Clinical trial results:
Multiple Phase 1/2 Cohorts of Nivolumab Monotherapy or Nivolumab Combination Regimens Across Relapsed/Refractory Hematologic Malignancies

Summary

EudraCT number	2018-001030-17
Trial protocol	GR BE PL IT
Global end of trial date	09 July 2024

Results information

Result version number	v1 (current)
This version publication date	26 July 2025
First version publication date	26 July 2025

Trial information

Trial identification

Sponsor protocol code	CA209-039

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	Global Submission Management, Clinical Trials, Bristol-Myers Squibb, mg-gsm-ct@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, mg-gsm-ct@bms.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	09 July 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 July 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To establish the tolerability of the combination of nivolumab and daratumumab in subjects with relapsed/refractory MM.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial subjects were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 August 2012
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	France: 8
Country: Number of subjects enrolled	Greece: 10
Country: Number of subjects enrolled	Poland: 21
Country: Number of subjects enrolled	United States: 279
Worldwide total number of subjects	320
EEA total number of subjects	41

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	197

From 65 to 84 years	110
85 years and over	13

Subject disposition

Recruitment

Recruitment details:

For the phase 1 nivo monotherapy dose escalation included in this study, it was derived from CA209-003. It was concluded that 3mg/kg of nivolumab would be used for the dose expansion phase 2 of this study (CA209-039) based on the conclusions derived from CA209-003.

Pre-assignment

Screening details:

316 participants treated

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Nivolumab Monotherapy (expansion)

Arm description:

3mg/kg of nivolumab

Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

1mg/kg or 3mg/kg

Arm title	Nivolumab + Ipilimumab

Arm description:

3 mg/kg of nivolumab and 1 mg/kg of ipilimumab Q3W for 4 doses, followed by nivolumab alone at 3 mg/kg Q2W

Arm type	Experimental
Investigational medicinal product name	ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

1mg/kg

Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

1mg/kg or 3mg/kg

Arm title	Nivolumab + Lirilumab

Arm description: 3 mg/kg of nivolumab Q2W + 3 mg/kg of lirilumab Q4W	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use
Dosage and administration details: 1mg/kg or 3mg/kg	
Investigational medicinal product name	lirilumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Emulsion for infusion
Routes of administration	Intravenous use
Dosage and administration details: 3mg/kg	
Arm title	Nivolumab + Daratumumab_Cohort A1
Arm description: ND regimen: Nivolumab (240 mg up to cycle 6, then 480 mg) + Daratumumab (16 mg/Kg)	
Arm type	Experimental
Investigational medicinal product name	Daratumumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for concentrate for solution for infusion, Infusion
Routes of administration	Intravenous use
Dosage and administration details: 100mg (20mg/mL) and 400mg (20mg/mL)	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: 100mg (10mg/mL)	
Arm title	Nivolumab + Daratumumab_Cohort A2
Arm description: ND-PD regimen; Nivolumab + Daratumumab + Pomalidomide + Dexamethasone	
Arm type	Experimental
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: 100mg (10mg/mL)	
Investigational medicinal product name	Daratumumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for concentrate for solution for infusion, Infusion

Routes of administration	Intravenous use
Dosage and administration details: 100mg (20mg/mL) and 400mg (20mg/mL)	
Investigational medicinal product name	dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: 2mg or 4mg	
Investigational medicinal product name	dexamethasone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: 4mg/mL	
Investigational medicinal product name	Pomalidomide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: 1mg, 2mg, 3mg and 4mg	
Arm title	Nivolumab + Daratumumab_Cohort B1
Arm description: ND regimen: Nivolumab (240 mg cycle 1, then 480 mg) + Daratumumab (16 mg/Kg)	
Arm type	Experimental
Investigational medicinal product name	Daratumumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for concentrate for solution for infusion, Infusion
Routes of administration	Intravenous use
Dosage and administration details: 100mg (20mg/mL) and 400mg (20mg/mL)	
Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use
Dosage and administration details: 100mg (10mg/mL)	
Arm title	Nivolumab + Daratumumab_Cohort B2
Arm description: D regimen: Daratumumab alone	
Arm type	Experimental

Investigational medicinal product name	Daratumumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder and solvent for concentrate for solution for infusion, Infusion
Routes of administration	Intravenous use

Dosage and administration details:

100mg (20mg/mL) and 400mg (20mg/mL)

Investigational medicinal product name	nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

100mg (10mg/mL)

Number of subjects in period 1[1]	Nivolumab Monotherapy (expansion)	Nivolumab + Ipilimumab	Nivolumab + Lirilumab
Started	105	65	72
Completed	1	40	0
Not completed	104	25	72
Other Reasons	6	-	10
Request to discontinue study treatment	5	-	2
Maximum clinical benefit	11	1	7
AE unrelated to study drug	4	3	-
No longer meets study criteria	1	-	-
Study Drug Toxicity	14	3	-
Withdrew consent	1	2	1
Disease Progression	62	16	52

Number of subjects in period 1[1]	Nivolumab + Daratumumab_Cohort A1	Nivolumab + Daratumumab_Cohort A2	Nivolumab + Daratumumab_Cohort B1
Started	6	5	41
Completed	1	1	7
Not completed	5	4	34
Other Reasons	-	-	1
Request to discontinue study treatment	-	1	2
Maximum clinical benefit	1	-	-
AE unrelated to study drug	-	-	-
No longer meets study criteria	-	-	-
Study Drug Toxicity	-	-	-
Withdrew consent	1	-	-

Disease Progression	3	3	31

Number of subjects in period 1[1]	Nivolumab + Daratumumab_Cohort B2
Started	22
Completed	6
Not completed	16
Other Reasons	-
Request to discontinue study treatment	-
Maximum clinical benefit	-
AE unrelated to study drug	1
No longer meets study criteria	-
Study Drug Toxicity	1
Withdrew consent	-
Disease Progression	14

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Study includes subjects enrolled from CA209-003 which were used in CA209-039 dose finding.

Baseline characteristics

Reporting groups	
Reporting group title	Nivolumab Monotherapy (expansion)
Reporting group description:	
3mg/kg of nivolumab	
Reporting group title	Nivolumab + Ipilimumab
Reporting group description:	
3 mg/kg of nivolumab and 1 mg/kg of ipilimumab Q3W for 4 doses, followed by nivolumab alone at 3 mg/kg Q2W	
Reporting group title	Nivolumab + Lirilumab
Reporting group description:	
3 mg/kg of nivolumab Q2W + 3 mg/kg of lirilumab Q4W	
Reporting group title	Nivolumab + Daratumumab_Cohort A1
Reporting group description:	
ND regimen: Nivolumab (240 mg up to cycle 6, then 480 mg) + Daratumumab (16 mg/Kg)	
Reporting group title	Nivolumab + Daratumumab_Cohort A2
Reporting group description:	
ND-PD regimen; Nivolumab + Daratumumab + Pomalidomide + Dexamethasone	
Reporting group title	Nivolumab + Daratumumab_Cohort B1
Reporting group description:	
ND regimen: Nivolumab (240 mg cycle 1, then 480 mg) + Daratumumab (16 mg/Kg)	
Reporting group title	Nivolumab + Daratumumab_Cohort B2
Reporting group description:	
D regimen: Daratumumab alone	

Reporting group values	Nivolumab Monotherapy (expansion)	Nivolumab + Ipilimumab	Nivolumab + Lirilumab
Number of subjects	105	65	72
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	66	46	52
>=65 years	39	19	20
Sex: Female, Male Units: Participants			
Female	45	28	26
Male	60	37	46
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	1	0
Native Hawaiian or Other Pacific Islander	1	0	0
Black or African American	11	5	7
White	89	58	63
More than one race	0	0	0
Unknown or Not Reported	2	1	2
Ethnicity (NIH/OMB)			

Units: Subjects			
Hispanic or Latino	13	3	2
Not Hispanic or Latino	91	62	69
Unknown or Not Reported	1	0	1

Reporting group values	Nivolumab + Daratumumab_Cohort A1	Nivolumab + Daratumumab_Cohort A2	Nivolumab + Daratumumab_Cohort B1
Number of subjects	6	5	41
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	3	2	16
>=65 years	3	3	25
Sex: Female, Male Units: Participants			
Female	3	1	24
Male	3	4	17
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	1
White	5	5	36
More than one race	0	0	0
Unknown or Not Reported	1	0	4
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	2
Not Hispanic or Latino	6	5	27
Unknown or Not Reported	0	0	12

Reporting group values	Nivolumab + Daratumumab_Cohort B2	Total	
Number of subjects	22	316	
Age Categorical Units: Participants			
<=18 years	0	0	
Between 18 and 65 years	11	196	
>=65 years	11	120	
Sex: Female, Male Units: Participants			
Female	8	135	
Male	14	181	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	3	
Native Hawaiian or Other Pacific Islander	0	1	
Black or African American	2	26	

White	19	275	
More than one race	0	0	
Unknown or Not Reported	1	11	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	20	
Not Hispanic or Latino	17	277	
Unknown or Not Reported	5	19	

End points

End points reporting groups

Reporting group title	Nivolumab Monotherapy (expansion)
Reporting group description: 3mg/kg of nivolumab	
Reporting group title	Nivolumab + Ipilimumab
Reporting group description: 3 mg/kg of nivolumab and 1 mg/kg of ipilimumab Q3W for 4 doses, followed by nivolumab alone at 3 mg/kg Q2W	
Reporting group title	Nivolumab + Lirilumab
Reporting group description: 3 mg/kg of nivolumab Q2W + 3 mg/kg of lirilumab Q4W	
Reporting group title	Nivolumab + Daratumumab_Cohort A1
Reporting group description: ND regimen: Nivolumab (240 mg up to cycle 6, then 480 mg) + Daratumumab (16 mg/Kg)	
Reporting group title	Nivolumab + Daratumumab_Cohort A2
Reporting group description: ND-PD regimen; Nivolumab + Daratumumab + Pomalidomide + Dexamethasone	
Reporting group title	Nivolumab + Daratumumab_Cohort B1
Reporting group description: ND regimen: Nivolumab (240 mg cycle 1, then 480 mg) + Daratumumab (16 mg/Kg)	
Reporting group title	Nivolumab + Daratumumab_Cohort B2
Reporting group description: D regimen: Daratumumab alone	
Subject analysis set title	Cohort A-1
Subject analysis set type	Sub-group analysis
Subject analysis set description: ND Regimen Each cycle is 28 days Nivolumab: Cycle 1: 240 mg iv Day 15 Cycle 2-6: 240 mg iv Days 1, 15 Cycle 7 & beyond: 480 mg iv Day 1 Daratumumab: Cycle 1-2: 16 mg/kg iv Days 1, 8, 15, 22 Cycle 3-6: 16 mg/kg iv Days 1, 15 Cycle 7 & beyond: 16 mg/kg iv Day 1 Pomalidomide: 4 mg po daily (Days 1-21) of each 28-day cycle Dexamethasone: Weeks without daratumumab dosing 40 mg po per day (Days 1, 8, 15, 22) of each 28-day cycle for subjects 75 years old 20 mg po per day (Days 1, 8, 15, 22) of each 28-day cycle for subjects > 75 years old	
Subject analysis set title	Cohort B-1
Subject analysis set type	Per protocol
Subject analysis set description: ND Regimen Each cycle is 28 days Nivolumab: Cycle 1: 240 mg iv Day 15 Cycle 2 & beyond: 480 mg iv Day 1 Daratumumab: Cycle 1*-2: 16 mg/kg iv Days 1, 8, 15, 22	

Cycle 3-6: 16 mg/kg iv Days 1, 15
Cycle 7 & beyond: 16 mg/kg iv Day 1

Subject analysis set title	Cohort B-2
Subject analysis set type	Sub-group analysis

Subject analysis set description:

D Monotherapy Regimen

Each cycle is 28 days
Daratumumab:
Cycle 1*-2: 16 mg/kg iv Days 1, 8, 15, 22
Cycle 3-6: 16 mg/kg iv Days 1, 15
Cycle 7 & beyond: 16 mg/kg iv Day 1

Subject analysis set title	Cohort A-1
Subject analysis set type	Sub-group analysis

Subject analysis set description:

ND Regimen

Each cycle is 28 days
Nivolumab:
Cycle 1: 240 mg iv Day 15
Cycle 2-6: 240 mg iv Days 1, 15
Cycle 7 & beyond: 480 mg iv Day 1
Daratumumab:
Cycle 1-2: 16 mg/kg iv Days 1, 8, 15, 22
Cycle 3-6: 16 mg/kg iv Days 1, 15
Cycle 7 & beyond: 16 mg/kg iv Day 1
Pomalidomide:
4 mg po daily (Days 1-21) of each 28-day cycle
Dexamethasone:
Weeks without daratumumab dosing
40 mg po per day (Days 1, 8, 15, 22) of each
28-day cycle for subjects 75 years old
20 mg po per day (Days 1, 8, 15, 22) of each
28-day cycle for subjects > 75 years old

Subject analysis set title	Cohort A-2
Subject analysis set type	Sub-group analysis

Subject analysis set description:

ND-Pd Regimen

Each cycle is 28 days
Nivolumab:
Cycle 1: 240 mg iv Day 15
Cycle 2-6: 240 mg iv Days 1, 15
Cycle 7 & beyond: 480 mg iv Day 1
Daratumumab:
Cycle 1-2: 16 mg/kg iv Days 1, 8, 15, 22
Cycle 3-6: 16 mg/kg iv Days 1, 15
Cycle 7 & beyond: 16 mg/kg iv Day 1

Subject analysis set title	Cohort B-1
Subject analysis set type	Sub-group analysis

Subject analysis set description:

ND Regimen

Each cycle is 28 days
Nivolumab:
Cycle 1: 240 mg iv Day 15
Cycle 2 & beyond: 480 mg iv Day 1
Daratumumab:
Cycle 1*-2: 16 mg/kg iv Days 1, 8, 15, 22
Cycle 3-6: 16 mg/kg iv Days 1, 15
Cycle 7 & beyond: 16 mg/kg iv Day 1

Subject analysis set title	Cohort B-2
Subject analysis set type	Sub-group analysis

Subject analysis set description:

D Monotherapy Regimen

Each cycle is 28 days
Daratumumab:
Cycle 1*-2: 16 mg/kg iv Days 1, 8, 15, 22
Cycle 3-6: 16 mg/kg iv Days 1, 15
Cycle 7 & beyond: 16 mg/kg iv Day 1

Subject analysis set title	Cohort A-2
Subject analysis set type	Sub-group analysis

Subject analysis set description:

ND-Pd Regimen

Each cycle is 28 days
Nivolumab:
Cycle 1: 240 mg iv Day 15
Cycle 2-6: 240 mg iv Days 1, 15
Cycle 7 & beyond: 480 mg iv Day 1
Daratumumab:
Cycle 1-2: 16 mg/kg iv Days 1, 8, 15, 22
Cycle 3-6: 16 mg/kg iv Days 1, 15
Cycle 7 & beyond: 16 mg/kg iv Day 1

Subject analysis set title	Cohort B-1
Subject analysis set type	Sub-group analysis

Subject analysis set description:

ND Regimen

Each cycle is 28 days
Nivolumab:
Cycle 1: 240 mg iv Day 15
Cycle 2 & beyond: 480 mg iv Day 1
Daratumumab:
Cycle 1*-2: 16 mg/kg iv Days 1, 8, 15, 22
Cycle 3-6: 16 mg/kg iv Days 1, 15
Cycle 7 & beyond: 16 mg/kg iv Day 1

Primary: Number of participants that experienced drug related Grade 3-4 SAEs

End point title	Number of participants that experienced drug related Grade 3-4 SAEs[1][2]

End point description:

Number and percent of participants that experienced drug related Grade 3-4 SAEs occurring up to 100 days after the last dose of study drug.

End point type	Primary

End point timeframe:

Nivo Mono: approximately up to 6 years and 9 months Nivo Ipi: approximately up to 5 months Nivo Liri: approximately up to 4 years 1 month

Notes:

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

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: no further statistical analysis done for this endpoint

End point values	Nivolumab Monotherapy (expansion)	Nivolumab + Ipilimumab	Nivolumab + Lirilumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	105	65	72	
Units: Participants	28	8	3	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants that experienced drug related Grade 3-4 AEs

End point title	Number of participants that experienced drug related Grade 3-4 AEs[3][4]

End point description:

Number and percent of participants that experienced drug related Grade 3-4 AEs occurring up to 100 days after the last dose of study drug.

End point type	Primary

End point timeframe:

Nivo Mono: approximately up to 6 years and 9 months Nivo Ipi: approximately up to 5 months Nivo Liri: approximately up to 4 years 1 month

Notes:

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

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: no further statistical analysis done for this endpoint

End point values	Nivolumab Monotherapy (expansion)	Nivolumab + Ipilimumab	Nivolumab + Lirilumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	105	65	72	
Units: Participants	19	18	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with clinical laboratory abnormalities by worst toxicity grade - Liver

End point title	Number of participants with clinical laboratory abnormalities by worst toxicity grade - Liver[5][6]

End point description:

Number and percent of participants that experienced drug related Grade 3-4 AEs occurring up to 100 days after the last dose of study drug.

End point type	Primary

End point timeframe:

Nivo Mono: approximately up to 6 years and 9 months Nivo Ipi: approximately up to 5 months Nivo Liri: approximately up to 4 years 1 month

Notes:

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

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: no further statistical analysis done for this endpoint

End point values	Nivolumab Monotherapy (expansion)	Nivolumab + Ipilimumab	Nivolumab + Lirilumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	105	65	72	
Units: Participants				
ALT OR AST > 3XULN	3	1	4	
ALT OR AST > 5XULN	1	0	2	
ALT OR AST > 10XULN	1	0	1	
ALT OR AST > 20XULN	1	0	0	
TOTAL BILIRUBIN > 2XULN	1	1	2	
ALT/AST > 3xULN & Bilirubin > 2xULN in 1 day	1	0	1	
ALT/AST > 3xULN & Bilirubin > 2xULN in 30 days	1	0	1	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with clinical laboratory abnormalities by worst toxicity grade - Thyroid

End point title	Number of participants with clinical laboratory abnormalities by worst toxicity grade - Thyroid[7][8]

End point description:

End point type	Primary

End point timeframe:

Nivo Mono: approximately up to 6 years and 9 months Nivo Ipi: approximately up to 5 months Nivo Liri: approximately up to 4 years 1 month

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: no further statistical analysis done for this endpoint

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: no further statistical analysis done for this endpoint

End point values	Nivolumab Monotherapy (expansion)	Nivolumab + Ipilimumab	Nivolumab + Lirilumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	83	47	72	
Units: Participants				
TSH > ULN	14	19	15	

TSH > ULN WITH TSH <= ULN AT BASELINE	11	13	9	
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	0	7	1	
TSH >ULN WITH ALL OTHER FT3/FT4 TEST VALUES ≥ LLN	1	1	1	
TSH > ULN WITH FT3/FT4 TEST MISSING	13	11	13	
TSH < LLN	8	6	6	
TSH <LLN WITH TSH ≥ LLN AT BASELINE	5	6	4	
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	0	1	1	
TSH <LLN WITH ALL OTHER FT3/FT4 TEST VALUES ≤ ULN	0	0	0	
TSH < LLN WITH FT3/FT4 TEST MISSING	8	5	5	

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants that experienced drug-related grade 3-4 AEs in the Nivolumab + Daratumumab Cohort

End point title	Number of participants that experienced drug-related grade 3-4 AEs in the Nivolumab + Daratumumab Cohort[9][10]

End point description:

End point type	Primary

End point timeframe:

approximately up to 4 years

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: no further statistical analysis done for this endpoint

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: no further statistical analysis done for this endpoint

End point values	Nivolumab + Daratumumab_ Cohort A1	Nivolumab + Daratumumab_ Cohort A2	Nivolumab + Daratumumab_ Cohort B1	Nivolumab + Daratumumab_ Cohort B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	5	41	22
Units: Participants	2	5	13	2

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants that experienced drug-related grade 3-4 SAEs in the Nivolumab + Daratumumab Cohort

End point title	Number of participants that experienced drug-related grade 3-4 SAEs in the Nivolumab + Daratumumab Cohort[11][12]

End point description:

End point type	Primary

End point timeframe:

approximately up to 4 years

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: no further statistical analysis done for this endpoint

[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: no further statistical analysis done for this endpoint

End point values	Nivolumab + Daratumumab_ Cohort A1	Nivolumab + Daratumumab_ Cohort A2	Nivolumab + Daratumumab_ Cohort B1	Nivolumab + Daratumumab_ Cohort B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	5	41	22
Units: Participants	2	4	10	6

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with clinical laboratory abnormalities by worst toxicity grade in the Nivolumab + Daratumumab Cohort - Hematology

End point title	Number of participants with clinical laboratory abnormalities by worst toxicity grade in the Nivolumab + Daratumumab Cohort - Hematology[13][14]

End point description:

End point type	Primary

End point timeframe:

approximately up to 4 years

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: no further statistical analysis done for this endpoint

[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: no further statistical analysis done for this endpoint

End point values	Nivolumab + Daratumumab_ Cohort A1	Nivolumab + Daratumumab_ Cohort A2	Nivolumab + Daratumumab_ Cohort B1	Nivolumab + Daratumumab_ Cohort B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	5	41	22
Units: Participants				
Hemoglobin|Grade 0	0	0	3	1
Platelet count|Grade 0	3	1	19	8
Leukocytes|Grade 0	2	0	10	5
Lymphocytes (Absolute)|Grade 0	3	0	6	3
Absolute Neutrophil Count|Grade 0	3	0	14	10
Hemoglobin|Grade 1	2	2	13	13
Platelet count|Grade 1	2	3	11	9
Leukocytes|Grade 1	1	0	6	9
Lymphocytes (Absolute)|Grade 1	0	0	9	5
Absolute Neutrophil Count|Grade 1	2	0	8	6
Hemoglobin|Grade 2	2	2	20	5
Platelet count|Grade 2	0	1	3	3
Leukocytes|Grade 2	2	2	15	5
Lymphocytes (Absolute)|Grade 2	0	0	9	7
Absolute Neutrophil Count|Grade 2	0	0	6	6
Hemoglobin|Grade 3	2	1	5	2
Platelet count|Grade 3	0	0	3	0
Leukocytes|Grade 3	0	2	9	2
Lymphocytes (Absolute)|Grade 3	2	3	15	5
Absolute Neutrophil Count|Grade 3	1	3	9	0
Hemoglobin|Grade 4	0	0	0	0
Platelet count|Grade 4	1	0	5	1
Leukocytes|Grade 4	1	1	1	0
Lymphocytes (Absolute)|Grade 4	1	2	2	1
Absolute Neutrophil Count|Grade 4	0	2	4	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with clinical laboratory abnormalities by worst toxicity grade in the Nivolumab + Daratumumab Cohort - Liver

End point title	Number of participants with clinical laboratory abnormalities by worst toxicity grade in the Nivolumab + Daratumumab Cohort - Liver[15][16]

End point description:

End point type	Primary

End point timeframe:

approximately up to 4 years

Notes:

[15] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: no further statistical analysis done for this endpoint

[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: no further statistical analysis done for this endpoint

End point values	Nivolumab + Daratumumab_ Cohort A1	Nivolumab + Daratumumab_ Cohort A2	Nivolumab + Daratumumab_ Cohort B1	Nivolumab + Daratumumab_ Cohort B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	5	41	22
Units: Participants				
ALT or AST >3xULN	0	0	0	0
ALT or AST >5xULN	1	3	9	0
ALT or AST >10xULN	1	3	9	0
ALT or AST >20xULN	1	3	9	0
Total Bilirubin > 2xULN	1	3	9	0
ALT/AST > 3xULN & Bilirubin > 2xULN in 1 days	1	3	9	0
ALT/AST > 3xULN & Bilirubin > 2xULN in 30 days	1	3	9	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with clinical laboratory abnormalities by worst toxicity grade in the Nivolumab + Daratumumab Cohort - Thyroid

End point title	Number of participants with clinical laboratory abnormalities by worst toxicity grade in the Nivolumab + Daratumumab Cohort - Thyroid[17][18]

End point description:

End point type	Primary

End point timeframe:

approximately up to 4 years

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: no further statistical analysis done for this endpoint

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: no further statistical analysis done for this endpoint

End point values	Nivolumab + Daratumumab_ Cohort A1	Nivolumab + Daratumumab_ Cohort A2	Nivolumab + Daratumumab_ Cohort B1	Nivolumab + Daratumumab_ Cohort B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	5	38	19
Units: Participants				
TSH>ULN	3	1	8	3
TSH > ULN WITH TSH <= ULN AT BASELINE	1	1	7	2

TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	1	0	1	0
TSH >ULN WITH ALL OTHER FT3/FT4 TEST VALUES ≥ LLN	0	0	5	2
WITH FT3/FT4 TEST MISSING	2	1	2	1
TSH < LLN	0	2	2	2
TSH < LLN WITH TSH >= LLN AT BASELINE	0	2	2	1
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	0	0	0	0
TSH <LLN WITH ALL OTHER FT3/FT4 TEST VALUES ≤ ULN	0	0	1	2
TSH < LLN WITH FT3/FT4 TEST MISSING	0	2	1	0

Statistical analyses

No statistical analyses for this end point

Secondary: Best Overall Response

End point title	Best Overall Response[19]

End point description:

the best response designation over the study as a whole, recorded between the date of first dose and the last efficacy assessment prior to
subsequent therapy.

Measured in Complete Response and Partial Response

End point type	Secondary

End point timeframe:

Nivo Mono: approximately up to 6 years and 9 months Nivo Ipi: approximately up to 5 months Nivo Liri: approximately up to 4 years 1 month

Notes:

[19] - 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: no further statistical analysis done for this endpoint

End point values	Nivolumab Monotherapy (expansion)	Nivolumab + Ipilimumab	Nivolumab + Lirilumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	77	58	62	
Units: Percentage of participants				
number (confidence interval 95%)				
Complete Response	10.4 (4.6 to 19.4)	13.8 (6.1 to 25.4)	9.7 (3.6 to 19.9)	
Partial Response	33.8 (23.4 to 45.4)	34.5 (22.5 to 48.1)	29.0 (18.2 to 41.9)	

Statistical analyses

No statistical analyses for this end point

Secondary: Best Overall Response - Multiple Myeloma Group

End point title	Best Overall Response - Multiple Myeloma Group[20]

End point description:

the best response designation over the study as a whole, recorded between the date of first dose and the last efficacy assessment prior to subsequent therapy.

here "99999 and -99999" = NA

End point type	Secondary

End point timeframe:

Nivo Mono: approximately up to 6 years and 9 months Nivo Ipi: approximately up to 5 months Nivo Liri: approximately up to 4 years 1 month

Notes:

[20] - 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: no further statistical analysis done for this endpoint

End point values	Nivolumab Monotherapy (expansion)	Nivolumab + Ipilimumab	Nivolumab + Lirilumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	27	7	10	
Units: Percentage				
number (confidence interval 95%)				
Complete Remission	3.7 (0.1 to 19.0)	0 (0 to 41.0)	0 (0 to 30.8)	
Partial Remission	0 (0.0 to 12.8)	0 (0 to 41.0)	0 (0 to 30.8)	
Very Good Partial Response	0 (0.0 to 12.8)	0 (0 to 41.0)	99999 (-99999 to 99999)	
Stringent Compete Response	0 (0.0 to 12.8)	0 (0 to 41.0)	99999 (-99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response - Multiple Myeloma Group

End point title	Duration of Response - Multiple Myeloma Group[21]

End point description:

the best response designation over the study as a whole, recorded between the date of first dose and the last efficacy assessment prior to
subsequent therapy.

Measured in Complete Response and Partial Response

here "99999 and -99999" = NA

End point type	Secondary

End point timeframe:

Nivo Mono: approximately up to 6 years and 9 months Nivo Ipi: approximately up to 5 months Nivo Liri: approximately up to 4 years 1 month

Notes:

[21] - 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: no further statistical analysis done for this endpoint

End point values	Nivolumab Monotherapy (expansion)	Nivolumab + Ipilimumab	Nivolumab + Lirilumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	0[22]	0[23]	
Units: Months				
median (full range (min-max))	99999 (99999 to 99999)	(to)	(to)	

Notes:

[22] - no subjects analyzed

[23] - no subjects analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response

End point title	Duration of Response[24]

End point description:

the best response designation over the study as a whole, recorded between the date of first dose and the last efficacy assessment prior to
subsequent therapy.

Measured in Complete Remission and Partial Remission

End point type	Secondary

End point timeframe:

Nivo Mono: approximately up to 6 years and 9 months Nivo Ipi: approximately up to approximately 37 months Nivo Liri: approximately up to 4 years 1 month

Notes:

[24] - 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: no further statistical analysis done for this endpoint

End point values	Nivolumab Monotherapy (expansion)	Nivolumab + Ipilimumab	Nivolumab + Lirilumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	34	28	24	
Units: Months				
median (full range (min-max))	22.83 (0.0 to 48.6)	24.84 (0.0 to 36.5)	19.38 (0.0 to 45.5)	

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival

End point title	Progression Free Survival[25]

End point description:

Progression free survival (PFS) is defined as the time between date of randomization and date of progression or death, whichever occurs first. Participants who died without a reported prior progression were considered to have progressed on the date of their death. Subjects who did not progress or die were censored on the date of their last efficacy assessment.

End point type	Secondary

End point timeframe:

From date of randomization to date of progression or death, whichever occurs first (up to approximately 24 months)

Notes:

[25] - 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: no further statistical analysis done for this endpoint

End point values	Nivolumab Monotherapy (expansion)	Nivolumab + Ipilimumab	Nivolumab + Lirilumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	104	65	72	
Units: Months				
median (confidence interval 95%)	6.24 (3.48 to 9.79)	6.93 (2.79 to 19.15)	3.02 (1.84 to 5.52)	

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival Rate

End point title	Progression Free Survival Rate[26]

End point description:

The percentage of participants remaining progression free at the specified timepoints (up to 48 Months)

here "99999 and -99999" = NA

End point type	Secondary

End point timeframe:

From randomization to the specified timepoints (up to 48 months)

Notes:

[26] - 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: no further statistical analysis done for this endpoint

End point values	Nivolumab Monotherapy (expansion)	Nivolumab + Ipilimumab	Nivolumab + Lirilumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	104	65	72	
Units: Percentage of Participants				
number (confidence interval 95%)				
2 Months	99999 (99999 to 99999)	99999 (99999 to 99999)	58.0 (45.3 to 68.8)	

4 Months	99999 (99999 to 99999)	99999 (99999 to 99999)	42.4 (30.4 to 54.0)	
6 Months	50.5 (39.8 to 60.3)	51.5 (38.1 to 63.4)	34.3 (23.0 to 45.8)	
9 Months	99999 (99999 to 99999)	99999 (99999 to 99999)	32.5 (21.4 to 44.0)	
12 Months	34.8 (24.2 to 45.5)	45.3 (32.0 to 57.7)	99999 (99999 to 99999)	
18 Months	31.0 (20.7 to 42.0)	40.1 (26.8 to 53.1)	99999 (99999 to 99999)	
24 Months	20.3 (11.1 to 31.5)	30.9 (18.0 to 44.9)	99999 (99999 to 99999)	
36 Months	15.8 (7.6 to 26.8)	99999 (99999 to 99999)	99999 (99999 to 99999)	
48 Months	13.2 (5.6 to 24.1)	99999 (99999 to 99999)	99999 (99999 to 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival

End point title	Overall Survival[27]

End point description:

The percentage of participants remaining alive. Median values are computed using Kaplan-Meier method

here "99999 and -99999" = NA

End point type	Secondary

End point timeframe:

Nivo Mono: approximately up to 6 years and 9 months Nivo Ipi: approximately up to3 years Nivo Liri: approximately up to 4 years 1 month

Notes:

[27] - 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: no further statistical analysis done for this endpoint

End point values	Nivolumab Monotherapy (expansion)	Nivolumab + Ipilimumab	Nivolumab + Lirilumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	104	65	72	
Units: Months				
median (confidence interval 95%)	52.57 (29.0 to 99999)	30.39 (13.24 to 99999)	14.95 (9.36 to 34.23)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with PD-L1 expression

End point title	Number of Participants with PD-L1 expression[28]

End point description:

Number of Participants with PD-L1 expression in the following categories

-baseline PD-L1 expression ≥ 1%
-baseline PD-L1 expression < 1%
-without PD-L1 quantifiable at baseline

End point type	Secondary

End point timeframe:

At baseline (prior to start of study treatment)

Notes:

[28] - 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: no further statistical analysis done for this endpoint

End point values	Nivolumab Monotherapy (expansion)	Nivolumab + Ipilimumab	Nivolumab + Lirilumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	105	65	72	
Units: Number of Participants				
Baseline PD-L1 expression ≥ 1%	25	26	16	
Baseline PD-L1 expression < 1%	16	14	20	
PD-L1 not quantifiable at baseline	64	25	36	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage change from baseline in the Modified Severity Weighted Assessment Tool (mSWAT) score

End point title	Percentage change from baseline in the Modified Severity Weighted Assessment Tool (mSWAT) score[29]

End point description:

mSWAT is a scoring technique involving the direct assessment of the percentage of body-surface-area (BSA) affected by skin lesions.
There are 12 body regions (each one assigned a different percentage of BSA). For each body region, the assigned BSA percentage is multiplied by a factor weighing the type and severity of lesion observed (patch= x1, plaque = x2, tumor= x4).
The sum of the individual body region sub-scores is then summed to generate the final mSWAT score, which ranges from 0 (best outcome) to 400 (worst outcome).

here "99999 and -99999" = NA

End point type	Secondary

End point timeframe:

From baseline (last measurement before start of study treatment) to last available measurement after start of study treatment (88 weeks for Nivo mono, 93 weeks for nivo+ipi, 25 weeks for nivo+liri)

Notes:

[29] - 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: no further statistical analysis done for this endpoint

End point values	Nivolumab Monotherapy (expansion)	Nivolumab + Ipilimumab	Nivolumab + Lirilumab	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	1	1	1	
Units: Percent of change from baseline				
arithmetic mean (standard deviation)	8.70 (± 99999)	63.03 (± 99999)	-39.49 (± 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to MRD Negativity Status in the Nivolumab + Daratumumab Cohort

End point title	Time to MRD Negativity Status in the Nivolumab + Daratumumab Cohort

End point description:

Time to MRD Negativity status in specific NGS and NGF sensitivity levels

here "99999 and -99999" = NA

End point type	Secondary

End point timeframe:

approximately up to 4 years

End point values	Cohort A-1	Cohort B-1	Cohort B-2	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	1	6	4	
Units: Months				
arithmetic mean (standard deviation)				
NGS sensitivity level=10e-4	3.02 (± 99999)	3.60 (± 2.409)	2.83 (± 99999)	
NGS sensitivity level=10e-5	3.02 (± 99999)	5.45 (± 4.788)	99999 (± 99999)	
NGS sensitivity level=10e-6	30.85 (± 99999)	99999 (± 99999)	99999 (± 99999)	
NGF sensitivity level=10e-4	99999 (± 99999)	2.94 (± 0.230)	4.20 (± 2.766)	
NGF sensitivity level=10e-5	99999 (± 99999)	6.97 (± 6.776)	99999 (± 99999)	
NGF sensitivity level=10e-6	99999 (± 99999)	12.30 (± 3.508)	99999 (± 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate in the Nivolumab + Daratumumab Cohort

End point title	Objective Response Rate in the Nivolumab + Daratumumab

	Cohort

End point description:

End point type	Secondary

End point timeframe:
approximately up to 4 years

End point values	Cohort A-1	Cohort A-2	Cohort B-1	Cohort B-2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	7	43	22
Units: Percentage				
number (confidence interval 95%)	66.7 (22.3 to 95.7)	71.4 (29.0 to 93.3)	51.2 (35.5 to 66.7)	36.4 (17.2 to 59.3)

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response in the Nivolumab + Daratumumab Cohort

End point title	Duration of response in the Nivolumab + Daratumumab Cohort

End point description:
here "99999 and -99999" = NA

End point type	Secondary

End point timeframe:
approximately up to 4 years

End point values	Cohort A-1	Cohort A-2	Cohort B-1	Cohort B-2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	7	43	22
Units: Months				
median (confidence interval 95%)	99999 (6.47 to 99999)	99999 (9.30 to 99999)	6.70 (3.71 to 14.29)	12.98 (2.20 to 99999)

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival in the Nivolumab + Daratumumab Cohort

End point title	Progression Free Survival in the Nivolumab + Daratumumab Cohort

End point description: here "99999 and -99999" = NA	
End point type	Secondary
End point timeframe: approximately up to 4 years	

End point values	Cohort A-1	Cohort A-2	Cohort B-1	Cohort B-2
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	6	7	43	22
Units: Months				
median (confidence interval 95%)	7.56 (3.19 to 99999)	16.95 (-99999 to 99999)	7.49 (4.67 to 9.46)	7.01 (2.96 to 12.94)

Statistical analyses

No statistical analyses for this end point

Secondary: Cmax in the Nivolumab + Daratumumab Cohort

End point title	Cmax in the Nivolumab + Daratumumab Cohort[30]
End point description: Maximum observed serum concentration	
End point type	Secondary
End point timeframe: approximately up to 4 years	

Notes:

[30] - 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: no further statistical analysis done for this endpoint

End point values	Nivolumab + Daratumumab_ Cohort A1	Nivolumab + Daratumumab_ Cohort A2	Nivolumab + Daratumumab_ Cohort B1	Nivolumab + Daratumumab_ Cohort B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[31]	0[32]	0[33]	0[34]
Units: ug/mL				
arithmetic mean (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[31] - Data Not Collected

[32] - Data Not Collected

[33] - Data Not Collected

[34] - Data Not Collected

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax in the Nivolumab + Daratumumab Cohort

End point title	Tmax in the Nivolumab + Daratumumab Cohort[35]

End point description:

Time of maximum observed serum concentration

End point type	Secondary

End point timeframe:

approximately up to 4 years

Notes:

[35] - 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: no further statistical analysis done for this endpoint

End point values	Nivolumab + Daratumumab_ Cohort A1	Nivolumab + Daratumumab_ Cohort A2	Nivolumab + Daratumumab_ Cohort B1	Nivolumab + Daratumumab_ Cohort B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[36]	0[37]	0[38]	0[39]
Units: weeks				
arithmetic mean (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[36] - Data Not Collected

[37] - Data Not Collected

[38] - Data Not Collected

[39] - Data Not Collected

Statistical analyses

No statistical analyses for this end point

Secondary: Cmin in the Nivolumab + Daratumumab Cohort

End point title	Cmin in the Nivolumab + Daratumumab Cohort[40]

End point description:

Serum concentration achieved at the end of dosing interval (trough concentration)

End point type	Secondary

End point timeframe:

approximately up to 4 years

Notes:

[40] - 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: no further statistical analysis done for this endpoint

End point values	Nivolumab + Daratumumab_ Cohort A1	Nivolumab + Daratumumab_ Cohort A2	Nivolumab + Daratumumab_ Cohort B1	Nivolumab + Daratumumab_ Cohort B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[41]	0[42]	0[43]	0[44]
Units: ug/mL				
arithmetic mean (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[41] - Data Not Collected

[42] - Data Not Collected

[43] - Data Not Collected

[44] - Data Not Collected

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (0-T) in the Nivolumab + Daratumumab Cohort

End point title	AUC (0-T) in the Nivolumab + Daratumumab Cohort[45]

End point description:

Area under the plasma concentration-time curve from time zero to the last time of the last quantifiable concentration

End point type	Secondary

End point timeframe:

approximately up to 4 years

Notes:

[45] - 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: no further statistical analysis done for this endpoint

End point values	Nivolumab + Daratumumab_ Cohort A1	Nivolumab + Daratumumab_ Cohort A2	Nivolumab + Daratumumab_ Cohort B1	Nivolumab + Daratumumab_ Cohort B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[46]	0[47]	0[48]	0[49]
Units: ug/mL				
arithmetic mean (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[46] - Data Not Collected

[47] - Data Not Collected

[48] - Data Not Collected

[49] - Data Not Collected

Statistical analyses

No statistical analyses for this end point

Secondary: AUC (TAU) in the Nivolumab + Daratumumab Cohort

End point title	AUC (TAU) in the Nivolumab + Daratumumab Cohort[50]

End point description:

Area under the concentration-time curve in one dosing interval

End point type	Secondary

End point timeframe:

approximately up to 4 years

Notes:

[50] - 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: no further statistical analysis done for this endpoint

End point values	Nivolumab + Daratumumab_ Cohort A1	Nivolumab + Daratumumab_ Cohort A2	Nivolumab + Daratumumab_ Cohort B1	Nivolumab + Daratumumab_ Cohort B2
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[51]	0[52]	0[53]	0[54]
Units: ug/mL				
arithmetic mean (confidence interval 95%)	(to)	(to)	(to)	(to)

Notes:

[51] - Data Not Collected

[52] - Data Not Collected

[53] - Data Not Collected

[54] - Data Not Collected

Statistical analyses

No statistical analyses for this end point

Secondary: End of Infusion Nivolumab concentration levels in the Nivolumab + Daratumumab Cohort

End point title	End of Infusion Nivolumab concentration levels in the Nivolumab + Daratumumab Cohort

End point description:

Serum concentration achieved at the end of study drug infusion

here "99999 and -99999" = NA

End point type	Secondary

End point timeframe:

Measurements collected at cycles 1, 2, 3, 5, 7, and 11; each cycle is 28 days

End point values	Cohort A-1	Cohort A-2	Cohort B-1	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	6	5	41	
Units: ug/mL				
arithmetic mean (standard deviation)				
Cycle 1	57.28 (± 6.78)	99999 (± 99999)	69.59 (± 18.79)	
Cycle 2	99999 (± 99999)	99999 (± 99999)	175.73 (± 88.94)	
Cycle 3	105.14 (± 31.41)	99999 (± 99999)	193.38 (± 69.74)	
Cycle 5	99999 (± 99999)	99999 (± 99999)	208.14 (± 58.38)	
Cycle 7	227.75 (± 26.79)	206.00 (± 99999)	193.00 (± 70.06)	
Cycle 11	99999 (± 99999)	206.00 (± 99999)	212.00 (± 38.20)	

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Nivo Mono: approximately up to 6 years and 9 months
Nivo Ipi: approximately up to 5 months
Nivo Liri: approximately up to 4 years 1 month
Nivo Dara: approximately 4 years

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Nivolumab Monotherapy (expansion)

Reporting group description:

3mg/kg of nivolumab

Reporting group title	Nivolumab + Lirilumab

Reporting group description:

3 mg/kg of nivolumab Q2W +
3 mg/kg of lirilumab Q4W

Reporting group title	Nivolumab + Daratumumab_Cohort B2

Reporting group description:

D regimen: Daratumumab alone

Reporting group title	Nivolumab + Daratumumab_Cohort A2

Reporting group description:

ND-PD regimen; Nivolumab + Daratumumab + Pomalidomide + Dexamethasone

Reporting group title	Nivolumab + Daratumumab_Cohort B1

Reporting group description:

ND regimen: Nivolumab (240 mg cycle 1, then 480 mg) + Daratumumab (16 mg/Kg)

Reporting group title	Nivolumab + Ipilimumab

Reporting group description:

3 mg/kg of nivolumab and
1 mg/kg of ipilimumab Q3W for 4 doses, followed by nivolumab alone at 3 mg/kg Q2W

Reporting group title	Nivolumab + Daratumumab_Cohort A1

Reporting group description:

ND regimen: Nivolumab (240 mg up to cycle 6, then 480 mg) + Daratumumab (16 mg/Kg)

Serious adverse events	Nivolumab Monotherapy (expansion)	Nivolumab + Lirilumab	Nivolumab + Daratumumab_Cohort B2
Total subjects affected by serious adverse events			
subjects affected / exposed	50 / 105 (47.62%)	34 / 72 (47.22%)	9 / 22 (40.91%)
number of deaths (all causes)	53	42	13
number of deaths resulting from adverse events	16	15	5
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			

subjects affected / exposed	13 / 105 (12.38%)	14 / 72 (19.44%)	2 / 22 (9.09%)
occurrences causally related to treatment / all	0 / 13	0 / 15	0 / 2
deaths causally related to treatment / all	0 / 12	0 / 13	0 / 2
Neoplasm malignant			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Plasma cell myeloma			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Second primary malignancy			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant melanoma			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Metastases to skin			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Myelodysplastic syndrome			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Tumour flare			
subjects affected / exposed	0 / 105 (0.00%)	2 / 72 (2.78%)	0 / 22 (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
Tumour invasion			

subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Myelodysplastic syndrome with single lineage dysplasia			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	2 / 105 (1.90%)	0 / 72 (0.00%)	0 / 22 (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
Hypotension			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Embolism			
subjects affected / exposed	1 / 105 (0.95%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oedema peripheral			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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

Pyrexia			
subjects affected / exposed	6 / 105 (5.71%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 6	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Asthenia			
subjects affected / exposed	3 / 105 (2.86%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Chills			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Gait disturbance			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Fatigue			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Influenza like illness			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Malaise			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Mucosal inflammation			

subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease			
subjects affected / exposed	2 / 105 (1.90%)	0 / 72 (0.00%)	0 / 22 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	3 / 105 (2.86%)	2 / 72 (2.78%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 1	0 / 0
Pneumonitis			
subjects affected / exposed	5 / 105 (4.76%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	5 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 / 105 (0.95%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Acute respiratory distress syndrome			
subjects affected / exposed	2 / 105 (1.90%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0

Atelectasis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cough			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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 distress			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Haemoptysis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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 / 105 (0.95%)	2 / 72 (2.78%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 2	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Psychiatric disorders			
Completed suicide			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Confusional state			

subjects affected / exposed	2 / 105 (1.90%)	0 / 72 (0.00%)	0 / 22 (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
Delirium			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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			
Stent malfunction			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 creatine phosphokinase increased			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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

Blood creatinine increased			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Accidental overdose			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Humerus fracture			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural fever			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Procedural pneumothorax			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Transfusion reaction			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 infarction			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Tachycardia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Cardiomyopathy			

subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ataxia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Cognitive disorder			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 105 (0.00%)	2 / 72 (2.78%)	0 / 22 (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
Headache			

subjects affected / exposed	1 / 105 (0.95%)	1 / 72 (1.39%)	0 / 22 (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
Seizure			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	2 / 105 (1.90%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Myasthenic syndrome			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophilia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Febrile neutropenia			

subjects affected / exposed	3 / 105 (2.86%)	4 / 72 (5.56%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 3	1 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperviscosity syndrome			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Lymphadenitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic microangiopathy			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	1 / 105 (0.95%)	1 / 72 (1.39%)	0 / 22 (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
Eye disorders			
Diplopia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Vision blurred			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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			

Diverticular perforation			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 enterocolitis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 distension			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Abdominal mass			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Abdominal pain			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Colitis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 pancreatitis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	1 / 105 (0.95%)	1 / 72 (1.39%)	0 / 22 (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
Diarrhoea			

subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Enteritis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Enterocolitis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 105 (0.00%)	3 / 72 (4.17%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Fistula of small intestine			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 perforation			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Vomiting			

subjects affected / exposed	1 / 105 (0.95%)	1 / 72 (1.39%)	0 / 22 (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
Small intestinal obstruction			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 disease			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Rash maculo-papular			

subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 psoriasiform			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Rash morbilliform			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	3 / 105 (2.86%)	3 / 72 (4.17%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	1 / 3	1 / 3	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			

Myalgia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Arthralgia			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Groin pain			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Osteonecrosis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 chest pain			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Myositis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Muscular weakness			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Infections and infestations			

Bronchitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Diverticulitis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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 / 105 (0.00%)	1 / 72 (1.39%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia haemophilus			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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	3 / 105 (2.86%)	2 / 72 (2.78%)	3 / 22 (13.64%)
occurrences causally related to treatment / all	0 / 3	0 / 2	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rhinovirus infection			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Upper respiratory tract infection			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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	2 / 105 (1.90%)	0 / 72 (0.00%)	0 / 22 (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
Pneumonia viral			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 device infection			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	1 / 105 (0.95%)	1 / 72 (1.39%)	0 / 22 (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
Cytomegalovirus infection			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Encephalitis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Endocarditis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Herpes simplex pharyngitis			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Herpes zoster			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Mucosal infection			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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 infection			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			

subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oral candidiasis			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Neutropenic sepsis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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 aspiration			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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 legionella			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Skin infection			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Sepsis			
subjects affected / exposed	4 / 105 (3.81%)	2 / 72 (2.78%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	2 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Sepsis syndrome			

subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Pneumonia mycoplasmal			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Staphylococcal bacteraemia			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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 sepsis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Streptococcal bacteraemia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	3 / 105 (2.86%)	3 / 72 (4.17%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Dehydration			
subjects affected / exposed	1 / 105 (0.95%)	2 / 72 (2.78%)	0 / 22 (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
Diabetic ketoacidosis			

subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (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
Decreased appetite			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Hyperglycaemia			
subjects affected / exposed	2 / 105 (1.90%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypervolaemia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (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
Tumour lysis syndrome			
subjects affected / exposed	0 / 105 (0.00%)	2 / 72 (2.78%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 105 (0.95%)	1 / 72 (1.39%)	0 / 22 (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
Hypoglycaemia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
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	Nivolumab + Daratumumab_Cohort A2	Nivolumab + Daratumumab_Cohort B1	Nivolumab + Ipilimumab

Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	15 / 41 (36.59%)	39 / 65 (60.00%)
number of deaths (all causes)	3	24	33
number of deaths resulting from adverse events	0	4	15
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 5 (0.00%)	3 / 41 (7.32%)	13 / 65 (20.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 13
deaths causally related to treatment / all	0 / 0	0 / 2	0 / 13
Neoplasm malignant			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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
Plasma cell myeloma			
subjects affected / exposed	0 / 5 (0.00%)	2 / 41 (4.88%)	0 / 65 (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
Second primary malignancy			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (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
Malignant melanoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metastases to skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 flare			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 invasion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myelodysplastic syndrome with single lineage dysplasia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (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
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Oedema peripheral			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (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
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	7 / 65 (10.77%)
occurrences causally related to treatment / all	0 / 0	1 / 1	4 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden cardiac death			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chills			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gait disturbance			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 like illness			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Drug hypersensitivity			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Graft versus host disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	5 / 65 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	4 / 65 (6.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	4 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Acute respiratory distress syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atelectasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cough			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 distress			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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			

Completed suicide			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 / 5 (0.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Product issues			
Stent malfunction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Platelet count decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver function test increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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			
Accidental overdose			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (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
Fall			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (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
Humerus fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 fever			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 / 5 (0.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pneumothorax			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transfusion reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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
Myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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
Atrial fibrillation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Cardiac failure congestive			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Tachycardia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular extrasystoles			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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
Ataxia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dizziness			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenic syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eosinophilia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 / 5 (0.00%)	0 / 41 (0.00%)	3 / 65 (4.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperviscosity syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphadenitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic microangiopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vision blurred			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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			
Diverticular perforation			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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 distension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 mass			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 / 5 (0.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Autoimmune pancreatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	3 / 65 (4.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enteritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Pancreatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fistula of small intestine			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Small intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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			
Autoimmune hepatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Hepatobiliary disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Hyperbilirubinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis bullous			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pruritus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis psoriasiform			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 morbilliform			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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			
Renal failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 / 5 (0.00%)	0 / 41 (0.00%)	3 / 65 (4.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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
Arthralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteonecrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	3 / 41 (7.32%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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
Clostridium difficile infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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
Pneumonia haemophilus			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (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			
subjects affected / exposed	2 / 5 (40.00%)	1 / 41 (2.44%)	5 / 65 (7.69%)
occurrences causally related to treatment / all	1 / 2	0 / 3	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia respiratory syncytial viral			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (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
Rhinovirus infection			

subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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
Septic shock			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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	1 / 5 (20.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (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 viral			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (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
Vascular device infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Device related infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	4 / 65 (6.15%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 6
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes simplex pharyngitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Oral candidiasis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Neutropenic sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 legionella			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 mycoplasmal			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Staphylococcal sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	3 / 65 (4.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decreased appetite			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
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 lysis syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Nivolumab + Daratumumab_Cohort A1		
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 6 (50.00%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neoplasm malignant			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Plasma cell myeloma			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Second primary malignancy			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant melanoma			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metastases to skin			

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myelodysplastic syndrome				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour flare				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour invasion				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myelodysplastic syndrome with single lineage dysplasia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Deep vein thrombosis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotension				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hypertension				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Embolism				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
General disorders and administration site conditions				
Multiple organ dysfunction syndrome				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oedema peripheral				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sudden cardiac death				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Asthenia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chills				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gait disturbance				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fatigue				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza like illness				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Malaise				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mucosal inflammation				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune system disorders				
Drug hypersensitivity				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Graft versus host disease				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Dyspnoea				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			

Hypoxia				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Acute respiratory distress syndrome				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atelectasis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cough				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Haemoptysis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea exertional				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Completed suicide				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Confusional state				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Delirium				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Product issues				
Stent malfunction				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Investigations				
Platelet count decreased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood bilirubin increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Alanine aminotransferase increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aspartate aminotransferase increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood creatine phosphokinase increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood creatinine increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Liver function test increased				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Accidental overdose				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hip fracture				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Humerus fracture				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Post procedural fever				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infusion related reaction				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Procedural pneumothorax				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal fracture				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transfusion reaction				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Sinus tachycardia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myocardial infarction				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Atrial fibrillation				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac failure congestive				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tachycardia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiomyopathy				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ventricular extrasystoles				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Ischaemic stroke				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paraesthesia				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ataxia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cognitive disorder				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Seizure				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Somnolence				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myasthenic syndrome				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Thrombocytopenia				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anaemia				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Eosinophilia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Febrile neutropenia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperviscosity syndrome				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymphadenitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancytopenia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Thrombotic microangiopathy				

subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vision blurred			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Diverticular perforation			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal mass			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Abdominal pain				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Autoimmune pancreatitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Constipation				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diarrhoea				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enteritis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Enterocolitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fistula of small intestine				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastric perforation				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal haemorrhage				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disorders				
Autoimmune hepatitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatic failure				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hepatobiliary disease				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperbilirubinaemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin and subcutaneous tissue disorders				
Dermatitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dermatitis bullous				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash maculo-papular				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pruritus				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dermatitis psoriasiform				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rash morbilliform				

subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematuria			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Bone pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Arthralgia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Groin pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Osteonecrosis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal chest pain				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Myositis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Bronchitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Influenza				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia haemophilus				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	2 / 6 (33.33%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pneumonia respiratory syncytial viral				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rhinovirus infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Septic shock				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Urinary tract infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Upper respiratory tract infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Wound infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia viral				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular device infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Bacteraemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cytomegalovirus infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related sepsis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Encephalitis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Endocarditis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes simplex pharyngitis				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Herpes zoster				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mucosal infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oesophageal candidiasis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Oral candidiasis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Neutropenic sepsis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumocystis jirovecii pneumonia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia aspiration				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia legionella				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin infection				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis syndrome				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia mycoplasmal				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal bacteraemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Staphylococcal sepsis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Streptococcal infection				

subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Streptococcal bacteraemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Hypercalcaemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dehydration				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diabetic ketoacidosis				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Decreased appetite				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hyperglycaemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypervolaemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Tumour lysis syndrome				

subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Nivolumab Monotherapy (expansion)	Nivolumab + Lirilumab	Nivolumab + Daratumumab_Cohort B2
Total subjects affected by non-serious adverse events			
subjects affected / exposed	102 / 105 (97.14%)	69 / 72 (95.83%)	16 / 22 (72.73%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colorectal adenoma			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Tumour flare			
subjects affected / exposed	0 / 105 (0.00%)	4 / 72 (5.56%)	0 / 22 (0.00%)
occurrences (all)	0	4	0
Vascular disorders			
Hypertension			
subjects affected / exposed	6 / 105 (5.71%)	1 / 72 (1.39%)	1 / 22 (4.55%)
occurrences (all)	9	1	1
Hypotension			

subjects affected / exposed	8 / 105 (7.62%)	3 / 72 (4.17%)	0 / 22 (0.00%)
occurrences (all)	10	3	0
Hot flush			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Flushing			
subjects affected / exposed	3 / 105 (2.86%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Haematoma			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
Varicose vein			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 105 (2.86%)	3 / 72 (4.17%)	1 / 22 (4.55%)
occurrences (all)	4	3	1
Chills			
subjects affected / exposed	10 / 105 (9.52%)	6 / 72 (8.33%)	2 / 22 (9.09%)
occurrences (all)	11	7	3
Fatigue			
subjects affected / exposed	46 / 105 (43.81%)	30 / 72 (41.67%)	3 / 22 (13.64%)
occurrences (all)	55	34	3
Influenza like illness			
subjects affected / exposed	0 / 105 (0.00%)	4 / 72 (5.56%)	2 / 22 (9.09%)
occurrences (all)	0	6	3
Oedema peripheral			
subjects affected / exposed	11 / 105 (10.48%)	7 / 72 (9.72%)	1 / 22 (4.55%)
occurrences (all)	11	7	1
Pain			
subjects affected / exposed	5 / 105 (4.76%)	3 / 72 (4.17%)	0 / 22 (0.00%)
occurrences (all)	5	3	0
Pyrexia			

subjects affected / exposed	27 / 105 (25.71%)	8 / 72 (11.11%)	3 / 22 (13.64%)
occurrences (all)	33	9	3
Non-cardiac chest pain			
subjects affected / exposed	3 / 105 (2.86%)	4 / 72 (5.56%)	2 / 22 (9.09%)
occurrences (all)	3	4	2
Chest discomfort			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Feeling hot			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	3 / 105 (2.86%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences (all)	1	0	1
Respiratory, thoracic and mediastinal disorders			
Rhinitis allergic			
subjects affected / exposed	2 / 105 (1.90%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	2	1	0
Cough			
subjects affected / exposed	29 / 105 (27.62%)	11 / 72 (15.28%)	0 / 22 (0.00%)
occurrences (all)	45	14	0
Dyspnoea			
subjects affected / exposed	17 / 105 (16.19%)	7 / 72 (9.72%)	1 / 22 (4.55%)
occurrences (all)	18	7	1
Nasal congestion			
subjects affected / exposed	11 / 105 (10.48%)	4 / 72 (5.56%)	0 / 22 (0.00%)
occurrences (all)	15	5	0
Rhinorrhoea			
subjects affected / exposed	5 / 105 (4.76%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	6	1	0
Bronchospasm			

subjects affected / exposed	2 / 105 (1.90%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Dysphonia			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Productive cough			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Tachypnoea			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	5 / 105 (4.76%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences (all)	7	0	1
Pleural effusion			
subjects affected / exposed	5 / 105 (4.76%)	3 / 72 (4.17%)	0 / 22 (0.00%)
occurrences (all)	5	3	0
Dyspnoea exertional			
subjects affected / exposed	7 / 105 (6.67%)	2 / 72 (2.78%)	1 / 22 (4.55%)
occurrences (all)	7	2	1
Oropharyngeal pain			
subjects affected / exposed	2 / 105 (1.90%)	3 / 72 (4.17%)	1 / 22 (4.55%)
occurrences (all)	2	3	1
Pneumonitis			
subjects affected / exposed	9 / 105 (8.57%)	2 / 72 (2.78%)	0 / 22 (0.00%)
occurrences (all)	10	5	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	7 / 105 (6.67%)	5 / 72 (6.94%)	0 / 22 (0.00%)
occurrences (all)	8	5	0
Anxiety			
subjects affected / exposed	6 / 105 (5.71%)	5 / 72 (6.94%)	0 / 22 (0.00%)
occurrences (all)	6	5	0
Investigations			
Neutrophil count decreased			

subjects affected / exposed	1 / 105 (0.95%)	6 / 72 (8.33%)	0 / 22 (0.00%)
occurrences (all)	1	7	0
Blood alkaline phosphatase increased			
subjects affected / exposed	4 / 105 (3.81%)	6 / 72 (8.33%)	0 / 22 (0.00%)
occurrences (all)	5	7	0
Blood bilirubin increased			
subjects affected / exposed	2 / 105 (1.90%)	3 / 72 (4.17%)	0 / 22 (0.00%)
occurrences (all)	2	3	0
Blood creatinine increased			
subjects affected / exposed	10 / 105 (9.52%)	4 / 72 (5.56%)	3 / 22 (13.64%)
occurrences (all)	12	4	3
Lipase increased			
subjects affected / exposed	9 / 105 (8.57%)	3 / 72 (4.17%)	0 / 22 (0.00%)
occurrences (all)	10	4	0
Amylase increased			
subjects affected / exposed	1 / 105 (0.95%)	4 / 72 (5.56%)	0 / 22 (0.00%)
occurrences (all)	1	15	0
Platelet count decreased			
subjects affected / exposed	0 / 105 (0.00%)	7 / 72 (9.72%)	1 / 22 (4.55%)
occurrences (all)	0	8	2
White blood cell count decreased			
subjects affected / exposed	4 / 105 (3.81%)	8 / 72 (11.11%)	1 / 22 (4.55%)
occurrences (all)	4	8	1
Bilirubin conjugated increased			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	0 / 105 (0.00%)	2 / 72 (2.78%)	0 / 22 (0.00%)
occurrences (all)	0	8	0
Influenza A virus test positive			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	6 / 105 (5.71%)	2 / 72 (2.78%)	0 / 22 (0.00%)
occurrences (all)	6	2	0

Alanine aminotransferase increased			
subjects affected / exposed	11 / 105 (10.48%)	8 / 72 (11.11%)	0 / 22 (0.00%)
occurrences (all)	12	9	0
Aspartate aminotransferase increased			
subjects affected / exposed	13 / 105 (12.38%)	5 / 72 (6.94%)	0 / 22 (0.00%)
occurrences (all)	15	6	0
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 105 (1.90%)	9 / 72 (12.50%)	0 / 22 (0.00%)
occurrences (all)	2	15	0
Lymphocyte count decreased			
subjects affected / exposed	2 / 105 (1.90%)	9 / 72 (12.50%)	1 / 22 (4.55%)
occurrences (all)	2	9	4
Weight increased			
subjects affected / exposed	4 / 105 (3.81%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	4	1	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	4 / 105 (3.81%)	13 / 72 (18.06%)	4 / 22 (18.18%)
occurrences (all)	6	15	4
Fall			
subjects affected / exposed	2 / 105 (1.90%)	1 / 72 (1.39%)	1 / 22 (4.55%)
occurrences (all)	2	2	1
Foot fracture			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Fracture			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hip fracture			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Contusion			
subjects affected / exposed	2 / 105 (1.90%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Skin laceration			

subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	2 / 105 (1.90%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	3	1	0
Angina pectoris			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	9 / 105 (8.57%)	2 / 72 (2.78%)	0 / 22 (0.00%)
occurrences (all)	9	2	0
Headache			
subjects affected / exposed	16 / 105 (15.24%)	5 / 72 (6.94%)	1 / 22 (4.55%)
occurrences (all)	16	6	1
Peripheral sensory neuropathy			
subjects affected / exposed	3 / 105 (2.86%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	3	1	0
Dysgeusia			
subjects affected / exposed	2 / 105 (1.90%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	2	0	0
Akathisia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	1 / 105 (0.95%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Memory impairment			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			

subjects affected / exposed	0 / 105 (0.00%)	2 / 72 (2.78%)	0 / 22 (0.00%)
occurrences (all)	0	2	0
Syncope			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Disturbance in attention			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	9 / 105 (8.57%)	1 / 72 (1.39%)	1 / 22 (4.55%)
occurrences (all)	9	1	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	23 / 105 (21.90%)	18 / 72 (25.00%)	4 / 22 (18.18%)
occurrences (all)	26	19	6
Neutropenia			
subjects affected / exposed	12 / 105 (11.43%)	7 / 72 (9.72%)	2 / 22 (9.09%)
occurrences (all)	15	7	2
Thrombocytopenia			
subjects affected / exposed	21 / 105 (20.00%)	5 / 72 (6.94%)	2 / 22 (9.09%)
occurrences (all)	24	6	2
Pancytopenia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Leukopenia			
subjects affected / exposed	13 / 105 (12.38%)	4 / 72 (5.56%)	1 / 22 (4.55%)
occurrences (all)	16	5	2
Lymphopenia			
subjects affected / exposed	9 / 105 (8.57%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	9	2	0
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Eye disorders			

Vision blurred			
subjects affected / exposed	1 / 105 (0.95%)	4 / 72 (5.56%)	0 / 22 (0.00%)
occurrences (all)	1	5	0
Dry eye			
subjects affected / exposed	1 / 105 (0.95%)	2 / 72 (2.78%)	0 / 22 (0.00%)
occurrences (all)	1	2	0
Uveitis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Vitreous haemorrhage			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	24 / 105 (22.86%)	15 / 72 (20.83%)	2 / 22 (9.09%)
occurrences (all)	31	17	2
Abdominal pain			
subjects affected / exposed	9 / 105 (8.57%)	5 / 72 (6.94%)	0 / 22 (0.00%)
occurrences (all)	9	8	0
Constipation			
subjects affected / exposed	12 / 105 (11.43%)	15 / 72 (20.83%)	0 / 22 (0.00%)
occurrences (all)	15	16	0
Diarrhoea			
subjects affected / exposed	28 / 105 (26.67%)	21 / 72 (29.17%)	4 / 22 (18.18%)
occurrences (all)	38	29	4
Vomiting			
subjects affected / exposed	13 / 105 (12.38%)	8 / 72 (11.11%)	0 / 22 (0.00%)
occurrences (all)	16	8	0
Gastritis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 105 (2.86%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Large intestine polyp			

subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Abdominal hernia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	2 / 105 (1.90%)	2 / 72 (2.78%)	0 / 22 (0.00%)
occurrences (all)	2	2	0
Dyspepsia			
subjects affected / exposed	1 / 105 (0.95%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Dry mouth			
subjects affected / exposed	3 / 105 (2.86%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	3	1	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	8 / 105 (7.62%)	2 / 72 (2.78%)	0 / 22 (0.00%)
occurrences (all)	8	2	0
Hyperhidrosis			
subjects affected / exposed	6 / 105 (5.71%)	2 / 72 (2.78%)	1 / 22 (4.55%)
occurrences (all)	8	4	1
Pruritus			
subjects affected / exposed	25 / 105 (23.81%)	9 / 72 (12.50%)	0 / 22 (0.00%)
occurrences (all)	29	12	0
Rash			
subjects affected / exposed	22 / 105 (20.95%)	8 / 72 (11.11%)	0 / 22 (0.00%)
occurrences (all)	26	8	0
Rash maculo-papular			
subjects affected / exposed	3 / 105 (2.86%)	5 / 72 (6.94%)	1 / 22 (4.55%)
occurrences (all)	3	7	1
Erythema			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
Night sweats			
subjects affected / exposed	4 / 105 (3.81%)	4 / 72 (5.56%)	0 / 22 (0.00%)
occurrences (all)	4	5	0

Alopecia			
subjects affected / exposed	6 / 105 (5.71%)	4 / 72 (5.56%)	0 / 22 (0.00%)
occurrences (all)	6	4	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	5 / 105 (4.76%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	5	1	0
Proteinuria			
subjects affected / exposed	3 / 105 (2.86%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	6 / 105 (5.71%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	6	1	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	6 / 105 (5.71%)	5 / 72 (6.94%)	2 / 22 (9.09%)
occurrences (all)	7	5	2
Back pain			
subjects affected / exposed	17 / 105 (16.19%)	14 / 72 (19.44%)	1 / 22 (4.55%)
occurrences (all)	18	14	1
Bone pain			
subjects affected / exposed	2 / 105 (1.90%)	1 / 72 (1.39%)	2 / 22 (9.09%)
occurrences (all)	2	1	3
Muscle spasms			
subjects affected / exposed	8 / 105 (7.62%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	9	0	0
Musculoskeletal chest pain			
subjects affected / exposed	6 / 105 (5.71%)	3 / 72 (4.17%)	0 / 22 (0.00%)
occurrences (all)	7	3	0
Arthralgia			
subjects affected / exposed	18 / 105 (17.14%)	11 / 72 (15.28%)	0 / 22 (0.00%)
occurrences (all)	19	13	0
Pain in extremity			
subjects affected / exposed	9 / 105 (8.57%)	6 / 72 (8.33%)	1 / 22 (4.55%)
occurrences (all)	11	7	1

Arthritis			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Muscular weakness			
subjects affected / exposed	1 / 105 (0.95%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Neck pain			
subjects affected / exposed	5 / 105 (4.76%)	3 / 72 (4.17%)	1 / 22 (4.55%)
occurrences (all)	5	3	1
Sacral pain			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Pneumonia			
subjects affected / exposed	6 / 105 (5.71%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	8	1	0
Bronchitis			
subjects affected / exposed	0 / 105 (0.00%)	1 / 72 (1.39%)	1 / 22 (4.55%)
occurrences (all)	0	1	1
Sinusitis			
subjects affected / exposed	6 / 105 (5.71%)	1 / 72 (1.39%)	1 / 22 (4.55%)
occurrences (all)	7	1	1
Upper respiratory tract infection			
subjects affected / exposed	17 / 105 (16.19%)	13 / 72 (18.06%)	3 / 22 (13.64%)
occurrences (all)	21	17	4
Urinary tract infection			
subjects affected / exposed	7 / 105 (6.67%)	3 / 72 (4.17%)	2 / 22 (9.09%)
occurrences (all)	17	3	2
Bronchitis haemophilus			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			

subjects affected / exposed	1 / 105 (0.95%)	1 / 72 (1.39%)	0 / 22 (0.00%)
occurrences (all)	1	1	0
Paronychia			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pneumonia haemophilus			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	2 / 22 (9.09%)
occurrences (all)	0	0	2
COVID-19			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	1 / 22 (4.55%)
occurrences (all)	0	0	1
Wound infection			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	17 / 105 (16.19%)	14 / 72 (19.44%)	3 / 22 (13.64%)
occurrences (all)	18	14	3
Hyperuricaemia			
subjects affected / exposed	12 / 105 (11.43%)	2 / 72 (2.78%)	0 / 22 (0.00%)
occurrences (all)	13	2	0
Hypercalcaemia			
subjects affected / exposed	9 / 105 (8.57%)	4 / 72 (5.56%)	0 / 22 (0.00%)
occurrences (all)	10	4	0
Hyperglycaemia			
subjects affected / exposed	16 / 105 (15.24%)	8 / 72 (11.11%)	2 / 22 (9.09%)
occurrences (all)	17	9	2
Hyperkalaemia			
subjects affected / exposed	2 / 105 (1.90%)	3 / 72 (4.17%)	0 / 22 (0.00%)
occurrences (all)	2	3	0

Dehydration			
subjects affected / exposed	3 / 105 (2.86%)	2 / 72 (2.78%)	0 / 22 (0.00%)
occurrences (all)	4	3	0
Hypocalcaemia			
subjects affected / exposed	14 / 105 (13.33%)	5 / 72 (6.94%)	3 / 22 (13.64%)
occurrences (all)	16	6	4
Hypokalaemia			
subjects affected / exposed	11 / 105 (10.48%)	1 / 72 (1.39%)	2 / 22 (9.09%)
occurrences (all)	13	1	2
Hypomagnesaemia			
subjects affected / exposed	4 / 105 (3.81%)	0 / 72 (0.00%)	2 / 22 (9.09%)
occurrences (all)	5	0	3
Hyponatraemia			
subjects affected / exposed	9 / 105 (8.57%)	7 / 72 (9.72%)	1 / 22 (4.55%)
occurrences (all)	9	11	1
Hypophosphataemia			
subjects affected / exposed	8 / 105 (7.62%)	5 / 72 (6.94%)	2 / 22 (9.09%)
occurrences (all)	9	5	2
Hypermagnesaemia			
subjects affected / exposed	1 / 105 (0.95%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	1	0	0
Hypoglycaemia			
subjects affected / exposed	3 / 105 (2.86%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	3	0	0
Type 2 diabetes mellitus			
subjects affected / exposed	0 / 105 (0.00%)	0 / 72 (0.00%)	0 / 22 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	10 / 105 (9.52%)	2 / 72 (2.78%)	1 / 22 (4.55%)
occurrences (all)	11	2	3

Non-serious adverse events	Nivolumab + Daratumumab_Cohort A2	Nivolumab + Daratumumab_Cohort B1	Nivolumab + Ipilimumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	35 / 41 (85.37%)	62 / 65 (95.38%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Colorectal adenoma			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Tumour flare			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	3 / 41 (7.32%)	1 / 65 (1.54%)
occurrences (all)	0	3	2
Hypotension			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	1
Hot flush			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	5 / 65 (7.69%)
occurrences (all)	0	0	5
Flushing			
subjects affected / exposed	1 / 5 (20.00%)	1 / 41 (2.44%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Haematoma			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Varicose vein			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 5 (20.00%)	4 / 41 (9.76%)	3 / 65 (4.62%)
occurrences (all)	1	4	3
Chills			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	10 / 65 (15.38%)
occurrences (all)	1	0	13
Fatigue			
subjects affected / exposed	2 / 5 (40.00%)	8 / 41 (19.51%)	30 / 65 (46.15%)
occurrences (all)	2	9	30
Influenza like illness			

subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Oedema peripheral			
subjects affected / exposed	2 / 5 (40.00%)	1 / 41 (2.44%)	8 / 65 (12.31%)
occurrences (all)	4	1	8
Pain			
subjects affected / exposed	0 / 5 (0.00%)	3 / 41 (7.32%)	4 / 65 (6.15%)
occurrences (all)	0	3	4
Pyrexia			
subjects affected / exposed	1 / 5 (20.00%)	4 / 41 (9.76%)	25 / 65 (38.46%)
occurrences (all)	1	5	34
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	4 / 65 (6.15%)
occurrences (all)	0	0	4
Chest discomfort			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Feeling hot			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Rhinitis allergic			
subjects affected / exposed	2 / 5 (40.00%)	2 / 41 (4.88%)	0 / 65 (0.00%)
occurrences (all)	2	2	0
Cough			
subjects affected / exposed	2 / 5 (40.00%)	4 / 41 (9.76%)	22 / 65 (33.85%)
occurrences (all)	6	4	34
Dyspnoea			

subjects affected / exposed	3 / 5 (60.00%)	5 / 41 (12.20%)	11 / 65 (16.92%)
occurrences (all)	4	5	15
Nasal congestion			
subjects affected / exposed	2 / 5 (40.00%)	1 / 41 (2.44%)	14 / 65 (21.54%)
occurrences (all)	2	1	21
Rhinorrhoea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences (all)	1	0	3
Bronchospasm			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Dysphonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	2
Productive cough			
subjects affected / exposed	2 / 5 (40.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	0	0
Tachypnoea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	5 / 65 (7.69%)
occurrences (all)	0	0	5
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	2 / 65 (3.08%)
occurrences (all)	0	1	2
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	5 / 65 (7.69%)
occurrences (all)	0	1	5
Pneumonitis			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	6 / 65 (9.23%)
occurrences (all)	0	1	8
Psychiatric disorders			

Insomnia			
subjects affected / exposed	0 / 5 (0.00%)	3 / 41 (7.32%)	10 / 65 (15.38%)
occurrences (all)	0	3	10
Anxiety			
subjects affected / exposed	0 / 5 (0.00%)	2 / 41 (4.88%)	2 / 65 (3.08%)
occurrences (all)	0	2	2
Investigations			
Neutrophil count decreased			
subjects affected / exposed	3 / 5 (60.00%)	2 / 41 (4.88%)	2 / 65 (3.08%)
occurrences (all)	9	2	2
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 5 (0.00%)	3 / 41 (7.32%)	7 / 65 (10.77%)
occurrences (all)	0	3	10
Blood bilirubin increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	4 / 65 (6.15%)
occurrences (all)	1	0	6
Blood creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	2 / 41 (4.88%)	3 / 65 (4.62%)
occurrences (all)	0	2	9
Lipase increased			
subjects affected / exposed	1 / 5 (20.00%)	1 / 41 (2.44%)	8 / 65 (12.31%)
occurrences (all)	2	2	13
Amylase increased			
subjects affected / exposed	2 / 5 (40.00%)	0 / 41 (0.00%)	5 / 65 (7.69%)
occurrences (all)	4	0	10
Platelet count decreased			
subjects affected / exposed	2 / 5 (40.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences (all)	3	0	2
White blood cell count decreased			
subjects affected / exposed	2 / 5 (40.00%)	0 / 41 (0.00%)	4 / 65 (6.15%)
occurrences (all)	2	0	6
Bilirubin conjugated increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Influenza A virus test positive			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Weight decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	4 / 65 (6.15%)
occurrences (all)	0	1	4
Alanine aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	9 / 65 (13.85%)
occurrences (all)	0	1	14
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	8 / 65 (12.31%)
occurrences (all)	0	1	17
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	6 / 65 (9.23%)
occurrences (all)	0	0	6
Lymphocyte count decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	6 / 65 (9.23%)
occurrences (all)	0	2	6
Weight increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	7 / 65 (10.77%)
occurrences (all)	0	0	7
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	2 / 5 (40.00%)	10 / 41 (24.39%)	10 / 65 (15.38%)
occurrences (all)	2	10	11
Fall			
subjects affected / exposed	1 / 5 (20.00%)	3 / 41 (7.32%)	2 / 65 (3.08%)
occurrences (all)	1	7	2
Foot fracture			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Fracture			

subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Hip fracture			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	2	0	0
Contusion			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	3 / 65 (4.62%)
occurrences (all)	0	1	3
Skin laceration			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	7 / 65 (10.77%)
occurrences (all)	1	0	9
Sinus tachycardia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 41 (2.44%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Angina pectoris			
subjects affected / exposed	1 / 5 (20.00%)	1 / 41 (2.44%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 5 (40.00%)	3 / 41 (7.32%)	2 / 65 (3.08%)
occurrences (all)	3	3	2
Headache			
subjects affected / exposed	3 / 5 (60.00%)	3 / 41 (7.32%)	7 / 65 (10.77%)
occurrences (all)	3	3	8
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 5 (20.00%)	3 / 41 (7.32%)	3 / 65 (4.62%)
occurrences (all)	1	3	4
Dysgeusia			
subjects affected / exposed	1 / 5 (20.00%)	1 / 41 (2.44%)	1 / 65 (1.54%)
occurrences (all)	2	1	1
Akathisia			

subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	0 / 65 (0.00%)
occurrences (all)	0	1	0
Lethargy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Memory impairment			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Syncope			
subjects affected / exposed	1 / 5 (20.00%)	1 / 41 (2.44%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Disturbance in attention			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	2 / 65 (3.08%)
occurrences (all)	0	1	2
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	4 / 5 (80.00%)	10 / 41 (24.39%)	12 / 65 (18.46%)
occurrences (all)	4	13	17
Neutropenia			
subjects affected / exposed	4 / 5 (80.00%)	9 / 41 (21.95%)	6 / 65 (9.23%)
occurrences (all)	11	15	6
Thrombocytopenia			
subjects affected / exposed	1 / 5 (20.00%)	5 / 41 (12.20%)	7 / 65 (10.77%)
occurrences (all)	1	11	13
Pancytopenia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	1
Leukopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1

Lymphopenia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	2 / 65 (3.08%)
occurrences (all)	0	2	2
Ear and labyrinth disorders			
Hypoacusis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	2 / 5 (40.00%)	0 / 41 (0.00%)	4 / 65 (6.15%)
occurrences (all)	2	0	4
Dry eye			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences (all)	0	0	2
Uveitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	1
Vitreous haemorrhage			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	2 / 5 (40.00%)	4 / 41 (9.76%)	17 / 65 (26.15%)
occurrences (all)	2	5	22
Abdominal pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	10 / 65 (15.38%)
occurrences (all)	1	0	13
Constipation			
subjects affected / exposed	3 / 5 (60.00%)	1 / 41 (2.44%)	10 / 65 (15.38%)
occurrences (all)	3	1	10
Diarrhoea			
subjects affected / exposed	4 / 5 (80.00%)	6 / 41 (14.63%)	20 / 65 (30.77%)
occurrences (all)	8	11	24
Vomiting			
subjects affected / exposed	2 / 5 (40.00%)	2 / 41 (4.88%)	9 / 65 (13.85%)
occurrences (all)	2	2	12
Gastritis			

subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 5 (40.00%)	1 / 41 (2.44%)	3 / 65 (4.62%)
occurrences (all)	2	1	3
Large intestine polyp			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Abdominal hernia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	4 / 65 (6.15%)
occurrences (all)	0	0	4
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	4 / 65 (6.15%)
occurrences (all)	0	0	4
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	4 / 65 (6.15%)
occurrences (all)	0	1	4
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 5 (0.00%)	2 / 41 (4.88%)	3 / 65 (4.62%)
occurrences (all)	0	2	3
Hyperhidrosis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences (all)	1	0	2
Pruritus			
subjects affected / exposed	4 / 5 (80.00%)	4 / 41 (9.76%)	11 / 65 (16.92%)
occurrences (all)	4	4	11
Rash			
subjects affected / exposed	1 / 5 (20.00%)	1 / 41 (2.44%)	12 / 65 (18.46%)
occurrences (all)	2	1	14
Rash maculo-papular			
subjects affected / exposed	0 / 5 (0.00%)	3 / 41 (7.32%)	8 / 65 (12.31%)
occurrences (all)	0	3	8

Erythema			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences (all)	1	0	2
Night sweats			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	4 / 65 (6.15%)
occurrences (all)	0	0	4
Alopecia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	1 / 65 (1.54%)
occurrences (all)	0	1	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	3 / 65 (4.62%)
occurrences (all)	2	0	3
Proteinuria			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	10 / 65 (15.38%)
occurrences (all)	0	1	10
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	2 / 5 (40.00%)	1 / 41 (2.44%)	3 / 65 (4.62%)
occurrences (all)	2	1	3
Back pain			
subjects affected / exposed	1 / 5 (20.00%)	4 / 41 (9.76%)	11 / 65 (16.92%)
occurrences (all)	1	4	13
Bone pain			
subjects affected / exposed	1 / 5 (20.00%)	6 / 41 (14.63%)	2 / 65 (3.08%)
occurrences (all)	1	6	2
Muscle spasms			
subjects affected / exposed	1 / 5 (20.00%)	1 / 41 (2.44%)	3 / 65 (4.62%)
occurrences (all)	1	1	4
Musculoskeletal chest pain			
subjects affected / exposed	2 / 5 (40.00%)	1 / 41 (2.44%)	4 / 65 (6.15%)
occurrences (all)	2	1	4

Arthralgia			
subjects affected / exposed	3 / 5 (60.00%)	4 / 41 (9.76%)	10 / 65 (15.38%)
occurrences (all)	4	7	12
Pain in extremity			
subjects affected / exposed	1 / 5 (20.00%)	3 / 41 (7.32%)	5 / 65 (7.69%)
occurrences (all)	1	3	5
Arthritis			
subjects affected / exposed	1 / 5 (20.00%)	1 / 41 (2.44%)	1 / 65 (1.54%)
occurrences (all)	1	1	1
Muscular weakness			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	2 / 65 (3.08%)
occurrences (all)	0	1	2
Neck pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	3 / 65 (4.62%)
occurrences (all)	1	0	4
Sacral pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Pneumonia			
subjects affected / exposed	3 / 5 (60.00%)	3 / 41 (7.32%)	4 / 65 (6.15%)
occurrences (all)	3	3	5
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	5 / 41 (12.20%)	1 / 65 (1.54%)
occurrences (all)	0	7	1
Sinusitis			
subjects affected / exposed	1 / 5 (20.00%)	2 / 41 (4.88%)	4 / 65 (6.15%)
occurrences (all)	1	2	6
Upper respiratory tract infection			
subjects affected / exposed	4 / 5 (80.00%)	9 / 41 (21.95%)	10 / 65 (15.38%)
occurrences (all)	13	12	11
Urinary tract infection			
subjects affected / exposed	0 / 5 (0.00%)	2 / 41 (4.88%)	4 / 65 (6.15%)
occurrences (all)	0	2	4
Bronchitis haemophilus			

subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Cellulitis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	2 / 65 (3.08%)
occurrences (all)	1	0	2
Oral candidiasis			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences (all)	1	0	1
Paronychia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Pneumonia haemophilus			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Pneumonia respiratory syncytial viral			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	0	0	0
COVID-19			
subjects affected / exposed	1 / 5 (20.00%)	1 / 41 (2.44%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Wound infection			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 5 (20.00%)	2 / 41 (4.88%)	12 / 65 (18.46%)
occurrences (all)	2	2	12
Hyperuricaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	3 / 65 (4.62%)
occurrences (all)	0	0	4
Hypercalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	4 / 65 (6.15%)
occurrences (all)	0	0	4

Hyperglycaemia			
subjects affected / exposed	2 / 5 (40.00%)	0 / 41 (0.00%)	11 / 65 (16.92%)
occurrences (all)	3	0	17
Hyperkalaemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	4 / 65 (6.15%)
occurrences (all)	1	0	4
Dehydration			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	6 / 65 (9.23%)
occurrences (all)	1	0	6
Hypocalcaemia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 41 (2.44%)	7 / 65 (10.77%)
occurrences (all)	0	1	10
Hypokalaemia			
subjects affected / exposed	1 / 5 (20.00%)	3 / 41 (7.32%)	3 / 65 (4.62%)
occurrences (all)	1	3	5
Hypomagnesaemia			
subjects affected / exposed	4 / 5 (80.00%)	3 / 41 (7.32%)	0 / 65 (0.00%)
occurrences (all)	7	5	0
Hyponatraemia			
subjects affected / exposed	1 / 5 (20.00%)	2 / 41 (4.88%)	5 / 65 (7.69%)
occurrences (all)	1	3	10
Hypophosphataemia			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	5 / 65 (7.69%)
occurrences (all)	1	0	9
Hypermagnesaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	3
Hypoglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	1 / 65 (1.54%)
occurrences (all)	0	0	1
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 5 (20.00%)	0 / 41 (0.00%)	0 / 65 (0.00%)
occurrences (all)	1	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 41 (0.00%)	6 / 65 (9.23%)
occurrences (all)	0	0	6

Non-serious adverse events	Nivolumab + Daratumumab_Cohort A1		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Colorectal adenoma			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Tumour flare			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hot flush			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	2		
Flushing			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Haematoma			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Varicose vein			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Chills			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Fatigue			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	3		
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Oedema peripheral			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	2		
Pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Chest discomfort			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Feeling hot			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Peripheral swelling			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			

Rhinitis allergic				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Cough				
subjects affected / exposed	3 / 6 (50.00%)			
occurrences (all)	3			
Dyspnoea				
subjects affected / exposed	2 / 6 (33.33%)			
occurrences (all)	3			
Nasal congestion				
subjects affected / exposed	2 / 6 (33.33%)			
occurrences (all)	2			
Rhinorrhoea				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Bronchospasm				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Dysphonia				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Productive cough				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Tachypnoea				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Upper-airway cough syndrome				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Pleural effusion				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Dyspnoea exertional				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			

Oropharyngeal pain			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Anxiety			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Investigations			
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Blood alkaline phosphatase increased			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Lipase increased			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Amylase increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
White blood cell count decreased			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Bilirubin conjugated increased			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Influenza A virus test positive			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Alanine aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Lymphocyte count decreased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Weight increased			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	2		
Fall			

subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Foot fracture			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Fracture			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Hip fracture			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Contusion			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Skin laceration			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Angina pectoris			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Peripheral sensory neuropathy			

subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Akathisia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Lethargy			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Memory impairment			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	2		
Syncope			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Disturbance in attention			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Neuropathy peripheral			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 6 (50.00%)		
occurrences (all)	3		
Neutropenia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Thrombocytopenia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		

Pancytopenia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Leukopenia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Lymphopenia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Ear and labyrinth disorders Hypoacusis subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Eye disorders Vision blurred subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Dry eye subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Uveitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Vitreous haemorrhage subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Gastrointestinal disorders Nausea subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Abdominal pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Constipation subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Diarrhoea			

subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Vomiting			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Gastritis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Large intestine polyp			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Abdominal hernia			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Abdominal distension			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		
Hyperhidrosis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	1 / 6 (16.67%)		
occurrences (all)	1		

Rash subjects affected / exposed occurrences (all) Rash maculo-papular subjects affected / exposed occurrences (all) Erythema subjects affected / exposed occurrences (all) Night sweats subjects affected / exposed occurrences (all) Alopecia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0		
Renal and urinary disorders Acute kidney injury subjects affected / exposed occurrences (all) Proteinuria subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0 0 / 6 (0.00%) 0		
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Musculoskeletal and connective tissue disorders Myalgia subjects affected / exposed occurrences (all) Back pain subjects affected / exposed occurrences (all) Bone pain subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1 0 / 6 (0.00%) 0 0 / 6 (0.00%) 0		

Muscle spasms subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 2		
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Arthralgia subjects affected / exposed occurrences (all)	3 / 6 (50.00%) 4		
Pain in extremity subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Arthritis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Muscular weakness subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Neck pain subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Sacral pain subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Infections and infestations Pneumonia subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0		
Bronchitis subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Sinusitis subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1		
Upper respiratory tract infection			

subjects affected / exposed	2 / 6 (33.33%)		
occurrences (all)	4		
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Bronchitis haemophilus			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Oral candidiasis			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Paronychia			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pneumonia haemophilus			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Pneumonia respiratory syncytial viral			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
COVID-19			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Wound infection			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 6 (0.00%)		
occurrences (all)	0		

Hyperuricaemia				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Hypercalcaemia				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Hyperglycaemia				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	2			
Hyperkalaemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Dehydration				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Hypocalcaemia				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			
Hypokalaemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Hypomagnesaemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Hyponatraemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Hypophosphataemia				
subjects affected / exposed	0 / 6 (0.00%)			
occurrences (all)	0			
Hypermagnesaemia				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	2			
Hypoglycaemia				
subjects affected / exposed	1 / 6 (16.67%)			
occurrences (all)	1			

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

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 December 2012	Eliminate the highest (10 mg/kg) of three dose levels scheduled to be examined, require that 8 of 16 subjects with multiple myeloma be required to undergo bone marrow biopsy while on therapy, and modify the discontinuation criteria to be more stringent
25 June 2013	Eliminate the CML cohort in the expansion phase as recruitment would be difficult due to lack of concomitant therapy with a tyrosine kinase inhibitor and increase the size of the remaining four cohorts from 16 to 23 subjects to redistribute the allotted patients from the eliminated CML cohort.
19 December 2013	Adds an additional set of cohorts (approximately 75 additional subjects) for dose escalation and dose expansion with combination of ipilimumab and nivolumab.
20 August 2014	Adds an additional set of cohorts (approximately 80 additional subjects) for dose expansion with combination of lirilumab and nivolumab
05 February 2015	Removes exploratory cohorts from the nivolumab/ipilimumab cohorts
09 August 2016	Adds an additional set of cohorts (approximately 60 additional subjects) for dose expansion in multiple myeloma patients treated with Nivolumab and Daratumumab with or without Pomalidomide and Dexamethasone
19 January 2017	This amendment includes corrections and updates pertinent only to the nivolumab/daratumumab cohorts. Additional biomarkers evaluations from peripheral blood specimens have been included. Daratumumab specific requirements for eligibility, dose delays and discontinuation, drug preparation and administration. Prevention and management of infusion related reactions, and permitted and restricted treatments have been aligned with the daratumumab IB and daratumumab standard protocol elements.

04 August 2017	Major changes are corrections and updates pertinent only to the nivolumab/daratumumab cohorts as follows: Changes in eligibility for subjects with multiple myeloma (MM) for enrollment in the nivolumab/daratumumab cohorts include: − Eligible subjects must have failed prior treatment with an immune modulatory drug (IMiD) and/or a proteasome inhibitor (PI) rather than the requirement of failure to treatment with both prior treatment types. Refractory and relapsed refractory definitions removed as criterion definitions. − Subjects who received prior treatment with pomalidomide are no longer excluded from eligibility. The randomization ratio has been changed to a 2:1 ratio, which increases the nivolumab + daratumumab + pomalidomide (NDPd) regimen cohort to 40 and reduces the nivolumab + daratumumab (ND) regimen cohort to 20. The sample size calculation has been updated to support change in randomization ratio. Changes to the biomarkers plan were made to align with the program level approach and small corrections were made to the biomarkers collections schedule to ensure consistency throughout the protocol. In addition, Biomarker collections from peripheral blood specimens have been clarified to remove duplicate collections. Daratumumab specific requirements for dose delays and discontinuation, drug preparation and administration, prevention and management of infusion related reactions, and permitted and restricted treatments have been aligned with the daratumumab IB and daratumumab standard protocol elements.
15 February 2018	Major changes: In compliance with requests from the FDA, enrollment into the nivolumab +daratumumab with and without pomalidomide (NDPd: Cohort A) has been stopped. Cohort B (nivolumab +daratumumab vs daratumumab monotherapy [ND, D]) has been opened, with at 2:1 randomization. o Eligibility changes to the patient population for patients to be enrolled in Cohort B and toxicity stopping rules for the ND arm have been incorporated. o Cohort B patients (only) treated in the ND arm: Dose regimen change: nivolumab 480 mg every 4 weeks (Day 1) will begin at Cycle 2 rather than at Cycle 7 and continue until the end of treatment. Cycle 1 dose: 240 mg on Day 15. The biomarker assessments have been aligned to the multiple myeloma program wide biomarkers evaluations. All content related to the nivolumab +ipilimumab combination has been removed because all study procedures for this cohort, including follow-up evaluations, have been completed.
23 April 2019	Incorporated Administrative Letter 10 Updated the medical monitor Removed all references to the lirilumab/nivolumab and nivolumab monotherapy cohorts. Removed all references to the dose selection phase. Removed references to non-Hodgkin and Hodgkin lymphoma. Added option for split-dosing of daratumumab at C1D1 Added requirements for HBV DNA testing and updated requirements for hepatitis B and C criteria and testing to address daratumumab safety concerns Clarified timing of interim and final analyses. Deleted appendices that are no longer applicable

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported