Clinical trial results:
A PHASE 1/2 DOSE ESCALATION AND COMBINATION COHORT STUDY TO EVALUATE THE SAFETY AND TOLERABILITY, PHARMACOKINETICS, AND EFFICACY OF BMS-986226 (ANTI-ICOS MAB) ALONE OR IN COMBINATION WITH NIVOLUMAB OR IPILIMUMAB IN PATIENTS WITH ADVANCED SOLID TUMORS

Summary

EudraCT number	2017-000238-73
Trial protocol	ES
Global end of trial date	20 December 2021

Results information

Result version number	v1 (current)
This version publication date	01 January 2023
First version publication date	01 January 2023

Trial information

Trial identification

Sponsor protocol code	CA021-002

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	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	22 April 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	20 December 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To characterize the safety and tolerability of BMS-986226 administered alone and in combination with nivolumab or ipilimumab in participants with advanced solid tumors

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	01 September 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Spain: 32
Country: Number of subjects enrolled	Switzerland: 15
Country: Number of subjects enrolled	United States: 28
Worldwide total number of subjects	80
EEA total number of subjects	32

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)	50
From 65 to 84 years	29

85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

No participants were treated with BMS-986226 in combination with nivolumab (Parts B1 and B2) and no participants were treated in Parts D and E

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Preliminary - BMS-986226 2 mg

Arm description:

Preliminary safety cohort participants received BMS-986226 2 mg every 4 weeks

Arm type	Experimental
Investigational medicinal product name	BMS-986226
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

BMS-986226 2 mg every 4 weeks

Arm title	Preliminary - BMS-986226 8 mg

Arm description:

Preliminary safety cohort participants received BMS-986226 8 mg every 4 weeks

Arm type	Experimental
Investigational medicinal product name	BMS-986226
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

BMS-986226 8 mg every 4 weeks

Arm title	Part A - BMS-986226 25 mg

Arm description:

Part A cohort participants received BMS-986226 25 mg every 4 weeks for 24 weeks

Arm type	Experimental
Investigational medicinal product name	BMS-986226
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

BMS-986226 25 mg every 4 weeks

Arm title	Part A - BMS-986226 80 mg
Arm description:	
Part A cohort participants received BMS-986226 80 mg every 4 weeks for 24 weeks	
Arm type	Experimental
Investigational medicinal product name	BMS-986226
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
BMS-986226 80 mg every 4 weeks	
Arm title	Part A - BMS-986226 200 mg
Arm description:	
Part A cohort participants received BMS-986226 200 mg every 4 weeks for 24 weeks	
Arm type	Experimental
Investigational medicinal product name	BMS-986226
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
BMS-986226 200 mg every 4 weeks	
Arm title	Part A - BMS-986226 400 mg
Arm description:	
Part A cohort participants received BMS-986226 400 mg every 4 weeks for 24 weeks	
Arm type	Experimental
Investigational medicinal product name	BMS-986226
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
BMS-986226 400 mg every 4 weeks	
Arm title	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg
Arm description:	
Part C1 cohort participants received BMS-986226 25 mg every 12 weeks plus Ipilimumab 3 mg/kg every 4 weeks	
Arm type	Experimental
Investigational medicinal product name	BMS-986226
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use
Dosage and administration details:	
BMS-986226 25 mg every 12 weeks	
Investigational medicinal product name	Ipilimumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

Ipilimumab 3 mg every 4 weeks

Arm title	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg

Arm description:

Part C1 cohort participants received BMS-986226 200 mg every 12 weeks plus Ipilimumab 3 mg/kg every 4 weeks

Arm type	Experimental
Investigational medicinal product name	BMS-986226
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

BMS-986226 3 mg every 4 weeks

Investigational medicinal product name	BMS-986226
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

BMS-986226 200 mg every 12 weeks

Arm title	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg

Arm description:

Part C2 cohort participants received BMS-986226 25 mg every 4 weeks plus Ipilimumab 3 mg/kg every 4 weeks

Arm type	Experimental
Investigational medicinal product name	BMS-986226
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

BMS-986226 3 mg every 4 weeks

Investigational medicinal product name	BMS-986226
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Intravenous use

Dosage and administration details:

BMS-986226 3 mg every 4 weeks

Number of subjects in period 1	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg
Started	6	7	7
Completed	0	0	0
Not completed	6	7	7
Adverse event, serious fatal	-	1	-
Adverse Event unrelated to study drug	-	-	-
Other Reasons	-	-	-
Study Drug Toxicity	-	-	-
Disease Progression	6	6	7
Participant request to discontinue study treatment	-	-	-

Number of subjects in period 1	Part A - BMS-986226 80 mg	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg
Started	11	9	9
Completed	0	0	0
Not completed	11	9	9
Adverse event, serious fatal	1	1	1
Adverse Event unrelated to study drug	1	-	1
Other Reasons	-	-	-
Study Drug Toxicity	1	-	-
Disease Progression	8	8	7
Participant request to discontinue study treatment	-	-	-

Number of subjects in period 1	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg
Started	10	12	9
Completed	3	1	1
Not completed	7	11	8
Adverse event, serious fatal	-	-	-
Adverse Event unrelated to study drug	1	-	-
Other Reasons	-	-	1
Study Drug Toxicity	-	-	1
Disease Progression	6	10	6
Participant request to discontinue study treatment	-	1	-

Baseline characteristics

Reporting groups	
Reporting group title	Preliminary - BMS-986226 2 mg
Reporting group description:	
Preliminary safety cohort participants received BMS-986226 2 mg every 4 weeks	
Reporting group title	Preliminary - BMS-986226 8 mg
Reporting group description:	
Preliminary safety cohort participants received BMS-986226 8 mg every 4 weeks	
Reporting group title	Part A - BMS-986226 25 mg
Reporting group description:	
Part A cohort participants received BMS-986226 25 mg every 4 weeks for 24 weeks	
Reporting group title	Part A - BMS-986226 80 mg
Reporting group description:	
Part A cohort participants received BMS-986226 80 mg every 4 weeks for 24 weeks	
Reporting group title	Part A - BMS-986226 200 mg
Reporting group description:	
Part A cohort participants received BMS-986226 200 mg every 4 weeks for 24 weeks	
Reporting group title	Part A - BMS-986226 400 mg
Reporting group description:	
Part A cohort participants received BMS-986226 400 mg every 4 weeks for 24 weeks	
Reporting group title	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg
Reporting group description:	
Part C1 cohort participants received BMS-986226 25 mg every 12 weeks plus Ipilimumab 3 mg/kg every 4 weeks	
Reporting group title	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Reporting group description:	
Part C1 cohort participants received BMS-986226 200 mg every 12 weeks plus Ipilimumab 3 mg/kg every 4 weeks	
Reporting group title	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg
Reporting group description:	
Part C2 cohort participants received BMS-986226 25 mg every 4 weeks plus Ipilimumab 3 mg/kg every 4 weeks	

Reporting group values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg
Number of subjects	6	7	7
Age categorical Units: Subjects			
Adults (18-64 years)	4	5	4
From 65-84 years	2	2	3
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	59.3	58.3	63.6
standard deviation	± 10.4	± 7.8	± 12.3
Sex: Female, Male Units: Participants			
Female	1	2	3
Male	5	5	4

Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	4	6	6
More than one race	0	0	0
Unknown or Not Reported	1	1	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	1	1
Not Hispanic or Latino	5	5	4
Unknown or Not Reported	0	1	2

Reporting group values	Part A - BMS-986226 80 mg	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg
Number of subjects	11	9	9
Age categorical Units: Subjects			
Adults (18-64 years)	7	5	4
From 65-84 years	4	4	5
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	62.5	55.3	61.7
standard deviation	± 9.7	± 15.9	± 16.9
Sex: Female, Male Units: Participants			
Female	5	3	3
Male	6	6	6
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	10	9	9
More than one race	0	0	0
Unknown or Not Reported	1	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	1
Not Hispanic or Latino	5	4	2
Unknown or Not Reported	6	5	6

Reporting group values	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg
Number of subjects	10	12	9

Age categorical Units: Subjects			
Adults (18-64 years)	7	7	7
From 65-84 years	3	4	2
85 years and over	0	1	0
Age Continuous Units: Years			
arithmetic mean	55.7	62.3	58.3
standard deviation	± 9.6	± 11.7	± 7.1
Sex: Female, Male Units: Participants			
Female	4	5	2
Male	6	7	7
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	0
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	2
White	7	12	6
More than one race	0	0	0
Unknown or Not Reported	2	0	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	1
Not Hispanic or Latino	6	8	5
Unknown or Not Reported	3	4	3

Reporting group values	Total		
Number of subjects	80		
Age categorical Units: Subjects			
Adults (18-64 years)	50		
From 65-84 years	29		
85 years and over	1		
Age Continuous Units: Years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: Participants			
Female	28		
Male	52		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0		
Asian	1		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	3		
White	69		

More than one race	0		
Unknown or Not Reported	7		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	6		
Not Hispanic or Latino	44		
Unknown or Not Reported	30		

End points

End points reporting groups

Reporting group title	Preliminary - BMS-986226 2 mg
Reporting group description:	
Preliminary safety cohort participants received BMS-986226 2 mg every 4 weeks	
Reporting group title	Preliminary - BMS-986226 8 mg
Reporting group description:	
Preliminary safety cohort participants received BMS-986226 8 mg every 4 weeks	
Reporting group title	Part A - BMS-986226 25 mg
Reporting group description:	
Part A cohort participants received BMS-986226 25 mg every 4 weeks for 24 weeks	
Reporting group title	Part A - BMS-986226 80 mg
Reporting group description:	
Part A cohort participants received BMS-986226 80 mg every 4 weeks for 24 weeks	
Reporting group title	Part A - BMS-986226 200 mg
Reporting group description:	
Part A cohort participants received BMS-986226 200 mg every 4 weeks for 24 weeks	
Reporting group title	Part A - BMS-986226 400 mg
Reporting group description:	
Part A cohort participants received BMS-986226 400 mg every 4 weeks for 24 weeks	
Reporting group title	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg
Reporting group description:	
Part C1 cohort participants received BMS-986226 25 mg every 12 weeks plus Ipilimumab 3 mg/kg every 4 weeks	
Reporting group title	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Reporting group description:	
Part C1 cohort participants received BMS-986226 200 mg every 12 weeks plus Ipilimumab 3 mg/kg every 4 weeks	
Reporting group title	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg
Reporting group description:	
Part C2 cohort participants received BMS-986226 25 mg every 4 weeks plus Ipilimumab 3 mg/kg every 4 weeks	

Primary: The Number of Participants Experiencing Adverse Events (AEs)

End point title	The Number of Participants Experiencing Adverse Events
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	Primary
End point timeframe:	
From first dose up to 100 days post last dose, up to approximately 31 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 were planned for this endpoint	

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	7	11
Units: Participants	6	7	7	11

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	9	10	12
Units: Participants	9	9	10	12

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Participants	9			

Statistical analyses

No statistical analyses for this end point

Primary: The Number of Participants Experiencing Serious Adverse Events (SAEs)

End point title	The Number of Participants Experiencing Serious Adverse Events (SAEs)[2]

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	Primary

End point timeframe:

From first dose up to 100 days post last dose, up to approximately 31 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 statistics were planned for this endpoint

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	7	11
Units: Participants	2	3	2	10

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	9	10	12
Units: Participants	5	9	5	9

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Participants	5			

Statistical analyses

No statistical analyses for this end point

Primary: The Number of Participants Experiencing Adverse Events Leading to Discontinuation

End point title	The Number of Participants Experiencing Adverse Events Leading to Discontinuation[3]

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	Primary

End point timeframe:

From first dose up to 100 days post last dose, up to approximately 31 months

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only summary statistics were planned for this endpoint

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	7	11
Units: Participants	0	0	0	1

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	9	10	12
Units: Participants	1	4	0	3

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Participants	2			

Statistical analyses

No statistical analyses for this end point

Primary: The Number of Participants Experiencing Adverse Events Resulting in Death

End point title	The Number of Participants Experiencing Adverse Events Resulting in Death[4]

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	Primary

End point timeframe:

From first dose up to 100 days post last dose, up to approximately 31 months

Notes:

[4] - 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 were planned for this endpoint

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	7	11
Units: Participants	5	3	5	8

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	9	10	12
Units: Participants	5	7	7	8

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Participants	5			

Statistical analyses

No statistical analyses for this end point

Primary: The Number of Participants Experiencing Clinical Laboratory Abnormalities

End point title	The Number of Participants Experiencing Clinical Laboratory Abnormalities[5]

End point description:

The number of participants experiencing abnormal laboratory results of Grade 3 or higher. Laboratory values will be graded according to National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v4.03 with Grade 3=severe and Grade 4=life threatening.

End point type	Primary

End point timeframe:

From first dose up to 30 days post last dose (approximately 28 months)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only summary statistics were planned for this endpoint

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	7	11
Units: Participants				
HEMOGLOBIN	1	0	0	1
LYMPHOCYTES (ABSOLUTE)	0	1	1	3
LYMPHOCYTES (RELATIVE)	0	1	0	0
ALKALINE PHOSPHATASE	0	0	0	2
ASPARTATE AMINOTRANSFERASE	0	0	0	1
ALANINE AMINOTRANSFERASE	0	0	0	0
G-GLUTAMYL TRANSFERASE	1	2	1	4
BILIRUBIN, TOTAL	0	0	0	2
PHOSPHATE	0	0	0	0
LIPASE, TOTAL	0	1	1	0
HYPONATREMIA	0	0	0	0
HYPERKALEMIA	0	0	0	1
HYPERGLYCEMIA	1	0	0	0
HYPOKALEMIA	0	0	0	0

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	9	10	12
Units: Participants				
HEMOGLOBIN	1	2	0	1
LYMPHOCYTES (ABSOLUTE)	2	3	2	4
LYMPHOCYTES (RELATIVE)	0	1	1	0
ALKALINE PHOSPHATASE	1	2	3	2
ASPARTATE AMINOTRANSFERASE	1	0	1	1
ALANINE AMINOTRANSFERASE	1	0	1	0
G-GLUTAMYL TRANSFERASE	3	2	6	3
BILIRUBIN, TOTAL	1	0	0	0
PHOSPHATE	0	1	0	1
LIPASE, TOTAL	0	0	2	1
HYPONATREMIA	1	1	0	0
HYPERKALEMIA	0	0	0	0
HYPERGLYCEMIA	0	0	0	0
HYPOKALEMIA	0	0	1	0

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			

Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Participants				
HEMOGLOBIN	1			
LYMPHOCYTES (ABSOLUTE)	3			
LYMPHOCYTES (RELATIVE)	0			
ALKALINE PHOSPHATASE	0			
ASPARTATE AMINOTRANSFERASE	1			
ALANINE AMINOTRANSFERASE	1			
G-GLUTAMYL TRANSFERASE	1			
BILIRUBIN, TOTAL	0			
PHOSPHATE	1			
LIPASE, TOTAL	1			
HYPONATREMIA	1			
HYPERKALEMIA	0			
HYPERGLYCEMIA	0			
HYPOKALEMIA	0			

Statistical analyses

No statistical analyses for this end point

Primary: The Number of Participants Experiencing Adverse Events (AEs) Meeting Dose Limiting Toxicity (DLT) Criteria

End point title	The Number of Participants Experiencing Adverse Events (AEs) Meeting Dose Limiting Toxicity (DLT) Criteria[6]

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. Dose limiting toxicity (DLT) is defined based on the incidence, intensity, and duration of AEs for which no clear alternative cause is identified. The DLT period will be 28 days (4 weeks) in the Preliminary Safety Cohorts. Any toxicities that occur beyond the 4-week DLT period will also be considered in dose-level decisions. For the purpose of participant management, any AE that meets DLT criteria, regardless of the cycle in which it occurs, will lead to discontinuation of study treatment. AEs will be graded according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v4.03.

End point type	Primary

End point timeframe:

From first dose up to 100 days post last dose, up to approximately 31 months

Notes:

[6] - 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 were planned for this endpoint

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	7	11
Units: Participants	0	0	0	1

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	9	10	12
Units: Participants	0	0	0	1

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR)

End point description:

ORR is defined as the percentage of all treated participants whose best overall response (BOR) is either complete response (CR) or partial response (PR) as assessed by investigator per RECIST v1.1. CR is defined as the disappearance of all target and non-target lesions. Any pathological lymph nodes (whether target or non-target) must also have reduction in the short axis to < 10 mm. PR is defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters. BOR for a participant is defined as the best response designation recorded between the date of first dose (or date of randomization) and the date of first objectively documented progression per RECIST 1.1 or the date of subsequent therapy, whichever occurs first.

End point type	Secondary

End point timeframe:

From first dose up to documented disease progression, up to 48 months

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	7	9
Units: Percentage of participants				
median (confidence interval 95%)	0 (0.0 to 45.9)	0 (0.0 to 41.0)	0 (0.0 to 41.0)	0 (0.0 to 28.5)

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	9	10	12
Units: Percentage of participants				
median (confidence interval 95%)	0 (0.0 to 33.6)	0 (0.0 to 33.6)	0 (0.0 to 30.8)	8.3 (0.2 to 38.5)

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Percentage of participants				
median (confidence interval 95%)	0 (0.0 to 33.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Median Duration of Response (DOR)

End point title	Median Duration of Response (DOR)

End point description:

DOR for a participant with confirmed response is defined as the time from the date of first response CR or PR to the date of first objectively documented tumor progression as determined using RECIST v1.1 or death due to any cause, whichever occurs first. Participant who remain alive and have not progressed will be censored on the date of their last tumor assessment. Participants who started subsequent anticancer therapy without a prior reported progression will be censored at the last tumor assessment prior to initiation of the subsequent anticancer therapy. CR is defined as the disappearance of all target and non-target lesions. Any pathological lymph nodes (whether target or non-target) must also have reduction in the short axis to < 10 mm. PR is defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as reference the baseline sum diameters.

End point type	Secondary

End point timeframe:

From first dose up to the date of the first objectively documented tumor progression or death, whichever occurs first (up to approximately 24 months)

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[7]	0[8]	0[9]	0[10]
Units: Months				
median (full range (min-max))	(to)	(to)	(to)	(to)

Notes:

[7] - Data not reported due to insufficient number of participants with evaluable responses.

[8] - Data not reported due to insufficient number of participants with evaluable responses.

[9] - Data not reported due to insufficient number of participants with evaluable responses.

[10] - Data not reported due to insufficient number of participants with evaluable responses.

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[11]	0[12]	0[13]	1
Units: Months				
median (full range (min-max))	(to)	(to)	(to)	23.4 (23.4 to 23.4)

Notes:

[11] - Data not reported due to insufficient number of participants with evaluable responses.

[12] - Data not reported due to insufficient number of participants with evaluable responses.

[13] - Data not reported due to insufficient number of participants with evaluable responses.

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	0[14]			
Units: Months				
median (full range (min-max))	(to)			

Notes:

[14] - Data not reported due to insufficient number of participants with evaluable responses.

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS) Rate at 24 Weeks

End point title	Progression Free Survival (PFS) Rate at 24 Weeks

End point description:

The PFSR is defined as the percentage of treated participants remaining progression free and surviving at the prespecified timepoint of 24 weeks since the first dosing date. Progressive Disease (PD) is defined as at least a 20% increase in the sum of the diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. (Note: The appearance of 1 or more new lesions is also considered progression.)

End point type	Secondary

End point timeframe:

At 24 weeks

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	7	11
Units: Percentage of participants				
median (confidence interval 95%)	16.7 (0.8 to 51.7)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	9	10	12
Units: Percentage of participants				
median (confidence interval 95%)	0 (0 to 0)	0 (0 to 0)	0 (0 to 0)	8.3 (0.5 to 31.1)

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Percentage of participants				
median (confidence interval 95%)	18.8 (1.1 to 53.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Accumulation Index - Area Under Curve (AI-AUC)

End point title	Accumulation Index - Area Under Curve (AI-AUC)

End point description:

Accumulation Index is defined as the extent of drug accumulation and determined by the ratio of plasma concentration at plateau over plasma concentration after the first dose. The area under curve is defined as the area under the plot of plasma concentration of a drug versus time after dosage which reflects the extent of exposure to a drug and its clearance rate from the body.
"99999"=N/A
Geometric Coefficient of Variation=%CV

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 4, 24, 72, 168, 336, 504 hours post dose on C1D1, C2D1, and C3D1 (approximately 31 months)

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[15]	1	0[16]	3
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	()	99999 (± 99999)	()	99999 (± 99999)
C2D1	()	99999 (± 99999)	()	1.07 (± 9)
C3D1	()	0.100 (± 99999)	()	0.808 (± 99999)

Notes:

[15] - Data not reported due to insufficient number of participants with evaluable responses.

[16] - Data not reported due to insufficient number of participants with evaluable responses.

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	1	0[17]	0[18]
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	99999 (± 99999)	99999 (± 99999)	()	()
C2D1	0.856 (± 14)	0.953 (± 99999)	()	()
C3D1	1.28 (± 99999)	99999 (± 99999)	()	()

Notes:

[17] - Data not reported due to insufficient number of participants with evaluable responses.

[18] - Data not reported due to insufficient number of participants with evaluable responses.

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	0[19]			
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	()			
C2D1	()			
C3D1	()			

Notes:

[19] - Data not reported due to insufficient number of participants with evaluable responses.

Statistical analyses

No statistical analyses for this end point

Secondary: Accumulation Index - Cmax (AI-Cmax)

End point title	Accumulation Index - Cmax (AI-Cmax)

End point description:

Accumulation Index is defined as the extent of drug accumulation and determined by the ratio of plasma concentration at plateau over plasma concentration after the first dose. Cmax is the maximum serum concentration that a drug achieves after the drug has been administered and before the administration of a second dose.

"99999"=N/A

Note: Coefficient of variation is reported in lieu of geometric coefficient of variation

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 4, 24, 72, 168, 336, 504 hours post dose on C1D1, C2D1 and C3D1. Pre-dose and 0.5 post dose on C4D1. (Approximately 31 months)

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[20]	1	1	3
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D1	()	0.475 (± 99999)	99999 (± 99999)	1.19 (± 99999)
C3D1	()	0.457 (± 99999)	0.309 (± 99999)	0.920 (± 99999)
C4D1	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Notes:

[20] - Data not reported due to insufficient number of participants with evaluable responses.

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	0[21]	1
Units: ng/mL				

geometric mean (geometric coefficient of variation)				
C1D1	99999 (± 99999)	99999 (± 99999)	()	99999 (± 99999)
C2D1	0.951 (± 99999)	0.861 (± 99999)	()	99999 (± 99999)
C3D1	1.11 (± 99999)	0.940 (± 99999)	()	99999 (± 99999)
C4D1	99999 (± 99999)	99999 (± 99999)	()	0.633 (± 99999)

Notes:

[21] - Data not reported due to insufficient number of participants with evaluable responses.

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	2			
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	99999 (± 99999)			
C2D1	0.687 (± 23)			
C3D1	1.11 (± 99999)			
C4D1	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants with Anti-Drug Antibodies (ADA) for BMS-986226

End point title	Number of Participants with Anti-Drug Antibodies (ADA) for BMS-986226

End point description:

ADA for BMS-986226 is defined as the number of participants found to have seroconverted or boosted their pre-existing ADA during the study period. Baseline ADA positive is defined as ADA is detected in the last sample before initiation of treatment. ADA positive is defined as 1) an ADA detected (positive seroconversion) sample in a participant for whom ADA is not detected at baseline, or (2) an ADA detected sample with ADA titer to be at least 4-fold or greater (≥) than baseline positive titer.

End point type	Secondary

End point timeframe:

Predose on cycles 1-6, post dose on C1D15, and 30, 60, and 100 days post last dose (up to approximately 31 months)

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	6	6	11
Units: Participants				
Baseline ADA Positive	0	0	0	1
ADA Positive after initiation of treatment	4	6	3	8

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	8	11
Units: Participants				
Baseline ADA Positive	0	1	0	0
ADA Positive after initiation of treatment	4	4	8	9

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Participants				
Baseline ADA Positive	0			
ADA Positive after initiation of treatment	8			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (Cmax)

End point title	Maximum Observed Plasma Concentration (Cmax)

End point description:

Cmax is the maximum serum concentration that a drug achieves after the drug has been administered and before the administration of a second dose.

"99999"=N/A

Note: Coefficient of variation is reported in lieu of geometric coefficient of variation

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 4, 24, 72, 168, 336, 504 hours post dose on C1D1, C2D1, and C3D1 (approximately 31 months)

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	7	6	11
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	733 (± 37)	2250 (± 20)	6609 (± 23)	19524 (± 28)
C2D1	99999 (± 99999)	1050 (± 99999)	7220 (± 99999)	23322 (± 16)
C3D1	99999 (± 99999)	1060 (± 99999)	3168 (± 12)	15000 (± 99999)

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	8	11
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	41698 (± 33)	85905 (± 37)	5440 (± 35)	43309 (± 28)
C2D1	45054 (± 36)	91931 (± 108)	99999 (± 99999)	30200 (± 99999)
C3D1	41700 (± 99999)	76700 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	3451 (± 99999)			
C2D1	2697 (± 99999)			
C3D1	3880 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Effective Elimination Half-Life (T-HALFeff)

End point title	Effective Elimination Half-Life (T-HALFeff)

End point description:

Effective elimination half-life that explains the degree of accumulation observed

"99999"=N/A

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 4, 24, 72, 168, 336, 504 hours post dose on C2D1 and C3D1 (approximately 31 months)

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[22]	0[23]	0[24]	2
Units: Hours				
arithmetic mean (standard deviation)				
C2D1	()	()	()	212 (± 9.4)
C3D1	()	()	()	99999 (± 99999)

Notes:

[22] - Data not reported due to insufficient number of participants with evaluable responses.

[23] - Data not reported due to insufficient number of participants with evaluable responses.

[24] - Data not reported due to insufficient number of participants with evaluable responses.

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0[25]	0[26]	0[27]
Units: Hours				
arithmetic mean (standard deviation)				
C2D1	102 (± 99999)	()	()	()
C3D1	308 (± 99999)	()	()	()

Notes:

[25] - Data not reported due to insufficient number of participants with evaluable responses.

[26] - Data not reported due to insufficient number of participants with evaluable responses.

[27] - Data not reported due to insufficient number of participants with evaluable responses.

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	0[28]			
Units: Hours				
arithmetic mean (standard deviation)				

C2D1	()			
C3D1	()			

Notes:

[28] - Data not reported due to insufficient number of participants with evaluable responses.

Statistical analyses

No statistical analyses for this end point

Secondary: Trough Observed Serum Concentrations (Ctrough)

End point title	Trough Observed Serum Concentrations (Ctrough)

End point description:

Trough observed serum concentrations (Ctrough) is defined as the concentration reached by a drug immediately before the next dose is administered.

"99999"=N/A

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 4, 24, 72, 168, 336, 504 hours post dose on C2D1 and C3D1. Pre-dose and 0.5 post dose on C4D1. Pre-dose on C5D1 and C6D1. Pre-dose and 0.5 hours post dose on C7D1. (approximately 31 months)

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	2	3
Units: ng/mL				
arithmetic mean (standard deviation)				
Cycle 2 Day 1	99999 (± 99999)	12.5 (± 99999)	27.0 (± 99999)	943 (± 584.4)
Cycle 3 Day 1	99999 (± 99999)	12.5 (± 99999)	27.2 (± 20.72)	892 (± 99999)
Cycle 4 Day 1	12.5 (± 99999)	99999 (± 99999)	12.5 (± 99999)	504 (± 99999)
Cycle 5 Day 1	12.5 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Cycle 6 Day 1	12.5 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Cycle 7 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	1	1
Units: ng/mL				

arithmetic mean (standard deviation)				
Cycle 2 Day 1	1501 (± 1202.9)	1491 (± 1287.3)	12.5 (± 99999)	99999 (± 99999)
Cycle 3 Day 1	180 (± 99999)	3150 (± 99999)	12.5 (± 99999)	99999 (± 99999)
Cycle 4 Day 1	800 (± 401.1)	99999 (± 99999)	12.5 (± 99999)	99999 (± 99999)
Cycle 5 Day 1	3300 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Cycle 6 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
Cycle 7 Day 1	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	12.5 (± 99999)

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	1			
Units: ng/mL				
arithmetic mean (standard deviation)				
Cycle 2 Day 1	12.5 (± 99999)			
Cycle 3 Day 1	12.5 (± 99999)			
Cycle 4 Day 1	12.5 (± 99999)			
Cycle 5 Day 1	12.5 (± 99999)			
Cycle 6 Day 1	99999 (± 99999)			
Cycle 7 Day 1	12.5 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time of Maximum Observed Serum Concentration (Tmax)

End point title	Time of Maximum Observed Serum Concentration (Tmax)

End point description:

Tmax is defined as the amount of time that a drug is present at the maximum concentration in serum.

"99999"=N/A

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 4, 24, 72, 168, 336, 504 hours post dose on C1D1, C2D1, and C3D1 (approximately 31 months)

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	6	7	6	11
Units: Hours				
median (full range (min-max))				
C1D1	4.00 (0.067 to 4.22)	0.283 (0.133 to 4.00)	0.534 (0.467 to 4.50)	1.25 (0.467 to 21.7)
C2D1	99999 (99999 to 99999)	0.600 (0.600 to 0.600)	0.967 (0.967 to 0.967)	4.00 (0.483 to 4.00)
C3D1	99999 (99999 to 99999)	0.133 (0.133 to 0.133)	0.534 (0.517 to 0.550)	0.467 (0.467 to 0.467)

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	8	11
Units: Hours				
median (full range (min-max))				
C1D1	3.88 (0.467 to 24.0)	4.00 (0.500 to 24.0)	2.88 (0.467 to 4.50)	1.02 (0.483 to 18.9)
C2D1	1.00 (0.433 to 4.52)	4.00 (0.383 to 4.00)	99999 (99999 to 99999)	2.83 (2.83 to 2.83)
C3D1	1.03 (1.03 to 1.03)	0.967 (0.967 to 0.967)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: Hours				
median (full range (min-max))				
C1D1	0.600 (0.467 to 22.0)			
C2D1	2.24 (0.483 to 4.00)			
C3D1	0.500 (0.500 to 0.500)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under Concentration-Time Curve from Time 0 to the Time of the Last Quantifiable Concentration [AUC (0-T)]

End point title	Area Under Concentration-Time Curve from Time 0 to the Time of the Last Quantifiable Concentration [AUC (0-T)]

End point description:

AUC(0-t) (partial AUC) is defined as the area under the concentration-time curve from dosing (time 0) to time t. AUC(0-t) may be computed for one or more values of t, with specific values of t determined after observing the data.

"99999"=N/A

Note: Coefficient of variation is reported in lieu of geometric coefficient of variation.

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 4, 24, 72, 168, 336, 504 hours post dose on C1D1, C2D1, and C3D1 (approximately 31 months)

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	7	6	11
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	33704 (± 12)	175228 (± 33)	682168 (± 23)	1951486 (± 52)
C2D1	99999 (± 99999)	13921 (± 99999)	933038 (± 99999)	3534177 (± 14)
C3D1	99999 (± 99999)	18442 (± 99999)	81982 (± 128)	2727643 (± 99999)

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	8	11
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	4966612 (± 53)	8346408 (± 25)	370356 (± 41)	4805561 (± 60)
C2D1	5887547 (± 45)	4070442 (± 60)	99999 (± 99999)	2528949 (± 99999)
C3D1	5157593 (± 99999)	7511434 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part C2 - BMS-			

	986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	277927 (± 54)			
C2D1	35464 (± 39)			
C3D1	55178 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Concentration-Time Curve in 1 Dosing Interval [AUC (TAU)]

End point title	Area Under the Concentration-Time Curve in 1 Dosing Interval [AUC (TAU)]

End point description:

AUC (TAU) is defined as the area under the plasma concentration-time curve from time zero to the end of the dosing interval.

"99999"=N/A

Note: Coefficient of variation is reported in lieu of geometric coefficient of variation

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 4, 24, 72, 168, 336, 504 hours post dose on C1D1, C2D1, and C3D1 (approximately 31 months)

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	7	6	11
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	37392 (± 18)	189031 (± 32)	704072 (± 22)	1992589 (± 51)
C2D1	99999 (± 99999)	99999 (± 99999)	933038 (± 99999)	3693517 (± 12)
C3D1	99999 (± 99999)	19007 (± 99999)	373429 (± 99999)	2727643 (± 99999)

End point values	Part A - BMS-	Part A - BMS-	Part C1 - BMS-	Part C1 - BMS-

	986226 200 mg	986226 400 mg	986226 25 mg + Ipilimumab 3 mg/kg	986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	8	8	11
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	5148217 (± 51)	8740936 (± 26)	404651 (± 42)	5006775 (± 67)
C2D1	5766681 (± 55)	10833374 (± 4)	99999 (± 99999)	99999 (± 99999)
C3D1	5157593 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	9			
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	301365 (± 53)			
C2D1	99999 (± 99999)			
C3D1	99999 (± 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Total Body Clearance (CLT)

End point title	Total Body Clearance (CLT)

End point description:

CLT is defined as the elimination of the drug from the body

"99999"=N/A

Note: Coefficient of variation is reported in lieu of geometric coefficient of variation

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 4, 24, 72, 168, 336, 504 hours post dose on C1D1, C2D1, and C3D1 (approximately 31 months)

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[29]	1	1	3
Units: mL/h				
geometric mean (geometric coefficient of variation)				
C1D1	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D1	()	99999 (± 99999)	26.8 (± 99999)	21.7 (± 13)
C3D1	()	421 (± 99999)	99999 (± 99999)	29.3 (± 99999)

Notes:

[29] - Data not reported due to insufficient number of participants with evaluable responses.

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	0[30]	0[31]
Units: mL/h				
geometric mean (geometric coefficient of variation)				
C1D1	99999 (± 99999)	99999 (± 99999)	()	()
C2D1	34.7 (± 59)	36.9 (± 4)	()	()
C3D1	38.8 (± 99999)	99999 (± 99999)	()	()

Notes:

[30] - Data not reported due to insufficient number of participants with evaluable responses.

[31] - Data not reported due to insufficient number of participants with evaluable responses.

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	0[32]			
Units: mL/h				
geometric mean (geometric coefficient of variation)				
C1D1	()			
C2D1	()			
C3D1	()			

Notes:

[32] - Data not reported due to insufficient number of participants with evaluable responses.

Statistical analyses

No statistical analyses for this end point

Secondary: Average Concentration over a Dosing Interval (Css-avg)

End point title	Average Concentration over a Dosing Interval (Css-avg)

End point description:

Css-avg is defined as the average concentration over a dosing interval (AUC[TAU]/tau)

Note: Coefficient of variation is reported in lieu of geometric coefficient of variation

"99999"=N/A

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 4, 24, 72, 168, 336, 504 hours post dose on C1D1, C2D1, and C3D1 (approximately 31 months)

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[33]	1	1	3
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	()	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)
C2D1	()	99999 (± 99999)	1397 (± 99999)	5499 (± 12)
C3D1	()	28.3 (± 99999)	556 (± 99999)	4065 (± 99999)

Notes:

[33] - Data not reported due to insufficient number of participants with evaluable responses.

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	2	0[34]	0[35]
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	99999 (± 99999)	99999 (± 99999)	()	()
C2D1	8581 (± 55)	16115 (± 4)	()	()
C3D1	7666 (± 99999)	99999 (± 99999)	()	()

Notes:

[34] - Data not reported due to insufficient number of participants with evaluable responses.

[35] - Data not reported due to insufficient number of participants with evaluable responses.

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	0[36]			
Units: ng/mL				

geometric mean (geometric coefficient of variation)				
C1D1	()			
C2D1	()			
C3D1	()			

Notes:

[36] - Data not reported due to insufficient number of participants with evaluable responses.

Statistical analyses

No statistical analyses for this end point

Secondary: Accumulation Index - Concentrations at the End of Dosing Interval (AI-CTAU)

End point title	Accumulation Index - Concentrations at the End of Dosing Interval (AI-CTAU)

End point description:

Accumulation Index is defined as the extent of drug accumulation and determined by the ratio of plasma concentration at plateau over plasma concentration after the first dose.

"99999"=N/A

Note: Coefficient of variation is reported in lieu of geometric coefficient of variation

End point type	Secondary

End point timeframe:

Pre-dose, 0.5, 4, 24, 72, 168, 336, 504 hours post dose on C1D1, C2D1 and C3D1. Pre-dose and 0.5 post dose on C4D1. (Approximately 31 months)

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[37]	1	0[38]	3
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	()	99999 (± 99999)	()	99999 (± 99999)
C2D1	()	99999 (± 99999)	()	0.640 (± 99999)
C3D1	()	99999 (± 99999)	()	0.391 (± 99999)
C4D1	()	99999 (± 99999)	()	99999 (± 99999)

Notes:

[37] - Note: Coefficient of variation is reported in lieu of geometric coefficient of variation

[38] - Note: Coefficient of variation is reported in lieu of geometric coefficient of variation

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	1	0[39]	0[40]
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	99999 (± 99999)	99999 (± 99999)	()	()
C2D1	1.12 (± 99999)	1.38 (± 99999)	()	()
C3D1	33.3 (± 99999)	99999 (± 99999)	()	()
C4D1	99999 (± 99999)	99999 (± 99999)	()	()

Notes:

[39] - Note: Coefficient of variation is reported in lieu of geometric coefficient of variation

[40] - Note: Coefficient of variation is reported in lieu of geometric coefficient of variation

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	0[41]			
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
C1D1	()			
C2D1	()			
C3D1	()			
C4D1	()			

Notes:

[41] - Note: Coefficient of variation is reported in lieu of geometric coefficient of variation

Statistical analyses

No statistical analyses for this end point

Secondary: Changes from Baseline in Cell Surface ICOS Expression on T Cells

End point title	Changes from Baseline in Cell Surface ICOS Expression on T Cells

End point description:

Summary measures of changes from baseline to the last evaluable time point in cell surface Inducible costimulator (ICOS) expression on T cells. Baseline = last non missing value prior or on to the first dosing.

"99999"=N/A

Note: Coefficient of variation is reported in lieu of geometric coefficient of variation

End point type	Secondary

End point timeframe:

From baseline up to pre-dose and 4 hours post dose on C1D1 and pre-dose and 4 hours post dose on C2D1 (approximately 31 months)

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	7	10
Units: Melt Flow Index (MFI)				
median (full range (min-max))				
Baseline Response	985.5 (554 to 1243)	659.0 (455 to 775)	878.0 (599 to 1361)	482 (197 to 912)
C1D1- Pre-Dose	-394.0 (-394 to 394)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)
C1D1- 4 hours post dose	-1049.0 (-1049 to -1049)	-603.0 (-603 to -603)	-762.0 (-847 to -565)	-391.0 (-635 to -176)
C2D1- Pre-Dose	-421.0 (-729 to -31)	-26.0 (-538 to 104)	-414.0 (-1101 to 630)	-153.0 (-774 to -38)
C2D1- 4 hours post dose	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	-167.5 (-229 to -106)

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	9	10
Units: Melt Flow Index (MFI)				
median (full range (min-max))				
Baseline Response	434.0 (169 to 884)	634.0 (94 to 1166)	592.0 (162 to 933)	714.0 (234 to 1438)
C1D1- Pre-Dose	99999 (99999 to 99999)	-636.0 (-636 to -636)	99999 (99999 to 99999)	99999 (99999 to 99999)
C1D1- 4 hours post dose	-324.0 (-481 to -95)	-545.0 (-1029 to -184)	-382.5 (-649 to -116)	-654.5 (-1405 to -214)
C2D1- Pre-Dose	-185.0 (-865 to -177)	-627.0 (-632 to -622)	-294.0 (-500 to 308)	-185.5 (-1155 to 430)
C2D1- 4 hours post dose	-336.5 (-507 to -166)	-567.0 (-615 to -372)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	6			
Units: Melt Flow Index (MFI)				
median (full range (min-max))				
Baseline Response	506.5 (20 to 943)			
C1D1- Pre-Dose	99999 (99999 to 99999)			
C1D1- 4 hours post dose	-490.0 (-928 to -429)			
C2D1- Pre-Dose	11.5 (-104 to 148)			

C2D1- 4 hours post dose	-465.5 (-911 to 254)			

Statistical analyses

No statistical analyses for this end point

Secondary: Changes from Baseline in ICOS Ligand+ B Cells

End point title	Changes from Baseline in ICOS Ligand+ B Cells

End point description:

Summary measures of changes from baseline to the last evaluable time point in ICOS ligand+ B cells in the tumor and peripheral blood. Baseline = last non missing value prior or on to the first dosing.

End point type	Secondary

End point timeframe:

From baseline up to pre-dose and 4 hours post dose on C1D1, 72 hours post dose on C1D4, and pre-dose on C2D1 (approximately 31 months)

End point values	Preliminary - BMS-986226 2 mg	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	6	10
Units: Melt Flow Index (MFI)				
median (full range (min-max))				
Baseline Response	-9.0 (-94 to 185)	-33.0 (-70 to 67)	2.5 (-99 to 95)	40.5 (-90 to 127)
C1D1 - 4 hours post dose	-106.0 (-106 to -106)	-2.0 (-2 to -2)	-3.0 (-48 to 37)	1.0 (-9 to 23)
C1D4- 72 hours post dose	11.0 (-181 to 58)	102.0 (-28 to 190)	170.0 (118 to 210)	37.0 (-143 to 231)
C2D1- Pre dose	-4.0 (-267 to 54)	-24.0 (-211 to 24)	96.0 (-167 to 207)	-17.0 (-100 to 170)

End point values	Part A - BMS-986226 200 mg	Part A - BMS-986226 400 mg	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	9	9	10
Units: Melt Flow Index (MFI)				
median (full range (min-max))				
Baseline Response	-60.5 (-171 to 74)	57.0 (-100 to 182)	-15.0 (-79 to 70)	-11.5 (-113 to 41)
C1D1 - 4 hours post dose	-13.5 (-55 to 0)	9.5 (-16 to 99)	3.5 (1 to 6)	0.0 (-14 to 37)

C1D4- 72 hours post dose	64.5 (-71 to 127)	29.0 (-106 to 88)	90.0 (17 to 163)	70.0 (3 to 143)
C2D1- Pre dose	103.5 (-39 to 216)	-28.0 (-74 to 18)	-9.0 (-129 to 83)	61.5 (-20 to 186)

End point values	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg			
Subject group type	Reporting group			
Number of subjects analysed	8			
Units: Melt Flow Index (MFI)				
median (full range (min-max))				
Baseline Response	39.0 (-56 to 103)			
C1D1 - 4 hours post dose	-6.0 (-21 to 40)			
C1D4- 72 hours post dose	33.5 (-28 to 121)			
C2D1- Pre dose	-17.0 (-175 to 103)			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

Participants were assessed for all-cause mortality from their enrollment to study completion, (up to approximately 50 months). SAEs and Other AEs were assessed from first dose to 100 days following last dose (up to approximately 31 months)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.1

Reporting groups

Reporting group title	Preliminary - BMS-986226 8 mg

Reporting group description:

Preliminary safety cohort participants received BMS-986226 8 mg every 4 weeks

Reporting group title	Part A - BMS-986226 25 mg

Reporting group description:

Part A cohort participants received BMS-986226 25 mg every 4 weeks for 24 weeks

Reporting group title	Part A - BMS-986226 80 mg

Reporting group description:

Part A cohort participants received BMS-986226 80 mg every 4 weeks for 24 weeks

Reporting group title	Part A - BMS-986226 200 mg

Reporting group description:

Part A cohort participants received BMS-986226 200 mg every 4 weeks for 24 weeks

Reporting group title	Preliminary - BMS-986226 2 mg

Reporting group description:

Preliminary safety cohort participants received BMS-986226 2 mg every 4 weeks

Reporting group title	Part A - BMS-986226 400 mg

Reporting group description:

Part A cohort participants received BMS-986226 400 mg every 4 weeks for 24 weeks

Reporting group title	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg

Reporting group description:

Part C1 cohort participants received BMS-986226 25 mg every 12 weeks plus Ipilimumab 3 mg/kg every 4 weeks

Reporting group title	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg

Reporting group description:

Part C1 cohort participants received BMS-986226 200 mg every 12 weeks plus Ipilimumab 3 mg/kg every 4 weeks

Reporting group title	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg

Reporting group description:

Part C2 cohort participants received BMS-986226 25 mg every 4 weeks plus Ipilimumab 3 mg/kg every 4 weeks

Reporting group title	Total

Reporting group description:

Total treated participants

Serious adverse events	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 7 (42.86%)	2 / 7 (28.57%)	10 / 11 (90.91%)
number of deaths (all causes)	3	5	8
number of deaths resulting from adverse events	1	1	4
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 11 (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 / 7 (28.57%)	0 / 7 (0.00%)	5 / 11 (45.45%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 4
Tumour associated fever			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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			
Shock			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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			
Dyspnoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Assisted suicide			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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 / 7 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocarditis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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			
Cerebrovascular accident			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	2 / 11 (18.18%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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			
Biliary obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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			
Bone pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Otitis media			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
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	Part A - BMS-986226 200 mg	Preliminary - BMS-986226 2 mg	Part A - BMS-986226 400 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 9 (55.56%)	2 / 6 (33.33%)	9 / 9 (100.00%)
number of deaths (all causes)	5	5	7
number of deaths resulting from adverse events	4	1	6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	4 / 9 (44.44%)	1 / 6 (16.67%)	6 / 9 (66.67%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 6
deaths causally related to treatment / all	0 / 4	0 / 1	0 / 6
Tumour associated fever			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Shock			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			

subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
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 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Assisted suicide			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocarditis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
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 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	2 / 9 (22.22%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Large intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			

subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Otitis media			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Urinary tract infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 10 (50.00%)	9 / 12 (75.00%)	5 / 9 (55.56%)
number of deaths (all causes)	7	8	5
number of deaths resulting from adverse events	4	7	4
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant neoplasm progression			
subjects affected / exposed	5 / 10 (50.00%)	6 / 12 (50.00%)	4 / 9 (44.44%)
occurrences causally related to treatment / all	0 / 5	0 / 6	0 / 4
deaths causally related to treatment / all	0 / 4	0 / 5	0 / 4
Tumour associated fever			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Vascular disorders			
Shock			

subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			

subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epistaxis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 10 (0.00%)	2 / 12 (16.67%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Assisted suicide			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hallucination			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase			

increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood bilirubin increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocarditis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysarthria			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			

subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			

subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Otitis media			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic infection			

subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Total		
Total subjects affected by serious adverse events			
subjects affected / exposed	50 / 80 (62.50%)		
number of deaths (all causes)	53		
number of deaths resulting from adverse events	32		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Malignant neoplasm progression			
subjects affected / exposed	33 / 80 (41.25%)		
occurrences causally related to treatment / all	0 / 33		
deaths causally related to treatment / all	0 / 29		

Tumour associated fever				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Tumour haemorrhage				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Vascular disorders				
Shock				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
General disorders and administration site conditions				
Chest pain				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Fatigue				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
General physical health deterioration				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Pain				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pyrexia				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			

Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Epistaxis			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Pneumonitis			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Assisted suicide			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Hallucination			

subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Blood bilirubin increased			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences causally related to treatment / all	1 / 4		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Myocarditis			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pericarditis			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Cerebrovascular accident			

subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Dysarthria				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Encephalopathy				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal pain				
subjects affected / exposed	4 / 80 (5.00%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 0			
Ascites				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Intestinal obstruction				
subjects affected / exposed	3 / 80 (3.75%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 1			
Large intestinal obstruction				

subjects affected / exposed	2 / 80 (2.50%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Rectal haemorrhage			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyperbilirubinaemia			
subjects affected / exposed	3 / 80 (3.75%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Jaundice			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Bone pain			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Infections and infestations			
Otitis media			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pelvic infection			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 1		
Sepsis			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Vascular device infection			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Preliminary - BMS-986226 8 mg	Part A - BMS-986226 25 mg	Part A - BMS-986226 80 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)	7 / 7 (100.00%)	10 / 11 (90.91%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 7 (0.00%)	2 / 7 (28.57%)	0 / 11 (0.00%)
occurrences (all)	0	2	0
Hypertension			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Hot flush			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Fatigue			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	4 / 11 (36.36%)
occurrences (all)	1	1	4
Malaise			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Pain			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	1 / 11 (9.09%)
occurrences (all)	1	1	1
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oedema genital			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 7 (28.57%)	1 / 7 (14.29%)	1 / 11 (9.09%)
occurrences (all)	2	1	1
Dyspnoea			
subjects affected / exposed	2 / 7 (28.57%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	2	1	0
Haemoptysis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Nasal congestion			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Hiccups			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			

subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Rhinorrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Hallucination			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Investigations			
Amylase increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	3 / 7 (42.86%)	0 / 7 (0.00%)	2 / 11 (18.18%)
occurrences (all)	3	0	2
Blood alkaline phosphatase increased			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	3 / 11 (27.27%)
occurrences (all)	1	1	3
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
CD4 lymphocytes decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Lipase increased			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	1 / 11 (9.09%)
occurrences (all)	0	1	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Fall			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	3 / 7 (42.86%)	3 / 7 (42.86%)	5 / 11 (45.45%)
occurrences (all)	3	3	6
Muscle strain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Subdural haematoma			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Dysaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Lethargy			

subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	2 / 7 (28.57%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1
Neuralgia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Tremor			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	3 / 11 (27.27%)
occurrences (all)	0	0	3
Eosinophilia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0

Lymphopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Ascites			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	3 / 11 (27.27%)
occurrences (all)	1	1	4
Constipation			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	1	0	1
Diarrhoea			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	3 / 11 (27.27%)
occurrences (all)	0	0	3
Dyspepsia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Melaena			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	2 / 7 (28.57%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	2	0	1
Rectal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Hepatobiliary disease			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1

Hyperbilirubinaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Portal hypertension			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Erythema			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Nail disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Urticaria			

subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Renal disorder			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	1	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Back pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Bone pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Flank pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	0 / 11 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Fungal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Mucosal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1

Upper respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0
Soft tissue infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	2 / 11 (18.18%)
occurrences (all)	1	1	2
Dehydration			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	2 / 11 (18.18%)
occurrences (all)	0	0	2
Hypercalcaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 7 (14.29%)	1 / 7 (14.29%)	1 / 11 (9.09%)
occurrences (all)	1	1	2
Hypernatraemia			
subjects affected / exposed	0 / 7 (0.00%)	1 / 7 (14.29%)	1 / 11 (9.09%)
occurrences (all)	0	1	2
Hyperphosphataemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			

subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	1 / 11 (9.09%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 7 (0.00%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	1 / 7 (14.29%)	0 / 7 (0.00%)	0 / 11 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Part A - BMS-986226 200 mg	Preliminary - BMS-986226 2 mg	Part A - BMS-986226 400 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 9 (100.00%)	6 / 6 (100.00%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Fatigue			
subjects affected / exposed	3 / 9 (33.33%)	2 / 6 (33.33%)	5 / 9 (55.56%)
occurrences (all)	3	2	6
Malaise			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Mucosal inflammation			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Oedema peripheral			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	2 / 9 (22.22%)
occurrences (all)	1	0	2
Pyrexia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	3 / 9 (33.33%)
occurrences (all)	1	0	4
Reproductive system and breast disorders			
Pelvic pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Oedema genital			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 9 (11.11%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Dyspnoea			

subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinorrhoea			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Anxiety			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1

Insomnia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Investigations			
Amylase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Alanine aminotransferase increased			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 9 (11.11%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	3 / 9 (33.33%)
occurrences (all)	0	0	3
CD4 lymphocytes decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	4
Platelet count decreased			

subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Clavicle fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	8 / 9 (88.89%)	0 / 6 (0.00%)	8 / 9 (88.89%)
occurrences (all)	9	0	9
Muscle strain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Subdural haematoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tachycardia			

subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Dizziness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dysaesthesia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Lethargy			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Headache			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Paraesthesia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Presyncope			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Tremor			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 6 (16.67%)	3 / 9 (33.33%)
occurrences (all)	1	1	3
Eosinophilia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Asthenopia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Periorbital oedema			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	1 / 9 (11.11%)
occurrences (all)	0	1	1

Ascites			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	2 / 9 (22.22%)	0 / 6 (0.00%)	2 / 9 (22.22%)
occurrences (all)	2	0	2
Constipation			
subjects affected / exposed	1 / 9 (11.11%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Diarrhoea			
subjects affected / exposed	0 / 9 (0.00%)	2 / 6 (33.33%)	4 / 9 (44.44%)
occurrences (all)	0	3	4
Dyspepsia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Flatulence			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Haematochezia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Nausea			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	6 / 9 (66.67%)
occurrences (all)	0	1	6

Rectal haemorrhage			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 9 (22.22%)	1 / 6 (16.67%)	2 / 9 (22.22%)
occurrences (all)	2	1	2
Hepatobiliary disorders			
Hepatobiliary disease			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Portal hypertension			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Erythema			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pruritus			

subjects affected / exposed	0 / 9 (0.00%)	2 / 6 (33.33%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Nail disorder			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Urticaria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Urinary tract obstruction			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Bone pain			

subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	2 / 9 (22.22%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Pain in jaw			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis viral			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Herpes zoster			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mucosal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Skin infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 9 (11.11%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	1	0	1
Vaginal infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	5 / 9 (55.56%)
occurrences (all)	0	1	5
Dehydration			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hypercalcaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			

subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hypernatraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 6 (16.67%)	2 / 9 (22.22%)
occurrences (all)	0	1	3
Hyponatraemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 6 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1

Non-serious adverse events	Part C1 - BMS-986226 25 mg + Ipilimumab 3 mg/kg	Part C1 - BMS-986226 200 mg + Ipilimumab 3 mg/kg	Part C2 - BMS-986226 25 mg + Ipilimumab 3 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)	12 / 12 (100.00%)	9 / 9 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Flushing			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypertension			

subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	2 / 9 (22.22%)
occurrences (all)	0	1	2
Hot flush			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hypotension			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	2 / 9 (22.22%)
occurrences (all)	0	1	2
Fatigue			
subjects affected / exposed	3 / 10 (30.00%)	5 / 12 (41.67%)	1 / 9 (11.11%)
occurrences (all)	3	5	1
Malaise			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 10 (10.00%)	1 / 12 (8.33%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	2 / 10 (20.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	3	1	0
Reproductive system and breast disorders			

Pelvic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oedema genital			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Vaginal discharge			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	2 / 9 (22.22%)
occurrences (all)	0	1	2
Dyspnoea			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Dyspnoea exertional			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			

subjects affected / exposed	0 / 10 (0.00%)	2 / 12 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Rhinorrhoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hallucination			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Investigations			
Amylase increased			
subjects affected / exposed	1 / 10 (10.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	1	5	0
Alanine aminotransferase increased			
subjects affected / exposed	2 / 10 (20.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences (all)	2	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	4 / 10 (40.00%)	3 / 12 (25.00%)	1 / 9 (11.11%)
occurrences (all)	4	4	2
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 10 (0.00%)	2 / 12 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	3	0
Blood bilirubin increased			
subjects affected / exposed	2 / 10 (20.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	2	1	0
Blood creatinine increased			

subjects affected / exposed	0 / 10 (0.00%)	3 / 12 (25.00%)	0 / 9 (0.00%)
occurrences (all)	0	4	0
CD4 lymphocytes decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Lipase increased			
subjects affected / exposed	1 / 10 (10.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	1	4	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Platelet count decreased			
subjects affected / exposed	0 / 10 (0.00%)	2 / 12 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Weight decreased			
subjects affected / exposed	1 / 10 (10.00%)	2 / 12 (16.67%)	0 / 9 (0.00%)
occurrences (all)	1	2	0
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Clavicle fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Infusion related reaction			
subjects affected / exposed	4 / 10 (40.00%)	6 / 12 (50.00%)	3 / 9 (33.33%)
occurrences (all)	5	7	4
Muscle strain			

subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed	0 / 10 (0.00%)	2 / 12 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Subdural haematoma			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Sinus tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Dysaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Lethargy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Headache			

subjects affected / exposed	0 / 10 (0.00%)	2 / 12 (16.67%)	2 / 9 (22.22%)
occurrences (all)	0	4	2
Neuralgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	2 / 10 (20.00%)	4 / 12 (33.33%)	0 / 9 (0.00%)
occurrences (all)	3	4	0
Eosinophilia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Lymphopenia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Thrombocytopenia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0

Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Asthenopia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Conjunctival haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Periorbital oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Ascites			
subjects affected / exposed	1 / 10 (10.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Abdominal pain			
subjects affected / exposed	3 / 10 (30.00%)	3 / 12 (25.00%)	0 / 9 (0.00%)
occurrences (all)	3	3	0
Constipation			
subjects affected / exposed	1 / 10 (10.00%)	3 / 12 (25.00%)	2 / 9 (22.22%)
occurrences (all)	1	3	2
Diarrhoea			
subjects affected / exposed	1 / 10 (10.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Dyspepsia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Haematochezia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Inguinal hernia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 10 (30.00%)	3 / 12 (25.00%)	0 / 9 (0.00%)
occurrences (all)	3	3	0
Rectal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	1 / 10 (10.00%)	4 / 12 (33.33%)	3 / 9 (33.33%)
occurrences (all)	1	4	6
Hepatobiliary disorders			
Hepatobiliary disease			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Hyperbilirubinaemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Jaundice			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0

Portal hypertension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 10 (0.00%)	2 / 12 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Dermatitis acneiform			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	1 / 10 (10.00%)	4 / 12 (33.33%)	1 / 9 (11.11%)
occurrences (all)	1	4	1
Nail disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	1 / 10 (10.00%)	1 / 12 (8.33%)	1 / 9 (11.11%)
occurrences (all)	1	1	1
Rash maculo-papular			
subjects affected / exposed	1 / 10 (10.00%)	3 / 12 (25.00%)	0 / 9 (0.00%)
occurrences (all)	1	5	0
Urticaria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Urinary tract obstruction			

subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Renal disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	1	1	0
Back pain			
subjects affected / exposed	2 / 10 (20.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	2	0	0
Bone pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Flank pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Myalgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	2 / 9 (22.22%)
occurrences (all)	0	0	2
Pain in jaw			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Neck pain			

subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Fungal infection			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis viral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	1 / 9 (11.11%)
occurrences (all)	0	1	1
Oral herpes			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Mucosal infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1
Skin infection			
subjects affected / exposed	0 / 10 (0.00%)	2 / 12 (16.67%)	0 / 9 (0.00%)
occurrences (all)	0	2	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Soft tissue infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	1 / 9 (11.11%)
occurrences (all)	0	0	1

Urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 10 (20.00%)	3 / 12 (25.00%)	0 / 9 (0.00%)
occurrences (all)	2	3	0
Dehydration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypercalcaemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	3	0
Hypernatraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperphosphataemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hyperuricaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			

subjects affected / exposed	0 / 10 (0.00%)	1 / 12 (8.33%)	0 / 9 (0.00%)
occurrences (all)	0	1	0
Hyponatraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 12 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Total		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	79 / 80 (98.75%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Vascular disorders			
Flushing			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Hypertension			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	4		
Hot flush			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Hypotension			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
General disorders and administration site conditions			
Chills			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	4		
Fatigue			
subjects affected / exposed	25 / 80 (31.25%)		
occurrences (all)	26		
Malaise			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		

Mucosal inflammation subjects affected / exposed occurrences (all)	1 / 80 (1.25%) 1		
Non-cardiac chest pain subjects affected / exposed occurrences (all)	2 / 80 (2.50%) 2		
Oedema peripheral subjects affected / exposed occurrences (all)	6 / 80 (7.50%) 6		
Pain subjects affected / exposed occurrences (all)	4 / 80 (5.00%) 4		
Pyrexia subjects affected / exposed occurrences (all)	10 / 80 (12.50%) 12		
Reproductive system and breast disorders			
Pelvic pain subjects affected / exposed occurrences (all)	1 / 80 (1.25%) 1		
Oedema genital subjects affected / exposed occurrences (all)	1 / 80 (1.25%) 1		
Vaginal discharge subjects affected / exposed occurrences (all)	1 / 80 (1.25%) 1		
Respiratory, thoracic and mediastinal disorders			
Cough subjects affected / exposed occurrences (all)	9 / 80 (11.25%) 9		
Dyspnoea subjects affected / exposed occurrences (all)	5 / 80 (6.25%) 5		
Haemoptysis subjects affected / exposed occurrences (all)	1 / 80 (1.25%) 1		
Dyspnoea exertional			

subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Nasal congestion			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Hiccups			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Oropharyngeal pain			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Rhinitis allergic			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Pleural effusion			
subjects affected / exposed	3 / 80 (3.75%)		
occurrences (all)	3		
Rhinorrhoea			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Psychiatric disorders			
Confusional state			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Anxiety			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Hallucination			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Investigations			
Amylase increased			

subjects affected / exposed	3 / 80 (3.75%)			
occurrences (all)	7			
Alanine aminotransferase increased				
subjects affected / exposed	6 / 80 (7.50%)			
occurrences (all)	7			
Aspartate aminotransferase increased				
subjects affected / exposed	15 / 80 (18.75%)			
occurrences (all)	17			
Blood alkaline phosphatase increased				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences (all)	3			
Blood bilirubin increased				
subjects affected / exposed	8 / 80 (10.00%)			
occurrences (all)	8			
Blood creatinine increased				
subjects affected / exposed	6 / 80 (7.50%)			
occurrences (all)	7			
CD4 lymphocytes decreased				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences (all)	1			
Gamma-glutamyltransferase increased				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences (all)	3			
Lipase increased				
subjects affected / exposed	4 / 80 (5.00%)			
occurrences (all)	7			
Lymphocyte count decreased				
subjects affected / exposed	3 / 80 (3.75%)			
occurrences (all)	5			
Platelet count decreased				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences (all)	2			
Weight decreased				

subjects affected / exposed	3 / 80 (3.75%)		
occurrences (all)	3		
Injury, poisoning and procedural complications			
Abdominal wound dehiscence			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Clavicle fracture			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Fall			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Infusion related reaction			
subjects affected / exposed	40 / 80 (50.00%)		
occurrences (all)	46		
Muscle strain			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Procedural pain			
subjects affected / exposed	3 / 80 (3.75%)		
occurrences (all)	3		
Subdural haematoma			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Cardiac disorders			
Angina pectoris			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Sinus tachycardia			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Tachycardia			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Nervous system disorders			

Amnesia				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences (all)	1			
Dizziness				
subjects affected / exposed	3 / 80 (3.75%)			
occurrences (all)	3			
Dysaesthesia				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences (all)	2			
Lethargy				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences (all)	1			
Hypoaesthesia				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences (all)	2			
Headache				
subjects affected / exposed	7 / 80 (8.75%)			
occurrences (all)	9			
Neuralgia				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences (all)	2			
Neuropathy peripheral				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences (all)	2			
Paraesthesia				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences (all)	2			
Peripheral sensory neuropathy				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences (all)	1			
Presyncope				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences (all)	1			
Tremor				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences (all)	1			

Somnolence			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	14 / 80 (17.50%)		
occurrences (all)	15		
Eosinophilia			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Lymphopenia			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Thrombocytopenia			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Ear and labyrinth disorders			
Deafness			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Eye disorders			
Asthenopia			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Conjunctival haemorrhage			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Periorbital oedema			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	4		
Ascites			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		

Abdominal pain				
subjects affected / exposed	15 / 80 (18.75%)			
occurrences (all)	16			
Constipation				
subjects affected / exposed	10 / 80 (12.50%)			
occurrences (all)	10			
Diarrhoea				
subjects affected / exposed	11 / 80 (13.75%)			
occurrences (all)	12			
Dyspepsia				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences (all)	2			
Flatulence				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences (all)	1			
Haematochezia				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences (all)	1			
Gastrooesophageal reflux disease				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences (all)	1			
Inguinal hernia				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences (all)	1			
Melaena				
subjects affected / exposed	1 / 80 (1.25%)			
occurrences (all)	1			
Intestinal obstruction				
subjects affected / exposed	3 / 80 (3.75%)			
occurrences (all)	3			
Nausea				
subjects affected / exposed	16 / 80 (20.00%)			
occurrences (all)	16			
Rectal haemorrhage				
subjects affected / exposed	2 / 80 (2.50%)			
occurrences (all)	2			

Stomatitis			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Vomiting			
subjects affected / exposed	14 / 80 (17.50%)		
occurrences (all)	17		
Hepatobiliary disorders			
Hepatobiliary disease			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Hyperbilirubinaemia			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Jaundice			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Portal hypertension			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Dermatitis acneiform			
subjects affected / exposed	3 / 80 (3.75%)		
occurrences (all)	3		
Erythema			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Hyperhidrosis			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Pruritus			
subjects affected / exposed	9 / 80 (11.25%)		
occurrences (all)	9		
Nail disorder			

subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	3 / 80 (3.75%)		
occurrences (all)	3		
Rash maculo-papular			
subjects affected / exposed	6 / 80 (7.50%)		
occurrences (all)	8		
Urticaria			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Renal and urinary disorders			
Haematuria			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Urinary tract obstruction			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Renal disorder			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	3 / 80 (3.75%)		
occurrences (all)	3		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 80 (3.75%)		
occurrences (all)	3		
Back pain			
subjects affected / exposed	3 / 80 (3.75%)		
occurrences (all)	3		
Bone pain			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Flank pain			

subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Musculoskeletal chest pain			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Myalgia			
subjects affected / exposed	5 / 80 (6.25%)		
occurrences (all)	5		
Pain in jaw			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Pain in extremity			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Neck pain			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Cystitis			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Fungal infection			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Gastroenteritis viral			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Herpes zoster			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Oral herpes			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		

Mucosal infection			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Pneumonia			
subjects affected / exposed	3 / 80 (3.75%)		
occurrences (all)	3		
Skin infection			
subjects affected / exposed	3 / 80 (3.75%)		
occurrences (all)	3		
Upper respiratory tract infection			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Soft tissue infection			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Urinary tract infection			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Vaginal infection			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	15 / 80 (18.75%)		
occurrences (all)	15		
Dehydration			
subjects affected / exposed	3 / 80 (3.75%)		
occurrences (all)	3		
Hypercalcaemia			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Hyperkalaemia			
subjects affected / exposed	5 / 80 (6.25%)		
occurrences (all)	8		
Hypernatraemia			

subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	3		
Hyperphosphataemia			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Hyperuricaemia			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Hypoalbuminaemia			
subjects affected / exposed	1 / 80 (1.25%)		
occurrences (all)	1		
Hypoglycaemia			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		
Hypomagnesaemia			
subjects affected / exposed	4 / 80 (5.00%)		
occurrences (all)	5		
Hyponatraemia			
subjects affected / exposed	2 / 80 (2.50%)		
occurrences (all)	2		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 July 2017	Preliminary safety cohort added
03 April 2018	Combination escalation modification of BMS-986226 with either nivolumab (Part B) or ipilimumab (Part C) to include and prioritize a Q12W dosing schedule. On-treatment biopsy collections were changed to Q2W and Q12W. A tetanus booster will be administered to capture pharmacodynamic activity in an antigen-specific context. Treatment duration of BMS-986226 in combination with nivolumab or ipilimumab will be 2 years.
02 December 2018	The eligibility criteria was modified to include additional tumor types, including but not limited to Cervical Cancer (CC), Melanoma (MEL), Renal Cell Carcinoma (RCC) and Triple Negative Breast Cancer (TNBC). The eligibility criteria was modified to allow for up to three prior lines of systemic therapy. The requirement for ICOS expression confirmation by IHC in pretreatment biopsies prior to start of treatment was removed. The protocol was modified to require tetanus booster administration 3-7 days prior to first treatment. The protocol was modified to optimize sample collection for pharmacokinetic, pharmacodynamic and biomarker analysis. The option for retreatment was removed from the protocol.
31 May 2019	Fasting glucose testing was limited to the Screening Period; on treatment glucose testing can be non-fasting. Guidance for premedication was added.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Study CA021002 was terminated because the Sponsor discontinued further development of BMS-986226. The decision for the study closure was not related to any safety concerns associated with BMS-986226.

Notes: