Clinical trial results:
A Phase 2 Study of REGN2810, a Fully Human Monoclonal Antibody to Programmed Death-1 (PD-1), in Patients With Advanced Cutaneous Squamous Cell Carcinoma

Summary

EudraCT number	2016-000105-36
Trial protocol	DE ES GR IT
Global end of trial date	18 October 2023

Results information

Result version number	v1 (current)
This version publication date	01 November 2024
First version publication date	01 November 2024

Trial information

Trial identification

Sponsor protocol code	R2810-ONC-1540

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02760498
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Regeneron Pharmaceuticals, Inc.
Sponsor organisation address	777 Old Saw Mill River Rd., Tarrytown, NY, United States, 10591
Public contact	Clinical Trials Administrator, Regeneron Pharmaceuticals, Inc., 001 844-734-6643, clinicaltrials@regeneron.com
Scientific contact	Clinical Trials Administrator, Regeneron Pharmaceuticals, Inc., 001 844-734-6643, clinicaltrials@regeneron.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	18 October 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 October 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The goals of this study are to evaluate the clinical benefit and safety of cemiplimab in participants with metastatic (nodal or distant) Cutaneous Squamous Cell Carcinoma (CSCC), or unresectable locally advanced CSCC.

Protection of trial subjects:

It is the responsibility of both the sponsor and the investigator(s) to ensure that this clinical study is conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki, and that are consistent with the ICH guidelines for GCP and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 April 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 172
Country: Number of subjects enrolled	Brazil: 4
Country: Number of subjects enrolled	France: 56
Country: Number of subjects enrolled	Germany: 48
Country: Number of subjects enrolled	Greece: 4
Country: Number of subjects enrolled	Italy: 4
Country: Number of subjects enrolled	Spain: 30
Country: Number of subjects enrolled	United States: 114
Worldwide total number of subjects	432
EEA total number of subjects	142

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	98
From 65 to 84 years	278
85 years and over	56

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 432 participants with advanced cutaneous squamous cell carcinoma (CSCC) (metastatic CSCC [mCSCC] or locally advanced CSCC [laCSCC]) were enrolled.

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	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W

Arm description:

Participants received cemiplimab 3 milligrams (mg)/kilogram (kg) intravenously (IV) every 2 weeks (Q2W) during each 8-week treatment cycle, for up to 96 weeks (12 cycles).

Arm type	Experimental
Investigational medicinal product name	Cemiplimab
Investigational medicinal product code	REGN2810
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received cemiplimab 3 milligrams (mg)/kilogram (kg) intravenously (IV) every 2 weeks (Q2W) during each 8-week treatment cycle, for up to 96 weeks (12 cycles).

Arm title	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W

Arm description:

Participants received cemiplimab 3 mg/kg IV Q2W during each 8-week treatment cycle, for up to 96 weeks (12 cycles).

Arm type	Experimental
Investigational medicinal product name	Cemiplimab
Investigational medicinal product code	REGN2810
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received cemiplimab 3 mg/kg IV Q2W during each 8-week treatment cycle, for up to 96 weeks (12 cycles).

Arm title	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W

Arm description:

Participants received cemiplimab 350 mg IV every 3 weeks (Q3W) during each 9-week treatment cycle, for up to 54 weeks (6 cycles).

Arm type	Experimental

Investigational medicinal product name	Cemiplimab
Investigational medicinal product code	REGN2810
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received cemiplimab 350 mg IV every 3 weeks (Q3W) during each 9-week treatment cycle, for up to 54 weeks (6 cycles).

Arm title	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W

Arm description:

Participants received cemiplimab 600 mg IV every 4 weeks (Q4W) during each 8-week treatment cycle, for up to 48 weeks (6 cycles).

Arm type	Experimental
Investigational medicinal product name	Cemiplimab
Investigational medicinal product code	REGN2810
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received cemiplimab 600 mg IV every 4 weeks (Q4W) during each 8-week treatment cycle, for up to 48 weeks (6 cycles).

Arm title	Group 5 (mCSCC & laCSCC): Cemiplimab 438 mg SC + 350 mg IV Q3W

Arm description:

Participants received a single 438 mg subcutaneous (SC) dose of cemiplimab followed by cemiplimab 350 mg IV Q3W during each 9-week treatment cycle, for up to 54 weeks (6 cycles).

Arm type	Experimental
Investigational medicinal product name	Cemiplimab
Investigational medicinal product code	REGN2810
Other name	
Pharmaceutical forms	Solution for infusion, Solution for injection
Routes of administration	Intravenous use, Subcutaneous use

Dosage and administration details:

Participants received a single 438 mg subcutaneous (SC) dose of cemiplimab followed by cemiplimab 350 mg IV Q3W during each 9-week treatment cycle, for up to 54 weeks (6 cycles).

Arm title	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W

Arm description:

Participants received cemiplimab 350 mg IV Q3W during each 9-week treatment cycle, for up to 108 weeks (12 cycles).

Arm type	Experimental
Investigational medicinal product name	Cemiplimab
Investigational medicinal product code	REGN2810
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received cemiplimab 350 mg IV Q3W during each 9-week treatment cycle, for up to 108 weeks (12 cycles).

Number of subjects in period 1	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W
Started	59	78	56
Received at least 1 dose of study drug	59	78	56
Completed Treatment	24	20 [1]	22
Completed	19	28	22
Not completed	40	50	34
Adverse event, serious fatal	7	5	5
Consent withdrawn by subject	4	7	5
Physician decision	3	4	1
Participant decision	1	4	2
Disease progression	21	19	20
Adverse event, non-fatal	3	3	1
Non-compliance with study drug	-	2	-
Other than specified	1	6	-
Sponsor decision	-	-	-
Lost to follow-up	-	-	-
Not treated	-	-	-

Number of subjects in period 1	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W	Group 5 (mCSCC & laCSCC): Cemiplimab 438 mg SC + 350 mg IV Q3W	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W
Started	63	9	167
Received at least 1 dose of study drug	63	9	165
Completed Treatment	27	5	50 [2]
Completed	24	3	64
Not completed	39	6	103
Adverse event, serious fatal	7	-	23
Consent withdrawn by subject	1	-	6
Physician decision	4	-	2
Participant decision	2	1	6
Disease progression	18	4	55
Adverse event, non-fatal	1	-	6
Non-compliance with study drug	-	-	-
Other than specified	3	1	-
Sponsor decision	3	-	-
Lost to follow-up	-	-	3
Not treated	-	-	2

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Participants completed treatment

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Participants completed treatment

Baseline characteristics

Reporting groups	
Reporting group title	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W
Reporting group description:	
Participants received cemiplimab 3 milligrams (mg)/kilogram (kg) intravenously (IV) every 2 weeks (Q2W) during each 8-week treatment cycle, for up to 96 weeks (12 cycles).	
Reporting group title	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W
Reporting group description:	
Participants received cemiplimab 3 mg/kg IV Q2W during each 8-week treatment cycle, for up to 96 weeks (12 cycles).	
Reporting group title	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W
Reporting group description:	
Participants received cemiplimab 350 mg IV every 3 weeks (Q3W) during each 9-week treatment cycle, for up to 54 weeks (6 cycles).	
Reporting group title	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W
Reporting group description:	
Participants received cemiplimab 600 mg IV every 4 weeks (Q4W) during each 8-week treatment cycle, for up to 48 weeks (6 cycles).	
Reporting group title	Group 5 (mCSCC & laCSCC): Cemiplimab 438 mg SC + 350 mg IV Q3W
Reporting group description:	
Participants received a single 438 mg subcutaneous (SC) dose of cemiplimab followed by cemiplimab 350 mg IV Q3W during each 9-week treatment cycle, for up to 54 weeks (6 cycles).	
Reporting group title	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W
Reporting group description:	
Participants received cemiplimab 350 mg IV Q3W during each 9-week treatment cycle, for up to 108 weeks (12 cycles).	

Reporting group values	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W
Number of subjects	59	78	56
Age Categorical Units: participants			
< 65 years	16	19	14
>= 65 to < 75 years	23	23	20
>= 75 years	20	36	22
Sex: Female, Male Units: participants			
Female	5	19	8
Male	54	59	48
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	2	1
Not Hispanic or Latino	58	75	55
Unknown or Not Reported	0	1	0
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	2	2

Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0
White	58	75	54
More than one race	0	0	0
Unknown or Not Reported	0	1	0

Reporting group values	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W	Group 5 (mCSCC & laCSCC): Cemiplimab 438 mg SC + 350 mg IV Q3W	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W
Number of subjects	63	9	167
Age Categorical Units: participants			
< 65 years	16	3	30
>= 65 to < 75 years	17	4	43
>= 75 years	30	2	94
Sex: Female, Male Units: participants			
Female	10	4	37
Male	53	5	130
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	4
Not Hispanic or Latino	62	8	147
Unknown or Not Reported	0	1	16
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	1	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	61	8	164
More than one race	0	0	0
Unknown or Not Reported	0	0	3

Reporting group values	Total		
Number of subjects	432		
Age Categorical Units: participants			
< 65 years	98		
>= 65 to < 75 years	130		
>= 75 years	204		
Sex: Female, Male Units: participants			
Female	83		
Male	349		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	9		
Not Hispanic or Latino	405		

Unknown or Not Reported	18		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	7		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	1		
White	420		
More than one race	0		
Unknown or Not Reported	4		

End points

End points reporting groups

Reporting group title	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W
Reporting group description:	
Participants received cemiplimab 3 milligrams (mg)/kilogram (kg) intravenously (IV) every 2 weeks (Q2W) during each 8-week treatment cycle, for up to 96 weeks (12 cycles).	
Reporting group title	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W
Reporting group description:	
Participants received cemiplimab 3 mg/kg IV Q2W during each 8-week treatment cycle, for up to 96 weeks (12 cycles).	
Reporting group title	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W
Reporting group description:	
Participants received cemiplimab 350 mg IV every 3 weeks (Q3W) during each 9-week treatment cycle, for up to 54 weeks (6 cycles).	
Reporting group title	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W
Reporting group description:	
Participants received cemiplimab 600 mg IV every 4 weeks (Q4W) during each 8-week treatment cycle, for up to 48 weeks (6 cycles).	
Reporting group title	Group 5 (mCSCC & laCSCC): Cemiplimab 438 mg SC + 350 mg IV Q3W
Reporting group description:	
Participants received a single 438 mg subcutaneous (SC) dose of cemiplimab followed by cemiplimab 350 mg IV Q3W during each 9-week treatment cycle, for up to 54 weeks (6 cycles).	
Reporting group title	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W
Reporting group description:	
Participants received cemiplimab 350 mg IV Q3W during each 9-week treatment cycle, for up to 108 weeks (12 cycles).	

Primary: Overall Response Rate (ORR) by Independent Central Review

End point title	Overall Response Rate (ORR) by Independent Central
End point description:	
ORR defined as percentage of participants with best overall response (BOR) of complete response (CR) or partial response (PR). For participants with mCSCC, Response Evaluation Criteria in Solid Tumors (RECIST) version 1.1 was used to determine BOR. For participants with unresectable laCSCC, clinical response criteria were used. RECIST v1.1 Criteria: CR: Disappearance of all target lesions. Any pathological lymph nodes (target/non-target) must have reduction in short axis to <10 millimeter (mm) <1 (centimeter (cm). PR: At least a 30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters. Clinical Response Criteria: CR: All target and nontarget lesion(s) no longer visible, maintained for at least 4 weeks and no new lesions. PR: Decrease of at least 50% in the sum the products of perpendicular longest dimensions of target lesion(s), maintained for at least 4 weeks and no new lesions. Full Analysis Set (FAS): all enrolled participants.	
End point type	Primary
End point timeframe:	
Up to 108 weeks	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Primary analysis is based on exact binomial confidence interval (CI) approach of ORR.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only Groups 1, 2, 3, 4, and 6 were planned for this analysis.

End point values	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	78	56	63
Units: percentage of participants				
number (confidence interval 95%)	50.8 (37.5 to 64.1)	44.9 (33.6 to 56.6)	46.4 (33.0 to 60.3)	61.9 (48.8 to 73.9)

End point values	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W			
Subject group type	Reporting group			
Number of subjects analysed	167			
Units: percentage of participants				
number (confidence interval 95%)	47.3 (39.5 to 55.2)			

Statistical analyses

No statistical analyses for this end point

Secondary: ORR by Investigator Assessment

End point title	ORR by Investigator Assessment[3]

End point description:

ORR was defined as percentage of participants with BOR of CR or PR. For participants with metastatic disease, RECIST v1.1 was used to determine BOR. For participants with unresectable locally advanced disease, clinical response criteria were used. RECIST v1.1 Criteria: -CR: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm <1 cm. -PR: At least a 30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters. Clinical Response Criteria: -CR: All target and nontarget lesion(s) no longer visible, maintained for at least 4 weeks and no new lesions. -PR: Decrease of at least 50% in the sum the products of perpendicular longest dimensions of target lesion(s), maintained for at least 4 weeks and no new lesions. The FAS included all enrolled participants. Only Groups 1, 2, 3, 4, and 6 were planned for this outcome measure.

End point type	Secondary

End point timeframe:

Up to 108 weeks

Notes:

[3] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only Groups 1, 2, 3, 4, and 6 were planned for this analysis.

End point values	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	78	56	63
Units: percentage of participants				
number (confidence interval 95%)	50.8 (37.5 to 64.1)	56.4 (44.7 to 67.6)	55.4 (41.5 to 68.7)	63.5 (50.4 to 75.3)

End point values	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W			
Subject group type	Reporting group			
Number of subjects analysed	167			
Units: percentage of participants				
number (confidence interval 95%)	52.7 (44.8 to 60.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) by Independent Central Review

End point title	Duration of Response (DOR) by Independent Central Review[4]

End point description:

DOR was measured from the time measurement criteria were first met for CR/PR, whichever was recorded first, until the first date of recurrent or Progressive Disease (PD) or death due to any cause in participants with BOR of CR or PR. For mCSCC, RECIST v1.1 was used to determine BOR. For unresectable laCSCC, clinical response criteria were used. RECIST v1.1 Criteria: -PD: At least a 20% increase in the sum of the diameters of target lesions with the sum demonstrating an absolute increase of at least 5 mm (0.5 cm), or the appearance of one or more new lesions and/or unequivocal progression of existing non-target lesions. Clinical Response Criteria: -PD: increase of ≥ 25% (WHO criteria) in the sum of the products of perpendicular longest dimensions of target lesion(s) and/or the appearance of new lesions. FAS: all enrolled participants. Here, 'Overall number of participants analyzed' signifies participants with confirmed CR or PR who were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Up to approximately 43 months

Notes:

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only Groups 1, 2, 3, 4, and 6 were planned for this analysis.

End point values	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	35	26	39
Units: months				
median (confidence interval 95%)	99999 (20.7 to 99999)	41.9 (20.5 to 54.6)	41.3 (40.8 to 46.3)	99999 (30.5 to 99999)

End point values	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W			
Subject group type	Reporting group			
Number of subjects analysed	79			
Units: months				
median (confidence interval 95%)	31.6 (29.5 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) by Independent Central Review

End point title	Progression-Free Survival (PFS) by Independent Central

End point description:

PFS was measured from start of treatment until the first date of recurrent or PD, or death due to any cause. For participants with metastatic disease, RECIST v1.1 was used to determine PD. For participants with unresectable locally advanced disease, clinical response criteria were used. RECIST v1.1 Criteria: -PD: At least a 20% increase in the sum of the diameters of target lesions with the sum demonstrating an absolute increase of at least 5 mm (0.5 cm), or the appearance of one or more new lesions and/or unequivocal progression of existing non-target lesions. Clinical Response Criteria: -PD: increase of ≥ 25% (WHO criteria) in the sum of the products of perpendicular longest dimensions of target lesion(s) and/or the appearance of new lesions. The FAS included all enrolled participants. Here, 'Overall number of participants analyzed' signifies participants who received at least one dose of cemiplimab and were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Up to approximately 43 months

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only Groups 1, 2, 3, 4, and 6 were planned for this analysis.

End point values	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	78	56	63
Units: months				
median (confidence interval 95%)	18.4 (7.3 to 53.2)	18.5 (11.1 to 43.8)	21.7 (3.8 to 43.3)	32.2 (16.6 to 99999)

End point values	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W			
Subject group type	Reporting group			
Number of subjects analysed	165			
Units: months				
median (confidence interval 95%)	16.6 (12.4 to 31.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: DOR by Investigator Assessment

End point title	DOR by Investigator Assessment[6]

End point description:

DOR was measured from the time measurement criteria were first met for CR/PR, whichever was recorded first, until the first date of recurrent or Progressive Disease (PD) or death due to any cause in participants with BOR of CR or PR. For mCSCC, RECIST v1.1 was used to determine BOR. For unresectable laCSCC, clinical response criteria were used. RECIST v1.1 Criteria: -PD: At least a 20% increase in the sum of the diameters of target lesions with the sum demonstrating an absolute increase of at least 5 mm (0.5 cm), or the appearance of one or more new lesions and/or unequivocal progression of existing non-target lesions. Clinical Response Criteria: -PD: increase of ≥ 25% (WHO criteria) in the sum of the products of perpendicular longest dimensions of target lesion(s) and/or the appearance of new lesions. FAS: all enrolled participants. Here, 'Overall number of participants analyzed' signifies participants with confirmed CR or PR who were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Up to approximately 43 months

Notes:

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: Only Groups 1, 2, 3, 4, and 6 were planned for this analysis.

End point values	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30[7]	44[8]	31	40[9]
Units: months				
median (confidence interval 95%)	99999 (30.7 to 99999)	41.9 (-99999 to 99999)	44.2 (25.4 to 44.2)	99999 (27.1 to 99999)

Notes:

[7] - 99999 = Not reached due to insufficient number of events

[8] - 99999 = Not reached due to insufficient number of events

[9] - 99999 = Not reached due to insufficient number of events

End point values	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W			
Subject group type	Reporting group			
Number of subjects analysed	88[10]			
Units: months				
median (confidence interval 95%)	99999 (29.5 to 99999)			

Notes:

[10] - 99999 = Not reached due to insufficient number of events

Statistical analyses

No statistical analyses for this end point

Secondary: PFS by Investigator Assessment

End point title	PFS by Investigator Assessment[11]

End point description:

PFS was measured from start of treatment until the first date of recurrent or PD, or death due to any cause. For participants with metastatic disease, RECIST v1.1 was used to determine PD. For participants with unresectable locally advanced disease, clinical response criteria were used. RECIST v1.1 Criteria: -PD: At least a 20% increase in the sum of the diameters of target lesions with the sum demonstrating an absolute increase of at least 5 mm (0.5 cm), or the appearance of one or more new lesions and/or unequivocal progression of existing non-target lesions. Clinical Response Criteria: -PD: increase of ≥ 25% (WHO criteria) in the sum of the products of perpendicular longest dimensions of target lesion(s) and/or the appearance of new lesions. The FAS included all enrolled participants. Here, 'Overall number of participants analyzed' signifies participants who received at least one dose of cemiplimab and were evaluable for this outcome measure.

End point type	Secondary

End point timeframe:

Up to approximately 43 months

Notes:

[11] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only Groups 1, 2, 3, 4, and 6 were planned for this analysis.

End point values	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	78	56	63
Units: months				
median (confidence interval 95%)	16.6 (7.3 to 99999)	32.5 (17.1 to 43.8)	15.2 (4.1 to 43.0)	25.3 (8.2 to 99999)

End point values	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W			
Subject group type	Reporting group			
Number of subjects analysed	165			
Units: months				
median (confidence interval 95%)	16.5 (10.3 to 31.3)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)[12]

End point description:

OS was measured from start of treatment until death due to any cause. The FAS included all enrolled participants. Here, 'Overall number of participants analyzed' signifies participants who received at least one dose of cemiplimab and were evaluable for this outcome measure. Only Groups 1, 2, 3, 4, and 6 were planned for this outcome measure.

End point type	Secondary

End point timeframe:

Up to approximately 43 months

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only Groups 1, 2, 3, 4, and 6 were planned for this analysis.

End point values	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	78	56	63
Units: months				

median (confidence interval 95%)	57.7 (29.3 to 99999)	99999 (58.3 to 99999)	48.4 (29.5 to 99999)	99999 (28.6 to 99999)

End point values	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W			
Subject group type	Reporting group			
Number of subjects analysed	165			
Units: months				
median (confidence interval 95%)	99999 (99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Complete Response (CR) Rate by Independent Central Review

End point title	Complete Response (CR) Rate by Independent Central

End point description:

CR rate was defined as percentage of participants with BOR of CR. For participants with metastatic disease, RECIST v1.1 was used to determine BOR. For participants with unresectable locally advanced disease, clinical response criteria were used. RECIST v1.1 Criteria: -CR: Disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm <1 cm. Clinical Response Criteria: -CR: All target and nontarget lesion(s) no longer visible, maintained for at least 4 weeks and no new lesions. The FAS included all enrolled participants. Only Groups 1, 2, 3, 4, and 6 were planned for this outcome measure.

End point type	Secondary

End point timeframe:

Up to approximately 43 months

Notes:

[13] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only Groups 1, 2, 3, 4, and 6 were planned for this analysis.

End point values	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	78	56	63
Units: percentage of participants				
number (confidence interval 95%)	20.3 (11.0 to 32.8)	12.8 (6.3 to 22.3)	19.6 (10.2 to 32.4)	22.2 (12.7 to 34.5)

End point values	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W			
Subject group type	Reporting group			
Number of subjects analysed	167			
Units: percentage of participants				
number (confidence interval 95%)	10.8 (6.5 to 16.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) Global Health Status (GHS) Score

End point title	Change from Baseline in European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Core 30 (EORTC QLQ-C30) Global Health Status (GHS) Score[14]

End point description:

EORTC QLQ-C30 is a 30-question tool used to assess the overall quality of life (QoL) in cancer participants. Items contributing to the GHS/QoL, were scored 1 ("very poor") to 7 ("excellent"). A linear transformation was applied to the raw scores so that transformed score lies between 0 to 100. A higher score indicates better global health status/functioning and a negative change from baseline indicated less improvement. The FAS included all enrolled participants. Here, 'Overall number of participants analyzed' signifies participants evaluable for this outcome measure and "Number Analyzed" is the number evaluable at each time point. Only Groups 1, 2, 3, and 4 were planned for this outcome measure.

End point type	Secondary

End point timeframe:

Baseline, Up to Cycle 12 Day 1 (Week 89)

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only Groups 1, 2, 3, 4, and 6 were planned for this analysis.

End point values	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	68	38	54
Units: score on a scale				
arithmetic mean (standard deviation)				
Cycle 2 Day 1 (C2D1) n=42, 60, 34, 52	0.00 (± 21.464)	5.56 (± 18.895)	6.86 (± 19.621)	0.96 (± 17.670)
C3D1 n=37, 55, 30, 43	11.26 (± 19.267)	5.30 (± 21.717)	15.28 (± 20.655)	3.88 (± 15.680)
C4D1 n=36, 39, 29, 38	6.25 (± 25.069)	8.76 (± 19.585)	13.51 (± 22.539)	4.39 (± 15.099)

C5D1 n=36, 41, 27, 36	4.17 (± 22.316)	8.33 (± 21.246)	13.27 (± 21.466)	5.79 (± 18.774)
C6D1 n=31, 44, 26, 33	5.11 (± 17.437)	5.68 (± 28.118)	12.18 (± 24.521)	0.25 (± 21.599)
C7D1 n=32, 40, 12, 15	6.51 (± 17.676)	9.17 (± 22.393)	22.22 (± 23.659)	4.44 (± 18.598)
C8D1 n=29, 33, 11, 15	4.60 (± 21.080)	10.10 (± 21.425)	30.30 (± 19.816)	5.00 (± 25.158)
C9D1 n=26, 29, 10, 13	6.09 (± 18.938)	6.61 (± 26.199)	26.67 (± 24.470)	7.69 (± 20.543)
C10D1 n=27, 23, 9, 10	12.04 (± 20.844)	13.77 (± 26.064)	28.70 (± 13.889)	5.83 (± 22.923)
C11D1 n=25, 19, 10, 9	10.33 (± 28.186)	11.40 (± 22.603)	32.50 (± 14.407)	14.81 (± 19.444)
C12D1 n=24, 17, 9, 9	8.33 (± 22.388)	12.75 (± 24.494)	27.78 (± 16.667)	2.78 (± 26.021)

Statistical analyses

No statistical analyses for this end point

Secondary: Peak Concentration (Cmax) of Cemiplimab

End point title	Peak Concentration (Cmax) of Cemiplimab

End point description:

The Pharmacokinetic (PK) analysis set included all participants who had received cemiplimab and had at least 1 qualified (non-missing) post-baseline measurement of cemiplimab concentration in serum. Here, "Overall number of participants analyzed" is the number of participants evaluable for this outcome measure, and "Number analyzed" is the number of participants evaluable at each specified point.

End point type	Secondary

End point timeframe:

Up to approximately 43 months

End point values	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	58	75	52	62
Units: milligram per liter (mg/L)				
arithmetic mean (standard deviation)				
After the First Dose	108 (± 147)	84.1 (± 105)	132 (± 203)	174 (± 50.1)
At Steady State n=38, 58, 33, 41, 7, 104	151 (± 83.7)	148 (± 76.6)	151 (± 46.2)	281 (± 235)

End point values	Group 5 (mCSCC & laCSCC): Cemiplimab	Group 6 (mCSCC & laCSCC): Cemiplimab		

	438 mg SC + 350 mg IV Q3W	350 mg IV Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	162		
Units: milligram per liter (mg/L)				
arithmetic mean (standard deviation)				
After the First Dose	52.9 (± 18.4)	96.3 (± 56.2)		
At Steady State n=38, 58, 33, 41, 7, 104	174 (± 62.2)	142 (± 78.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with any Treatment Emergent Adverse Event (TEAE)

End point title	Number of Participants with any Treatment Emergent Adverse Event (TEAE)

End point description:

An AE was defined as any untoward medical occurrence in a participant who received study drug without regard to possibility of causal relationship. Serious Adverse Events (SAEs) were defined as death, a life-threatening AE, inpatient hospitalization or prolongation of existing hospitalization, persistent or significant disability or incapacity, a congenital anomaly or birth defect, or an important medical event that jeopardized participant and required medical intervention to prevent 1 of the outcomes listed in this definition. Treatment-emergent adverse events (TEAEs) are defined as those not present at baseline or represent the exacerbation of a condition present at baseline during the on-treatment period or follow-up period. A summary of other non-serious AEs and all serious AEs, regardless of causality is located in Reported AE section. The Safety Analysis Set (SAF) included all enrolled participants who received at least one dose of study drug.

End point type	Secondary

End point timeframe:

From date of first dose until 105 days after last dose (Up to approximately 46 months)

End point values	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	59	78	56	63
Units: Participants	59	78	55	63

End point values	Group 5 (mCSCC & laCSCC): Cemiplimab 438 mg SC + 350 mg IV Q3W	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	165		
Units: Participants	9	163		

Statistical analyses

No statistical analyses for this end point

Secondary: Trough Concentration (Ctrough) of Cemiplimab

End point title	Trough Concentration (Ctrough) of Cemiplimab

End point description:

The PK analysis set included all participants who had received cemiplimab and had at least 1 qualified (non-missing) post-baseline measurement of cemiplimab concentration in serum. Here, "Overall number of participants analyzed" is the number of participants evaluable for this outcome measure, and "Number analyzed" is the number of participants evaluable at each specified point.

End point type	Secondary

End point timeframe:

Up to approximately 43 months

End point values	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	71	46	58
Units: mg/L				
arithmetic mean (standard deviation)				
After the First Dose	21.5 (± 7.12)	26.3 (± 14.3)	33.6 (± 32.1)	32.1 (± 10.4)
At Steady State n=38, 58, 37, 44, 7, 106	69.9 (± 19.3)	67.5 (± 29.8)	62.7 (± 28.3)	62.5 (± 24.1)

End point values	Group 5 (mCSCC & laCSCC): Cemiplimab 438 mg SC + 350 mg IV Q3W	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	9	143		
Units: mg/L				
arithmetic mean (standard deviation)				
After the First Dose	34.1 (± 14.1)	23.0 (± 10.9)		
At Steady State n=38, 58, 37, 44, 7, 106	65.9 (± 22.9)	53.3 (± 20.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Treatment-Emergent Anti-cemiplimab Antibodies

End point title	Number of Participants with Treatment-Emergent Anti-cemiplimab Antibodies

End point description:

The Anti-drug Antibody (ADA) population for cemiplimab included all treated participants who had at least 1 postdose ADA result for cemiplimab.

End point type	Secondary

End point timeframe:

Up to approximately 43 months

End point values	Group 1 (mCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	66	41	50
Units: Participants	1	0	0	0

End point values	Group 5 (mCSCC & laCSCC): Cemiplimab 438 mg SC + 350 mg IV Q3W	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	133		
Units: Participants	0	5		

Statistical analyses

No statistical analyses for this end point

Secondary: ORR by Independent Central Review for Participants with Evaluable PD-

L1 Assays

End point title	ORR by Independent Central Review for Participants with Evaluable PD-L1 Assays[15]

End point description:

ORR was defined as percentage of participants with BOR of CR or PR. Expression level of PD-L1 was assessed in tumor biopsy samples by immunohistochemistry (IHC). -CR: All target and nontarget lesion(s) no longer visible, maintained for at least 4 weeks and no new lesions. -PR: Decrease of at least 50% in the sum the products of perpendicular longest dimensions of target lesion(s), maintained for at least 4 weeks and no new lesions. The biomarker analysis set (BAS) included all participants in the FAS who had samples evaluable for PD-L1 assay. Here, 'Overall number of participants analyzed' signifies participants who are evaluable for this outcome measure and "Number analyzed" is the number of participants in each row category. Only Group 6 was planned for this outcome measure.

End point type	Secondary

End point timeframe:

Up to 108 weeks

Notes:

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

End point values	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W			
Subject group type	Reporting group			
Number of subjects analysed	96			
Units: percentage of participants				
number (confidence interval 95%)				
PD-L1 < 1% n=37	40.5 (24.8 to 57.9)			
PD-L1 >= 1% n=59	49.2 (35.9 to 62.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: DOR by Independent Central Review for Participants with Evaluable PD-L1 Assays

End point title	DOR by Independent Central Review for Participants with Evaluable PD-L1 Assays[16]

End point description:

DOR was measured from the time measurement criteria are first met for CR/PR, as defined in Outcome Measure 13, whichever was recorded first, until the first date of recurrent or PD or death due to any cause in participants with BOR of CR or PR. Expression level of PD-L1 was assessed in tumor biopsy samples by IHC. -PD: increase of ≥ 25% (WHO criteria) in the sum of the products of perpendicular longest dimensions of target lesion(s) and/or the appearance of new lesions. The biomarker analysis set (BAS) included all participants in the FAS who had samples evaluable for PD-L1 assay. Here, 'Overall number of participants analyzed' signifies participants who are evaluable for this outcome measure and "Number analyzed" is the number of participants in each row category. Only Group 6 was planned for this outcome measure.

End point type	Secondary

End point timeframe:

Up to approximately 43 months

Notes:

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

End point values	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W			
Subject group type	Reporting group			
Number of subjects analysed	44			
Units: months				
median (confidence interval 95%)				
PD-L1 < 1% n=15	31.6 (12.6 to 99999)			
PD-L1 >= 1% n=29	99999 (99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: PFS by Independent Central Review for Participants with Evaluable PD-L1 Assays

End point title	PFS by Independent Central Review for Participants with Evaluable PD-L1 Assays[17]

End point description:

PFS was measured from time of enrollment until the first date of recurrent or progressive disease, or death due to any cause. Expression level of PD-L1 was assessed in tumor biopsy samples. -PD: increase of ≥ 25% (WHO criteria) in the sum of the products of perpendicular longest dimensions of target lesion(s) and/or the appearance of new lesions. The biomarker analysis set (BAS) included all participants in the FAS who had samples evaluable for PD-L1 assay. Here, 'Overall number of participants analyzed' signifies participants who are evaluable for this outcome measure and "Number analyzed" is the number of participants in each row category. Only Group 6 was planned for this

End point type	Secondary

End point timeframe:

Up to approximately 43 months

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Only Groups 1, 2, 3, 4, and 6 were planned for this analysis.

End point values	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W			
Subject group type	Reporting group			
Number of subjects analysed	96			

Units: months				
median (confidence interval 95%)				
PD-L1 < 1% n=37 PD-L1 >= 1% n=59	10.7 (3.0 to 15.3) 16.6 (4.0 to 99999)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From signing of informed consent until 105 days after last dose (Up to approximately 46 months)

Adverse event reporting additional description:

The Safety Analysis Set (SAF) included all enrolled participants who received any study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Group 1 (mCSCC): Cemiplimab 3mg/kg IV Q2W

Reporting group description:

Participants received cemiplimab 3 milligrams (mg)/kilogram (kg) intravenously (IV) every 2 weeks (Q2W) during each 8-week treatment cycle, for up to 96 weeks (12 cycles).

Reporting group title	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W

Reporting group description:

Participants received cemiplimab 3 mg/kg IV Q2W during each 8-week treatment cycle, for up to 96 weeks (12 cycles).

Reporting group title	Group 5 (mCSCC & laCSCC): Cemiplimab 438 mg SC + 350 mg IV Q3W

Reporting group description:

Participants received a single 438 mg subcutaneous (SC) dose of cemiplimab followed by cemiplimab 350 mg IV Q3W during each 9-week treatment cycle, for up to 54 weeks (6 cycles).

Reporting group title	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W

Reporting group description:

Participants received cemiplimab 350 mg IV Q3W during each 9-week treatment cycle, for up to 108 weeks (12 cycles).

Reporting group title	Group6a(mCSCC&laCSCC):Cemiplimab 350mg IV Q3W to 350mg SC Q3W

Reporting group description:

Participants in group 6 who received cemiplimab 350 mg IV Q3W and opted to switch to cemiplimab 350 mg SC Q3W for up to a total (IV + SC) of 108 weeks.

Reporting group title	Group6b(mCSCC&laCSCC):Cemiplimab 350mg IV Q3W to 1050mg SC Q6W

Reporting group description:

Participants in group 6 who received cemiplimab 350 mg IV Q3W and opted to switch to cemiplimab 1050 mg SC Q6W for up to a total (IV + SC) of 108 weeks.

Reporting group title	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W

Reporting group description:

Participants received cemiplimab 350 mg IV every 3 weeks (Q3W) during each 9-week treatment cycle, for up to 54 weeks (6 cycles).

Reporting group title	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W

Reporting group description:

Participants received cemiplimab 600 mg IV every 4 weeks (Q4W) during each 8-week treatment cycle, for up to 48 weeks (6 cycles).

Serious adverse events	Group 1 (mCSCC): Cemiplimab 3mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 5 (mCSCC & laCSCC): Cemiplimab 438 mg SC + 350 mg IV Q3W
Total subjects affected by serious adverse events			
subjects affected / exposed	24 / 59 (40.68%)	28 / 78 (35.90%)	2 / 9 (22.22%)
number of deaths (all causes)	27	19	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 59 (0.00%)	2 / 78 (2.56%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Follicular lymphoma			
subjects affected / exposed	1 / 59 (1.69%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected neoplasm			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial haemorrhage			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoedema			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 59 (0.00%)	2 / 78 (2.56%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	1 / 59 (1.69%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	1 / 1	0 / 0
Fatigue			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug withdrawal syndrome			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammation			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			
subjects affected / exposed	4 / 59 (6.78%)	4 / 78 (5.13%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	5 / 6	5 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 59 (1.69%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			

subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated lung disease			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary oedema			

subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary toxicity			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Adjustment disorder			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			

Device occlusion			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza A virus test positive			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
International normalised ratio increased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			

subjects affected / exposed	1 / 59 (1.69%)	2 / 78 (2.56%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye contusion			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound haemorrhage			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			

subjects affected / exposed	1 / 59 (1.69%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve disease			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac flutter			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral ischaemia			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery aneurysm			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal dyscognitive seizures			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasogenic cerebral oedema			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Coagulopathy			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Ulcerative keratitis			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Proctitis			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	2 / 9 (22.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (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
Duodenal ulcer haemorrhage			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal motility disorder			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (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
Overflow diarrhoea			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (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
Small intestinal obstruction			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			

subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune hepatitis			
subjects affected / exposed	0 / 59 (0.00%)	2 / 78 (2.56%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pemphigoid			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis bullous			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			

Immune-mediated nephritis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	2 / 59 (3.39%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune nephritis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal insufficiency			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (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-mediated hypophysitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 59 (0.00%)	2 / 78 (2.56%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			

subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue necrosis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Erysipelas			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	2 / 59 (3.39%)	5 / 78 (6.41%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 6	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Cellulitis			
subjects affected / exposed	4 / 59 (6.78%)	2 / 78 (2.56%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 59 (1.69%)	2 / 78 (2.56%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			

subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoas abscess			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			

subjects affected / exposed	1 / 59 (1.69%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 59 (1.69%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal sepsis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 59 (0.00%)	1 / 78 (1.28%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess bacterial			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal skin infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin infection			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Medical device site infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis aseptic			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (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
Pneumonia pneumococcal			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urosepsis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	1 / 59 (1.69%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg IV Q3W	Group6a(mCSCC&laCSCC):Cemiplimab 350mg IV Q3W to 350mg SC Q3W	Group6b(mCSCC&laCSCC):Cemiplimab 350mg IV Q3W to 1050mg SC Q6W
Total subjects affected by serious adverse events			
subjects affected / exposed	85 / 165 (51.52%)	4 / 12 (33.33%)	1 / 7 (14.29%)
number of deaths (all causes)	59	2	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basal cell carcinoma			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Follicular lymphoma			

subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal cell carcinoma			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute myeloid leukaemia			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Infected neoplasm			
subjects affected / exposed	2 / 165 (1.21%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung neoplasm malignant			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal cancer			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Vascular disorders			
Hypertension			

subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arterial haemorrhage			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphoedema			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	2 / 165 (1.21%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			

subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	2 / 165 (1.21%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug withdrawal syndrome			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	2 / 165 (1.21%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral swelling			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inflammation			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			

subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated lung disease			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			

subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary oedema			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary toxicity			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Adjustment disorder			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			

subjects affected / exposed	4 / 165 (2.42%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Depression			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device occlusion			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza A virus test positive			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical condition abnormal			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lipase increased			

subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
International normalised ratio increased			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Troponin I increased			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	4 / 165 (2.42%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye contusion			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foot fracture			

subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius fracture			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Limb injury			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple fractures			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin laceration			
subjects affected / exposed	1 / 165 (0.61%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural haemorrhage			
subjects affected / exposed	2 / 165 (1.21%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound haemorrhage			

subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound complication			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	2 / 165 (1.21%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Myocarditis			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aortic valve disease			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrioventricular block complete			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			

subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac flutter			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	4 / 165 (2.42%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebral ischaemia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			

subjects affected / exposed	2 / 165 (1.21%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Brain oedema			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carotid artery aneurysm			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Focal dyscognitive seizures			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhagic stroke			

subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lethargy			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasogenic cerebral oedema			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Coagulopathy			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			

subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Ulcerative keratitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Proctitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal ulcer haemorrhage			

subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Gastrointestinal motility disorder			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal haemorrhage			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Overflow diarrhoea			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophagitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune hepatitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pemphigoid			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis bullous			

subjects affected / exposed	2 / 165 (1.21%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Immune-mediated nephritis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune nephritis			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			

subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary retention			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Adrenal insufficiency			
subjects affected / exposed	3 / 165 (1.82%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hypophysitis			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Myositis			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	2 / 165 (1.21%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue necrosis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Erysipelas			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	7 / 165 (4.24%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 9	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	2 / 165 (1.21%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	2 / 165 (1.21%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia influenzal			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Influenza			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psoas abscess			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			

subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal infection			
subjects affected / exposed	2 / 165 (1.21%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Soft tissue infection			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin infection			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 165 (0.61%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Abdominal sepsis			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	2 / 165 (1.21%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess bacterial			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthritis infective			

subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacterial infection			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	2 / 165 (1.21%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia urinary tract infection			

subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fungal skin infection			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Groin infection			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infected skin ulcer			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Klebsiella sepsis			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Medical device site infection			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			

subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis aseptic			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia pneumococcal			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural infection			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	2 / 165 (1.21%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Urosepsis			

subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Viral infection			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			
subjects affected / exposed	1 / 165 (0.61%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 165 (0.61%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W	
Total subjects affected by serious adverse events			
subjects affected / exposed	23 / 56 (41.07%)	35 / 63 (55.56%)	
number of deaths (all causes)	26	23	

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Follicular lymphoma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal cell carcinoma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute myeloid leukaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected neoplasm			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung neoplasm malignant			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal cancer			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arterial haemorrhage			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Deep vein thrombosis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphoedema			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug withdrawal syndrome			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (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	1 / 56 (1.79%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral swelling			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inflammation			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pneumonitis			
subjects affected / exposed	1 / 56 (1.79%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epistaxis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory distress syndrome			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung disorder			

subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Interstitial lung disease			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated lung disease			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (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 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary oedema			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary toxicity			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Adjustment disorder			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Confusional state			
subjects affected / exposed	0 / 56 (0.00%)	3 / 63 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depression			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device occlusion			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			

Blood creatinine increased				
subjects affected / exposed	0 / 56 (0.00%)	2 / 63 (3.17%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
Influenza A virus test positive				
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
General physical condition abnormal				
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)		
occurrences causally related to treatment / all	0 / 0	0 / 1		
deaths causally related to treatment / all	0 / 0	0 / 0		
Lipase increased				
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
International normalised ratio increased				
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)		
occurrences causally related to treatment / all	0 / 2	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		
Troponin I increased				
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (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				
Fall				
subjects affected / exposed	0 / 56 (0.00%)	2 / 63 (3.17%)		
occurrences causally related to treatment / all	0 / 0	0 / 2		
deaths causally related to treatment / all	0 / 0	0 / 0		
Eye contusion				
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)		
occurrences causally related to treatment / all	0 / 0	0 / 0		
deaths causally related to treatment / all	0 / 0	0 / 0		

Hip fracture			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acetabulum fracture			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foot fracture			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion related reaction			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Limb injury			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple fractures			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin laceration			

subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound complication			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 56 (0.00%)	2 / 63 (3.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Myocarditis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block complete			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac flutter			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (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			
Cerebral ischaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Ischaemic stroke			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Brain oedema			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery aneurysm			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Focal dyscognitive seizures			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			

subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Cerebral infarction			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhagic stroke			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lethargy			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuropathy peripheral			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	1 / 56 (1.79%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasogenic cerebral oedema			

subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Coagulopathy			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia			
subjects affected / exposed	1 / 56 (1.79%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Ulcerative keratitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Proctitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Colitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal ulcer haemorrhage			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal motility disorder			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	1 / 56 (1.79%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal haemorrhage			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overflow diarrhoea			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophagitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune hepatitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated hepatitis			

subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pemphigoid			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis bullous			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash maculo-papular			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin ulcer			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Immune-mediated nephritis			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	2 / 56 (3.57%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute kidney injury			

subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune nephritis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (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 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephrolithiasis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary retention			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal insufficiency			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophysitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated hypophysitis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthralgia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myositis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue necrosis			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (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			

Erysipelas			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 56 (0.00%)	3 / 63 (4.76%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cellulitis			
subjects affected / exposed	1 / 56 (1.79%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 1	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	1 / 56 (1.79%)	3 / 63 (4.76%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Encephalitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia influenzal			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoas abscess			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural abscess			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Staphylococcal infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Soft tissue infection			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal sepsis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wound infection			
subjects affected / exposed	0 / 56 (0.00%)	2 / 63 (3.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess bacterial			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthritis infective			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (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 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Catheter site infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cystitis			

subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocarditis			
subjects affected / exposed	0 / 56 (0.00%)	2 / 63 (3.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia urinary tract infection			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fungal skin infection			
subjects affected / exposed	1 / 56 (1.79%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Groin infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Klebsiella sepsis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Medical device site infection			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis aseptic			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia pneumococcal			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 56 (3.57%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypervolaemia			
subjects affected / exposed	0 / 56 (0.00%)	1 / 63 (1.59%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			

subjects affected / exposed	1 / 56 (1.79%)	2 / 63 (3.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Group 1 (mCSCC): Cemiplimab 3mg/kg IV Q2W	Group 2 (laCSCC): Cemiplimab 3 mg/kg IV Q2W	Group 5 (mCSCC & laCSCC): Cemiplimab 438 mg SC + 350 mg IV Q3W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	56 / 59 (94.92%)	75 / 78 (96.15%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Squamous cell carcinoma of skin			
subjects affected / exposed	5 / 59 (8.47%)	4 / 78 (5.13%)	0 / 9 (0.00%)
occurrences (all)	10	6	0
Squamous cell carcinoma			
subjects affected / exposed	0 / 59 (0.00%)	4 / 78 (5.13%)	0 / 9 (0.00%)
occurrences (all)	0	6	0
Basal cell carcinoma			
subjects affected / exposed	3 / 59 (5.08%)	10 / 78 (12.82%)	0 / 9 (0.00%)
occurrences (all)	6	15	0
Bowen's disease			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Tumour pain			
subjects affected / exposed	3 / 59 (5.08%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Tumour haemorrhage			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Keratoacanthoma			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	6 / 59 (10.17%)	7 / 78 (8.97%)	0 / 9 (0.00%)
occurrences (all)	6	11	0
Hot flush			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Lymphoedema			
subjects affected / exposed	3 / 59 (5.08%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	15 / 59 (25.42%)	34 / 78 (43.59%)	1 / 9 (11.11%)
occurrences (all)	18	41	1
Oedema peripheral			
subjects affected / exposed	4 / 59 (6.78%)	4 / 78 (5.13%)	0 / 9 (0.00%)
occurrences (all)	4	4	0
Facial pain			
subjects affected / exposed	0 / 59 (0.00%)	5 / 78 (6.41%)	1 / 9 (11.11%)
occurrences (all)	0	5	1
Pyrexia			
subjects affected / exposed	0 / 59 (0.00%)	6 / 78 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	8	0
Chills			
subjects affected / exposed	0 / 59 (0.00%)	6 / 78 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	7	0
Asthenia			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Catheter site rash			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
General physical health deterioration			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infusion site extravasation			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Terminal agitation			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Injection site discomfort			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	6 / 59 (10.17%)	6 / 78 (7.69%)	1 / 9 (11.11%)
occurrences (all)	7	6	1
Cough			
subjects affected / exposed	11 / 59 (18.64%)	16 / 78 (20.51%)	0 / 9 (0.00%)
occurrences (all)	12	18	0
Dysphonia			
subjects affected / exposed	0 / 59 (0.00%)	4 / 78 (5.13%)	0 / 9 (0.00%)
occurrences (all)	0	4	0
Oropharyngeal pain			
subjects affected / exposed	6 / 59 (10.17%)	4 / 78 (5.13%)	0 / 9 (0.00%)
occurrences (all)	7	4	0
Epistaxis			
subjects affected / exposed	5 / 59 (8.47%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	6	0	0
Nasal congestion			

subjects affected / exposed	5 / 59 (8.47%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	5	0	0
Pneumonitis			
subjects affected / exposed	3 / 59 (5.08%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Pulmonary fibrosis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	5 / 59 (8.47%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	5	0	0
Insomnia			
subjects affected / exposed	0 / 59 (0.00%)	8 / 78 (10.26%)	1 / 9 (11.11%)
occurrences (all)	0	8	1
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	5 / 59 (8.47%)	10 / 78 (12.82%)	1 / 9 (11.11%)
occurrences (all)	5	10	1
Blood alkaline phosphatase increased			
subjects affected / exposed	4 / 59 (6.78%)	8 / 78 (10.26%)	0 / 9 (0.00%)
occurrences (all)	5	8	0
Weight decreased			
subjects affected / exposed	0 / 59 (0.00%)	7 / 78 (8.97%)	0 / 9 (0.00%)
occurrences (all)	0	7	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 59 (0.00%)	6 / 78 (7.69%)	1 / 9 (11.11%)
occurrences (all)	0	6	1
Blood creatinine increased			

subjects affected / exposed	4 / 59 (6.78%)	5 / 78 (6.41%)	1 / 9 (11.11%)
occurrences (all)	6	5	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 59 (0.00%)	4 / 78 (5.13%)	0 / 9 (0.00%)
occurrences (all)	0	4	0
Blood bilirubin increased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Lymphocyte count decreased			
subjects affected / exposed	4 / 59 (6.78%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	5	0	2
Neutrophil count decreased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Red blood cell count increased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	3
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	5 / 59 (8.47%)	4 / 78 (5.13%)	1 / 9 (11.11%)
occurrences (all)	5	4	1
Infusion related reaction			
subjects affected / exposed	0 / 59 (0.00%)	4 / 78 (5.13%)	0 / 9 (0.00%)
occurrences (all)	0	5	0
Contusion			
subjects affected / exposed	4 / 59 (6.78%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	4	0	0
Face injury			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Jaw fracture			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Radiation skin injury			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Scar			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin laceration			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myocardial ischaemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	11 / 59 (18.64%)	7 / 78 (8.97%)	1 / 9 (11.11%)
occurrences (all)	12	8	1
Dizziness			
subjects affected / exposed	8 / 59 (13.56%)	5 / 78 (6.41%)	0 / 9 (0.00%)
occurrences (all)	9	5	0
Dysgeusia			
subjects affected / exposed	4 / 59 (6.78%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	5	0	0
Syncope			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Memory impairment			
subjects affected / exposed	3 / 59 (5.08%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Lethargy			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	7 / 59 (11.86%)	8 / 78 (10.26%)	1 / 9 (11.11%)
occurrences (all)	9	13	1
Thrombocytopenia			
subjects affected / exposed	0 / 59 (0.00%)	5 / 78 (6.41%)	1 / 9 (11.11%)
occurrences (all)	0	5	1
Neutropenia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Otorrhoea			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Eye disorders			
Retinal haemorrhage			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 59 (0.00%)	4 / 78 (5.13%)	0 / 9 (0.00%)
occurrences (all)	0	5	0
Eye swelling			

subjects affected / exposed	0 / 59 (0.00%)	4 / 78 (5.13%)	0 / 9 (0.00%)
occurrences (all)	0	4	0
Dry eye			
subjects affected / exposed	3 / 59 (5.08%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	3	0	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	17 / 59 (28.81%)	23 / 78 (29.49%)	3 / 9 (33.33%)
occurrences (all)	29	42	3
Nausea			
subjects affected / exposed	14 / 59 (23.73%)	20 / 78 (25.64%)	2 / 9 (22.22%)
occurrences (all)	17	25	2
Constipation			
subjects affected / exposed	10 / 59 (16.95%)	10 / 78 (12.82%)	0 / 9 (0.00%)
occurrences (all)	12	11	0
Dry mouth			
subjects affected / exposed	5 / 59 (8.47%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	5	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 59 (5.08%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	4	0	0
Dysphagia			
subjects affected / exposed	0 / 59 (0.00%)	4 / 78 (5.13%)	0 / 9 (0.00%)
occurrences (all)	0	4	0
Colitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Vomiting			
subjects affected / exposed	6 / 59 (10.17%)	11 / 78 (14.10%)	1 / 9 (11.11%)
occurrences (all)	8	13	1
Abdominal pain			
subjects affected / exposed	3 / 59 (5.08%)	12 / 78 (15.38%)	1 / 9 (11.11%)
occurrences (all)	3	12	1
Toothache			
subjects affected / exposed	4 / 59 (6.78%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	5	0	0

Stomatitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Poor dental condition			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	11 / 59 (18.64%)	11 / 78 (14.10%)	3 / 9 (33.33%)
occurrences (all)	18	15	3
Pruritus			
subjects affected / exposed	11 / 59 (18.64%)	23 / 78 (29.49%)	1 / 9 (11.11%)
occurrences (all)	14	29	1
Actinic keratosis			
subjects affected / exposed	4 / 59 (6.78%)	12 / 78 (15.38%)	0 / 9 (0.00%)
occurrences (all)	4	15	0
Rash erythematous			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Dermatitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	9 / 59 (15.25%)	8 / 78 (10.26%)	4 / 9 (44.44%)
occurrences (all)	11	13	7
Dry skin			
subjects affected / exposed	6 / 59 (10.17%)	8 / 78 (10.26%)	0 / 9 (0.00%)
occurrences (all)	6	9	0
Skin lesion			

subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tumour pruritus			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	3 / 59 (5.08%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Renal failure			
subjects affected / exposed	3 / 59 (5.08%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Renal impairment			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hyperparathyroidism			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hypothyroidism			
subjects affected / exposed	6 / 59 (10.17%)	9 / 78 (11.54%)	2 / 9 (22.22%)
occurrences (all)	6	9	2
Thyroid mass			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	5 / 59 (8.47%)	8 / 78 (10.26%)	0 / 9 (0.00%)
occurrences (all)	7	8	0
Arthralgia			

subjects affected / exposed	12 / 59 (20.34%)	11 / 78 (14.10%)	1 / 9 (11.11%)
occurrences (all)	16	12	3
Psoriatic arthropathy			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	2
Pain in extremity			
subjects affected / exposed	4 / 59 (6.78%)	5 / 78 (6.41%)	0 / 9 (0.00%)
occurrences (all)	4	7	0
Myalgia			
subjects affected / exposed	4 / 59 (6.78%)	5 / 78 (6.41%)	1 / 9 (11.11%)
occurrences (all)	5	6	1
Neck pain			
subjects affected / exposed	0 / 59 (0.00%)	6 / 78 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	7	0
Trismus			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	6 / 59 (10.17%)	9 / 78 (11.54%)	3 / 9 (33.33%)
occurrences (all)	13	12	3
Wound infection			
subjects affected / exposed	4 / 59 (6.78%)	7 / 78 (8.97%)	0 / 9 (0.00%)
occurrences (all)	6	7	0
Urinary tract infection			
subjects affected / exposed	6 / 59 (10.17%)	5 / 78 (6.41%)	0 / 9 (0.00%)
occurrences (all)	13	11	0
Cellulitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
COVID-19			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Lower respiratory tract infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infected cyst			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fungal skin infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 59 (0.00%)	4 / 78 (5.13%)	0 / 9 (0.00%)
occurrences (all)	0	5	0
Skin infection			
subjects affected / exposed	4 / 59 (6.78%)	4 / 78 (5.13%)	0 / 9 (0.00%)
occurrences (all)	7	5	0
Bacterial infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nail infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonia viral			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Oral candidiasis			
subjects affected / exposed	5 / 59 (8.47%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	5	0	1

Nasopharyngitis			
subjects affected / exposed	5 / 59 (8.47%)	0 / 78 (0.00%)	1 / 9 (11.11%)
occurrences (all)	9	0	1
Postoperative wound infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	8 / 59 (13.56%)	7 / 78 (8.97%)	1 / 9 (11.11%)
occurrences (all)	9	7	1
Hypokalaemia			
subjects affected / exposed	4 / 59 (6.78%)	8 / 78 (10.26%)	0 / 9 (0.00%)
occurrences (all)	4	10	0
Hyponatraemia			
subjects affected / exposed	0 / 59 (0.00%)	5 / 78 (6.41%)	1 / 9 (11.11%)
occurrences (all)	0	5	1
Hyperkalaemia			
subjects affected / exposed	0 / 59 (0.00%)	6 / 78 (7.69%)	0 / 9 (0.00%)
occurrences (all)	0	6	0
Hypomagnesaemia			
subjects affected / exposed	3 / 59 (5.08%)	7 / 78 (8.97%)	0 / 9 (0.00%)
occurrences (all)	5	8	0
Hyperuricaemia			
subjects affected / exposed	0 / 59 (0.00%)	7 / 78 (8.97%)	0 / 9 (0.00%)
occurrences (all)	0	10	0
Dehydration			
subjects affected / exposed	3 / 59 (5.08%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	3	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 78 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 59 (0.00%)	7 / 78 (8.97%)	1 / 9 (11.11%)
occurrences (all)	0	9	1

Non-serious adverse events	Group 6 (mCSCC & laCSCC): Cemiplimab 350 mg	Group6a(mCSCC&laCSCC):Cemiplimab 350mg	Group6b(mCSCC&laCSCC):Cemiplimab 350mg

	IV Q3W	IV Q3W to 350mg SC Q3W	IV Q3W to 1050mg SC Q6W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	147 / 165 (89.09%)	9 / 12 (75.00%)	5 / 7 (71.43%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Squamous cell carcinoma of skin			
subjects affected / exposed	10 / 165 (6.06%)	2 / 12 (16.67%)	0 / 7 (0.00%)
occurrences (all)	19	2	0
Squamous cell carcinoma			
subjects affected / exposed	12 / 165 (7.27%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	25	1	0
Basal cell carcinoma			
subjects affected / exposed	14 / 165 (8.48%)	2 / 12 (16.67%)	2 / 7 (28.57%)
occurrences (all)	32	6	5
Bowen's disease			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Tumour pain			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Tumour haemorrhage			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Keratoacanthoma			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	12 / 165 (7.27%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	18	0	0
Hot flush			

subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphoedema			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	44 / 165 (26.67%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	49	1	0
Oedema peripheral			
subjects affected / exposed	16 / 165 (9.70%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	18	2	0
Facial pain			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	15 / 165 (9.09%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	16	0	0
Chills			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Asthenia			
subjects affected / exposed	26 / 165 (15.76%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	35	1	0
Catheter site rash			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General physical health deterioration			
subjects affected / exposed	9 / 165 (5.45%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	9	0	0
Infusion site extravasation			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Terminal agitation			

subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Injection site discomfort			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	11 / 165 (6.67%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	12	0	0
Cough			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dysphonia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Epistaxis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pneumonitis			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pulmonary fibrosis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Sinus congestion			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Delirium			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	9 / 165 (5.45%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	9	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	12 / 165 (7.27%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	15	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	12 / 165 (7.27%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	13	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			

subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Red blood cell count increased			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
White blood cell count decreased			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	14 / 165 (8.48%)	2 / 12 (16.67%)	0 / 7 (0.00%)
occurrences (all)	16	2	0
Infusion related reaction			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Face injury			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Jaw fracture			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Radiation skin injury			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Scar			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Skin laceration			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Atrial flutter			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Myocardial ischaemia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Sinus bradycardia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	15 / 165 (9.09%)	0 / 12 (0.00%)	1 / 7 (14.29%)
occurrences (all)	16	0	1
Dizziness			
subjects affected / exposed	13 / 165 (7.88%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	13	0	0
Dysgeusia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myoclonus			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hypoaesthesia			

subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	11 / 165 (6.67%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	13	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Otorrhoea			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Retinal haemorrhage			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Lacrimation increased			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Eye swelling			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	39 / 165 (23.64%)	0 / 12 (0.00%)	1 / 7 (14.29%)
occurrences (all)	58	0	2
Nausea			
subjects affected / exposed	33 / 165 (20.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	37	0	0
Constipation			

subjects affected / exposed	22 / 165 (13.33%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	25	0	0
Dry mouth			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	17 / 165 (10.30%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	26	0	0
Abdominal pain			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Poor dental condition			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Rash			

subjects affected / exposed	11 / 165 (6.67%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	13	0	0
Pruritus			
subjects affected / exposed	43 / 165 (26.06%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	55	2	0
Actinic keratosis			
subjects affected / exposed	17 / 165 (10.30%)	2 / 12 (16.67%)	2 / 7 (28.57%)
occurrences (all)	30	2	2
Rash erythematous			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyperkeratosis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	18 / 165 (10.91%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	23	0	0
Dry skin			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	10 / 165 (6.06%)	2 / 12 (16.67%)	1 / 7 (14.29%)
occurrences (all)	26	5	1
Tumour pruritus			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Haematuria			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

Pollakiuria			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Renal failure			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Renal impairment			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Hyperparathyroidism			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypothyroidism			
subjects affected / exposed	14 / 165 (8.48%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	15	1	0
Thyroid mass			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	16 / 165 (9.70%)	2 / 12 (16.67%)	1 / 7 (14.29%)
occurrences (all)	17	2	1
Arthralgia			
subjects affected / exposed	24 / 165 (14.55%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	32	0	0
Psoriatic arthropathy			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Myalgia			

subjects affected / exposed	11 / 165 (6.67%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	12	0	0
Neck pain			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Trismus			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Wound infection			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
COVID-19			
subjects affected / exposed	13 / 165 (7.88%)	4 / 12 (33.33%)	0 / 7 (0.00%)
occurrences (all)	14	4	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Infected cyst			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Fungal skin infection			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

Bronchitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	10 / 165 (6.06%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	16	0	0
Bacterial infection			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nail infection			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Pneumonia viral			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Postoperative wound infection			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	22 / 165 (13.33%)	0 / 12 (0.00%)	1 / 7 (14.29%)
occurrences (all)	23	0	1
Hypokalaemia			

subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Hypomagnesaemia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dehydration			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 165 (0.00%)	0 / 12 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 165 (0.00%)	1 / 12 (8.33%)	0 / 7 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Group 3 (mCSCC): Cemiplimab 350 mg IV Q3W	Group 4 (mCSCC & laCSCC): Cemiplimab 600 mg IV Q4W	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	49 / 56 (87.50%)	59 / 63 (93.65%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Benign neoplasm of thyroid gland			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Squamous cell carcinoma of skin			
subjects affected / exposed	3 / 56 (5.36%)	0 / 63 (0.00%)	
occurrences (all)	3	0	
Squamous cell carcinoma			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Basal cell carcinoma			
subjects affected / exposed	3 / 56 (5.36%)	6 / 63 (9.52%)	
occurrences (all)	5	16	
Bowen's disease			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Tumour pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Tumour haemorrhage			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Keratoacanthoma			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Hypotension			
subjects affected / exposed	4 / 56 (7.14%)	0 / 63 (0.00%)	
occurrences (all)	4	0	
Hypertension			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Lymphoedema			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	17 / 56 (30.36%)	14 / 63 (22.22%)	
occurrences (all)	19	15	
Oedema peripheral			

subjects affected / exposed	6 / 56 (10.71%)	7 / 63 (11.11%)	
occurrences (all)	6	7	
Facial pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	0 / 56 (0.00%)	6 / 63 (9.52%)	
occurrences (all)	0	8	
Chills			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Asthenia			
subjects affected / exposed	0 / 56 (0.00%)	5 / 63 (7.94%)	
occurrences (all)	0	6	
Catheter site rash			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
General physical health deterioration			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Infusion site extravasation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Terminal agitation			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Injection site discomfort			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	3 / 56 (5.36%)	6 / 63 (9.52%)	
occurrences (all)	3	7	
Cough			

subjects affected / exposed	5 / 56 (8.93%)	7 / 63 (11.11%)	
occurrences (all)	5	9	
Dysphonia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Nasal congestion			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Pneumonitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Pulmonary fibrosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Sinus congestion			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Delirium			
subjects affected / exposed	3 / 56 (5.36%)	0 / 63 (0.00%)	
occurrences (all)	3	0	
Depression			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	3 / 56 (5.36%)	0 / 63 (0.00%)	
occurrences (all)	3	0	
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Weight decreased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Aspartate aminotransferase increased			
subjects affected / exposed	4 / 56 (7.14%)	0 / 63 (0.00%)	
occurrences (all)	4	0	
Blood creatinine increased			
subjects affected / exposed	5 / 56 (8.93%)	7 / 63 (11.11%)	
occurrences (all)	5	10	
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Blood bilirubin increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Lymphocyte count decreased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Neutrophil count decreased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Red blood cell count increased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
White blood cell count decreased			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			

Fall			
subjects affected / exposed	4 / 56 (7.14%)	4 / 63 (6.35%)	
occurrences (all)	6	6	
Infusion related reaction			
subjects affected / exposed	0 / 56 (0.00%)	4 / 63 (6.35%)	
occurrences (all)	0	6	
Contusion			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Face injury			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Jaw fracture			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Radiation skin injury			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Scar			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Skin laceration			
subjects affected / exposed	3 / 56 (5.36%)	0 / 63 (0.00%)	
occurrences (all)	3	0	
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Myocardial ischaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Sinus bradycardia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			

Headache			
subjects affected / exposed	3 / 56 (5.36%)	7 / 63 (11.11%)	
occurrences (all)	4	7	
Dizziness			
subjects affected / exposed	0 / 56 (0.00%)	5 / 63 (7.94%)	
occurrences (all)	0	5	
Dysgeusia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Syncope			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	4 / 56 (7.14%)	0 / 63 (0.00%)	
occurrences (all)	5	0	
Myoclonus			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Memory impairment			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Lethargy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Hypoaesthesia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	8 / 56 (14.29%)	8 / 63 (12.70%)	
occurrences (all)	8	13	
Thrombocytopenia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Neutropenia			

subjects affected / exposed occurrences (all)	0 / 56 (0.00%) 0	0 / 63 (0.00%) 0	
Ear and labyrinth disorders Otorrhoea subjects affected / exposed occurrences (all)	 0 / 56 (0.00%) 0	 0 / 63 (0.00%) 0	
Eye disorders Retinal haemorrhage subjects affected / exposed occurrences (all) Lacrimation increased subjects affected / exposed occurrences (all) Eye swelling subjects affected / exposed occurrences (all) Dry eye subjects affected / exposed occurrences (all)	 0 / 56 (0.00%) 0 0 / 56 (0.00%) 0 0 / 56 (0.00%) 0 0 / 56 (0.00%) 0	 0 / 63 (0.00%) 0 0 / 63 (0.00%) 0 0 / 63 (0.00%) 0 0 / 63 (0.00%) 0	
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Nausea subjects affected / exposed occurrences (all) Constipation subjects affected / exposed occurrences (all) Dry mouth subjects affected / exposed occurrences (all) Gastrooesophageal reflux disease subjects affected / exposed occurrences (all) Dysphagia	 13 / 56 (23.21%) 18 12 / 56 (21.43%) 12 10 / 56 (17.86%) 11 3 / 56 (5.36%) 3 0 / 56 (0.00%) 0	 17 / 63 (26.98%) 23 6 / 63 (9.52%) 6 15 / 63 (23.81%) 16 0 / 63 (0.00%) 0 0 / 63 (0.00%) 0	

subjects affected / exposed	3 / 56 (5.36%)	5 / 63 (7.94%)	
occurrences (all)	4	6	
Colitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Vomiting			
subjects affected / exposed	8 / 56 (14.29%)	6 / 63 (9.52%)	
occurrences (all)	8	6	
Abdominal pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Toothache			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Poor dental condition			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	10 / 56 (17.86%)	12 / 63 (19.05%)	
occurrences (all)	13	17	
Pruritus			
subjects affected / exposed	7 / 56 (12.50%)	16 / 63 (25.40%)	
occurrences (all)	8	20	
Actinic keratosis			
subjects affected / exposed	7 / 56 (12.50%)	8 / 63 (12.70%)	
occurrences (all)	7	13	
Rash erythematous			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Hyperkeratosis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Dermatitis			
subjects affected / exposed	0 / 56 (0.00%)	7 / 63 (11.11%)	
occurrences (all)	0	9	
Rash maculo-papular			
subjects affected / exposed	7 / 56 (12.50%)	8 / 63 (12.70%)	
occurrences (all)	8	10	
Dry skin			
subjects affected / exposed	4 / 56 (7.14%)	0 / 63 (0.00%)	
occurrences (all)	4	0	
Skin lesion			
subjects affected / exposed	3 / 56 (5.36%)	6 / 63 (9.52%)	
occurrences (all)	4	13	
Tumour pruritus			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 56 (0.00%)	7 / 63 (11.11%)	
occurrences (all)	0	7	
Haematuria			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Pollakiuria			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Renal failure			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Renal impairment			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	

Endocrine disorders			
Hyperparathyroidism			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Hypothyroidism			
subjects affected / exposed	7 / 56 (12.50%)	0 / 63 (0.00%)	
occurrences (all)	7	0	
Thyroid mass			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	6 / 56 (10.71%)	6 / 63 (9.52%)	
occurrences (all)	6	6	
Arthralgia			
subjects affected / exposed	10 / 56 (17.86%)	11 / 63 (17.46%)	
occurrences (all)	13	12	
Psoriatic arthropathy			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Pain in jaw			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	3 / 56 (5.36%)	0 / 63 (0.00%)	
occurrences (all)	3	0	
Myalgia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Neck pain			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Trismus			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			

Upper respiratory tract infection			
subjects affected / exposed	5 / 56 (8.93%)	8 / 63 (12.70%)	
occurrences (all)	6	12	
Wound infection			
subjects affected / exposed	3 / 56 (5.36%)	0 / 63 (0.00%)	
occurrences (all)	3	0	
Urinary tract infection			
subjects affected / exposed	0 / 56 (0.00%)	5 / 63 (7.94%)	
occurrences (all)	0	10	
Cellulitis			
subjects affected / exposed	3 / 56 (5.36%)	4 / 63 (6.35%)	
occurrences (all)	3	6	
COVID-19			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Infected cyst			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Fungal skin infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Skin infection			
subjects affected / exposed	0 / 56 (0.00%)	7 / 63 (11.11%)	
occurrences (all)	0	12	
Bacterial infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	

Nail infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Sinusitis			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Pneumonia viral			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Oral candidiasis			
subjects affected / exposed	0 / 56 (0.00%)	5 / 63 (7.94%)	
occurrences (all)	0	6	
Nasopharyngitis			
subjects affected / exposed	3 / 56 (5.36%)	0 / 63 (0.00%)	
occurrences (all)	3	0	
Postoperative wound infection			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	4 / 56 (7.14%)	7 / 63 (11.11%)	
occurrences (all)	4	7	
Hypokalaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Hyponatraemia			
subjects affected / exposed	0 / 56 (0.00%)	4 / 63 (6.35%)	
occurrences (all)	0	4	
Hyperkalaemia			
subjects affected / exposed	0 / 56 (0.00%)	4 / 63 (6.35%)	
occurrences (all)	0	4	
Hypomagnesaemia			

subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Hyperuricaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Dehydration			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	
Hypercalcaemia			
subjects affected / exposed	0 / 56 (0.00%)	5 / 63 (7.94%)	
occurrences (all)	0	9	
Hyperglycaemia			
subjects affected / exposed	0 / 56 (0.00%)	0 / 63 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 January 2016	The purpose of this amendment was to incorporate changes and clarifications requested by the FDA; additional changes apply
12 December 2016	The primary purpose of this amendment was to revise the text for toxicity management; additional changes apply
18 May 2017	The primary purpose of this amendment was to enroll metastatic (nodal or distant) cutaneous squamous cell carcinoma (CSCC) patients who are dosed at 350 mg flat dose every 3 weeks (Q3W) as Group 3; additional changes apply
22 June 2017	Added an exclusion criterion: Patients who have previously been treated with idelalisib; Additional safety guidance language added for the management of patients developing stomatitis or mucositis; An adverse event of special interest (AESI) has been added to the list of AESIs; additional changes apply
22 September 2017	In response to health authority guidance, added an interim analysis for Group 2 and revised the statistical considerations; Specified tumor staging will be collected at baseline; additional changes apply
23 August 2018	Two new cohorts were added, Group 4 and Group 5, to enroll patients with advanced CSCC; A secondary objective to measure tumor response via PET response criteria in solid tumors (EORTC) has been added to Group 4; End of Study definition revised; additional changes apply
21 October 2019	Added Group 6 to provide additional efficacy and safety data for cemiplimab monotherapy in patients with advanced CSCC; Collect additional PK samples at follow-up visits 3 and 4; Removed exclusion of patients with allergy or hypersensitivity to doxycycline or tetracycline; additional changes apply
09 September 2021	Added provisions to allow participants from Group 6 to switch to subcutaneous (SC) dosing, provided they meet certain criteria; Updated the imAE management guidelines to align with the Company Core Data Sheet (CCDS) for cemiplimab; Added language regarding clinical study conduct and oversight related to Coronavirus Disease 2019 (COVID-19); Updated cemiplimab rationale to include additional approved indications of non-small cell lung cancer (NSLC) and basal cell carcinoma (BCC); additional changes apply

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported