Clinical trial results:
A Randomized, Open-label, Phase II Clinical Trial of Relatlimab (anti-LAG-3) and Nivolumab in Combination with Chemotherapy Versus Nivolumab in Combination with Chemotherapy as First-Line Treatment in Patients with Gastric or Gastroesophageal Junction Adenocarcinoma

Summary

EudraCT number	2018-001069-18
Trial protocol	CZ DE GB ES NO BE PL AT IT
Global end of trial date	18 January 2024

Results information

Result version number	v1 (current)
This version publication date	31 January 2025
First version publication date	31 January 2025

Trial information

Trial identification

Sponsor protocol code	CA224-060

Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	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	28 February 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 January 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the efficacy of treatment with BMS-986213 (fixed-dose combination [FDC] relatlimab/nivolumab) plus investigator's choice chemotherapy compared with nivolumab in combination with investigator's choice chemotherapy in participants with previously untreated, unresectable, and either locally advanced or metastatic gastric cancer (GC) or GEJ adenocarcinoma in the LAG-3 positive population.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 October 2018
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	Austria: 2
Country: Number of subjects enrolled	Belgium: 10
Country: Number of subjects enrolled	Czechia: 12
Country: Number of subjects enrolled	France: 13
Country: Number of subjects enrolled	Germany: 39
Country: Number of subjects enrolled	Italy: 5
Country: Number of subjects enrolled	Norway: 11
Country: Number of subjects enrolled	Poland: 4
Country: Number of subjects enrolled	Spain: 25
Country: Number of subjects enrolled	United Kingdom: 27
Country: Number of subjects enrolled	Canada: 14
Country: Number of subjects enrolled	United States: 30
Country: Number of subjects enrolled	Argentina: 20
Country: Number of subjects enrolled	Australia: 46
Country: Number of subjects enrolled	Chile: 9
Country: Number of subjects enrolled	Puerto Rico: 2
Country: Number of subjects enrolled	Singapore: 5

Worldwide total number of subjects	274
EEA total number of subjects	121

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)	161
From 65 to 84 years	113
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

274 participants randomized and 271 treated.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	BMS986213 + Chemotherapy

Arm description:

BMS986213 Q3W + Investigator Choice (IC) Chemotherapy

Arm type	Experimental
Investigational medicinal product name	BMS986213
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Relatlimab 120 mg every 3 weeks

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

Dosage and administration details:

Oxaliplatin 130mg/m^2 Day 1 of each cycle

Investigational medicinal product name	Xelox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Capecitabine 1000mg/m^2 twice daily Day 1 - Day 14 of each cycle

Investigational medicinal product name	BMS986213
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Nivolumab 360 mg every 3 weeks

Investigational medicinal product name	Folfox
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Oxaliplatin 85mg/m^2 Day 1

Investigational medicinal product name	Folfox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Leucovorin 400 mg/m^2 Day 1

Investigational medicinal product name	Folfox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

fluorouracil 400 mg/m^2 Day 1

Investigational medicinal product name	Folfox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

fluorouracil 400 mg/m^2 continuous infusion for over 24 hours daily Day 1 and 2 of each cycle, every 2 weeks.

Investigational medicinal product name	Sox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oxaliplatin 130mg/m^2 twice daily Day 1 to 14 of each cycle, every 3 weeks

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

Dosage and administration details:

Oxaliplatin 130 mg/m^2 Day 1

Arm title	Nivolumab + Chemotherapy

Arm description:

Nivolumab Q3W + Investigator Choice (IC) Chemotherapy

Arm type	Active comparator
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

360 mg every 3 weeks

Investigational medicinal product name	Xelox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Capecitabine 1000mg/m^2 twice daily Day 1 - Day 14 of each cycle

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

Dosage and administration details:

Oxaliplatin 130mg/m^2 Day 1 of each cycle

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

Dosage and administration details:

480 mg every 4 weeks

Investigational medicinal product name	Sox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oxaliplatin 130mg/m^2 twice daily Day 1 to 14 of each cycle, every 3 weeks

Investigational medicinal product name	Folfox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

fluorouracil 400 mg/m^2 continuous infusion for over 24 hours daily Day 1 and 2 of each cycle, every 2 weeks.

Investigational medicinal product name	Folfox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

fluorouracil 400 mg/m^2 Day 1

Investigational medicinal product name	Folfox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Leucovorin 400 mg/m^2 Day 1

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

Dosage and administration details:

Oxaliplatin 130 mg/m^2 Day 1

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

Dosage and administration details:

Oxaliplatin 85mg/m^2 Day 1

Number of subjects in period 1	BMS986213 + Chemotherapy	Nivolumab + Chemotherapy
Started	138	136
Completed	136	135
Not completed	2	1
Other reasons	1	-
Participant no longer met study criteria	1	1

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	BMS986213 + Chemotherapy

Arm description:

BMS986213 Q3W + Investigator Choice (IC) Chemotherapy XELOX Q3W or BMS986213 Q4W + IC Chemotherapy FOLFOX Q2W or BMS986213 Q3W + IC Chemotherapy SOX Q3W

Arm type	Experimental
Investigational medicinal product name	BMS986213
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Relatlimab 120 mg every 3 weeks

Investigational medicinal product name	BMS986213
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: Nivolumab 360 mg every 3 weeks	
Investigational medicinal product name	Xelox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Oxaliplatin 130mg/m^2 Day 1 of each cycle	
Investigational medicinal product name	Xelox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Capecitabine 1000mg/m^2 twice daily Day 1 - Day 14 of each cycle	
Investigational medicinal product name	Folfox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details: Oxaliplatin 85mg/m^2 Day 1	
Investigational medicinal product name	Folfox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: fluorouracil 400 mg/m^2 Day 1	
Investigational medicinal product name	Folfox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details: Leucovorin 400 mg/m^2 Day 1	
Investigational medicinal product name	Sox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use
Dosage and administration details: Oxaliplatin 130mg/m^2 twice daily Day 1 to 14 of each cycle, every 3 weeks	
Investigational medicinal product name	Folfox
Investigational medicinal product code	
Other name	

Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

fluorouracil 400 mg/m^2 continuous infusion for over 24 hours daily Day 1 and 2 of each cycle, every 2 weeks.

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

Dosage and administration details:

Oxaliplatin 130 mg/m^2 Day 1

Arm title	Nivolumab + Chemotherapy

Arm description:

Nivolumab 360 mg Q3W + Investigator Choice (IC) Chemotherapy XELOX Q3W or Nivolumab 480 mg Q4W + IC Chemotherapy FOLFOX Q2W or Nivolumab 360 mg Q3W + IC Chemotherapy SOX Q3W

Arm type	Active comparator
Investigational medicinal product name	Nivolumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

360 mg every 3 weeks

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

Dosage and administration details:

480 mg every 4 weeks

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

Dosage and administration details:

Oxaliplatin 130mg/m^2 Day 1 of each cycle

Investigational medicinal product name	Xelox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Capecitabine 1000mg/m^2 twice daily Day 1 - Day 14 of each cycle

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

Dosage and administration details:

Oxaliplatin 130 mg/m^2 Day 1

Investigational medicinal product name	Folfox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Leucovorin 400 mg/m^2 Day 1

Investigational medicinal product name	Folfox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

fluorouracil 400 mg/m^2 Day 1

Investigational medicinal product name	Folfox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

fluorouracil 400 mg/m^2 continuous infusion for over 24 hours daily Day 1 and 2 of each cycle, every 2 weeks.

Investigational medicinal product name	Sox
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Oxaliplatin 130mg/m^2 twice daily Day 1 to 14 of each cycle, every 3 weeks

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

Dosage and administration details:

Oxaliplatin 85mg/m^2 Day 1

Number of subjects in period 2	BMS986213 + Chemotherapy	Nivolumab + Chemotherapy
Started	136	135
Completed	0	1
Not completed	136	134
Adverse event, serious fatal	11	9
Consent withdrawn by subject	1	1
Completed Treatment	-	2
Participant no longer meets study criteria	1	-
Adverse Event unrelated to Study Drug	7	6

maximum clinical benefit	-	2
Poor/Non-compliance	1	-
Other reasons	10	8
Study Drug Toxicity	19	9
Administrative reasons by sponsor	1	-
Disease Progression	85	97

Baseline characteristics

Reporting groups	
Reporting group title	BMS986213 + Chemotherapy
Reporting group description: BMS986213 Q3W + Investigator Choice (IC) Chemotherapy	
Reporting group title	Nivolumab + Chemotherapy
Reporting group description: Nivolumab Q3W + Investigator Choice (IC) Chemotherapy	

Reporting group values	BMS986213 + Chemotherapy	Nivolumab + Chemotherapy	Total
Number of subjects	138	136	274
Age categorical Units:			
Age Continuous Units: years			
arithmetic mean	59.4	61.8	
standard deviation	± 12.1	± 11.3	-
Sex: Female, Male Units: Participants			
Female	44	38	82
Male	94	98	192
Race/Ethnicity, Customized Units: Subjects			
White	128	122	250
Black or African American	0	1	1
Asian	5	3	8
Asian Indian	1	1	2
Chinese	0	5	5
American Indian or Alaska Native	1	0	1
Native Hawaiian or Other Pacific Islander	1	0	1
Other	2	4	6
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	17	10	27
Not Hispanic or Latino	73	80	153
Unknown or Not Reported	48	46	94

End points

End points reporting groups

Reporting group title	BMS986213 + Chemotherapy
Reporting group description: BMS986213 Q3W + Investigator Choice (IC) Chemotherapy	
Reporting group title	Nivolumab + Chemotherapy
Reporting group description: Nivolumab Q3W + Investigator Choice (IC) Chemotherapy	
Reporting group title	BMS986213 + Chemotherapy
Reporting group description: BMS986213 Q3W + Investigator Choice (IC) Chemotherapy XELOX Q3W or BMS986213 Q4W + IC Chemotherapy FOLFOX Q2W or BMS986213 Q3W + IC Chemotherapy SOX Q3W	
Reporting group title	Nivolumab + Chemotherapy
Reporting group description: Nivolumab 360 mg Q3W + Investigator Choice (IC) Chemotherapy XELOX Q3W or Nivolumab 480 mg Q4W + IC Chemotherapy FOLFOX Q2W or Nivolumab 360 mg Q3W + IC Chemotherapy SOX Q3W	

Primary: BICR-Assessed Objective Response Rate (ORR) in Randomized LAG-3 Positive (>=1 %) Participants

End point title	BICR-Assessed Objective Response Rate (ORR) in Randomized LAG-3 Positive (>=1 %) Participants[1]
End point description: The number of LAG-3 Positive (>=1%) participants with a Best Overall Response (BOR) of confirmed Complete Response (CR) or Partial Response (PR) divided by the number of randomized LAG-3 positive (>=1%) participants in each arm; recorded between randomization date and the date of objectively documented progression [per RECISIT 1.1], death due to any cause, or date of subsequent anticancer therapy, whichever occurs first. CR= Disappearance of all target lesions PR= At least a 30% decrease in the sum of diameters of target lesions	
End point type	Primary
End point timeframe: Up to 25 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 table planned for this endpoint

End point values	BMS986213 + Chemotherapy	Nivolumab + Chemotherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	97	98		
Units: Percentage of Participants				
number (confidence interval 95%)	48.5 (38.2 to 58.8)	61.2 (50.8 to 70.9)		

Statistical analyses

No statistical analyses for this end point

Primary: BICR-Assessed Objective Response Rate (ORR) in Randomized LAG-3 Positive (>=1 %) Participants - Extended Collection

End point title	BICR-Assessed Objective Response Rate (ORR) in Randomized LAG-3 Positive (>=1 %) Participants - Extended Collection[2]

End point description:

The number of LAG-3 Positive (>=1%) participants with a Best Overall Response (BOR) of confirmed Complete Response (CR) or Partial Response (PR) divided by the number of randomized LAG-3 positive (>=1%) participants in each arm; recorded between randomization date and the date of objectively documented progression [per RECISIT 1.1], death due to any cause, or date of subsequent anticancer therapy, whichever occurs first.
CR= Disappearance of all target lesions
PR= At least a 30% decrease in the sum of diameters of target lesions

End point type	Primary

End point timeframe:

From randomization date to the date of objectively documented progression, death due to any cause, or date of subsequent anticancer therapy, whichever occurs first (Up to 63 months)

Notes:

[2] - 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 table planned for this endpoint

End point values	BMS986213 + Chemotherapy	Nivolumab + Chemotherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	97	98		
Units: Percentage of Participants				
number (confidence interval 95%)	27.8 (19.2 to 37.9)	43.9 (33.9 to 54.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR)

End point description:

Objective response rate (ORR) based on Blinded Independent Central Review (BICR) and Investigator assessments is defined as the number of participants with a Best Overall Response (BOR) of confirmed Complete Response (CR) or Partial Response (PR) divided by the number of randomized participants in each arm; recorded between randomization date and the date of objectively documented progression [per RECISIT 1.1], death due to any cause, or date of subsequent anticancer therapy, whichever occurs first.
CR= Disappearance of all target lesions
PR= At least a 30% decrease in the sum of diameters of target lesions

End point type	Secondary

End point timeframe:

From randomization date to the date of objectively documented progression, death due to any cause, or date of subsequent anticancer therapy, whichever occurs first (Up to 63 months)

End point values	BMS986213 + Chemotherapy	Nivolumab + Chemotherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	138	136		
Units: Percentage of participants				
number (confidence interval 95%)				
BICR-assessed with LAG-3 expression <1%	26.8 (14.2 to 42.9)	36.8 (21.8 to 54.0)		
BICR-assessed Overall	27.5 (20.3 to 35.8)	41.9 (33.5 to 50.7)		
Investigator-assessed with LAG-3 expression >=1%	53.6 (43.2 to 63.8)	54.1 (43.7 to 64.2)		
Investigator-assessed with LAG-3 expression <1%	36.6 (22.1 to 53.1)	42.1 (26.3 to 59.2)		
Investigator-assessed Overall	48.6 (40.0 to 57.2)	50.7 (42.0 to 59.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR)

End point description:

Duration of Response (DOR) based on Blinded Independent Central Review (BICR) and investigator is defined as the time between the date of first documented complete response (CR) or partial response (PR) and the date of the first disease progression, per RECIST 1.1, or death due to any cause, or date of subsequent anticancer therapy, whichever occurs first.
CR= Disappearance of all target lesions
PR= At least a 30% decrease in the sum of diameters of target lesions

End point type	Secondary

End point timeframe:

From the date of first dose to the date of the first disease progression or death due to any cause, or date of subsequent anticancer therapy, whichever occurs first (Up to 63 months)

End point values	BMS986213 + Chemotherapy	Nivolumab + Chemotherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	67	69		
Units: Months				
median (confidence interval 95%)				
BICR-assessed with LAG-3 expression >=1%	7.72 (4.37 to 9.95)	10.78 (5.85 to 20.67)		
BICR-assessed with LAG-3 expression <1%	5.44 (3.06 to 7.00)	5.55 (3.48 to 9.95)		
BICR-assessed Overall	5.68 (5.32 to 9.63)	6.93 (5.55 to 12.25)		
Investigator-assessed with LAG-3 expression >=1%	6.21 (4.47 to 7.82)	10.28 (7.06 to 15.61)		
Investigator-assessed with LAG-3 expression <1%	5.54 (3.02 to 7.43)	8.31 (6.28 to 14.13)		

Investigator-assessed Overall	5.88 (4.47 to 6.93)	9.92 (7.13 to 13.60)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

Overall Survival (OS) is defined as the time between the date of randomization and the date of death due to any cause. For those without documentation of death, OS will be censored on the last date the participant was known to be alive.

End point type	Secondary

End point timeframe:

From the date of randomization to the date of death due to any cause (Up to 63 months)

End point values	BMS986213 + Chemotherapy	Nivolumab + Chemotherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	138	136		
Units: Months				
median (confidence interval 95%)				
LAG-3 Expression >=1%	14.19 (11.89 to 18.56)	14.98 (10.02 to 21.98)		
LAG-3 Expression <1%	9.72 (6.64 to 12.75)	15.51 (11.43 to 17.61)		
Overall	12.65 (10.91 to 14.49)	15.15 (11.50 to 17.61)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS)

End point title	Progression-Free Survival (PFS)

End point description:

Progression-Free Survival (PFS) per Blinded Independent Central Review (BICR) and Investigator is defined as the time between the date of randomization and the first date of documented progression, or death due to any cause, or date of subsequent anticancer therapy, whichever occurs first. Participants who die without a reported prior progression (and die without start of subsequent therapy) will be considered to have progressed on the date of death.
Progression=At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study and the sum must also demonstrate an absolute increase of at least 5 mm.

End point type	Secondary

End point timeframe:

From the date of randomization to the first date of documented progression, or death due to any cause, or date of subsequent anticancer therapy, whichever occurs first (Up to 63 months)

End point values	BMS986213 + Chemotherapy	Nivolumab + Chemotherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	138	136		
Units: Months				
median (confidence interval 95%)				
BICR-assessed LAG-3 Expression >=1%	7.26 (6.64 to 11.07)	10.84 (7.43 to 15.70)		
BICR-assessed LAG-3 Expression <1%	6.80 (5.98 to 8.80)	10.45 (6.11 to 13.70)		
BICR-assessed Overall	7.13 (6.74 to 9.82)	10.45 (7.13 to 12.65)		
Investigator-assessed LAG-3 Expression >=1%	6.97 (5.78 to 8.34)	8.31 (5.88 to 9.72)		
Investigator-assessed LAG-3 Expression <1%	5.39 (4.37 to 7.98)	9.69 (6.87 to 13.70)		
Investigator-assessed Overall	6.64 (5.52 to 7.62)	8.31 (6.90 to 11.04)		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of Participants with Adverse Events (AEs) and Serious Adverse Events (SAEs)

End point description:

Number of participants with any grade adverse events (AEs), serious adverse events (SAE), and adverse events leading to discontinuation using National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE v 5.0). An 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. SAE is defined as any untoward medical occurrence that, at any dose results in death, is life threatening, requires inpatient hospitalization, results in significant disability, is a birth defect, or is an important medical event.

End point type	Secondary

End point timeframe:

From first dose to 30 days post last dose (Up to 60 months)

End point values	BMS986213 + Chemotherapy	Nivolumab + Chemotherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	136	135		
Units: Participants				
Adverse Events (AEs)	135	135		
Serious Adverse Events (SAEs)	99	87		
Adverse Events leading to discontinuation	76	56		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of Participants with Laboratory Abnormalities in Specific Liver Tests

End point description:

Number of participants with laboratory abnormalities in specific liver tests based on US conventional units. The number of participants with the following laboratory abnormalities from on-treatment evaluations will be summarized:
- ALT or AST > 3 x ULN, > 5 x ULN, > 10 x ULN and > 20 x ULN
- Total bilirubin > 2 x ULN
- ALP > 1.5 x ULN
- Concurrent (within 1 day) ALT or AST > 3 x ULN and total bilirubin > 1.5 x ULN
- Concurrent (within 30 days) ALT or AST > 3 x ULN and total bilirubin > 1.5 x ULN
- Concurrent (within 1 day) ALT or AST > 3 x ULN and total bilirubin > 2 x ULN
- Concurrent (within 30 days) ALT or AST > 3 x ULN and total bilirubin > 2 x ULN

End point type	Secondary

End point timeframe:

From first dose to 30 days post last dose (Up to 60 months)

End point values	BMS986213 + Chemotherapy	Nivolumab + Chemotherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	129	134		
Units: Participants				
ALT or AST > 3xULN	31	14		
ALT or AST > 5xULN	12	5		
ALT or AST > 10xULN	4	1		
ALT or AST > 20xULN	2	0		
TOTAL BILIRUBIN > 2xULN	6	3		
ALP > 1.5xULN	50	56		
ALT/AST>3xULN BILIRUBIN>1.5xULN w/n 1 DAY	5	2		
ALT/AST>3xULN WITH BILIRUBIN>1.5xULN w/n 30 DAYS	5	2		
ALT/AST>3xULN WITH BILIRUBIN>2xULN w/n 1 DAY	4	2		
ALT/AST>3xULN WITH BILIRUBIN>2xULN w/n 30 DAYS	4	2		

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:

Number of participants who died in each arm.

End point type	Secondary

End point timeframe:

Up to 63 months

End point values	BMS986213 + Chemotherapy	Nivolumab + Chemotherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	136	135		
Units: Participants	122	118		

Statistical analyses

No statistical analyses for this end point

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

End point title	Number of Participants with Laboratory Abnormalities in Specific Thyroid Tests

End point description:

Number of participants with laboratory abnormalities in specific thyroid tests based on US conventional units. The number of participants with the following laboratory abnormalities from on-treatment evaluations will be summarized:
- TSH value > ULN and
  - with baseline TSH value <= ULN
  - with at least one FT3/FT4 test value < LLN within 2-week window after the abnormal TSH test
  - with all FT3/FT4 test values >= LLN within 2-week window after the abnormal TSH test
  - with FT3/FT4 missing within 2-week window after the abnormal TSH test.
- TSH < LLN and
  - with baseline TSH value >= LLN
  - with at least one FT3/FT4 test value > ULN within 2-week window after the abnormal TSH test
  - with all FT3/FT4 test values <= ULN within 2-week window after the abnormal TSH test
  - with FT3/FT4 missing within 2-week window after the abnormal TSH test

End point type	Secondary

End point timeframe:

From first dose to 30 days post last dose (Up to 60 months)

End point values	BMS986213 + Chemotherapy	Nivolumab + Chemotherapy		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	129	133		
Units: Participants				
TSH > ULN	39	43		
TSH > ULN WITH TSH <= ULN AT BASELINE	35	33		
TSH>ULN WITH AT LEAST 1 FT3/FT4<LLN	24	20		
TSH>ULN WITH ALL OTHER FT3/FT4>= LLN	15	19		
TSH>ULN WITH FT3/FT4 TEST MISSING	18	24		
TSH < LLN	42	26		
TSH < LLN WITH TSH >= LLN AT BASELINE	40	22		
TSH<LLN WITH AT LEAST FT3/FT4>ULN	22	11		
TSH<LLN WITH ALL OTHER FT3/FT4<=ULN	12	10		
TSH<LLN WITH FT3/FT4 TEST MISSING	19	11		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Participants were assessed for all-cause mortality from their first dose to their study completion (up to approximately 63 months). SAEs and Other AEs were assessed from first dose up to 100 days post last dose (Up to approximately 63 months).

Adverse event reporting additional description:

The number at Risk for All-Cause Mortality represents all Randomized Participants. The number at Risk for Serious Adverse Events and Other (Not Including Serious) Adverse Events represents all participants that received at least 1 dose of study medication.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Nivolumab + Chemotherapy

Reporting group description:

Nivolumab Q3W + Investigator Choice (IC) Chemotherapy

Reporting group title	BMS986213 + Chemotherapy

Reporting group description:

BMS986213 Q3W + Investigator Choice (IC) Chemotherapy

Serious adverse events	Nivolumab + Chemotherapy	BMS986213 + Chemotherapy	
Total subjects affected by serious adverse events			
subjects affected / exposed	100 / 135 (74.07%)	110 / 136 (80.88%)	
number of deaths (all causes)	118	122	
number of deaths resulting from adverse events	43	45	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Gastric cancer			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adenocarcinoma			

subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall neoplasm			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected neoplasm			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphangiosis carcinomatosa			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Malignant neoplasm progression			
subjects affected / exposed	26 / 135 (19.26%)	30 / 136 (22.06%)	
occurrences causally related to treatment / all	0 / 27	0 / 30	
deaths causally related to treatment / all	25 / 25	26 / 26	
Metastases to central nervous system			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to liver			
subjects affected / exposed	0 / 135 (0.00%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to meninges			
subjects affected / exposed	2 / 135 (1.48%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Metastases to skin			

subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastatic gastric cancer			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuroendocrine tumour			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ovarian neoplasm			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour haemorrhage			
subjects affected / exposed	0 / 135 (0.00%)	3 / 136 (2.21%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	2 / 2	
Tumour pain			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour perforation			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Venous thrombosis limb			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			

subjects affected / exposed	0 / 135 (0.00%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	2 / 135 (1.48%)	3 / 136 (2.21%)	
occurrences causally related to treatment / all	1 / 2	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic venous thrombosis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Influenza like illness			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthenia			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disease progression			

subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Fatigue			
subjects affected / exposed	2 / 135 (1.48%)	3 / 136 (2.21%)	
occurrences causally related to treatment / all	1 / 2	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	6 / 135 (4.44%)	3 / 136 (2.21%)	
occurrences causally related to treatment / all	1 / 7	0 / 3	
deaths causally related to treatment / all	4 / 4	0 / 0	
Medical device pain			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	7 / 135 (5.19%)	12 / 136 (8.82%)	
occurrences causally related to treatment / all	1 / 10	5 / 15	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Contrast media reaction			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			

Immune-mediated lung disease			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	3 / 135 (2.22%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Lung disorder			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organising pneumonia			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	6 / 135 (4.44%)	6 / 136 (4.41%)	
occurrences causally related to treatment / all	0 / 8	0 / 7	
deaths causally related to treatment / all	0 / 0	1 / 1	
Pneumonitis			
subjects affected / exposed	7 / 135 (5.19%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	8 / 8	1 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Pulmonary embolism			
subjects affected / exposed	1 / 135 (0.74%)	3 / 136 (2.21%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory failure			
subjects affected / exposed	1 / 135 (0.74%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	1 / 1	2 / 2	
Psychiatric disorders			

Confusional state			
subjects affected / exposed	2 / 135 (1.48%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Device dislocation			
subjects affected / exposed	2 / 135 (1.48%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device malfunction			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubin increased			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 135 (0.00%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase increased			

subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical condition abnormal			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutrophil count decreased			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test increased			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver function test abnormal			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic enzyme increased			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Overdose			

subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion related reaction			
subjects affected / exposed	0 / 135 (0.00%)	5 / 136 (3.68%)	
occurrences causally related to treatment / all	0 / 0	5 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haemorrhage			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural complication			

subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	2 / 135 (1.48%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrioventricular block			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure acute			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			

subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocarditis			
subjects affected / exposed	2 / 135 (1.48%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Right ventricular failure			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arteriospasm coronary			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Encephalitis autoimmune			
subjects affected / exposed	0 / 135 (0.00%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Guillain-Barre syndrome			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Axonal neuropathy			

subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 135 (0.00%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	2 / 135 (1.48%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Presyncope			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	7 / 135 (5.19%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	2 / 8	1 / 2	
deaths causally related to treatment / all	1 / 1	0 / 0	
Febrile neutropenia			

subjects affected / exposed	2 / 135 (1.48%)	5 / 136 (3.68%)	
occurrences causally related to treatment / all	2 / 2	5 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune thrombocytopenia			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic microangiopathy			
subjects affected / exposed	0 / 135 (0.00%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			
Vestibular disorder			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Diplopia			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blindness unilateral			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			

Gastrointestinal haemorrhage			
subjects affected / exposed	3 / 135 (2.22%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	1 / 1	1 / 1	
Abdominal hernia			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	8 / 135 (5.93%)	6 / 136 (4.41%)	
occurrences causally related to treatment / all	1 / 9	0 / 9	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain lower			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	3 / 135 (2.22%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	3 / 135 (2.22%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	2 / 135 (1.48%)	3 / 136 (2.21%)	
occurrences causally related to treatment / all	3 / 3	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	2 / 135 (1.48%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			

subjects affected / exposed	8 / 135 (5.93%)	3 / 136 (2.21%)	
occurrences causally related to treatment / all	8 / 10	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	9 / 135 (6.67%)	4 / 136 (2.94%)	
occurrences causally related to treatment / all	0 / 9	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis haemorrhagic			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faeces discoloured			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 135 (0.00%)	3 / 136 (2.21%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	1 / 1	
Gastrointestinal inflammation			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal obstruction			
subjects affected / exposed	0 / 135 (0.00%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			

subjects affected / exposed	3 / 135 (2.22%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	2 / 135 (1.48%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	1 / 1	0 / 0	
Immune-mediated enterocolitis			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	8 / 135 (5.93%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 9	0 / 1	
deaths causally related to treatment / all	2 / 2	0 / 0	
Intestinal perforation			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Large intestinal obstruction			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			

subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	0 / 135 (0.00%)	3 / 136 (2.21%)	
occurrences causally related to treatment / all	0 / 0	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	6 / 135 (4.44%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	5 / 7	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction gastric			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal fistula			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal pain			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal ulcer			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			

subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Proctalgia			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	1 / 135 (0.74%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal stenosis			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	0 / 135 (0.00%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	7 / 135 (5.19%)	3 / 136 (2.21%)	
occurrences causally related to treatment / all	3 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal perforation			
subjects affected / exposed	0 / 135 (0.00%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Jaundice cholestatic			

subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Autoimmune hepatitis			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary colic			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gallbladder obstruction			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	1 / 1	
Hepatitis			
subjects affected / exposed	1 / 135 (0.74%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis acute			

subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disease			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertransaminasaemia			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated hepatitis			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	2 / 135 (1.48%)	5 / 136 (3.68%)	
occurrences causally related to treatment / all	2 / 2	4 / 5	
deaths causally related to treatment / all	1 / 1	1 / 1	
Hydronephrosis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nephropathy toxic			

subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	1 / 1	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	2 / 135 (1.48%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal tubular necrosis			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary incontinence			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Immune-mediated hypophysitis			
subjects affected / exposed	0 / 135 (0.00%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Adrenal insufficiency			
subjects affected / exposed	0 / 135 (0.00%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Autoimmune thyroiditis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Glucocorticoid deficiency			

subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophysitis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphocytic hypophysitis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Myositis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	1 / 135 (0.74%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Acute sinusitis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Adrenalitis			
subjects affected / exposed	0 / 135 (0.00%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19 pneumonia			
subjects affected / exposed	2 / 135 (1.48%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 2	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis infective			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	1 / 135 (0.74%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterobacter sepsis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis infectious			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile infection			

subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	2 / 135 (1.48%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	1 / 135 (0.74%)	4 / 136 (2.94%)	
occurrences causally related to treatment / all	0 / 1	3 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	2 / 135 (1.48%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Kidney infection			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine infection			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oral candidiasis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 135 (0.00%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			

subjects affected / exposed	2 / 135 (1.48%)	7 / 136 (5.15%)	
occurrences causally related to treatment / all	2 / 3	3 / 8	
deaths causally related to treatment / all	0 / 0	1 / 1	
Rash pustular			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural infection			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	2 / 135 (1.48%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Pneumonia			
subjects affected / exposed	8 / 135 (5.93%)	7 / 136 (5.15%)	
occurrences causally related to treatment / all	1 / 9	1 / 7	
deaths causally related to treatment / all	2 / 2	4 / 4	
Urinary tract infection			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular device infection			
subjects affected / exposed	2 / 135 (1.48%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suspected COVID-19			

subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	3 / 135 (2.22%)	3 / 136 (2.21%)	
occurrences causally related to treatment / all	1 / 3	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Decreased appetite			
subjects affected / exposed	5 / 135 (3.70%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 7	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic ketoacidosis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	1 / 135 (0.74%)	1 / 136 (0.74%)	
occurrences causally related to treatment / all	4 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	3 / 135 (2.22%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	2 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophosphataemia			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ketoacidosis			

subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 135 (0.00%)	2 / 136 (1.47%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetes mellitus inadequate control			
subjects affected / exposed	1 / 135 (0.74%)	0 / 136 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Nivolumab + Chemotherapy	BMS986213 + Chemotherapy	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	133 / 135 (98.52%)	130 / 136 (95.59%)	
Vascular disorders			
Hypertension			
subjects affected / exposed	15 / 135 (11.11%)	8 / 136 (5.88%)	
occurrences (all)	18	10	
Hypotension			
subjects affected / exposed	7 / 135 (5.19%)	7 / 136 (5.15%)	
occurrences (all)	10	7	
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	18 / 135 (13.33%)	17 / 136 (12.50%)	
occurrences (all)	19	19	
Pyrexia			
subjects affected / exposed	19 / 135 (14.07%)	33 / 136 (24.26%)	
occurrences (all)	28	51	
Non-cardiac chest pain			
subjects affected / exposed	9 / 135 (6.67%)	10 / 136 (7.35%)	
occurrences (all)	10	10	
Mucosal inflammation			

subjects affected / exposed	12 / 135 (8.89%)	16 / 136 (11.76%)	
occurrences (all)	13	20	
General physical health deterioration			
subjects affected / exposed	7 / 135 (5.19%)	2 / 136 (1.47%)	
occurrences (all)	8	2	
Fatigue			
subjects affected / exposed	70 / 135 (51.85%)	72 / 136 (52.94%)	
occurrences (all)	93	97	
Chills			
subjects affected / exposed	6 / 135 (4.44%)	8 / 136 (5.88%)	
occurrences (all)	6	8	
Asthenia			
subjects affected / exposed	21 / 135 (15.56%)	16 / 136 (11.76%)	
occurrences (all)	36	23	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	3 / 135 (2.22%)	8 / 136 (5.88%)	
occurrences (all)	5	16	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	23 / 135 (17.04%)	28 / 136 (20.59%)	
occurrences (all)	26	33	
Dyspnoea			
subjects affected / exposed	16 / 135 (11.85%)	23 / 136 (16.91%)	
occurrences (all)	17	24	
Epistaxis			
subjects affected / exposed	10 / 135 (7.41%)	6 / 136 (4.41%)	
occurrences (all)	10	6	
Oropharyngeal pain			
subjects affected / exposed	5 / 135 (3.70%)	8 / 136 (5.88%)	
occurrences (all)	5	8	
Pneumonitis			
subjects affected / exposed	5 / 135 (3.70%)	8 / 136 (5.88%)	
occurrences (all)	7	8	
Pulmonary embolism			

subjects affected / exposed	7 / 135 (5.19%)	2 / 136 (1.47%)	
occurrences (all)	7	2	
Rhinorrhoea			
subjects affected / exposed	3 / 135 (2.22%)	7 / 136 (5.15%)	
occurrences (all)	3	7	
Psychiatric disorders			
Depression			
subjects affected / exposed	8 / 135 (5.93%)	4 / 136 (2.94%)	
occurrences (all)	9	4	
Insomnia			
subjects affected / exposed	14 / 135 (10.37%)	18 / 136 (13.24%)	
occurrences (all)	14	21	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	16 / 135 (11.85%)	15 / 136 (11.03%)	
occurrences (all)	19	19	
Aspartate aminotransferase increased			
subjects affected / exposed	16 / 135 (11.85%)	18 / 136 (13.24%)	
occurrences (all)	20	25	
Blood alkaline phosphatase increased			
subjects affected / exposed	7 / 135 (5.19%)	10 / 136 (7.35%)	
occurrences (all)	9	10	
Gamma-glutamyltransferase increased			
subjects affected / exposed	8 / 135 (5.93%)	9 / 136 (6.62%)	
occurrences (all)	12	10	
Neutrophil count decreased			
subjects affected / exposed	16 / 135 (11.85%)	25 / 136 (18.38%)	
occurrences (all)	21	41	
Platelet count decreased			
subjects affected / exposed	23 / 135 (17.04%)	15 / 136 (11.03%)	
occurrences (all)	38	25	
Weight decreased			
subjects affected / exposed	21 / 135 (15.56%)	13 / 136 (9.56%)	
occurrences (all)	22	15	
White blood cell count decreased			

subjects affected / exposed	6 / 135 (4.44%)	9 / 136 (6.62%)	
occurrences (all)	11	14	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	11 / 135 (8.15%)	19 / 136 (13.97%)	
occurrences (all)	11	27	
Nervous system disorders			
Cold dysaesthesia			
subjects affected / exposed	8 / 135 (5.93%)	4 / 136 (2.94%)	
occurrences (all)	11	4	
Dizziness			
subjects affected / exposed	17 / 135 (12.59%)	12 / 136 (8.82%)	
occurrences (all)	24	12	
Dysgeusia			
subjects affected / exposed	16 / 135 (11.85%)	15 / 136 (11.03%)	
occurrences (all)	23	16	
Headache			
subjects affected / exposed	9 / 135 (6.67%)	16 / 136 (11.76%)	
occurrences (all)	11	17	
Neuropathy peripheral			
subjects affected / exposed	48 / 135 (35.56%)	39 / 136 (28.68%)	
occurrences (all)	69	46	
Paraesthesia			
subjects affected / exposed	14 / 135 (10.37%)	18 / 136 (13.24%)	
occurrences (all)	19	24	
Peripheral sensory neuropathy			
subjects affected / exposed	30 / 135 (22.22%)	27 / 136 (19.85%)	
occurrences (all)	35	31	
Polyneuropathy			
subjects affected / exposed	8 / 135 (5.93%)	9 / 136 (6.62%)	
occurrences (all)	10	9	
Blood and lymphatic system disorders			
Thrombocytopenia			
subjects affected / exposed	25 / 135 (18.52%)	21 / 136 (15.44%)	
occurrences (all)	39	33	
Neutropenia			

subjects affected / exposed	41 / 135 (30.37%)	37 / 136 (27.21%)	
occurrences (all)	85	62	
Leukopenia			
subjects affected / exposed	7 / 135 (5.19%)	5 / 136 (3.68%)	
occurrences (all)	15	5	
Anaemia			
subjects affected / exposed	32 / 135 (23.70%)	41 / 136 (30.15%)	
occurrences (all)	46	54	
Gastrointestinal disorders			
Dry mouth			
subjects affected / exposed	9 / 135 (6.67%)	12 / 136 (8.82%)	
occurrences (all)	9	13	
Constipation			
subjects affected / exposed	34 / 135 (25.19%)	40 / 136 (29.41%)	
occurrences (all)	46	51	
Abdominal pain upper			
subjects affected / exposed	12 / 135 (8.89%)	16 / 136 (11.76%)	
occurrences (all)	13	16	
Abdominal pain			
subjects affected / exposed	28 / 135 (20.74%)	28 / 136 (20.59%)	
occurrences (all)	40	33	
Abdominal distension			
subjects affected / exposed	7 / 135 (5.19%)	5 / 136 (3.68%)	
occurrences (all)	8	5	
Diarrhoea			
subjects affected / exposed	60 / 135 (44.44%)	56 / 136 (41.18%)	
occurrences (all)	122	119	
Vomiting			
subjects affected / exposed	49 / 135 (36.30%)	49 / 136 (36.03%)	
occurrences (all)	72	77	
Stomatitis			
subjects affected / exposed	19 / 135 (14.07%)	16 / 136 (11.76%)	
occurrences (all)	25	29	
Nausea			
subjects affected / exposed	79 / 135 (58.52%)	70 / 136 (51.47%)	
occurrences (all)	132	126	

Dysphagia			
subjects affected / exposed	15 / 135 (11.11%)	22 / 136 (16.18%)	
occurrences (all)	19	23	
Dyspepsia			
subjects affected / exposed	7 / 135 (5.19%)	7 / 136 (5.15%)	
occurrences (all)	7	8	
Gastrooesophageal reflux disease			
subjects affected / exposed	9 / 135 (6.67%)	8 / 136 (5.88%)	
occurrences (all)	9	10	
Skin and subcutaneous tissue disorders			
Rash maculo-papular			
subjects affected / exposed	1 / 135 (0.74%)	11 / 136 (8.09%)	
occurrences (all)	1	14	
Alopecia			
subjects affected / exposed	10 / 135 (7.41%)	9 / 136 (6.62%)	
occurrences (all)	10	9	
Dry skin			
subjects affected / exposed	11 / 135 (8.15%)	6 / 136 (4.41%)	
occurrences (all)	11	6	
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	18 / 135 (13.33%)	12 / 136 (8.82%)	
occurrences (all)	24	17	
Pruritus			
subjects affected / exposed	10 / 135 (7.41%)	14 / 136 (10.29%)	
occurrences (all)	12	15	
Rash			
subjects affected / exposed	24 / 135 (17.78%)	26 / 136 (19.12%)	
occurrences (all)	34	33	
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	3 / 135 (2.22%)	10 / 136 (7.35%)	
occurrences (all)	3	10	
Hypothyroidism			
subjects affected / exposed	18 / 135 (13.33%)	21 / 136 (15.44%)	
occurrences (all)	19	21	
Musculoskeletal and connective tissue disorders			

Arthralgia			
subjects affected / exposed	15 / 135 (11.11%)	18 / 136 (13.24%)	
occurrences (all)	15	19	
Back pain			
subjects affected / exposed	15 / 135 (11.11%)	16 / 136 (11.76%)	
occurrences (all)	17	19	
Muscular weakness			
subjects affected / exposed	9 / 135 (6.67%)	3 / 136 (2.21%)	
occurrences (all)	9	3	
Pain in extremity			
subjects affected / exposed	9 / 135 (6.67%)	5 / 136 (3.68%)	
occurrences (all)	10	5	
Infections and infestations			
Oral candidiasis			
subjects affected / exposed	12 / 135 (8.89%)	6 / 136 (4.41%)	
occurrences (all)	13	7	
Pneumonia			
subjects affected / exposed	3 / 135 (2.22%)	7 / 136 (5.15%)	
occurrences (all)	3	7	
Upper respiratory tract infection			
subjects affected / exposed	5 / 135 (3.70%)	10 / 136 (7.35%)	
occurrences (all)	6	10	
Urinary tract infection			
subjects affected / exposed	11 / 135 (8.15%)	13 / 136 (9.56%)	
occurrences (all)	13	14	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	46 / 135 (34.07%)	48 / 136 (35.29%)	
occurrences (all)	53	56	
Hyperglycaemia			
subjects affected / exposed	8 / 135 (5.93%)	9 / 136 (6.62%)	
occurrences (all)	8	15	
Hypocalcaemia			
subjects affected / exposed	3 / 135 (2.22%)	10 / 136 (7.35%)	
occurrences (all)	4	12	
Hypokalaemia			

subjects affected / exposed	13 / 135 (9.63%)	17 / 136 (12.50%)	
occurrences (all)	21	21	
Hypomagnesaemia			
subjects affected / exposed	7 / 135 (5.19%)	6 / 136 (4.41%)	
occurrences (all)	12	7	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 June 2018	Additional exclusion criterion added
16 November 2018	Revised text reflecting addition of Data Monitoring Committee
24 June 2019	Revised to update with current program requirements, updated company standards, and to provide additional clarifications throughout

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported