed	0 / 34 (0.00%)	2 / 29 (6.90%)	
occurrences (all)	0	2	
Muscular weakness			
subjects affected / exposed	2 / 34 (5.88%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Myalgia			
subjects affected / exposed	1 / 34 (2.94%)	2 / 29 (6.90%)	
occurrences (all)	1	2	
Neck pain			
subjects affected / exposed	0 / 34 (0.00%)	2 / 29 (6.90%)	
occurrences (all)	0	3	
Pain in extremity			
subjects affected / exposed	2 / 34 (5.88%)	3 / 29 (10.34%)	
occurrences (all)	2	5	
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 34 (0.00%)	0 / 29 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	2 / 34 (5.88%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Skin infection			
subjects affected / exposed	2 / 34 (5.88%)	0 / 29 (0.00%)	
occurrences (all)	3	0	
Pneumonia			

subjects affected / exposed	4 / 34 (11.76%)	0 / 29 (0.00%)	
occurrences (all)	6	0	
Rash pustular			
subjects affected / exposed	2 / 34 (5.88%)	0 / 29 (0.00%)	
occurrences (all)	2	0	
Urinary tract infection			
subjects affected / exposed	5 / 34 (14.71%)	4 / 29 (13.79%)	
occurrences (all)	6	5	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	3 / 34 (8.82%)	7 / 29 (24.14%)	
occurrences (all)	3	8	
Hyperglycaemia			
subjects affected / exposed	2 / 34 (5.88%)	1 / 29 (3.45%)	
occurrences (all)	2	2	
Hypercalcaemia			
subjects affected / exposed	2 / 34 (5.88%)	2 / 29 (6.90%)	
occurrences (all)	2	2	
Hypokalaemia			
subjects affected / exposed	2 / 34 (5.88%)	1 / 29 (3.45%)	
occurrences (all)	2	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
17 January 2019	The primary purpose of this amendment was to address comments regarding the design of the study.
09 August 2019	The main purpose of this amendment was to update the Protocol based on the information from the ongoing Phase 1 study, INCMGA 0012-101, and to update the pharmacokinetic sample collection schedule.
10 December 2019	The main purpose of this amendment was to adjust the overall study enrolment and statistical analysis, remove interim analysis and update the guidance for suspected immune related adverse events based on the data from ongoing studies with INCMGA00012 and recent Investigator's Brochure update.
25 November 2020	The main purpose of this amendment was to minimize the burden of data collection for ongoing participants after the primary objective of the study had been achieved. Disease follow-up and survival follow-up were removed.
23 June 2021	The purpose of this amendment was to update the guidelines for management of suspected immune related events.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported