



Clinical trial results:

A Phase 2, Fast Real-time Assessment of Combination Therapies in Immuno-ONcology Study in Participants With Advanced Gastric Cancer (FRACTION-Gastric Cancer)

Summary

EudraCT number	2016-002807-24
Trial protocol	NL DE IT
Global end of trial date	11 May 2022

Results information

Result version number	v1 (current)
This version publication date	28 May 2023
First version publication date	28 May 2023

Trial information

Trial identification

Sponsor protocol code	CA018-003
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02935634
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussee de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@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	11 August 2022
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	11 May 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this clinical study is to evaluate the preliminary efficacy, safety, tolerability, pharmacokinetics (PK), and pharmacodynamics of novel FRACTION-Gastric Cancer (GC) study treatment combinations in participants with advanced GC and/or esophageal cancer (EC).

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 participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	29 November 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 10
Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Germany: 5
Country: Number of subjects enrolled	Israel: 9
Country: Number of subjects enrolled	Italy: 25
Country: Number of subjects enrolled	Netherlands: 4
Country: Number of subjects enrolled	Singapore: 2
Country: Number of subjects enrolled	Switzerland: 7
Country: Number of subjects enrolled	United States: 123
Worldwide total number of subjects	190
EEA total number of subjects	34

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)	108
From 65 to 84 years	81
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

Of the 190 participants that were randomized, 104 were initially randomized to Track 1 and 86 were initially randomized to Track 2.

Pre-assignment

Screening details:

The 93 participants that started treatment in Track 2 include the total number of participants that received treatment in each arm which incorporates the 20 participants from Track 1 or 2 that were re-randomized to receive a different treatment combination in Track 2.

Period 1

Period 1 title	Randomization
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nivolumab + Ipilimumab

Arm description:

Participants received nivolumab 1 mg/kg via IV infusion followed by ipilimumab 3 mg/kg administered IV Q3W, followed 6 weeks after the last dose of combination study treatment by nivolumab 480 mg administered IV Q4W for 2 years.

Arm type	Experimental
Investigational medicinal product name	Nivolumab + Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 1 mg/kg via IV infusion followed by ipilimumab 3 mg/kg administered IV Q3W, followed 6 weeks after the last dose of combination study treatment by nivolumab 480 mg administered IV Q4W for 2 years

Arm title	Nivolumab + BMS-986016
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Arm description:

Participants received nivolumab 240 mg via IV infusion Q2W followed by BMS-986016 80 mg administered IV Q2W for 2 years.

Arm type	Experimental
Investigational medicinal product name	Nivolumab + BMS-986016
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 240 mg via IV infusion Q2W followed by BMS-986016 80 mg administered IV Q2W for 2 years.

Arm title	Nivolumab + BMS-986205
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Arm description:

Participants received nivolumab 480 mg Q4W and BMS-986205 100 mg QD for 104 weeks.

Arm type	Experimental
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Investigational medicinal product name	Nivolumab + BMS-986205
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

nivolumab 480 mg Q4W and BMS-986205 100 mg QD for 104 weeks.

Arm title	Nivolumab + Rucaparib
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Arm description:

Participants received nivolumab 480 mg administered IV Q4W in combination with rucaparib 600 mg administered orally twice daily for 2 years.

Arm type	Experimental
Investigational medicinal product name	Nivolumab + Rucaparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

nivolumab 480 mg administered IV Q4W in combination with rucaparib 600 mg administered orally twice daily for 2 years.

Arm title	Ipilimumab + Rucaparib
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Arm description:

Participants received ipilimumab 3 mg/kg administered IV Q4W in combination with rucaparib 600 mg orally twice daily for 2 years.

Arm type	Experimental
Investigational medicinal product name	Ipilimumab + Rucaparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

ipilimumab 3 mg/kg administered IV Q4W in combination with rucaparib 600 mg orally twice daily for 2 years.

Arm title	Nivolumab + Ipilimumab + Rucaparib
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Arm description:

Participants received nivolumab 480 mg administered IV Q4W in combination with ipilimumab 1 mg/kg administered IV Q6W and rucaparib 600 mg orally twice daily for 2 years.

Arm type	Experimental
Investigational medicinal product name	Nivolumab + Ipilimumab + Rucaparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

nivolumab 480 mg administered IV Q4W in combination with ipilimumab 1 mg/kg administered IV Q6W and rucaparib 600 mg orally twice daily for 2 years.

Number of subjects in period 1	Nivolumab + Ipilimumab	Nivolumab + BMS-986016	Nivolumab + BMS-986205
Started	42	54	62
Completed	40	50	59
Not completed	2	4	3
Adverse event, serious fatal	2	1	1
Consent withdrawn by subject	-	1	-
Other reasons	-	2	2

Number of subjects in period 1	Nivolumab + Rucaparib	Ipilimumab + Rucaparib	Nivolumab + Ipilimumab + Rucaparib
Started	12	10	10
Completed	12	10	10
Not completed	0	0	0
Adverse event, serious fatal	-	-	-
Consent withdrawn by subject	-	-	-
Other reasons	-	-	-

Period 2

Period 2 title	Treatment
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Nivolumab + Ipilimumab

Arm description:

Participants received nivolumab 1 mg/kg via IV infusion followed by ipilimumab 3 mg/kg administered IV Q3W, followed 6 weeks after the last dose of combination study treatment by nivolumab 480 mg administered IV Q4W for 2 years.

Arm type	Experimental
Investigational medicinal product name	Nivolumab + Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Suspension for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 1 mg/kg via IV infusion followed by ipilimumab 3 mg/kg administered IV Q3W, followed 6 weeks after the last dose of combination study treatment by nivolumab 480 mg administered IV Q4W for 2 years

Arm title	Nivolumab + BMS-986016
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Arm description:

Participants received nivolumab 240 mg via IV infusion Q2W followed by BMS-986016 80 mg administered IV Q2W for 2 years.

Arm type	Experimental
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Investigational medicinal product name	Nivolumab + BMS-986016
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab 240 mg via IV infusion Q2W followed by BMS-986016 80 mg administered IV Q2W for 2 years.	
Arm title	Nivolumab + BMS-986205
Arm description: Participants received nivolumab 480 mg Q4W and BMS-986205 100 mg QD for 104 weeks.	
Arm type	Experimental
Investigational medicinal product name	Nivolumab + BMS-986205
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: nivolumab 480 mg Q4W and BMS-986205 100 mg QD for 104 weeks.	
Arm title	Nivolumab + Rucaparib
Arm description: Participants received nivolumab 480 mg administered IV Q4W in combination with rucaparib 600 mg administered orally twice daily for 2 years.	
Arm type	Experimental
Investigational medicinal product name	Nivolumab + Rucaparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: nivolumab 480 mg administered IV Q4W in combination with rucaparib 600 mg administered orally twice daily for 2 years.	
Arm title	Ipilimumab + Rucaparib
Arm description: Participants received ipilimumab 3 mg/kg administered IV Q4W in combination with rucaparib 600 mg orally twice daily for 2 years.	
Arm type	Experimental
Investigational medicinal product name	Ipilimumab + Rucaparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: ipilimumab 3 mg/kg administered IV Q4W in combination with rucaparib 600 mg orally twice daily for 2 years.	
Arm title	Nivolumab + Ipilimumab + Rucaparib
Arm description: Participants received nivolumab 480 mg administered IV Q4W in combination with ipilimumab 1 mg/kg administered IV Q6W and rucaparib 600 mg orally twice daily for 2 years.	
Arm type	Experimental

Investigational medicinal product name	Nivolumab + Ipilimumab + Rucaparib
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

nivolumab 480 mg administered IV Q4W in combination with ipilimumab 1 mg/kg administered IV Q6W and rucaparib 600 mg orally twice daily for 2 years.

Number of subjects in period 2	Nivolumab + Ipilimumab	Nivolumab + BMS- 986016	Nivolumab + BMS- 986205
Started	40	50	59
Completed	2	2	1
Not completed	38	48	58
Disease progression	26	39	47
Participant withdrew consent	2	1	2
Study drug toxicity	6	4	3
Adverse event unrelated to study drug	2	3	2
Other reasons	-	-	2
Lost to follow-up	1	-	-
Participant request to discontinue study treatment	1	1	2

Number of subjects in period 2	Nivolumab + Rucaparib	Ipilimumab + Rucaparib	Nivolumab + Ipilimumab + Rucaparib
Started	12	10	10
Completed	1	0	0
Not completed	11	10	10
Disease progression	8	7	6
Participant withdrew consent	-	2	-
Study drug toxicity	-	-	1
Adverse event unrelated to study drug	3	-	3
Other reasons	-	-	-
Lost to follow-up	-	-	-
Participant request to discontinue study treatment	-	1	-

Baseline characteristics

Reporting groups

Reporting group title	Nivolumab + Ipilimumab
Reporting group description: Participants received nivolumab 1 mg/kg via IV infusion followed by ipilimumab 3 mg/kg administered IV Q3W, followed 6 weeks after the last dose of combination study treatment by nivolumab 480 mg administered IV Q4W for 2 years.	
Reporting group title	Nivolumab + BMS-986016
Reporting group description: Participants received nivolumab 240 mg via IV infusion Q2W followed by BMS-986016 80 mg administered IV Q2W for 2 years.	
Reporting group title	Nivolumab + BMS-986205
Reporting group description: Participants received nivolumab 480 mg Q4W and BMS-986205 100 mg QD for 104 weeks.	
Reporting group title	Nivolumab + Rucaparib
Reporting group description: Participants received nivolumab 480 mg administered IV Q4W in combination with rucaparib 600 mg administered orally twice daily for 2 years.	
Reporting group title	Ipilimumab + Rucaparib
Reporting group description: Participants received ipilimumab 3 mg/kg administered IV Q4W in combination with rucaparib 600 mg orally twice daily for 2 years.	
Reporting group title	Nivolumab + Ipilimumab + Rucaparib
Reporting group description: Participants received nivolumab 480 mg administered IV Q4W in combination with ipilimumab 1 mg/kg administered IV Q6W and rucaparib 600 mg orally twice daily for 2 years.	

Reporting group values	Nivolumab + Ipilimumab	Nivolumab + BMS-986016	Nivolumab + BMS-986205
Number of subjects	42	54	62
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	26	30	31
From 65-84 years	15	24	31
85 years and over	1	0	0
Age Continuous			
NOTE: 99 = Not available			
Units: years			
arithmetic mean	99	99	99
standard deviation	± 99	± 99	± 99
Sex: Female, Male			
Units: Participants			
Female	7	11	23

Male	35	43	39
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Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	2	0	2
Not Hispanic or Latino	27	42	34
Unknown or Not Reported	13	12	26
Race/Ethnicity, Customized			
Race			
Units: Subjects			
White	35	48	51
Black or African American	0	2	4
Asian	3	3	3
American Indian or Alaska Native	0	0	1
Native Hawaiian or Other Pacific Islander	1	0	0
Other	2	1	2
Not reported	1	0	1

Reporting group values	Nivolumab + Rucaparib	Ipilimumab + Rucaparib	Nivolumab + Ipilimumab + Rucaparib
Number of subjects	12	10	10
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	6	7	8
From 65-84 years	6	3	2
85 years and over	0	0	0
Age Continuous			
NOTE: 99 = Not available			
Units: years			
arithmetic mean	99	99	99
standard deviation	± 99	± 99	± 99
Sex: Female, Male			
Units: Participants			
Female	1	4	2
Male	11	6	8
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	5	4	6
Unknown or Not Reported	7	6	4
Race/Ethnicity, Customized			
Race			

Units: Subjects			
White	11	8	9
Black or African American	0	2	1
Asian	0	0	0
American Indian or Alaska Native	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Other	1	0	0
Not reported	0	0	0

Reporting group values	Total		
Number of subjects	190		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	108		
From 65-84 years	81		
85 years and over	1		
Age Continuous			
NOTE: 99 = Not available			
Units: years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male			
Units: Participants			
Female	48		
Male	142		
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	4		
Not Hispanic or Latino	118		
Unknown or Not Reported	68		
Race/Ethnicity, Customized			
Race			
Units: Subjects			
White	162		
Black or African American	9		
Asian	9		
American Indian or Alaska Native	1		
Native Hawaiian or Other Pacific Islander	1		
Other	6		
Not reported	2		

End points

End points reporting groups

Reporting group title	Nivolumab + Ipilimumab
Reporting group description: Participants received nivolumab 1 mg/kg via IV infusion followed by ipilimumab 3 mg/kg administered IV Q3W, followed 6 weeks after the last dose of combination study treatment by nivolumab 480 mg administered IV Q4W for 2 years.	
Reporting group title	Nivolumab + BMS-986016
Reporting group description: Participants received nivolumab 240 mg via IV infusion Q2W followed by BMS-986016 80 mg administered IV Q2W for 2 years.	
Reporting group title	Nivolumab + BMS-986205
Reporting group description: Participants received nivolumab 480 mg Q4W and BMS-986205 100 mg QD for 104 weeks.	
Reporting group title	Nivolumab + Rucaparib
Reporting group description: Participants received nivolumab 480 mg administered IV Q4W in combination with rucaparib 600 mg administered orally twice daily for 2 years.	
Reporting group title	Ipilimumab + Rucaparib
Reporting group description: Participants received ipilimumab 3 mg/kg administered IV Q4W in combination with rucaparib 600 mg orally twice daily for 2 years.	
Reporting group title	Nivolumab + Ipilimumab + Rucaparib
Reporting group description: Participants received nivolumab 480 mg administered IV Q4W in combination with ipilimumab 1 mg/kg administered IV Q6W and rucaparib 600 mg orally twice daily for 2 years.	
Reporting group title	Nivolumab + Ipilimumab
Reporting group description: Participants received nivolumab 1 mg/kg via IV infusion followed by ipilimumab 3 mg/kg administered IV Q3W, followed 6 weeks after the last dose of combination study treatment by nivolumab 480 mg administered IV Q4W for 2 years.	
Reporting group title	Nivolumab + BMS-986016
Reporting group description: Participants received nivolumab 240 mg via IV infusion Q2W followed by BMS-986016 80 mg administered IV Q2W for 2 years.	
Reporting group title	Nivolumab + BMS-986205
Reporting group description: Participants received nivolumab 480 mg Q4W and BMS-986205 100 mg QD for 104 weeks.	
Reporting group title	Nivolumab + Rucaparib
Reporting group description: Participants received nivolumab 480 mg administered IV Q4W in combination with rucaparib 600 mg administered orally twice daily for 2 years.	
Reporting group title	Ipilimumab + Rucaparib
Reporting group description: Participants received ipilimumab 3 mg/kg administered IV Q4W in combination with rucaparib 600 mg orally twice daily for 2 years.	
Reporting group title	Nivolumab + Ipilimumab + Rucaparib
Reporting group description: Participants received nivolumab 480 mg administered IV Q4W in combination with ipilimumab 1 mg/kg administered IV Q6W and rucaparib 600 mg orally twice daily for 2 years.	
Subject analysis set title	Nivolumab + Ipilimumab
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received nivolumab 1 mg/kg via IV infusion followed by ipilimumab 3 mg/kg administered IV Q3W, followed 6 weeks after the last dose of combination study treatment by nivolumab 480 mg administered IV Q4W for 2 years.

Subject analysis set title	Nivolumab + BMS-986016
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received nivolumab 240 mg via IV infusion Q2W followed by BMS-986016 80 mg administered IV Q2W for 2 years.

Subject analysis set title	Nivolumab + BMS-986205
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received nivolumab 480 mg Q4W and BMS-986205 100 mg QD for 104 weeks.

Subject analysis set title	Nivolumab + Rucaparib
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received nivolumab 480 mg administered IV Q4W in combination with rucaparib 600 mg administered orally twice daily for 2 years.

Subject analysis set title	Ipilimumab + Rucaparib
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received ipilimumab 3 mg/kg administered IV Q4W in combination with rucaparib 600 mg orally twice daily for 2 years.

Subject analysis set title	Nivolumab + Ipilimumab + Rucaparib
Subject analysis set type	Full analysis

Subject analysis set description:

Participants received nivolumab 480 mg administered IV Q4W in combination with ipilimumab 1 mg/kg administered IV Q6W and rucaparib 600 mg orally twice daily for 2 years.

Primary: Objective Response Rate (ORR) by Investigator

End point title	Objective Response Rate (ORR) by Investigator ^[1]
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End point description:

ORR is the percent of participants whose best overall response (BOR) is complete response (CR) or partial response (PR). BOR is the best response from the start of the study treatment until objectively documented progression per RECIST v1.1 or subsequent anticancer therapy, whichever occurs first. CR is the disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) have reduction in short axis to <10 mm. PR is at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. The Response Evaluation Criteria in Solid Tumors (RECIST) is a standard way to measure the response of a tumor to treatment. CR+PR, confidence interval based on Clopper and Pearson method.

End point type	Primary
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End point timeframe:

From first dose of study treatment until progression or subsequent anticancer therapy, whichever occurs first (up to approximately 65 months)

Notes:

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

Justification: Only summary statistics planned for this endpoint.

End point values	Nivolumab + Ipilimumab	Nivolumab + BMS-986016	Nivolumab + BMS-986205	Nivolumab + Rucaparib
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	46 ^[2]	56 ^[3]	60 ^[4]	13 ^[5]
Units: Percent of participants				
number (confidence interval 95%)				
Track 1	4.3 (0.1 to 21.9)	5.0 (0.1 to 24.9)	13.2 (4.4 to 28.1)	0 (0.0 to 41.0)

Track 2	8.7 (1.1 to 28.0)	5.6 (0.7 to 18.7)	0 (0.0 to 15.4)	0 (0.0 to 45.9)
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Notes:

[2] - Track 1 N= 23
Track 2 N= 23
[3] - Track 1 N= 20
Track 2 N= 36
[4] - Track 1 N= 38
Track 2 N= 22
[5] - Track 1 N= 7
Track 2 N= 6

End point values	Ipilimumab + Rucaparib	Nivolumab + Ipilimumab + Rucaparib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10 ^[6]	10 ^[7]		
Units: Percent of participants				
number (confidence interval 95%)				
Track 1	0 (0.0 to 36.9)	16.7 (0.4 to 64.1)		
Track 2	0 (0.0 to 84.2)	0 (0.0 to 60.2)		

Notes:

[6] - Track 1 N= 8
Track 2 N= 2
[7] - Track 1 N= 6
Track 2 N= 4

Statistical analyses

No statistical analyses for this end point

Primary: Median Duration of Response (DOR)

End point title	Median Duration of Response (DOR) ^[8]
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End point description:

Duration of Response (DOR) is the time between the date of first response and the date of first documented disease progression as determined by RECIST 1.1 or death due to any cause, whichever occurred first. Complete Response (CR) is the disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to <10 mm. Partial Response (PR) is at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. Median computed using Kaplan -Meier method.

Note: Median/Min/Max = 99999 = Not Available; unable to calculate; insufficient number of participants who responded

Nivo + BMS-986016 Track 1: Min=113.4; Max=113.4

Nivo + BMS-986205 Track 1 Min=37.3; Max=144.0

Nivo + Ipi + Ruca Track 1 Min=0.1; Max=0.1

End point type	Primary
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End point timeframe:

From first dose to date of first documented tumor progression or death due to any cause, whichever occurred first (up to approximately 65 months)

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only summary statistics planned for this endpoint.

End point values	Nivolumab + Ipilimumab	Nivolumab + BMS-986016	Nivolumab + BMS-986205	Nivolumab + Rucaparib
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	46 ^[9]	56 ^[10]	60 ^[11]	13 ^[12]
Units: Weeks				
median (full range (min-max))				
Track 1	156.0 (156.0 to 156.0)	99999 (-99999 to 99999)	99999 (-99999 to 99999)	99999 (-99999 to 99999)
Track 2	14.71 (0.1 to 14.71)	16.86 (8.1 to 25.6)	99999 (-99999 to 99999)	99999 (-99999 to 99999)

Notes:

[9] - Track 1 N= 1

Track 2 N= 2

[10] - Track 1 N= 1

Track 2 N= 2

[11] - Track 1 N= 5

Track 2 N= 0

[12] - Track 1 N= 0

Track 2 N= 0

End point values	Ipilimumab + Rucaparib	Nivolumab + Ipilimumab + Rucaparib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10 ^[13]	10 ^[14]		
Units: Weeks				
median (full range (min-max))				
Track 1	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Track 2	99999 (-99999 to 99999)	99999 (-99999 to 99999)		

Notes:

[13] - Track 1 N= 0

Track 2 N= 0

[14] - Track 1 N= 1

Track 2 N= 0

Statistical analyses

No statistical analyses for this end point

Primary: Kaplan-Meier Analysis of Progression Free Survival Rate (PFSR) at 24 Weeks

End point title	Kaplan-Meier Analysis of Progression Free Survival Rate (PFSR) at 24 Weeks ^[15]
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End point description:

The PFSR at 24 weeks is defined as the proportion of treated participants remaining progression free and surviving at 24 weeks since the first dosing date. Progressive Disease (PD) is at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study. In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. Point estimates are derived from Kaplan-Meier analyses, the 95% CIs are derived from Greenwood formula.

Note: 99999 = Not Available; insufficient number of participants with events

End point type	Primary
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End point timeframe:

24 weeks after first dose

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: Only summary statistics planned for this endpoint.

End point values	Nivolumab + Ipilimumab	Nivolumab + BMS-986016	Nivolumab + BMS-986205	Nivolumab + Rucaparib
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	46 ^[16]	56 ^[17]	60 ^[18]	13 ^[19]
Units: Proportion of participants				
number (confidence interval 95%)				
Track 1	99999 (-99999 to 99999)	99999 (-99999 to 99999)	0.240 (0.114 to 0.393)	99999 (-99999 to 99999)
Track 2	99999 (-99999 to 99999)	99999 (-99999 to 99999)	0.170 (0.063 to 0.322)	99999 (-99999 to 99999)

Notes:

[16] - Track 1 N= 23

Track 2 N= 23

[17] - Track 1 N= 20

Track 2 N= 36

[18] - Track 1 N= 38

Track 2 N= 22

[19] - Track 1 N= 7

Track 2 N= 6

End point values	Ipilimumab + Rucaparib	Nivolumab + Ipilimumab + Rucaparib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10 ^[20]	10 ^[21]		
Units: Proportion of participants				
number (confidence interval 95%)				
Track 1	99999 (-99999 to 99999)	99999 (-99999 to 99999)		
Track 2	99999 (-99999 to 99999)	99999 (-99999 to 99999)		

Notes:

[20] - Track 1 N= 8

Track 2 N= 2

[21] - Track 1 N= 6

Track 2 N= 4

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Adverse Events (AEs)

End point title	Number of Participants with Adverse Events (AEs)
End point description: An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment.	
End point type	Secondary
End point timeframe: From first dose to 100 days after last dose of study therapy (assessed up to approximately 30 months)	

End point values	Nivolumab + Ipilimumab	Nivolumab + BMS-986016	Nivolumab + BMS-986205	Nivolumab + Rucaparib
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	46 ^[22]	56 ^[23]	60 ^[24]	13 ^[25]
Units: Participants				
Track 1	23	20	38	7
Track 2	23	36	22	6

Notes:

[22] - Track 1 N= 23

Track 2 N= 23

[23] - Track 1 N= 20

Track 2 N= 36

[24] - Track 1 N= 38

Track 2 N= 22

[25] - Track 1 N= 7

Track 2 N= 6

End point values	Ipilimumab + Rucaparib	Nivolumab + Ipilimumab + Rucaparib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10 ^[26]	10 ^[27]		
Units: Participants				
Track 1	8	6		
Track 2	2	4		

Notes:

[26] - Track 1 N= 8

Track 2 N= 2

[27] - Track 1 N= 6

Track 2 N= 4

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Serious Adverse Events (SAEs)

End point title	Number of Participants with Serious Adverse Events (SAEs)
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End point description:

Serious Adverse Event (SAE) is defined as any untoward medical occurrence that, at any dose results in death, is life-threatening (defined as an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe), requires inpatient hospitalization or causes prolongation of existing hospitalization.

End point type	Secondary
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End point timeframe:

From first dose to 100 days after last dose of study therapy (assessed up to approximately 30 months)

End point values	Nivolumab + Ipilimumab	Nivolumab + BMS-986016	Nivolumab + BMS-986205	Nivolumab + Rucaparib
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	46 ^[28]	56 ^[29]	60 ^[30]	13 ^[31]
Units: Participants				
Track 1	19	15	24	5
Track 2	17	24	12	4

Notes:

[28] - Track 1 N= 23

Track 2 N= 23

[29] - Track 1 N= 20

Track 2 N= 36

[30] - Track 1 N= 38

Track 2 N= 22

[31] - Track 1 N= 7

Track 2 N= 6

End point values	Ipilimumab + Rucaparib	Nivolumab + Ipilimumab + Rucaparib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10 ^[32]	10 ^[33]		
Units: Participants				
Track 1	6	4		
Track 2	2	3		

Notes:

[32] - Track 1 N= 8

Track 2 N= 2

[33] - Track 1 N= 6

Track 2 N= 4

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Adverse Events (AEs) Leading to Discontinuation

End point title	Number of Participants with Adverse Events (AEs) Leading to Discontinuation
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End point description:

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment.

End point type	Secondary
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End point timeframe:

From first dose to 100 days after last dose of study therapy (assessed up to approximately 30 months)

End point values	Nivolumab + Ipilimumab	Nivolumab + BMS-986016	Nivolumab + BMS-986205	Nivolumab + Rucaparib
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	46 ^[34]	56 ^[35]	60 ^[36]	13 ^[37]
Units: Participants				
Track 1	9	7	11	3
Track 2	10	8	2	0

Notes:

[34] - Track 1 N= 23
Track 2 N= 23
[35] - Track 1 N= 20
Track 2 N= 36
[36] - Track 1 N= 38
Track 2 N= 22
[37] - Track 1 N= 7
Track 2 N= 6

End point values	Ipilimumab + Rucaparib	Nivolumab + Ipilimumab + Rucaparib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10 ^[38]	10 ^[39]		
Units: Participants				
Track 1	4	4		
Track 2	1	0		

Notes:

[38] - Track 1 N= 8
Track 2 N= 2
[39] - Track 1 N= 6
Track 2 N= 4

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants who Died

End point title	Number of Participants who Died
End point description:	Death is defined as the cessation of all vital functions of the body including the heartbeat, brain activity (including the brain stem), and breathing.
End point type	Secondary
End point timeframe:	From first dose to 100 days after last dose of study therapy (assessed up to approximately 30 months)

End point values	Nivolumab + Ipilimumab	Nivolumab + BMS-986016	Nivolumab + BMS-986205	Nivolumab + Rucaparib
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	46 ^[40]	56 ^[41]	60 ^[42]	13 ^[43]
Units: Participants				
Track 1	19	15	26	7
Track 2	19	26	13	3

Notes:

[40] - Track 1 N= 23
Track 2 N= 23
[41] - Track 1 N= 20
Track 2 N= 36
[42] - Track 1 N= 38
Track 2 N= 22
[43] - Track 1 N= 7
Track 2 N= 6

End point values	Ipilimumab +	Nivolumab +		
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	Rucaparib	Ipilimumab + Rucaparib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	10 ^[44]	10 ^[45]		
Units: Participants				
Track 1	5	4		
Track 2	2	3		

Notes:

[44] - Track 1 N= 8

Track 2 N= 2

[45] - Track 1 N= 6

Track 2 N= 4

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Laboratory Abnormalities in Specific Thyroid Tests - Track 1

End point title	Number of Participants with Laboratory Abnormalities in Specific Thyroid Tests - Track 1
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End point description:

The number of participants with laboratory abnormalities in specific thyroid tests based on US conventional units. TSH = Thyroid Stimulating Hormone LLN = Lower Limit of Normal ULN = Upper Limit of Normal.

End point type	Secondary
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End point timeframe:

From first dose to 100 days after last dose of study therapy (approximately 30 months)

End point values	Nivolumab + Ipilimumab	Nivolumab + BMS-986016	Nivolumab + BMS-986205	Nivolumab + Rucaparib
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	16	26	6
Units: Participants				
TSH > ULN	4	4	6	1
TSH > ULN WITH TSH ≤ ULN AT BASELINE	3	3	4	0
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	1	2	2	0
TSH >ULN WITH ALL OTHER FT3/FT4 TEST VALUES ≥ LLN	1	1	1	1
TSH > ULN WITH FT3/FT4 TEST MISSING	2	1	3	0
TSH < LLN	1	2	5	0
TSH <LLN WITH TSH ≥ LLN AT BASELINE	0	1	3	0
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	1	0	2	0
TSH <LLN WITH ALL OTHER FT3/FT4 TEST VALUES ≤ ULN	0	2	1	0
TSH < LLN WITH FT3/FT4 TEST MISSING	0	0	2	0

End point values	Ipilimumab + Rucaparib	Nivolumab + Ipilimumab + Rucaparib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	3		
Units: Participants				
TSH > ULN	1	1		
TSH > ULN WITH TSH ≤ ULN AT BASELINE	1	1		
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	1	1		
TSH >ULN WITH ALL OTHER FT3/FT4 TEST VALUES ≥ LLN	0	0		
TSH > ULN WITH FT3/FT4 TEST MISSING	0	0		
TSH < LLN	0	0		
TSH <LLN WITH TSH ≥ LLN AT BASELINE	0	0		
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	0	0		
TSH <LLN WITH ALL OTHER FT3/FT4 TEST VALUES ≤ ULN	0	0		
TSH < LLN WITH FT3/FT4 TEST MISSING	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Laboratory Abnormalities in Specific Liver Tests - Track 1

End point title	Number of Participants with Laboratory Abnormalities in Specific Liver Tests - Track 1
End point description:	The number of participants with laboratory abnormalities in specific liver tests based on US conventional units. ALT = Alanine Aminotransferase AST = Aspartate Aminotransferase ULN = Upper Limit of Normal
End point type	Secondary
End point timeframe:	From first dose to 100 days after last dose of study therapy (approximately 30 months)

End point values	Nivolumab + Ipilimumab	Nivolumab + BMS-986016	Nivolumab + BMS-986205	Nivolumab + Rucaparib
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	19	20	33	6
Units: Participants				
ALT OR AST > 3XULN	6	6	5	1
ALT OR AST > 5XULN	3	2	3	0

ALT OR AST > 10XULN	2	1	2	0
ALT OR AST > 20XULN	0	0	1	0
TOTAL BILIRUBIN > 2XULN	2	3	0	1
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN IN 1 DAY	2	2	0	1
ALT/AST ELEV>3XULN;TOTAL BILI>2XULN IN 30 DAYS	2	2	0	1

End point values	Ipilimumab + Rucaparib	Nivolumab + Ipilimumab + Rucaparib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	4		
Units: Participants				
ALT OR AST > 3XULN	2	1		
ALT OR AST > 5XULN	1	1		
ALT OR AST > 10XULN	0	0		
ALT OR AST > 20XULN	0	0		
TOTAL BILIRUBIN > 2XULN	1	1		
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN IN 1 DAY	1	1		
ALT/AST ELEV>3XULN;TOTAL BILI>2XULN IN 30 DAYS	1	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Laboratory Abnormalities in Specific Thyroid Tests - Track 2

End point title	Number of Participants with Laboratory Abnormalities in Specific Thyroid Tests - Track 2
End point description: The number of participants with laboratory abnormalities in specific thyroid tests based on US conventional units. TSH = Thyroid Stimulating Hormone LLN = Lower Limit of Normal ULN = Upper Limit of Normal.	
End point type	Secondary
End point timeframe: From first dose to 100 days after last dose of study therapy (approximately 30 months)	

End point values	Nivolumab + Ipilimumab	Nivolumab + BMS-986016	Nivolumab + BMS-986205	Nivolumab + Rucaparib
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	27	18	5
Units: Participants				
TSH > ULN	11	5	5	0
TSH > ULN WITH TSH <= ULN AT BASELINE	6	1	4	0
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	5	2	2	0
TSH >ULN WITH ALL OTHER FT3/FT4 TEST VALUES >= LLN	3	2	0	0
TSH > ULN WITH FT3/FT4 TEST MISSING	3	1	3	0
TSH < LLN	4	6	0	0
TSH <LLN WITH TSH >= LLN AT BASELINE	3	5	0	0
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	3	2	0	0
TSH <LLN WITH ALL OTHER FT3/FT4 TEST VALUES <= ULN	1	0	0	0
TSH < LLN WITH FT3/FT4 TEST MISSING	0	4	0	0

End point values	Ipilimumab + Rucaparib	Nivolumab + Ipilimumab + Rucaparib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1	3		
Units: Participants				
TSH > ULN	1	1		
TSH > ULN WITH TSH <= ULN AT BASELINE	1	0		
TSH >ULN WITH ATLEAST ONE FT3/FT4 TEST VALUE <LLN	0	1		
TSH >ULN WITH ALL OTHER FT3/FT4 TEST VALUES >= LLN	0	0		
TSH > ULN WITH FT3/FT4 TEST MISSING	1	0		
TSH < LLN	0	0		
TSH <LLN WITH TSH >= LLN AT BASELINE	0	0		
TSH <LLN WITH ATLEAST ONE FT3/FT4 TEST VALUE > ULN	0	0		
TSH <LLN WITH ALL OTHER FT3/FT4 TEST VALUES <= ULN	0	0		
TSH < LLN WITH FT3/FT4 TEST MISSING	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Laboratory Abnormalities in Specific Liver Tests - Track 2

End point title	Number of Participants with Laboratory Abnormalities in Specific Liver Tests - Track 2
End point description:	
The number of participants with laboratory abnormalities in specific liver tests based on US conventional units. ALT = Alanine Aminotransferase AST = Aspartate Aminotransferase ULN = Upper Limit of Normal	
End point type	Secondary
End point timeframe:	
From first dose to 100 days after last dose of study therapy (approximately 30 months)	

End point values	Nivolumab + Ipilimumab	Nivolumab + BMS-986016	Nivolumab + BMS-986205	Nivolumab + Rucaparib
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22	32	22	6
Units: Participants				
ALT OR AST > 3XULN	6	2	2	3
ALT OR AST> 5XULN	4	1	0	0
ALT OR AST> 10XULN	3	0	0	0
ALT OR AST > 20XULN	1	0	0	0
TOTAL BILIRUBIN > 2XULN	3	1	3	1
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN IN 1 DAY	2	0	0	1
ALT/AST ELEV>3XULN;TOTAL BILI>2XULN IN 30 DAYS	2	0	0	1

End point values	Ipilimumab + Rucaparib	Nivolumab + Ipilimumab + Rucaparib		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	2	3		
Units: Participants				
ALT OR AST > 3XULN	1	0		
ALT OR AST> 5XULN	1	0		
ALT OR AST> 10XULN	1	0		
ALT OR AST > 20XULN	0	0		
TOTAL BILIRUBIN > 2XULN	0	0		
ALT/AST ELEV>3XULN;TOTAL BILIRUBIN>2XULN IN 1 DAY	0	0		
ALT/AST ELEV>3XULN;TOTAL BILI>2XULN IN 30 DAYS	0	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

SAEs and NSAEs were assessed from first dose to 100 days after last dose of study therapy (up to approximately 30 months).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	25.0
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Reporting groups

Reporting group title	Track 1: Nivolumab + Ipilimumab
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Reporting group description:

Treatment naive participants received nivolumab 1 mg/kg via IV infusion followed by ipilimumab 3 mg/kg administered IV Q3W, followed 6 weeks after the last dose of combination study treatment by nivolumab 480 mg administered IV Q4W for 2 years.

Reporting group title	Track 1: Ipilimumab + Rucaparib
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Reporting group description:

Treatment naive participants received ipilimumab 3 mg/kg administered IV Q4W in combination with rucaparib 600 mg orally twice daily for 2 years.

Reporting group title	Track 1: Nivolumab + Rucaparib
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Reporting group description:

Treatment naive participants received nivolumab 480 mg administered IV Q4W in combination with rucaparib 600 mg administered orally twice daily for 2 years.

Reporting group title	Track 1: Nivolumab + BMS-986205
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Reporting group description:

Treatment naive participants received nivolumab 480 mg Q4W and BMS-986205 100 mg QD for 104 weeks.

Reporting group title	Track 1: Nivolumab + BMS-986016
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Reporting group description:

Treatment naive participants received nivolumab 240 mg via IV infusion Q2W followed by BMS-986016 80 mg administered IV Q2W for 2 years.

Reporting group title	Track 2: Ipilimumab + Rucaparib
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Reporting group description:

Treatment experienced participants received ipilimumab 3 mg/kg administered IV Q4W in combination with rucaparib 600 mg orally twice daily for 2 years.

Reporting group title	Track 2: Nivolumab + Rucaparib
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Reporting group description:

Treatment experienced participants received nivolumab 480 mg administered IV Q4W in combination with rucaparib 600 mg administered orally twice daily for 2 years.

Reporting group title	Track 2: Nivolumab + BMS-986205
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Reporting group description:

Treatment experienced participants received nivolumab 480 mg Q4W and BMS-986205 100 mg QD for 104 weeks.

Reporting group title	Track 2: Nivolumab + BMS-986016
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Reporting group description:

Treatment experienced participants received nivolumab 240 mg via IV infusion Q2W followed by BMS-986016 80 mg administered IV Q2W for 2 years.

Reporting group title	Track 2: Nivolumab + Ipilimumab
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Reporting group description:

Treatment experienced participants received nivolumab 1 mg/kg via IV infusion followed by ipilimumab 3 mg/kg administered IV Q3W, followed 6 weeks after the last dose of combination study treatment by nivolumab 480 mg administered IV Q4W for 2 years.

Reporting group title	Track 2: Nivolumab + Ipilimumab + Rucaparib
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Reporting group description:

Treatment experienced participants received nivolumab 480 mg administered IV Q4W in combination with ipilimumab 1 mg/kg administered IV Q6W and rucaparib 600 mg orally twice daily for 2 years.

Reporting group title

Track 1: Nivolumab + Ipilimumab + Rucaparib

Reporting group description:

Treatment naive participants received nivolumab 480 mg administered IV Q4W in combination with ipilimumab 1 mg/kg administered IV Q6W and rucaparib 600 mg orally twice daily for 2 years.

Serious adverse events	Track 1: Nivolumab + Ipilimumab	Track 1: Ipilimumab + Rucaparib	Track 1: Nivolumab + Rucaparib
Total subjects affected by serious adverse events			
subjects affected / exposed	19 / 23 (82.61%)	6 / 8 (75.00%)	5 / 7 (71.43%)
number of deaths (all causes)	19	5	7
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keratoacanthoma			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	11 / 23 (47.83%)	3 / 8 (37.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 11	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 10	0 / 1	0 / 0
Metastases to central nervous system			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour perforation			

subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava stenosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Fatigue			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 23 (0.00%)	1 / 8 (12.50%)	2 / 7 (28.57%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (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
Systemic inflammatory response syndrome			

subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	3 / 23 (13.04%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoxia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	3 / 23 (13.04%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic enzyme increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Weight decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Seizure			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			

Febrile neutropenia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal obstruction			

subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 23 (4.35%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 23 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nausea			

subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal perforation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			

subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic haematoma			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 23 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 23 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus ulcer			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			

subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocytic hypophysitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basedow's disease			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Intervertebral disc protrusion			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Atypical pneumonia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			

subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin bacterial infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			

subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Track 1: Nivolumab + BMS-986205	Track 1: Nivolumab + BMS-986016	Track 2: Ipilimumab + Rucaparib
Total subjects affected by serious adverse events			
subjects affected / exposed	24 / 38 (63.16%)	15 / 20 (75.00%)	2 / 2 (100.00%)
number of deaths (all causes)	26	15	2
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keratoacanthoma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	11 / 38 (28.95%)	6 / 20 (30.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 11	0 / 6	0 / 1
deaths causally related to treatment / all	0 / 11	0 / 6	0 / 1

Metastases to central nervous system			
subjects affected / exposed	0 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (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
Tumour haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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 perforation			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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
Tumour pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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			
Hypotension			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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
Superior vena cava stenosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest discomfort			

subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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
Asthenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (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
Performance status decreased			

subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	2 / 38 (5.26%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 2	0 / 0	0 / 0
Hypoxia			

subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (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
Pneumothorax			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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 enzyme increased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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
Weight decreased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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
Neutrophil count decreased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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
Femur fracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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 pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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
Cerebral infarction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Seizure			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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			
Febrile neutropenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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	2 / 38 (5.26%)	3 / 20 (15.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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 pain upper			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ascites			
subjects affected / exposed	1 / 38 (2.63%)	1 / 20 (5.00%)	0 / 2 (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
Constipation			
subjects affected / exposed	2 / 38 (5.26%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	4 / 38 (10.53%)	2 / 20 (10.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal obstruction			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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
Diarrhoea			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			

subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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
Large intestine perforation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (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
Oesophageal perforation			
subjects affected / exposed	0 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (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
Oesophageal stenosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	0 / 38 (0.00%)	2 / 20 (10.00%)	0 / 2 (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
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (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
Cholecystitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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 haematoma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

Rash			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus ulcer			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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			
Acute kidney injury			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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
Urinary tract obstruction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 38 (2.63%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocytic hypophysitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basedow's disease			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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
Flank pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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
Intervertebral disc protrusion			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Atypical pneumonia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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	2 / 38 (5.26%)	0 / 20 (0.00%)	1 / 2 (50.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin bacterial infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (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	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	2 / 38 (5.26%)	0 / 20 (0.00%)	0 / 2 (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
Hyponatraemia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (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
Hyperkalaemia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (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
Failure to thrive			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
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	Track 2: Nivolumab + Rucaparib	Track 2: Nivolumab + BMS-986205	Track 2: Nivolumab + BMS-986016
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 6 (66.67%)	12 / 22 (54.55%)	24 / 36 (66.67%)
number of deaths (all causes)	3	13	26
number of deaths resulting from adverse events			

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keratoacanthoma			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (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
Malignant neoplasm progression			
subjects affected / exposed	2 / 6 (33.33%)	8 / 22 (36.36%)	9 / 36 (25.00%)
occurrences causally related to treatment / all	0 / 2	0 / 8	0 / 10
deaths causally related to treatment / all	0 / 1	0 / 8	0 / 8
Metastases to central nervous system			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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 perforation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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 pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			

subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (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	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava stenosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Fatigue			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			

subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (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
Sudden death			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			

subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (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
Dyspnoea			
subjects affected / exposed	0 / 6 (0.00%)	2 / 22 (9.09%)	0 / 36 (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
Hypoxia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Psychiatric disorders			
Delirium			

subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood creatinine increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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 enzyme increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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 pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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			
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			

subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
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	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Haemorrhage intracranial			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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			
Febrile neutropenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	3 / 36 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (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 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (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
Haematemesis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
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 perforation			

subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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 stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (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
Cholecystitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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 haematoma			

subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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			
Rash			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus ulcer			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			

Adrenal insufficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocytic hypophysitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Basedow's disease			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (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 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (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

Muscular weakness			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (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
Infections and infestations			
Atypical pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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 viral			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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	1 / 6 (16.67%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin bacterial infection			

subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (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
Wound infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
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 / 6 (0.00%)	0 / 22 (0.00%)	2 / 36 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hyperkalaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (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
Metabolic acidosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
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	Track 2: Nivolumab + Ipilimumab	Track 2: Nivolumab + Ipilimumab + Rucaparib	Track 1: Nivolumab + Ipilimumab + Rucaparib
Total subjects affected by serious adverse events			
subjects affected / exposed	17 / 23 (73.91%)	3 / 4 (75.00%)	4 / 6 (66.67%)
number of deaths (all causes)	19	3	4
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Keratoacanthoma			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	5 / 23 (21.74%)	2 / 4 (50.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 5	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 5	0 / 2	0 / 0
Metastases to central nervous system			

subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour perforation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Superior vena cava stenosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest discomfort			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Asthenia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			

subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sudden death			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Systemic inflammatory response syndrome			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspiration			
subjects affected / exposed	0 / 23 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	1 / 23 (4.35%)	1 / 4 (25.00%)	0 / 6 (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
Hypoxia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
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 effusion			

subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Delirium			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Device dislocation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (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 bilirubin increased			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood creatinine increased			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (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
Hepatic enzyme increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acetabulum fracture			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Brain oedema			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebral infarction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Syncope			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient ischaemic attack			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	2 / 23 (8.70%)	1 / 4 (25.00%)	0 / 6 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 23 (13.04%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	2 / 23 (8.70%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	3 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Constipation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	3 / 23 (13.04%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal obstruction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	3 / 23 (13.04%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	2 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			

subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal perforation			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Autoimmune hepatitis			

subjects affected / exposed	2 / 23 (8.70%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic haematoma			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Portal vein thrombosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Decubitus ulcer			

subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 23 (0.00%)	1 / 4 (25.00%)	0 / 6 (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
Urinary tract obstruction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphocytic hypophysitis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (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
Basedow's disease			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (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
Secondary adrenocortical insufficiency			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			

subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Arthralgia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Atypical pneumonia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile infection			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (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
Ophthalmic herpes zoster			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia viral			

subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin bacterial infection			
subjects affected / exposed	0 / 23 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal bacteraemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			

subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wound infection			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	3 / 23 (13.04%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Failure to thrive			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

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

Non-serious adverse events	Track 1: Nivolumab + Ipilimumab	Track 1: Ipilimumab + Rucaparib	Track 1: Nivolumab + Rucaparib
Total subjects affected by non-serious adverse events			
subjects affected / exposed	21 / 23 (91.30%)	8 / 8 (100.00%)	7 / 7 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Jugular vein thrombosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hypertension			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Deep vein thrombosis			
subjects affected / exposed	1 / 23 (4.35%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	1	1	0
Orthostatic hypotension			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	4 / 23 (17.39%)	2 / 8 (25.00%)	0 / 7 (0.00%)
occurrences (all)	4	3	0
Chills			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	13 / 23 (56.52%)	5 / 8 (62.50%)	2 / 7 (28.57%)
occurrences (all)	14	6	2

General physical health deterioration subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Influenza like illness subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Malaise subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Mucosal inflammation subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Non-cardiac chest pain subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Pain subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Oedema peripheral subjects affected / exposed occurrences (all)	3 / 23 (13.04%) 3	1 / 8 (12.50%) 1	1 / 7 (14.29%) 1
Pyrexia subjects affected / exposed occurrences (all)	7 / 23 (30.43%) 9	2 / 8 (25.00%) 2	1 / 7 (14.29%) 2
Reproductive system and breast disorders Oedema genital subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Ejaculation disorder subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0

Cough			
subjects affected / exposed	6 / 23 (26.09%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	6	0	1
Dyspnoea			
subjects affected / exposed	4 / 23 (17.39%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	4	1	0
Dyspnoea exertional			
subjects affected / exposed	2 / 23 (8.70%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	1
Hiccups			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	2 / 23 (8.70%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	2 / 23 (8.70%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Pneumonitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Productive cough			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Confusional state			

subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	2 / 23 (8.70%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Insomnia			
subjects affected / exposed	0 / 23 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Panic attack			
subjects affected / exposed	0 / 23 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Restlessness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Suicidal ideation			
subjects affected / exposed	0 / 23 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 23 (0.00%)	3 / 8 (37.50%)	1 / 7 (14.29%)
occurrences (all)	0	3	1
Amylase increased			
subjects affected / exposed	1 / 23 (4.35%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	1	1	1
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 23 (0.00%)	3 / 8 (37.50%)	2 / 7 (28.57%)
occurrences (all)	0	3	2
Blood alkaline phosphatase increased			
subjects affected / exposed	3 / 23 (13.04%)	1 / 8 (12.50%)	3 / 7 (42.86%)
occurrences (all)	3	1	3
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			

subjects affected / exposed	2 / 23 (8.70%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	2	0	2
Blood creatine increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Blood urea increased			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	4 / 23 (17.39%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	4	0	3
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lymph node palpable			

subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	2 / 23 (8.70%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Neutrophil count decreased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Platelet count decreased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
White blood cell count decreased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	0	1	1
Weight decreased			
subjects affected / exposed	4 / 23 (17.39%)	2 / 8 (25.00%)	2 / 7 (28.57%)
occurrences (all)	4	2	2
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Arthropod bite			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			

Tachycardia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 23 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Atrial fibrillation			
subjects affected / exposed	2 / 23 (8.70%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	2 / 23 (8.70%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	2	0	1
Disturbance in attention			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Polyneuropathy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 23 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Tremor			

subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Restless legs syndrome subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Blood and lymphatic system disorders			
Anaemia subjects affected / exposed occurrences (all)	6 / 23 (26.09%) 6	3 / 8 (37.50%) 3	1 / 7 (14.29%) 1
Neutropenia subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Lymphopenia subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	1 / 8 (12.50%) 1	0 / 7 (0.00%) 0
Lymphadenopathy subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Leukocytosis subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Coagulopathy subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Ear and labyrinth disorders			
Cerumen impaction subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Eye disorders			
Vision blurred subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	7 / 23 (30.43%)	1 / 8 (12.50%)	2 / 7 (28.57%)
occurrences (all)	7	1	2
Abdominal distension			
subjects affected / exposed	2 / 23 (8.70%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Ascites			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Colitis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Constipation			
subjects affected / exposed	3 / 23 (13.04%)	2 / 8 (25.00%)	2 / 7 (28.57%)
occurrences (all)	3	2	2
Diarrhoea			
subjects affected / exposed	2 / 23 (8.70%)	1 / 8 (12.50%)	4 / 7 (57.14%)
occurrences (all)	4	1	5
Dry mouth			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dyspepsia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
subjects affected / exposed	6 / 23 (26.09%)	0 / 8 (0.00%)	3 / 7 (42.86%)
occurrences (all)	6	0	5
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Flatulence			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Ileus			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Large intestinal obstruction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Jejunal stenosis			
subjects affected / exposed	0 / 23 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Nausea			
subjects affected / exposed	8 / 23 (34.78%)	4 / 8 (50.00%)	4 / 7 (57.14%)
occurrences (all)	8	4	4
Oesophageal stenosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	2 / 7 (28.57%)
occurrences (all)	0	0	2
Oesophageal pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	7 / 23 (30.43%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	7	1	0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			

Alopecia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	3 / 23 (13.04%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	3	0	0
Rash maculo-papular			
subjects affected / exposed	5 / 23 (21.74%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	5	0	0
Rash			
subjects affected / exposed	1 / 23 (4.35%)	3 / 8 (37.50%)	0 / 7 (0.00%)
occurrences (all)	1	3	0
Pruritus			
subjects affected / exposed	2 / 23 (8.70%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Photosensitivity reaction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Skin fissures			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	2
Renal and urinary disorders			
Proteinuria			
subjects affected / exposed	0 / 23 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Dysuria			

subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Hyperthyroidism			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 23 (8.70%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Arthritis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 23 (8.70%)	1 / 8 (12.50%)	1 / 7 (14.29%)
occurrences (all)	2	1	1
Chondrocalcinosis pyrophosphate			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 23 (0.00%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	2 / 23 (8.70%)	1 / 8 (12.50%)	0 / 7 (0.00%)
occurrences (all)	2	1	0
Myalgia			

subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Pain in extremity subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	1 / 8 (12.50%) 1	0 / 7 (0.00%) 0
Neck pain subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Sacral pain subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	1 / 7 (14.29%) 1
Infections and infestations			
COVID-19 subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Bronchitis subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	1 / 8 (12.50%) 1	0 / 7 (0.00%) 0
Paronychia subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Lymph gland infection subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Genital herpes subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	1 / 7 (14.29%) 1
Clostridium difficile infection subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Cellulitis subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 8 (0.00%) 0	0 / 7 (0.00%) 0

Sepsis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	1	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	10 / 23 (43.48%)	2 / 8 (25.00%)	2 / 7 (28.57%)
occurrences (all)	10	2	4
Hyperkalaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	1	0	0
Dehydration			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypermagnesaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	3 / 23 (13.04%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	5	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	3 / 23 (13.04%)	0 / 8 (0.00%)	1 / 7 (14.29%)
occurrences (all)	3	0	1
Hypomagnesaemia			
subjects affected / exposed	2 / 23 (8.70%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	2	0	0
Hypophosphataemia			

subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	5 / 23 (21.74%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	6	0	0
Iron deficiency			
subjects affected / exposed	0 / 23 (0.00%)	0 / 8 (0.00%)	0 / 7 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Track 1: Nivolumab + BMS-986205	Track 1: Nivolumab + BMS-986016	Track 2: Ipilimumab + Rucaparib
Total subjects affected by non-serious adverse events			
subjects affected / exposed	38 / 38 (100.00%)	20 / 20 (100.00%)	2 / 2 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour haemorrhage			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Jugular vein thrombosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	2 / 38 (5.26%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Hypertension			
subjects affected / exposed	3 / 38 (7.89%)	1 / 20 (5.00%)	1 / 2 (50.00%)
occurrences (all)	3	1	1
Deep vein thrombosis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	4 / 38 (10.53%)	3 / 20 (15.00%)	0 / 2 (0.00%)
occurrences (all)	4	4	0

Chills			
subjects affected / exposed	2 / 38 (5.26%)	1 / 20 (5.00%)	1 / 2 (50.00%)
occurrences (all)	2	1	1
Early satiety			
subjects affected / exposed	2 / 38 (5.26%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Fatigue			
subjects affected / exposed	23 / 38 (60.53%)	11 / 20 (55.00%)	2 / 2 (100.00%)
occurrences (all)	24	11	2
General physical health deterioration			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	2 / 38 (5.26%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Malaise			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	3 / 38 (7.89%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	4	0	0
Pain			
subjects affected / exposed	2 / 38 (5.26%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Oedema peripheral			
subjects affected / exposed	3 / 38 (7.89%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Pyrexia			
subjects affected / exposed	8 / 38 (21.05%)	3 / 20 (15.00%)	0 / 2 (0.00%)
occurrences (all)	9	3	0
Reproductive system and breast disorders			

Oedema genital subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Ejaculation disorder subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	8 / 38 (21.05%) 9	4 / 20 (20.00%) 5	0 / 2 (0.00%) 0
Dyspnoea subjects affected / exposed occurrences (all)	7 / 38 (18.42%) 8	2 / 20 (10.00%) 2	0 / 2 (0.00%) 0
Dyspnoea exertional subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	1 / 20 (5.00%) 1	0 / 2 (0.00%) 0
Hiccups subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Nasal congestion subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	1 / 20 (5.00%) 1	0 / 2 (0.00%) 0
Oropharyngeal pain subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 3	1 / 20 (5.00%) 1	0 / 2 (0.00%) 0
Pleural effusion subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Pneumonitis subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	1 / 20 (5.00%) 1	0 / 2 (0.00%) 0
Upper-airway cough syndrome			

subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 3	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Productive cough subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Psychiatric disorders			
Anxiety subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	1 / 20 (5.00%) 1	0 / 2 (0.00%) 0
Confusional state subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Depression subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	3 / 38 (7.89%) 3	1 / 20 (5.00%) 1	1 / 2 (50.00%) 1
Panic attack subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Restlessness subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Suicidal ideation subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	7 / 38 (18.42%) 8	5 / 20 (25.00%) 7	1 / 2 (50.00%) 2
Amylase increased subjects affected / exposed occurrences (all)	4 / 38 (10.53%) 4	3 / 20 (15.00%) 5	1 / 2 (50.00%) 1
Aspartate aminotransferase increased			

subjects affected / exposed	8 / 38 (21.05%)	5 / 20 (25.00%)	1 / 2 (50.00%)
occurrences (all)	10	6	2
Blood alkaline phosphatase increased			
subjects affected / exposed	5 / 38 (13.16%)	3 / 20 (15.00%)	0 / 2 (0.00%)
occurrences (all)	6	3	0
Activated partial thromboplastin time prolonged			
subjects affected / exposed	2 / 38 (5.26%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Blood bilirubin increased			
subjects affected / exposed	3 / 38 (7.89%)	6 / 20 (30.00%)	0 / 2 (0.00%)
occurrences (all)	3	6	0
Blood creatine increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	3 / 38 (7.89%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	4	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 38 (5.26%)	2 / 20 (10.00%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
Blood urea increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			

subjects affected / exposed	2 / 38 (5.26%)	2 / 20 (10.00%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Lymph node palpable			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	3 / 38 (7.89%)	3 / 20 (15.00%)	0 / 2 (0.00%)
occurrences (all)	4	5	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 38 (2.63%)	1 / 20 (5.00%)	1 / 2 (50.00%)
occurrences (all)	1	1	1
Neutrophil count decreased			
subjects affected / exposed	0 / 38 (0.00%)	1 / 20 (5.00%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Platelet count decreased			
subjects affected / exposed	2 / 38 (5.26%)	2 / 20 (10.00%)	1 / 2 (50.00%)
occurrences (all)	2	2	1
White blood cell count decreased			
subjects affected / exposed	1 / 38 (2.63%)	2 / 20 (10.00%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Weight decreased			
subjects affected / exposed	4 / 38 (10.53%)	2 / 20 (10.00%)	0 / 2 (0.00%)
occurrences (all)	4	2	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Arthropod bite			

subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	1 / 20 (5.00%) 1	0 / 2 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Cardiac disorders Tachycardia subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	0 / 20 (0.00%) 0	1 / 2 (50.00%) 2
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Nervous system disorders Dizziness subjects affected / exposed occurrences (all)	5 / 38 (13.16%) 5	1 / 20 (5.00%) 1	0 / 2 (0.00%) 0
Disturbance in attention subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Polyneuropathy subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Peripheral sensory neuropathy subjects affected / exposed occurrences (all)	3 / 38 (7.89%) 3	1 / 20 (5.00%) 1	0 / 2 (0.00%) 0
Paraesthesia			

subjects affected / exposed	2 / 38 (5.26%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Headache			
subjects affected / exposed	6 / 38 (15.79%)	2 / 20 (10.00%)	0 / 2 (0.00%)
occurrences (all)	7	3	0
Dysgeusia			
subjects affected / exposed	0 / 38 (0.00%)	4 / 20 (20.00%)	1 / 2 (50.00%)
occurrences (all)	0	4	1
Tremor			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	12 / 38 (31.58%)	8 / 20 (40.00%)	0 / 2 (0.00%)
occurrences (all)	15	10	0
Neutropenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Leukocytosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Coagulopathy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Cerumen impaction			

subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Vision blurred			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	11 / 38 (28.95%)	7 / 20 (35.00%)	0 / 2 (0.00%)
occurrences (all)	14	8	0
Abdominal distension			
subjects affected / exposed	3 / 38 (7.89%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	3	0	0
Abdominal pain lower			
subjects affected / exposed	0 / 38 (0.00%)	3 / 20 (15.00%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Abdominal pain upper			
subjects affected / exposed	2 / 38 (5.26%)	4 / 20 (20.00%)	0 / 2 (0.00%)
occurrences (all)	2	5	0
Ascites			
subjects affected / exposed	2 / 38 (5.26%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Colitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	9 / 38 (23.68%)	5 / 20 (25.00%)	1 / 2 (50.00%)
occurrences (all)	9	6	1
Diarrhoea			
subjects affected / exposed	7 / 38 (18.42%)	5 / 20 (25.00%)	1 / 2 (50.00%)
occurrences (all)	14	5	1
Dry mouth			

subjects affected / exposed	2 / 38 (5.26%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Dyspepsia			
subjects affected / exposed	2 / 38 (5.26%)	2 / 20 (10.00%)	0 / 2 (0.00%)
occurrences (all)	2	2	0
Dysphagia			
subjects affected / exposed	8 / 38 (21.05%)	3 / 20 (15.00%)	0 / 2 (0.00%)
occurrences (all)	10	3	0
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 38 (5.26%)	4 / 20 (20.00%)	0 / 2 (0.00%)
occurrences (all)	2	4	0
Flatulence			
subjects affected / exposed	3 / 38 (7.89%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	3	1	0
Ileus			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Large intestinal obstruction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Jejunal stenosis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	17 / 38 (44.74%)	10 / 20 (50.00%)	0 / 2 (0.00%)
occurrences (all)	18	10	0
Oesophageal stenosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oesophageal pain			
subjects affected / exposed	1 / 38 (2.63%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Stomatitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			

subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	7 / 38 (18.42%)	5 / 20 (25.00%)	0 / 2 (0.00%)
occurrences (all)	10	5	0
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 38 (0.00%)	2 / 20 (10.00%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Night sweats			
subjects affected / exposed	2 / 38 (5.26%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Dry skin			
subjects affected / exposed	0 / 38 (0.00%)	3 / 20 (15.00%)	0 / 2 (0.00%)
occurrences (all)	0	3	0
Dermatitis acneiform			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	2 / 38 (5.26%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	2	1	0
Rash			
subjects affected / exposed	4 / 38 (10.53%)	2 / 20 (10.00%)	1 / 2 (50.00%)
occurrences (all)	4	3	1
Pruritus			
subjects affected / exposed	4 / 38 (10.53%)	1 / 20 (5.00%)	1 / 2 (50.00%)
occurrences (all)	4	1	1
Photosensitivity reaction			

subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Skin fissures subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Renal and urinary disorders Proteinuria subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 2	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	4 / 38 (10.53%) 5	3 / 20 (15.00%) 3	0 / 2 (0.00%) 0
Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 2	4 / 20 (20.00%) 4	0 / 2 (0.00%) 0
Arthritis subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	2 / 20 (10.00%) 2	0 / 2 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	3 / 38 (7.89%) 6	5 / 20 (25.00%) 5	0 / 2 (0.00%) 0
Chondrocalcinosis pyrophosphate subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Muscle spasms subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 2	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Muscular weakness			

subjects affected / exposed	2 / 38 (5.26%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	0 / 38 (0.00%)	1 / 20 (5.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	0 / 38 (0.00%)	2 / 20 (10.00%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Pain in extremity			
subjects affected / exposed	4 / 38 (10.53%)	2 / 20 (10.00%)	0 / 2 (0.00%)
occurrences (all)	6	2	0
Neck pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Lymph gland infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Genital herpes			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Clostridium difficile infection subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Cellulitis subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	1 / 2 (50.00%) 1
Urinary tract infection subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 2	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Sepsis subjects affected / exposed occurrences (all)	2 / 38 (5.26%) 2	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	1 / 20 (5.00%) 1	0 / 2 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	9 / 38 (23.68%) 9	10 / 20 (50.00%) 10	1 / 2 (50.00%) 1
Hyperkalaemia subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 2	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	4 / 38 (10.53%) 5	2 / 20 (10.00%) 4	0 / 2 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	3 / 38 (7.89%) 4	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Hypermagnesaemia subjects affected / exposed occurrences (all)	0 / 38 (0.00%) 0	0 / 20 (0.00%) 0	0 / 2 (0.00%) 0
Hypokalaemia subjects affected / exposed occurrences (all)	1 / 38 (2.63%) 1	3 / 20 (15.00%) 3	0 / 2 (0.00%) 0
Hypocalcaemia			

subjects affected / exposed	2 / 38 (5.26%)	2 / 20 (10.00%)	0 / 2 (0.00%)
occurrences (all)	2	3	0
Hypoalbuminaemia			
subjects affected / exposed	4 / 38 (10.53%)	5 / 20 (25.00%)	1 / 2 (50.00%)
occurrences (all)	4	5	1
Hypomagnesaemia			
subjects affected / exposed	3 / 38 (7.89%)	2 / 20 (10.00%)	1 / 2 (50.00%)
occurrences (all)	3	4	1
Hypophosphataemia			
subjects affected / exposed	1 / 38 (2.63%)	3 / 20 (15.00%)	1 / 2 (50.00%)
occurrences (all)	2	4	2
Hyponatraemia			
subjects affected / exposed	4 / 38 (10.53%)	5 / 20 (25.00%)	1 / 2 (50.00%)
occurrences (all)	5	5	1
Iron deficiency			
subjects affected / exposed	0 / 38 (0.00%)	0 / 20 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Track 2: Nivolumab + Rucaparib	Track 2: Nivolumab + BMS-986205	Track 2: Nivolumab + BMS-986016
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 6 (100.00%)	21 / 22 (95.45%)	34 / 36 (94.44%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Jugular vein thrombosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 6 (0.00%)	2 / 22 (9.09%)	2 / 36 (5.56%)
occurrences (all)	0	2	2
Hypertension			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Deep vein thrombosis			

subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Orthostatic hypotension			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Chills			
subjects affected / exposed	2 / 6 (33.33%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	2	0	0
Early satiety			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	5 / 6 (83.33%)	11 / 22 (50.00%)	22 / 36 (61.11%)
occurrences (all)	8	11	26
General physical health deterioration			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	2 / 36 (5.56%)
occurrences (all)	1	0	2
Mucosal inflammation			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	2	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 6 (0.00%)	2 / 22 (9.09%)	1 / 36 (2.78%)
occurrences (all)	0	2	1
Pain			

subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 22 (0.00%) 0	1 / 36 (2.78%) 1
Oedema peripheral subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	4 / 22 (18.18%) 4	5 / 36 (13.89%) 5
Pyrexia subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 2	2 / 22 (9.09%) 2	5 / 36 (13.89%) 5
Reproductive system and breast disorders Oedema genital subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Ejaculation disorder subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Respiratory, thoracic and mediastinal disorders Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	3 / 22 (13.64%) 3	7 / 36 (19.44%) 8
Dyspnoea subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 22 (4.55%) 1	6 / 36 (16.67%) 7
Dyspnoea exertional subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Hiccups subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Nasal congestion subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Oropharyngeal pain			

subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Pleural effusion			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Pneumonitis			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	3 / 36 (8.33%)
occurrences (all)	0	0	3
Productive cough			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 6 (16.67%)	2 / 22 (9.09%)	0 / 36 (0.00%)
occurrences (all)	1	2	0
Confusional state			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Depression			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	3 / 36 (8.33%)
occurrences (all)	0	1	3
Insomnia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Panic attack			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Suicidal ideation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0

Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	2 / 22 (9.09%)	3 / 36 (8.33%)
occurrences (all)	2	2	3
Amylase increased			
subjects affected / exposed	1 / 6 (16.67%)	3 / 22 (13.64%)	1 / 36 (2.78%)
occurrences (all)	1	4	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 6 (16.67%)	4 / 22 (18.18%)	3 / 36 (8.33%)
occurrences (all)	1	4	3
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 6 (0.00%)	4 / 22 (18.18%)	4 / 36 (11.11%)
occurrences (all)	0	4	5
Activated partial thromboplastin time prolonged			
subjects affected / exposed	0 / 6 (0.00%)	2 / 22 (9.09%)	2 / 36 (5.56%)
occurrences (all)	0	2	2
Blood bilirubin increased			
subjects affected / exposed	0 / 6 (0.00%)	3 / 22 (13.64%)	2 / 36 (5.56%)
occurrences (all)	0	4	3
Blood creatine increased			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Blood pressure increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	2
Blood urea increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			

subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 6 (0.00%)	2 / 22 (9.09%)	3 / 36 (8.33%)
occurrences (all)	0	2	3
Lymph node palpable			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Lipase increased			
subjects affected / exposed	0 / 6 (0.00%)	4 / 22 (18.18%)	1 / 36 (2.78%)
occurrences (all)	0	5	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 6 (0.00%)	3 / 22 (13.64%)	6 / 36 (16.67%)
occurrences (all)	0	4	8
Neutrophil count decreased			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Platelet count decreased			
subjects affected / exposed	0 / 6 (0.00%)	3 / 22 (13.64%)	2 / 36 (5.56%)
occurrences (all)	0	4	2
White blood cell count decreased			
subjects affected / exposed	0 / 6 (0.00%)	2 / 22 (9.09%)	4 / 36 (11.11%)
occurrences (all)	0	2	5
Weight decreased			

subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	2 / 22 (9.09%) 2	2 / 36 (5.56%) 2
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Arthropod bite			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Fall			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Palpitations			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Atrial fibrillation			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 6 (0.00%)	4 / 22 (18.18%)	9 / 36 (25.00%)
occurrences (all)	0	4	9
Disturbance in attention			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			

subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	3 / 36 (8.33%)
occurrences (all)	0	0	3
Paraesthesia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Headache			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	5 / 36 (13.89%)
occurrences (all)	0	1	6
Dysgeusia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Tremor			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Restless legs syndrome			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 6 (16.67%)	7 / 22 (31.82%)	11 / 36 (30.56%)
occurrences (all)	1	8	12
Neutropenia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	2 / 36 (5.56%)
occurrences (all)	2	0	2
Lymphopenia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	1 / 6 (16.67%)	1 / 22 (4.55%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Leukocytosis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0

Coagulopathy subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Ear and labyrinth disorders Cerumen impaction subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 22 (4.55%) 1	2 / 36 (5.56%) 2
Eye disorders Vision blurred subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 22 (0.00%) 0	1 / 36 (2.78%) 1
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	3 / 6 (50.00%) 3	1 / 22 (4.55%) 1	6 / 36 (16.67%) 6
Abdominal distension subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 22 (4.55%) 1	1 / 36 (2.78%) 2
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	3 / 22 (13.64%) 3	2 / 36 (5.56%) 2
Ascites subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 22 (0.00%) 0	2 / 36 (5.56%) 2
Colitis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Constipation subjects affected / exposed occurrences (all)	2 / 6 (33.33%) 2	4 / 22 (18.18%) 4	6 / 36 (16.67%) 6
Diarrhoea			

subjects affected / exposed	2 / 6 (33.33%)	3 / 22 (13.64%)	7 / 36 (19.44%)
occurrences (all)	2	3	9
Dry mouth			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Dyspepsia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	5 / 36 (13.89%)
occurrences (all)	0	1	5
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 6 (0.00%)	2 / 22 (9.09%)	1 / 36 (2.78%)
occurrences (all)	0	2	1
Flatulence			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	1 / 36 (2.78%)
occurrences (all)	0	1	2
Ileus			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Large intestinal obstruction			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Jejunal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	4 / 6 (66.67%)	6 / 22 (27.27%)	9 / 36 (25.00%)
occurrences (all)	5	6	10
Oesophageal stenosis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Oesophageal pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Stomatitis			

subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Rectal haemorrhage			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 6 (33.33%)	1 / 22 (4.55%)	7 / 36 (19.44%)
occurrences (all)	2	1	7
Hepatobiliary disorders			
Autoimmune hepatitis			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Dry skin			
subjects affected / exposed	1 / 6 (16.67%)	1 / 22 (4.55%)	5 / 36 (13.89%)
occurrences (all)	1	1	5
Dermatitis acneiform			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Rash papular			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	2 / 6 (33.33%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences (all)	2	0	1
Pruritus			

subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	2 / 22 (9.09%) 4	4 / 36 (11.11%) 5
Photosensitivity reaction subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Skin fissures subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Renal and urinary disorders Proteinuria subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 22 (4.55%) 1	1 / 36 (2.78%) 1
Dysuria subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	1 / 22 (4.55%) 1	0 / 36 (0.00%) 0
Hyperthyroidism subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	2 / 22 (9.09%) 2	3 / 36 (8.33%) 5
Arthritis subjects affected / exposed occurrences (all)	0 / 6 (0.00%) 0	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	3 / 6 (50.00%) 3	3 / 22 (13.64%) 3	3 / 36 (8.33%) 3
Chondrocalcinosis pyrophosphate subjects affected / exposed occurrences (all)	1 / 6 (16.67%) 1	0 / 22 (0.00%) 0	0 / 36 (0.00%) 0
Muscle spasms			

subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	2 / 36 (5.56%)
occurrences (all)	0	1	2
Muscular weakness			
subjects affected / exposed	1 / 6 (16.67%)	1 / 22 (4.55%)	1 / 36 (2.78%)
occurrences (all)	1	1	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Musculoskeletal pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	2 / 36 (5.56%)
occurrences (all)	1	0	2
Pain in extremity			
subjects affected / exposed	1 / 6 (16.67%)	1 / 22 (4.55%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Neck pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	3 / 36 (8.33%)
occurrences (all)	0	0	3
Sacral pain			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	1 / 6 (16.67%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Lymph gland infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0

Genital herpes			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Clostridium difficile infection			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Cellulitis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Sepsis			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 6 (33.33%)	8 / 22 (36.36%)	14 / 36 (38.89%)
occurrences (all)	3	8	16
Hyperkalaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Hyperglycaemia			
subjects affected / exposed	0 / 6 (0.00%)	4 / 22 (18.18%)	7 / 36 (19.44%)
occurrences (all)	0	9	13
Dehydration			
subjects affected / exposed	1 / 6 (16.67%)	3 / 22 (13.64%)	2 / 36 (5.56%)
occurrences (all)	1	3	2
Hypermagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Hypokalaemia			

subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Hypocalcaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	4 / 36 (11.11%)
occurrences (all)	0	2	4
Hypoalbuminaemia			
subjects affected / exposed	0 / 6 (0.00%)	3 / 22 (13.64%)	5 / 36 (13.89%)
occurrences (all)	0	4	6
Hypomagnesaemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	4 / 36 (11.11%)
occurrences (all)	0	1	5
Hypophosphataemia			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Hyponatraemia			
subjects affected / exposed	0 / 6 (0.00%)	1 / 22 (4.55%)	4 / 36 (11.11%)
occurrences (all)	0	1	7
Iron deficiency			
subjects affected / exposed	0 / 6 (0.00%)	0 / 22 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2

Non-serious adverse events	Track 2: Nivolumab + Ipilimumab	Track 2: Nivolumab + Ipilimumab + Rucaparib	Track 1: Nivolumab + Ipilimumab + Rucaparib
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 23 (100.00%)	4 / 4 (100.00%)	6 / 6 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour haemorrhage			
subjects affected / exposed	0 / 23 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Jugular vein thrombosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	2 / 23 (8.70%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Hypertension			

subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Deep vein thrombosis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Orthostatic hypotension			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Chills			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Early satiety			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	10 / 23 (43.48%)	2 / 4 (50.00%)	2 / 6 (33.33%)
occurrences (all)	11	2	2
General physical health deterioration			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Non-cardiac chest pain			

subjects affected / exposed occurrences (all)	3 / 23 (13.04%) 4	1 / 4 (25.00%) 1	0 / 6 (0.00%) 0
Pain subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Oedema peripheral subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	1 / 4 (25.00%) 1	1 / 6 (16.67%) 1
Pyrexia subjects affected / exposed occurrences (all)	4 / 23 (17.39%) 4	1 / 4 (25.00%) 1	0 / 6 (0.00%) 0
Reproductive system and breast disorders Oedema genital subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Ejaculation disorder subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Respiratory, thoracic and mediastinal disorders Chronic obstructive pulmonary disease subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Cough subjects affected / exposed occurrences (all)	4 / 23 (17.39%) 4	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Dyspnoea subjects affected / exposed occurrences (all)	5 / 23 (21.74%) 5	1 / 4 (25.00%) 1	0 / 6 (0.00%) 0
Dyspnoea exertional subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Hiccups subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Nasal congestion			

subjects affected / exposed	2 / 23 (8.70%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	2	1	0
Oropharyngeal pain			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Pleural effusion			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Pneumonitis			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Upper-airway cough syndrome			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 23 (8.70%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Confusional state			
subjects affected / exposed	3 / 23 (13.04%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Depression			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	3 / 23 (13.04%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Panic attack			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Restlessness			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1

Suicidal ideation subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	5 / 23 (21.74%) 5	0 / 4 (0.00%) 0	4 / 6 (66.67%) 4
Amylase increased subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	5 / 23 (21.74%) 6	1 / 4 (25.00%) 1	4 / 6 (66.67%) 4
Blood alkaline phosphatase increased subjects affected / exposed occurrences (all)	6 / 23 (26.09%) 6	0 / 4 (0.00%) 0	2 / 6 (33.33%) 2
Activated partial thromboplastin time prolonged subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Blood bilirubin increased subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 3	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Blood creatine increased subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	1 / 4 (25.00%) 1	0 / 6 (0.00%) 0
Blood pressure increased subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Blood creatinine increased subjects affected / exposed occurrences (all)	3 / 23 (13.04%) 3	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Blood urea increased			

subjects affected / exposed	0 / 23 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
C-reactive protein increased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Glomerular filtration rate decreased			
subjects affected / exposed	0 / 23 (0.00%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
International normalised ratio increased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymph node palpable			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	2 / 23 (8.70%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Neutrophil count decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	2
White blood cell count decreased			

subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Weight decreased subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	1 / 4 (25.00%) 1	0 / 6 (0.00%) 0
Injury, poisoning and procedural complications			
Contusion subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Arthropod bite subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Fall subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Cardiac disorders			
Tachycardia subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Sinus tachycardia subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Palpitations subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Atrial fibrillation subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Nervous system disorders			
Dizziness subjects affected / exposed occurrences (all)	5 / 23 (21.74%) 6	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Disturbance in attention			

subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Polyneuropathy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	2 / 6 (33.33%)
occurrences (all)	1	0	2
Dysgeusia			
subjects affected / exposed	1 / 23 (4.35%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Tremor			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Restless legs syndrome			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	7 / 23 (30.43%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	9	1	2
Neutropenia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Leukocytosis subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Coagulopathy subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Ear and labyrinth disorders Cerumen impaction subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Eye disorders Vision blurred subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Gastrointestinal disorders Abdominal pain subjects affected / exposed occurrences (all)	7 / 23 (30.43%) 7	2 / 4 (50.00%) 2	2 / 6 (33.33%) 2
Abdominal distension subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Abdominal pain lower subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 4 (0.00%) 0	2 / 6 (33.33%) 2
Ascites subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Colitis subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Constipation			

subjects affected / exposed	7 / 23 (30.43%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	7	1	2
Diarrhoea			
subjects affected / exposed	7 / 23 (30.43%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	9	1	6
Dry mouth			
subjects affected / exposed	2 / 23 (8.70%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	2	0	1
Dyspepsia			
subjects affected / exposed	3 / 23 (13.04%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Dysphagia			
subjects affected / exposed	4 / 23 (17.39%)	1 / 4 (25.00%)	2 / 6 (33.33%)
occurrences (all)	4	1	2
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Ileus			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Large intestinal obstruction			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Jejunal stenosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	10 / 23 (43.48%)	2 / 4 (50.00%)	2 / 6 (33.33%)
occurrences (all)	11	2	2
Oesophageal stenosis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Oesophageal pain			

subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Stomatitis subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Rectal haemorrhage subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Vomiting subjects affected / exposed occurrences (all)	7 / 23 (30.43%) 7	2 / 4 (50.00%) 2	2 / 6 (33.33%) 2
Hepatobiliary disorders Autoimmune hepatitis subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Skin and subcutaneous tissue disorders Alopecia subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Night sweats subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Dry skin subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	1 / 4 (25.00%) 1	1 / 6 (16.67%) 1
Dermatitis acneiform subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Rash papular subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Rash maculo-papular subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Rash			

subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Pruritus subjects affected / exposed occurrences (all)	6 / 23 (26.09%) 6	1 / 4 (25.00%) 1	2 / 6 (33.33%) 3
Photosensitivity reaction subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Skin fissures subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Renal and urinary disorders Proteinuria subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Dysuria subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Endocrine disorders Hypothyroidism subjects affected / exposed occurrences (all)	3 / 23 (13.04%) 3	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Hyperthyroidism subjects affected / exposed occurrences (all)	2 / 23 (8.70%) 2	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Musculoskeletal and connective tissue disorders Arthralgia subjects affected / exposed occurrences (all)	5 / 23 (21.74%) 6	1 / 4 (25.00%) 1	1 / 6 (16.67%) 1
Arthritis subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Back pain subjects affected / exposed occurrences (all)	3 / 23 (13.04%) 3	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Chondrocalcinosis pyrophosphate			

subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Muscular weakness			
subjects affected / exposed	1 / 23 (4.35%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	1 / 23 (4.35%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	1 / 23 (4.35%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Pain in extremity			
subjects affected / exposed	2 / 23 (8.70%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	2	0	0
Neck pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Sacral pain			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Lymph gland infection subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	1 / 4 (25.00%) 1	0 / 6 (0.00%) 0
Genital herpes subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Clostridium difficile infection subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Cellulitis subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Urinary tract infection subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Sepsis subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Metabolism and nutrition disorders			
Decreased appetite subjects affected / exposed occurrences (all)	7 / 23 (30.43%) 7	2 / 4 (50.00%) 2	0 / 6 (0.00%) 0
Hyperkalaemia subjects affected / exposed occurrences (all)	0 / 23 (0.00%) 0	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Hyperglycaemia subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 1	0 / 4 (0.00%) 0	0 / 6 (0.00%) 0
Dehydration subjects affected / exposed occurrences (all)	1 / 23 (4.35%) 2	0 / 4 (0.00%) 0	1 / 6 (16.67%) 1
Hypermagnesaemia			

subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	2 / 23 (8.70%)	1 / 4 (25.00%)	1 / 6 (16.67%)
occurrences (all)	3	1	1
Hypocalcaemia			
subjects affected / exposed	2 / 23 (8.70%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	4	0	0
Hypoalbuminaemia			
subjects affected / exposed	3 / 23 (13.04%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 23 (4.35%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	1	2	0
Hypophosphataemia			
subjects affected / exposed	3 / 23 (13.04%)	1 / 4 (25.00%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Hyponatraemia			
subjects affected / exposed	3 / 23 (13.04%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	3	0	0
Iron deficiency			
subjects affected / exposed	0 / 23 (0.00%)	0 / 4 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 December 2017	Revised to allow participants to continue on study treatment for up to 2 years, and re-treatment is not permitted.
05 February 2019	The FRACTION-Gastric Master Protocol was revised to expand indication to esophageal cancer based on the results of CheckMate-032 clinical study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported