Clinical trial results:
A Phase I/IIa Study of BMS 986148, a Mesothelin Directed Antibody Drug Conjugate, in Subjects with Select Advanced Solid Tumors

Summary

EudraCT number	2014-002485-70
Trial protocol	NL BE GB
Global end of trial date	07 May 2020

Results information

Result version number	v1 (current)
This version publication date	09 April 2022
First version publication date	09 April 2022

Trial information

Trial identification

Sponsor protocol code	CA008-002

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02341625
WHO universal trial number (UTN)	U1111-1165-9742

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	07 May 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	07 May 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and tolerability of BMS-986148 in subjects with select 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	19 June 2015
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	Netherlands: 13
Country: Number of subjects enrolled	United Kingdom: 1
Country: Number of subjects enrolled	Belgium: 30
Country: Number of subjects enrolled	Italy: 9
Country: Number of subjects enrolled	Australia: 23
Country: Number of subjects enrolled	Canada: 28
Country: Number of subjects enrolled	United States: 22
Worldwide total number of subjects	126
EEA total number of subjects	52

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)	73
From 65 to 84 years	53
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

126 participants treated

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	BMS-986148 0.1MG/KG Q3W

Arm description:

Part 1A Dose Escalation: BMS-986148 0.1 mg/kg IV Q3W in a 21-day cycle

Arm type	Experimental
Investigational medicinal product name	BMS-986148
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

0.1MG/KG Q3W infused within 60 minutes

Arm title	BMS-986148 0.2MG/KG Q3W

Arm description:

Part 1A Dose Escalation: BMS-986148 0.2 mg/kg IV Q3W in a 21-day cycle

Arm type	Experimental
Investigational medicinal product name	BMS-986148
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

0.2MG/KG Q3W infused within 60 minutes

Arm title	BMS-986148 0.4MG/KG Q3W

Arm description:

Part 1A Dose Escalation: BMS-986148 0.4 mg/kg IV Q3W in a 21-day cycle

Arm type	Experimental
Investigational medicinal product name	BMS-986148
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

0.4MG/KG Q3W infused within 60 minutes

Arm title	BMS-986148 0.8MG/KG Q3W

Arm description:	
Part 1A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W in a 21-day cycle	
Arm type	Experimental
Investigational medicinal product name	BMS-986148
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
0.8MG/KG Q3W infused within 60 minutes	
Arm title	BMS-986148 1.2MG/KG Q3W Es
Arm description:	
Part 1A Dose Escalation BMS-986148 1.2 mg/kg IV Q3W	
Arm type	Experimental
Investigational medicinal product name	BMS-986148
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
1.2MG/KG Q3W infused within 60 minutes	
Arm title	BMS-986148 1.6MG/KG Q3W
Arm description:	
Part 1A Dose Escalation: BMS-986148 1.6 mg/kg IV Q3W in a 21-day cycle	
Arm type	Experimental
Investigational medicinal product name	BMS-986148
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
1.6MG/KG Q3W infused within 60 minutes	
Arm title	BMS-986148 1.2MG/KG Q3W Ex
Arm description:	
Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer	
Arm type	Experimental
Investigational medicinal product name	BMS-986148
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use
Dosage and administration details:	
1.2MG/KG Q3W infused within 60 minutes	
Arm title	BMS-986148 0.4MG/KG QW
Arm description:	
Part 1B Dose Escalation: BMS-986148 0.4 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle	
Arm type	Experimental

Investigational medicinal product name	BMS-986148
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

0.4 MG/KG QW infused within 60 minutes

Arm title	BMS-986148 0.6MG/KG QW

Arm description:

Part 1B Dose Escalation: BMS-986148 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle

Arm type	Experimental
Investigational medicinal product name	BMS-986148
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

0.6 MG/KG QW infused within 60 minutes

Arm title	BMS-986148 0.8MG/KG Q3W+Nivolumab

Arm description:

Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle
Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer

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

Dosage and administration details:

360mg as a 30-minute infusion on Day 1 of each 21-day treatment cycle

Investigational medicinal product name	BMS-986148
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

0.8 MG/KG QW infused within 60 minutes

Number of subjects in period 1	BMS-986148 0.1MG/KG Q3W	BMS-986148 0.2MG/KG Q3W	BMS-986148 0.4MG/KG Q3W
Started	2	2	3
Completed	0	0	0
Not completed	2	2	3
Not Reported	-	-	-
Other Reasons	-	-	-
Participant Request to Discontinue Study Treatment	-	-	-

Completed Treatment as per Protocol	-	-	-
Adverse Event Unrelated to Study Drug	-	-	-
Study Drug Toxicity	-	-	-
Participant Withdrew Consent	-	-	-
Disease Progression	2	2	3

Number of subjects in period 1	BMS-986148 0.8MG/KG Q3W	BMS-986148 1.2MG/KG Q3W Es	BMS-986148 1.6MG/KG Q3W
Started	8	8	10
Completed	0	0	0
Not completed	8	8	10
Not Reported	-	-	-
Other Reasons	-	1	-
Participant Request to Discontinue Study Treatment	-	-	-
Completed Treatment as per Protocol	-	-	-
Adverse Event Unrelated to Study Drug	-	-	-
Study Drug Toxicity	1	-	3
Participant Withdrew Consent	1	-	-
Disease Progression	6	7	7

Number of subjects in period 1	BMS-986148 1.2MG/KG Q3W Ex	BMS-986148 0.4MG/KG QW	BMS-986148 0.6MG/KG QW
Started	51	8	4
Completed	0	0	0
Not completed	51	8	4
Not Reported	-	-	-
Other Reasons	5	-	-
Participant Request to Discontinue Study Treatment	6	2	-
Completed Treatment as per Protocol	-	-	-
Adverse Event Unrelated to Study Drug	2	1	-
Study Drug Toxicity	10	-	-
Participant Withdrew Consent	-	-	-
Disease Progression	28	5	4

Number of subjects in period 1	BMS-986148 0.8MG/KG Q3W+Nivolumab
Started	30
Completed	0
Not completed	30
Not Reported	3
Other Reasons	2

Participant Request to Discontinue Study Treatment	-
Completed Treatment as per Protocol	1
Adverse Event Unrelated to Study Drug	2
Study Drug Toxicity	3
Participant Withdrew Consent	-
Disease Progression	19

Baseline characteristics

Reporting groups	
Reporting group title	BMS-986148 0.1MG/KG Q3W
Reporting group description:	
Part 1A Dose Escalation: BMS-986148 0.1 mg/kg IV Q3W in a 21-day cycle	
Reporting group title	BMS-986148 0.2MG/KG Q3W
Reporting group description:	
Part 1A Dose Escalation: BMS-986148 0.2 mg/kg IV Q3W in a 21-day cycle	
Reporting group title	BMS-986148 0.4MG/KG Q3W
Reporting group description:	
Part 1A Dose Escalation: BMS-986148 0.4 mg/kg IV Q3W in a 21-day cycle	
Reporting group title	BMS-986148 0.8MG/KG Q3W
Reporting group description:	
Part 1A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W in a 21-day cycle	
Reporting group title	BMS-986148 1.2MG/KG Q3W Es
Reporting group description:	
Part 1A Dose Escalation BMS-986148 1.2 mg/kg IV Q3W	
Reporting group title	BMS-986148 1.6MG/KG Q3W
Reporting group description:	
Part 1A Dose Escalation: BMS-986148 1.6 mg/kg IV Q3W in a 21-day cycle	
Reporting group title	BMS-986148 1.2MG/KG Q3W Ex
Reporting group description:	
Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer	
Reporting group title	BMS-986148 0.4MG/KG QW
Reporting group description:	
Part 1B Dose Escalation: BMS-986148 0.4 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle	
Reporting group title	BMS-986148 0.6MG/KG QW
Reporting group description:	
Part 1B Dose Escalation: BMS-986148 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle	
Reporting group title	BMS-986148 0.8MG/KG Q3W+Nivolumab
Reporting group description:	
Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer	

Reporting group values	BMS-986148 0.1MG/KG Q3W	BMS-986148 0.2MG/KG Q3W	BMS-986148 0.4MG/KG Q3W
Number of subjects	2	2	3
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	2	0	2

From 65-84 years	0	2	1
85 years and over	0	0	0

Age Continuous			
Units: Years			
arithmetic mean	59.5	70.5	65.3
standard deviation	± 0.7	± 0.7	± 5.8
Sex: Female, Male			
Units: Participants			
Female	0	0	2
Male	2	2	1
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	1	2	3
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	1	0
Not Hispanic or Latino	2	1	3
Unknown or Not Reported	0	0	0

Reporting group values	BMS-986148 0.8MG/KG Q3W	BMS-986148 1.2MG/KG Q3W Es	BMS-986148 1.6MG/KG Q3W
Number of subjects	8	8	10
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	4	5	7
From 65-84 years	4	3	3
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	63.9	63.4	59.0
standard deviation	± 5.4	± 5.1	± 16.0
Sex: Female, Male			
Units: Participants			
Female	3	3	3
Male	5	5	7

Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	7	7	9
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	8	8	10
Unknown or Not Reported	0	0	0

Reporting group values	BMS-986148 1.2MG/KG Q3W Ex	BMS-986148 0.4MG/KG QW	BMS-986148 0.6MG/KG QW
Number of subjects	51	8	4
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	27	4	3
From 65-84 years	24	4	1
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	61.5	66.3	64.5
standard deviation	± 9.5	± 8.6	± 9.1
Sex: Female, Male Units: Participants			
Female	31	3	2
Male	20	5	2
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	2	0	1
White	46	8	3
More than one race	0	0	0
Unknown or Not Reported	3	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0

Not Hispanic or Latino	46	8	3
Unknown or Not Reported	5	0	1

Reporting group values	BMS-986148 0.8MG/KG Q3W+Nivolumab	Total	
Number of subjects	30	126	
Age categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	19	73	
From 65-84 years	11	53	
85 years and over	0	0	
Age Continuous Units: Years			
arithmetic mean	61.6		
standard deviation	± 9.4	-	
Sex: Female, Male Units: Participants			
Female	12	59	
Male	18	67	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	0	4	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	3	
White	30	116	
More than one race	0	0	
Unknown or Not Reported	0	3	
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	
Not Hispanic or Latino	25	114	
Unknown or Not Reported	5	11	

End points reporting groups

Reporting group title	BMS-986148 0.1MG/KG Q3W
Reporting group description: Part 1A Dose Escalation: BMS-986148 0.1 mg/kg IV Q3W in a 21-day cycle	
Reporting group title	BMS-986148 0.2MG/KG Q3W
Reporting group description: Part 1A Dose Escalation: BMS-986148 0.2 mg/kg IV Q3W in a 21-day cycle	
Reporting group title	BMS-986148 0.4MG/KG Q3W
Reporting group description: Part 1A Dose Escalation: BMS-986148 0.4 mg/kg IV Q3W in a 21-day cycle	
Reporting group title	BMS-986148 0.8MG/KG Q3W
Reporting group description: Part 1A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W in a 21-day cycle	
Reporting group title	BMS-986148 1.2MG/KG Q3W Es
Reporting group description: Part 1A Dose Escalation BMS-986148 1.2 mg/kg IV Q3W	
Reporting group title	BMS-986148 1.6MG/KG Q3W
Reporting group description: Part 1A Dose Escalation: BMS-986148 1.6 mg/kg IV Q3W in a 21-day cycle	
Reporting group title	BMS-986148 1.2MG/KG Q3W Ex
Reporting group description: Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer	
Reporting group title	BMS-986148 0.4MG/KG QW
Reporting group description: Part 1B Dose Escalation: BMS-986148 0.4 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle	
Reporting group title	BMS-986148 0.6MG/KG QW
Reporting group description: Part 1B Dose Escalation: BMS-986148 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle	
Reporting group title	BMS-986148 0.8MG/KG Q3W+Nivolumab
Reporting group description: Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer	
Subject analysis set title	BMS-986148 1.2MG/KG Q3W Es
Subject analysis set type	Full analysis
Subject analysis set description: Part 1A Dose Escalation BMS-986148 1.2 mg/kg IV Q3W and Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer	
Subject analysis set title	BMS 1.2MG/KG Q3W Ex
Subject analysis set type	Full analysis
Subject analysis set description: Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer	
Subject analysis set title	BMS 0.8MG/KG Q3W+Nivolumab Es
Subject analysis set type	Full analysis
Subject analysis set description: Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle	
Subject analysis set title	BMS 0.8MG/KG Q3W+Nivolumab Ex

Subject analysis set type	Full analysis

Subject analysis set description:

Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer

Subject analysis set title	BMS-986148 Mesothelioma
Subject analysis set type	Full analysis

Subject analysis set description:

Part 1A Dose Escalation: BMS-986148 starting with a dose of 0.1 mg/kg IV Q3W to a dose of 1.6 mg/kg IV Q3W in a 21-day cycle Part 1B Dose Escalation: BMS-986148 starting with a dose of 0.4 mg/kg IV QW to a dose of 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer

Subject analysis set title	BMS-986148+Nivolumab Mesothelioma
Subject analysis set type	Full analysis

Subject analysis set description:

Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer

Subject analysis set title	BMS-986148 Ovarian
Subject analysis set type	Full analysis

Subject analysis set description:

Part 1A Dose Escalation: BMS-986148 starting with a dose of 0.1 mg/kg IV Q3W to a dose of 1.6 mg/kg IV Q3W in a 21-day cycle Part 1B Dose Escalation: BMS-986148 starting with a dose of 0.4 mg/kg IV QW to a dose of 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer.

Subject analysis set title	BMS-986148+Nivolumab Ovarian
Subject analysis set type	Full analysis

Subject analysis set description:

Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer

Subject analysis set title	BMS-986148 Pancreatic
Subject analysis set type	Full analysis

Subject analysis set description:

Part 1A Dose Escalation: BMS-986148 starting with a dose of 0.8 mg/kg IV Q3W to a dose of 1.6 mg/kg IV Q3W in a 21-day cycle Part 1B Dose Escalation: BMS-986148 starting with a dose of 0.4 mg/kg IV QW to a dose of 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer.

Subject analysis set title	BMS-986148+Nivolumab Pancreatic
Subject analysis set type	Full analysis

Subject analysis set description:

Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer

Subject analysis set title	BMS-986148 NSCLC
Subject analysis set type	Full analysis

Subject analysis set description:

Part 1A Dose Escalation: BMS-986148 starting with a dose of 0.8 mg/kg IV Q3W to a dose of 1.6 mg/kg IV Q3W in a 21-day cycle Part 1B Dose Escalation: BMS-986148 starting with a dose of 0.4 mg/kg IV QW to a dose of 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer.

Subject analysis set title	BMS-986148+Nivolumab NSCLC
Subject analysis set type	Full analysis

Subject analysis set description:

Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five

tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer

Subject analysis set title	BMS-986148 Gastric
Subject analysis set type	Full analysis

Subject analysis set description:

Part 1A Dose Escalation: BMS-986148 starting with a dose of 0.8 mg/kg IV Q3W to a dose of 1.6 mg/kg IV Q3W in a 21-day cycle Part 1B Dose Escalation: BMS-986148 starting with a dose of 0.4 mg/kg IV QW to a dose of 0.6 mg/kg IV QW for 3 weeks and 1 week off in a 28-day cycle Part 2 Dose Expansion: BMS-986148 1.2 mg/kg IV Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer

Subject analysis set title	BMS-986148+Nivolumab Gastric
Subject analysis set type	Full analysis

Subject analysis set description:

Part 3A Dose Escalation: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W in a 21-day cycle Part 3B Dose Expansion: BMS-986148 0.8 mg/kg IV Q3W + Nivolumab 360 mg Q3W restricted to five tumor types: 1) mesothelioma; 2) pancreatic; 3) ovarian; 4) NSCLC; and 5) gastric cancer

Primary: Incidence of Participants with Adverse Events at Worst CTC Grade

End point title	Incidence of Participants with Adverse Events at Worst CTC Grade[1][2]

End point description:

Incidence of participants with adverse events at worst CTC grade including any grade adverse events (AEs), serious adverse events (SAEs), adverse events leading to discontinuations, and deaths grouped by dose + dose regimen.

End point type	Primary

End point timeframe:

From first dose to up to 100 days post last dose (Up to 6 months)

Notes:

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

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Baseline period arm is reported within the subject analysis set

End point values	BMS-986148 0.1MG/KG Q3W	BMS-986148 0.2MG/KG Q3W	BMS-986148 0.4MG/KG Q3W	BMS-986148 0.8MG/KG Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	8
Units: Participants				
Adverse Events (AEs)	1	2	3	8
Serious Adverse Events (SAEs)	1	1	1	5
AEs Leading to Discontinuation	0	0	0	1
Deaths	1	2	3	5

End point values	BMS-986148 1.6MG/KG Q3W	BMS-986148 0.4MG/KG QW	BMS-986148 0.6MG/KG QW	BMS-986148 0.8MG/KG Q3W+Nivolumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	8	4	30
Units: Participants				
Adverse Events (AEs)	10	8	4	30
Serious Adverse Events (SAEs)	4	6	3	21

AEs Leading to Discontinuation	3	1	0	7
Deaths	7	7	4	22

End point values	BMS-986148 1.2MG/KG Q3W Es			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: Participants				
Adverse Events (AEs)	59			
Serious Adverse Events (SAEs)	32			
AEs Leading to Discontinuation	11			
Deaths	38			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Laboratory Test Toxicity Grade Shifting from Baseline

End point title	Number of Participants with Laboratory Test Toxicity Grade Shifting from Baseline[3][4]

End point description:

Number of participants with laboratory test toxicity grade (Grade 0, 1, 2, 3, and 4) in hematology and chemistry shifting from baseline. An increase in baseline indicates a shift of participant to a greater toxicity grade. A decrease in baseline indicates a shift of participant to a lesser toxicity grade. Participants are grouped by dose + dose regimen assessed by NCT CTCAE V 4.03.

End point type	Primary

End point timeframe:

From first dose to up to 100 days post last dose (Up to 6 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 planned for this endpoint

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Baseline period arm is reported within the subject analysis set

End point values	BMS-986148 0.1MG/KG Q3W	BMS-986148 0.2MG/KG Q3W	BMS-986148 0.4MG/KG Q3W	BMS-986148 0.8MG/KG Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	8
Units: Participants				
Hemoglobin increase from baseline	1	1	0	3
Hemoglobin decrease from baseline	0	0	1	1
Platelet Count increase from baseline	0	0	0	3
Platelet Count decrease from baseline	0	0	0	0
Leukocytes increase from baseline	0	0	1	0
Leukocytes decrease from baseline	0	0	0	0

Neutrophils increase from baseline	0	0	0	0
Neutrophils decrease from baseline	0	0	0	0
Lymphocytes increase from baseline	1	2	1	3
Lymphocytes decrease from baseline	0	0	1	0
Absolute Neutrophil increase from baseline	0	0	0	0
Absolute Neutrophil decrease from baseline	0	0	0	0
ALP increase from baseline	0	1	1	6
ALP decrease from baseline	0	0	0	0
AST increase from baseline	0	1	1	6
AST decrease from baseline	0	0	0	0
ALT increase from baseline	0	0	0	7
ALT decrease from baseline	0	0	0	0
Bilirubin increase from baseline	0	1	0	2
Bilirubin decrease from baseline	0	0	0	0
Creatinine increase from baseline	0	0	1	2
Creatinine decrease from baseline	0	0	0	0
Sodium increase from baseline	0	1	1	4
Sodium decrease from baseline	1	0	0	0
Potassium increase from baseline	1	0	0	3
Potassium decrease from baseline	0	1	0	0
Calcium Total increase from baseline	0	0	0	5
Calcium Total decrease from baseline	0	0	0	0
Calcium Corrected increase from baseline	0	0	0	2
Calcium Corrected decrease from baseline	0	0	0	0
Phosphorus increase from baseline	2	0	2	3
Phosphorus decrease from baseline	0	0	0	0
Magnesium increase from baseline	0	1	1	2
Magnesium decrease from baseline	0	0	0	0
Glucose Fasting Serum increase from baseline	0	0	0	0
Glucose Fasting Serum decrease from baseline	0	0	0	0
Albumin increase from baseline	0	1	0	7
Albumin decrease from baseline	0	0	0	0
Amylase increase from baseline	0	0	0	0
Amylase decrease from baseline	0	0	0	0
Lipase increase from baseline	0	0	0	0
Lipase decrease from baseline	0	0	0	0
Creatine Kinase increase from baseline	0	0	1	0
Creatine Kinase decrease from baseline	0	0	0	0
Uric Acid increase from baseline	0	0	1	1
Uric Acid decrease from baseline	0	0	0	0

End point values	BMS-986148 1.6MG/KG Q3W	BMS-986148 0.4MG/KG QW	BMS-986148 0.6MG/KG QW	BMS-986148 0.8MG/KG Q3W+Nivolumab

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	8	4	30
Units: Participants				
Hemoglobin increase from baseline	3	2	1	12
Hemoglobin decrease from baseline	0	0	0	0
Platelet Count increase from baseline	4	0	1	6
Platelet Count decrease from baseline	0	0	0	0
Leukocytes increase from baseline	2	1	0	2
Leukocytes decrease from baseline	0	1	0	0
Neutrophils increase from baseline	1	0	0	1
Neutrophils decrease from baseline	0	0	0	0
Lymphocytes increase from baseline	6	6	3	19
Lymphocytes decrease from baseline	0	1	0	0
Absolute Neutrophil increase from baseline	2	0	0	2
Absolute Neutrophil decrease from baseline	0	0	0	0
ALP increase from baseline	10	5	4	24
ALP decrease from baseline	0	0	0	0
AST increase from baseline	10	6	4	26
AST decrease from baseline	0	0	0	0
ALT increase from baseline	10	5	3	25
ALT decrease from baseline	0	0	0	0
Bilirubin increase from baseline	3	2	2	7
Bilirubin decrease from baseline	0	0	0	0
Creatinine increase from baseline	2	1	3	5
Creatinine decrease from baseline	0	0	0	0
Sodium increase from baseline	4	1	2	17
Sodium decrease from baseline	0	0	0	0
Potassium increase from baseline	5	1	2	9
Potassium decrease from baseline	0	0	0	0
Calcium Total increase from baseline	4	3	1	10
Calcium Total decrease from baseline	0	0	0	1
Calcium Corrected increase from baseline	1	0	0	1
Calcium Corrected decrease from baseline	0	0	0	0
Phosphorus increase from baseline	4	1	2	7
Phosphorus decrease from baseline	0	1	0	0
Magnesium increase from baseline	4	1	2	5
Magnesium decrease from baseline	0	0	0	1
Glucose Fasting Serum increase from baseline	0	0	1	5
Glucose Fasting Serum decrease from baseline	0	0	0	1
Albumin increase from baseline	8	6	2	19
Albumin decrease from baseline	0	0	0	0
Amylase increase from baseline	0	0	0	1
Amylase decrease from baseline	0	0	0	0
Lipase increase from baseline	0	0	0	1
Lipase decrease from baseline	0	0	0	0
Creatine Kinase increase from baseline	0	0	0	3
Creatine Kinase decrease from baseline	0	0	0	0
Uric Acid increase from baseline	2	0	2	6

Uric Acid decrease from baseline	0	0	0	0

End point values	BMS-986148 1.2MG/KG Q3W Es			
Subject group type	Subject analysis set			
Number of subjects analysed	59			
Units: Participants				
Hemoglobin increase from baseline	20			
Hemoglobin decrease from baseline	3			
Platelet Count increase from baseline	14			
Platelet Count decrease from baseline	0			
Leukocytes increase from baseline	1			
Leukocytes decrease from baseline	1			
Neutrophils increase from baseline	3			
Neutrophils decrease from baseline	1			
Lymphocytes increase from baseline	27			
Lymphocytes decrease from baseline	0			
Absolute Neutrophil increase from baseline	3			
Absolute Neutrophil decrease from baseline	1			
ALP increase from baseline	46			
ALP decrease from baseline	0			
AST increase from baseline	53			
AST decrease from baseline	0			
ALT increase from baseline	50			
ALT decrease from baseline	1			
Bilirubin increase from baseline	16			
Bilirubin decrease from baseline	0			
Creatinine increase from baseline	7			
Creatinine decrease from baseline	0			
Sodium increase from baseline	23			
Sodium decrease from baseline	0			
Potassium increase from baseline	24			
Potassium decrease from baseline	3			
Calcium Total increase from baseline	17			
Calcium Total decrease from baseline	0			
Calcium Corrected increase from baseline	0			
Calcium Corrected decrease from baseline	0			
Phosphorus increase from baseline	24			
Phosphorus decrease from baseline	0			
Magnesium increase from baseline	22			
Magnesium decrease from baseline	3			
Glucose Fasting Serum increase from baseline	6			
Glucose Fasting Serum decrease from baseline	1			
Albumin increase from baseline	37			
Albumin decrease from baseline	0			

Amylase increase from baseline	0			
Amylase decrease from baseline	0			
Lipase increase from baseline	0			
Lipase decrease from baseline	0			
Creatine Kinase increase from baseline	9			
Creatine Kinase decrease from baseline	1			
Uric Acid increase from baseline	6			
Uric Acid decrease from baseline	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Serum Concentration (Cmax)

End point title	Maximum Observed Serum Concentration (Cmax)[5]

End point description:

Maximum observed serum concentration (Cmax) of BMS-986148 grouped by dose + dose regimen.
Note: The geometric CV was not calculated. Arithmetic % CV is reported instead.

End point type	Secondary

End point timeframe:

PK blood assessed on cycle 1, day 1

Notes:

[5] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Baseline period arm is reported within the subject analysis set

End point values	BMS-986148 0.1MG/KG Q3W	BMS-986148 0.2MG/KG Q3W	BMS-986148 0.4MG/KG Q3W	BMS-986148 0.8MG/KG Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2[6]	2[7]	3[8]	8[9]
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Total Antibody	2.3 (± 31.4)	2.8 (± 7.6)	3.3 (± 76.7)	16.4 (± 47.2)
Active Antibody-Drug Conjugate (ADC)	2.0 (± 29.8)	2.2 (± 8.2)	2.6 (± 76.1)	15.8 (± 46.4)
Unconjugated Tubulysin	99999 (± 99999)	99999 (± 99999)	0.5 (± 99999)	0.2 (± 17.1)

Notes:

[6] - Unconjugated Tubulysin = 0 participants analyzed

[7] - Unconjugated Tubulysin = 0 participants analyzed

[8] - Unconjugated Tubulysin =1 participants analyzed

[9] - Unconjugated Tubulysin = 4 participants analyzed

End point values	BMS-986148 1.2MG/KG Q3W Es	BMS-986148 1.6MG/KG Q3W	BMS-986148 0.4MG/KG QW	BMS-986148 0.6MG/KG QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8[10]	10[11]	8[12]	4[13]
Units: ug/mL				
geometric mean (geometric coefficient of variation)				

Total Antibody	28.5 (± 14.0)	39.8 (± 24.5)	9.3 (± 21.3)	14.5 (± 22.3)
Active Antibody-Drug Conjugate (ADC)	27.0 (± 18.6)	40.0 (± 26.3)	8.8 (± 20.3)	13.6 (± 31.0)
Unconjugated Tubulysin	0.4 (± 70.9)	0.4 (± 52.3)	0.1 (± 36.0)	0.4 (± 75.0)

Notes:

[10] - Total antibody and ADC = 7 participants analyzed

[11] - Unconjugated Tubulysin = 9 participants analyzed

[12] - Unconjugated Tubulysin = 2 participants analyzed

[13] - Unconjugated Tubulysin = 2 participants analyzed

End point values	BMS 1.2MG/KG Q3W Ex	BMS 0.8MG/KG Q3W+Nivolumab Es	BMS 0.8MG/KG Q3W+Nivolumab Ex	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	49[14]	11[15]	17[16]	
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Total Antibody	28.3 (± 22.5)	16.7 (± 19.7)	18.8 (± 22.4)	
Active Antibody-Drug Conjugate (ADC)	27.5 (± 22.6)	15.3 (± 27.6)	17.8 (± 24.6)	
Unconjugated Tubulysin	0.3 (± 58.2)	0.2 (± 42.5)	0.2 (± 42.5)	

Notes:

[14] - Unconjugated Tubulysin = 45 participants analyzed

[15] - Unconjugated Tubulysin = 5 participants analyzed

[16] - Unconjugated Tubulysin = 11 participants analyzed

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)[17]

End point description:

Time of maximum observed serum concentration (Tmax) of BMS-986148 grouped by dose + dose regimen.

End point type	Secondary

End point timeframe:

PK blood assessed on cycle 1, day 1

Notes:

[17] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Baseline period arm is reported within the subject analysis set

End point values	BMS-986148 0.1MG/KG Q3W	BMS-986148 0.2MG/KG Q3W	BMS-986148 0.4MG/KG Q3W	BMS-986148 0.8MG/KG Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2[18]	2[19]	3[20]	8[21]
Units: Hours				
median (full range (min-max))				
Total Antibody	2.2 (0.3 to 4.0)	2.2 (0.3 to 4.1)	3.9 (0.5 to 4.7)	4.0 (0.2 to 4.8)
Active Antibody-Drug Conjugate (ADC)	0.2 (0.1 to 0.3)	2.2 (0.3 to 4.1)	0.5 (0.1 to 3.9)	2.5 (0.2 to 4.0)
Unconjugated Tubulysin	99999 (99999 to 99999)	99999 (99999 to 99999)	25.5 (25.5 to 25.5)	120.2 (71.8 to 169.7)

Notes:

[18] - Unconjugated Tubulysin = 0 participants analyzed

[19] - Unconjugated Tubulysin = 0 participants analyzed

[20] - Unconjugated Tubulysin = 1 participants analyzed

[21] - Unconjugated Tubulysin = 4 participants analyzed

End point values	BMS-986148 1.2MG/KG Q3W Es	BMS-986148 1.6MG/KG Q3W	BMS-986148 0.4MG/KG QW	BMS-986148 0.6MG/KG QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8[22]	10[23]	8[24]	4[25]
Units: Hours				
median (full range (min-max))				
Total Antibody	4.1 (1.1 to 4.1)	3.9 (0.9 to 4.3)	4.0 (0.6 to 4.1)	3.8 (1.1 to 3.9)
Active Antibody-Drug Conjugate (ADC)	3.8 (1.0 to 4.1)	1.5 (0.8 to 4.3)	4.0 (0.6 to 4.1)	3.8 (1.1 to 3.9)
Unconjugated Tubulysin	168.8 (48.0 to 335.5)	167.3 (71.4 to 170.0)	168.2 (166.9 to 169.4)	166.7 (94.7 to 238.7)

Notes:

[22] - Total antibody and ADC = 7 participants analyzed

[23] - Unconjugated Tubulysin = 9 participants analyzed

[24] - Unconjugated Tubulysin = 2 participants analyzed

[25] - Unconjugated Tubulysin = 2 participants analyzed

End point values	BMS 1.2MG/KG Q3W Ex	BMS 0.8MG/KG Q3W+Nivolumab Es	BMS 0.8MG/KG Q3W+Nivolumab Ex	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	49[26]	11[27]	17[28]	
Units: Hours				
median (full range (min-max))				
Total Antibody	4.0 (0.8 to 24.1)	1.1 (0.6 to 24.1)	4.0 (0.9 to 23.8)	
Active Antibody-Drug Conjugate (ADC)	3.9 (0.8 to 4.7)	1.0 (0.6 to 4.2)	4.0 (0.9 to 4.0)	
Unconjugated Tubulysin	166.1 (24.3 to 338.8)	165.1 (48.0 to 170.9)	166.5 (47.8 to 335.9)	

Notes:

[26] - Unconjugated Tubulysin = 45 participants analyzed

[27] - Unconjugated Tubulysin = 5 participants analyzed

[28] - Unconjugated Tubulysin = 11 participants analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration at the End of a Dosing Interval (Ctau)

End point title	Concentration at the End of a Dosing Interval (Ctau)[29]

End point description:

Concentration at the end of a dosing interval (Ctau) of BMS-986148 grouped by dose + dose regimen. Note: The geometric CV was not calculated. Arithmetic % CV is reported instead.

End point type	Secondary

End point timeframe:

PK blood assessed on cycle 1, day 1

Notes:

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Baseline period arm is reported within the subject analysis set

End point values	BMS-986148 0.1MG/KG Q3W	BMS-986148 0.2MG/KG Q3W	BMS-986148 0.4MG/KG Q3W	BMS-986148 0.8MG/KG Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2[30]	2[31]	2[32]	8[33]
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Total Antibody	0.0035 (± 112.0)	0.0333 (± 115.7)	0.8233 (± 131.8)	0.4426 (± 106.1)
Active Antibody-Drug Conjugate (ADC)	0.0633 (± 141.3)	99999 (± 99999)	0.0058 (± 99999)	0.0309 (± 123.8)
Unconjugated Tubulysin	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Notes:

[30] - Unconjugated Tubulysin = 0 participants analyzed

[31] - Unconjugated Tubulysin and ADC = 0 participants analyzed

[32] - ADC = 1 participant analyzed Unconjugated Tubulysin = 0 participants analyzed

[33] - Unconjugated Tubulysin = 0 participants analyzed

End point values	BMS-986148 1.2MG/KG Q3W Es	BMS-986148 1.6MG/KG Q3W	BMS-986148 0.4MG/KG QW	BMS-986148 0.6MG/KG QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7[34]	10[35]	8[36]	3[37]
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Total Antibody	1.0917 (± 91.9)	1.4101 (± 101.8)	3.2035 (± 20.2)	3.8872 (± 46.1)
Active Antibody-Drug Conjugate (ADC)	0.2121 (± 111.3)	0.3049 (± 110.0)	1.2705 (± 39.5)	1.9068 (± 59.1)
Unconjugated Tubulysin	0.2590 (± 77.1)	0.1630 (± 0.9)	0.1388 (± 36.0)	0.3539 (± 75.0)

Notes:

[34] - Unconjugated Tubulysin = 3 participants analyzed

[35] - Total antibody - 8 participants analyzed Unconjugated Tubulysin = 2 participants analyzed

[36] - Unconjugated Tubulysin = 2 participants analyzed

[37] - Unconjugated Tubulysin = 2 participants analyzed

End point values	BMS 1.2MG/KG Q3W Ex	BMS 0.8MG/KG Q3W+Nivolumab Es	BMS 0.8MG/KG Q3W+Nivolumab Ex	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	46[38]	10[39]	17[40]	
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Total Antibody	1.1938 (± 98.7)	0.2133 (± 114.0)	0.7544 (± 83.5)	
Active Antibody-Drug Conjugate (ADC)	0.1558 (± 123.4)	0.1119 (± 187.1)	0.0797 (± 103.7)	

Unconjugated Tubulysin	0.1634 (± 48.2)	99999 (± 99999)	0.1330 (± 99999)	

Notes:

[38] - Unconjugated Tubulysin = 6 participants analyzed

[39] - Total antibody = 9 participants analyzed Unconjugated Tubulysin = 0 participants analyzed

[40] - Unconjugated Tubulysin = 1 participant analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Trough Observed Serum Concentration (Ctrough)

End point title	Trough Observed Serum Concentration (Ctrough)[41]

End point description:

Trough observed serum concentration (Ctrough) of BMS-986148 grouped by dose + dose regimen.
Note: The geometric CV was not calculated. Arithmetic % CV is reported instead.

End point type	Secondary

End point timeframe:

PK blood assessment include cycle 2-day 1 and cycle 1-day 8

Notes:

[41] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Baseline period arm is reported within the subject analysis set

End point values	BMS-986148 0.1MG/KG Q3W	BMS-986148 0.2MG/KG Q3W	BMS-986148 0.4MG/KG Q3W	BMS-986148 0.8MG/KG Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	7
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Total Antibody	0.1 (± 0.0)	0.1 (± 0.00)	0.1 (± 0.00)	0.79676 (± 92.4)
Active Antibody-Drug Conjugate (ADC)	0.1 (± 0.0)	0.1 (± 0.00)	0.1 (± 0.00)	0.27671 (± 95.3)
Unconjugated Tubulysin	0.0005 (± 0.0)	0.0005 (± 0.0)	0.0005 (± 0.0)	0.0005 (± 0.0)

End point values	BMS-986148 1.2MG/KG Q3W Es	BMS-986148 1.6MG/KG Q3W	BMS-986148 0.4MG/KG QW	BMS-986148 0.6MG/KG QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	6	8	3
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Total Antibody	1.23291 (± 81.7)	0.92146 (± 125.9)	3.20352 (± 20.2)	3.88717 (± 46.1)
Active Antibody-Drug Conjugate (ADC)	0.36894 (± 90.7)	0.21835 (± 152.7)	1.27047 (± 39.5)	1.90678 (± 59.1)
Unconjugated Tubulysin	0.0009 (± 127.6)	0.0007 (± 66.6)	0.0006 (± 64.7)	0.00018 (± 104.0)

End point values	BMS 1.2MG/KG Q3W Ex	BMS 0.8MG/KG Q3W+Nivolumab Es	BMS 0.8MG/KG Q3W+Nivolumab Ex	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	39	10	13	
Units: ug/mL				
geometric mean (geometric coefficient of variation)				
Total Antibody	1.14568 (± 104.4)	0.33875 (± 122.1)	0.77912 (± 79.1)	
Active Antibody-Drug Conjugate (ADC)	0.31524 (± 111.4)	0.18096 (± 97.4)	0.24389 (± 81.0)	
Unconjugated Tubulysin	0.0006 (± 80.7)	0.0005 (± 0.0)	0.0005 (± 40.8)	

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Concentration-Time Curve from Time Zero to Time T (AUC(0-t))

End point title	Area Under the Concentration-Time Curve from Time Zero to Time T (AUC(0-t))[42]

End point description:

Area under the concentration-time curve from time Zero to time T (AUC(0-t)) of BMS-986148 grouped by dose + dose regimen. Note: The geometric CV was not calculated. Arithmetic % CV is reported instead.

End point type	Secondary

End point timeframe:

PK blood assessment include cycle 1-day 1

Notes:

[42] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Baseline period arm is reported within the subject analysis set

End point values	BMS-986148 0.1MG/KG Q3W	BMS-986148 0.2MG/KG Q3W	BMS-986148 0.4MG/KG Q3W	BMS-986148 0.8MG/KG Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2[43]	2[44]	3[45]	8[46]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Total Antibody	152.6 (± 31.6)	232.5 (± 17.5)	129.6 (± 131.3)	1979.5 (± 69.6)
Active Antibody-Drug Conjugate (ADC)	88.6 (± 48.7)	70.7 (± 42.9)	60.8 (± 136.2)	1042.1 (± 68.6)
Unconjugated Tubulysin	99999 (± 99999)	99999 (± 99999)	49.6 (± 99999)	29.6 (± 42.8)

Notes:

[43] - Unconjugated Tubulysin = 0 participants analyzed

[44] - Unconjugated Tubulysin = 0 participants analyzed

[45] - Unconjugated Tubulysin = 1 participants analyzed

[46] - Unconjugated Tubulysin = 4 participants analyzed

End point values	BMS-986148 1.2MG/KG Q3W Es	BMS-986148 1.6MG/KG Q3W	BMS-986148 0.4MG/KG QW	BMS-986148 0.6MG/KG QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8[47]	10[48]	8[49]	4[50]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Total Antibody	4285.7 (± 29.3)	5399.8 (± 40.1)	858.0 (± 22.9)	1278.8 (± 35.1)
Active Antibody-Drug Conjugate (ADC)	2493.1 (± 25.1)	3083.6 (± 32.3)	565.4 (± 30.3)	927.3 (± 38.7)
Unconjugated Tubulysin	197.0 (± 59.4)	80.1 (± 73.4)	9.3 (± 73.0)	42.5 (± 84.3)

Notes:

[47] - Total antibody and ADC = 7 participants analyzed

[48] - Unconjugated Tubulysin = 9 participants analyzed

[49] - Unconjugated Tubulysin = 2 participants analyzed

[50] - Unconjugated Tubulysin = 2 participants analyzed

End point values	BMS-986148 0.8MG/KG Q3W+Nivolumab	BMS 1.2MG/KG Q3W Ex		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	11[51]	49[52]		
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Total Antibody	1815.8 (± 43.4)	3472.6 (± 47.1)		
Active Antibody-Drug Conjugate (ADC)	1059.0 (± 44.8)	1984.7 (± 45.7)		
Unconjugated Tubulysin	25.5 (± 58.8)	42.3 (± 80.4)		

Notes:

[51] - Unconjugated Tubulysin = 5 participants analyzed

[52] - Unconjugated Tubulysin = 45 participants analyzed

Statistical analyses

No statistical analyses for this end point

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

End point title	Area Under the Concentration-Time Curve in One Dosing Interval (AUC[TAU])[53]

End point description:

Area under the concentration-time curve in one dosing interval (AUC[TAU]) of BMS-986148 grouped by dose + dose regimen Note: The geometric CV was not calculated. Arithmetic % CV is reported instead

End point type	Secondary

End point timeframe:

PK blood assessment include cycle 1-day 1

Notes:

[53] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: Baseline period arm is reported within the subject analysis set

End point values	BMS-986148 0.1MG/KG Q3W	BMS-986148 0.2MG/KG Q3W	BMS-986148 0.4MG/KG Q3W	BMS-986148 0.8MG/KG Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2[54]	2[55]	2[56]	8[57]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Total Antibody	179.3 (± 34.8)	265.7 (± 13.3)	344.6 (± 98.5)	2059.3 (± 68.7)
Active Antibody-Drug Conjugate (ADC)	109.0 (± 35.2)	99999 (± 99999)	371.6 (± 99999)	1098.7 (± 67.5)
Unconjugated Tubulysin	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)	99999 (± 99999)

Notes:

[54] - Unconjugated Tubulysin = 0 participants analyzed

[55] - ADC and Unconjugated Tubulysin = 0 participants analyzed

[56] - ADC = 1 participants analyzed Unconjugated Tubulysin = 0 participants analyzed

[57] - Unconjugated Tubulysin = 0 participants analyzed

End point values	BMS-986148 1.2MG/KG Q3W Es	BMS-986148 1.6MG/KG Q3W	BMS-986148 0.4MG/KG QW	BMS-986148 0.6MG/KG QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7[58]	10[59]	8[60]	3[61]
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Total Antibody	4316.1 (± 28.8)	5318.6 (± 36.9)	858.0 (± 22.9)	1533.5 (± 19.2)
Active Antibody-Drug Conjugate (ADC)	2507.2 (± 24.7)	3246.0 (± 36.6)	565.4 (± 30.3)	1063.9 (± 32.2)
Unconjugated Tubulysin	197.0 (± 59.4)	173.4 (± 48.2)	9.3 (± 73.0)	42.5 (± 84.3)

Notes:

[58] - Unconjugated Tubulysin = 3 participants analyzed

[59] - Total Antibody = 8 participants analyzed Unconjugated Tubulysin = 2 participants analyzed

[60] - Unconjugated Tubulysin = 2 participants analyzed

[61] - Unconjugated Tubulysin = 2 participants analyzed

End point values	BMS 1.2MG/KG Q3W Ex	BMS 0.8MG/KG Q3W+Nivolumab Es	BMS 0.8MG/KG Q3W+Nivolumab Ex	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	46[62]	10[63]	17[64]	
Units: h*ug/mL				
geometric mean (geometric coefficient of variation)				
Total Antibody	4159.4 (± 39.5)	1839.0 (± 45.4)	2689.9 (± 34.0)	

Active Antibody-Drug Conjugate (ADC)	2271.7 (± 40.1)	1094.9 (± 48.0)	1478.1 (± 36.6)	
Unconjugated Tubulysin	148.9 (± 30.3)	99999 (± 99999)	102.4 (± 99999)	

Notes:

[62] - Unconjugated Tubulysin = 6 participants analyzed

[63] - Total antibody = 9 participants analyzed Unconjugated Tubulysin = 0 participants analyzed

[64] - Unconjugated Tubulysin = 1 participants analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Best Overall Response (BOR)

End point title	Best Overall Response (BOR)

End point description:

Best overall response is defined as the best response designation over the study as a whole, recorded between the dates of first dose until the last tumor assessment prior to subsequent therapy. Participants are grouped by cohorts (Mesothelioma, Pancreatic, Ovarian, Non-smell Cell Lung Cancer (NSCLC), and Gastric). Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes must have reduction in short axis to < 10 mm. Partial Response (PR): At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. Progressive Disease (PD): At least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study. The sum must also demonstrate an absolute increase of at least 5 mm. Stable Disease (SD): Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for PD, taking as reference the smallest sum diameters while on study.

End point type	Secondary

End point timeframe:

Up to 58 months

End point values	BMS-986148 Mesothelioma	BMS-986148+Nivolumab Mesothelioma	BMS-986148 Ovarian	BMS-986148+Nivolumab Ovarian
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	25	13	22	2
Units: Participants				
Complete Response (CR)	0	0	0	0
Partial Response (PR)	1	3	2	0
Stable Disease (SD)	13	8	11	2
Progressive Disease (PD)	7	1	7	0

End point values	BMS-986148 Pancreatic	BMS-986148+Nivolumab Pancreatic	BMS-986148 NSCLC	BMS-986148+Nivolumab NSCLC
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	6	4	2
Units: Participants				
Complete Response (CR)	0	0	0	0
Partial Response (PR)	0	0	0	0
Stable Disease (SD)	4	1	1	1

Progressive Disease (PD)	11	2	2	1

End point values	BMS-986148 Gastric	BMS-986148+Nivolumab Gastric		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	1		
Units: Participants				
Complete Response (CR)	0	0		
Partial Response (PR)	0	0		
Stable Disease (SD)	1	0		
Progressive Disease (PD)	2	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR)

End point description:

Objective response rate is defined as the total percentage of participants whose best overall response (BOR) is either a complete response or partial response divided by the total percentage of participants who are grouped by cohorts (Mesothelioma, Pancreatic, Ovarian, Non-smell Cell Lung (NSCL), and Gastric). Complete Response (CR): Disappearance of all target lesions. Any pathological lymph nodes must have reduction in short axis to < 10 mm. Partial Response (PR): At least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters.

End point type	Secondary

End point timeframe:

Up to 58 months

End point values	BMS-986148 Mesothelioma	BMS-986148+Nivolumab Mesothelioma	BMS-986148 Ovarian	BMS-986148+Nivolumab Ovarian
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	25	13	22	29
Units: Percentage of participants				
number (confidence interval 95%)	1 (0.1 to 20.4)	3 (3.0 to 53.8)	2 (1.1 to 29.2)	2 (0.8 to 22.8)

End point values	BMS-986148 Pancreatic	BMS-986148+Nivolumab Pancreatic	BMS-986148 NSCLC	BMS-986148+Nivolumab NSCLC
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	18	6	4	2
Units: Percentage of participants				

number (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)	99999 (99999 to 99999)

End point values	BMS-986148 Gastric	BMS-986148+Nivolumab Gastric		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	1		
Units: Percentage of participants				
number (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DoR)

End point title	Duration of Response (DoR)

End point description:

Duration of response is defined as the time between the date of first response and the subsequent date of objectively documented disease progression or death, whichever occurs first. Participants are grouped by cohorts (Mesothelioma, Pancreatic, Ovarian, Non-smell Cell Lung (NSCL), and Gastric).

End point type	Secondary

End point timeframe:

Up to 58 months

End point values	BMS-986148 Mesothelioma	BMS-986148+Nivolumab Mesothelioma	BMS-986148 Ovarian	BMS-986148+Nivolumab Ovarian
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	25	13	22	0[65]
Units: Months				
median (full range (min-max))	29.7 (29.7 to 29.7)	8.97 (5.1 to 13.3)	99999 (3.0 to 99999)	(to)

Notes:

[65] - 0 subjects analyzed

End point values	BMS-986148 Pancreatic	BMS-986148+Nivolumab Pancreatic	BMS-986148 NSCLC	BMS-986148+Nivolumab NSCLC
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[66]	6	4	0[67]
Units: Months				
median (full range (min-max))	(to)	99999 (99999 to 99999)	99999 (99999 to 99999)	(to)

Notes:

[66] - 0 subjects analyzed

[67] - 0 subjects analyzed

End point values	BMS-986148 Gastric	BMS-986148+Nivolumab Gastric		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[68]	0[69]		
Units: Months				
median (full range (min-max))	(to)	(to)		

Notes:

[68] - 0 subjects analyzed

[69] - 0 subjects analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS)

End point title	Progression Free Survival (PFS)

End point description:

Progression Free Survival is defined as the time from the first dose of study medication to the date of the first objective documentation of tumor progression or death due to any cause. Progression is defined with at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study and the sum must also demonstrate an absolute increase of at least 5 mm. Participants who did not progress nor died will be censored on the date of their last tumor assessment. Participants are grouped by cohorts (Mesothelioma, Pancreatic, Ovarian, Non-smell Cell Lung (NSCL), and Gastric).

End point type	Secondary

End point timeframe:

Up to 58 months

End point values	BMS-986148 Mesothelioma	BMS-986148+Nivolumab Mesothelioma	BMS-986148 Ovarian	BMS-986148+Nivolumab Ovarian
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	25	13	22	0[70]
Units: Months				
median (confidence interval 95%)	2.56 (1.41 to 4.01)	5.19 (2.56 to 12.06)	2.79 (1.28 to 4.17)	(to)

Notes:

[70] - 0 subjects analyzed

End point values	BMS-986148 Pancreatic	BMS-986148+Nivolumab Pancreatic	BMS-986148 NSCLC	BMS-986148+Nivolumab NSCLC
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[71]	6	4	0[72]
Units: Months				
median (confidence interval 95%)	(to)	1.66 (1.22 to 2.14)	1.49 (1.15 to 5.65)	(to)

Notes:

[71] - 0 subjects analyzed

[72] - 0 subjects analyzed

End point values	BMS-986148 Gastric	BMS-986148+Nivolumab Gastric		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[73]	0[74]		
Units: Months				
median (confidence interval 95%)	(to)	(to)		

Notes:

[73] - 0 subjects analyzed

[74] - 0 subjects analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival Rate (PFSR) at Week t

End point title	Progression Free Survival Rate (PFSR) at Week t

End point description:

Progression free survival rate is defined as the percentage of participants who remain progression free and surviving at 't' weeks (t=4-12 months). The percentage will be calculated by the product-limit method (Kaplan-Meier estimate) which takes into account censored data. Participants are grouped by cohorts (Mesothelioma, Pancreatic, Ovarian, Non-smell Cell Lung (NSCL), and Gastric).

End point type	Secondary

End point timeframe:

Up to 58 months

End point values	BMS-986148 Mesothelioma	BMS-986148+Nivolumab Mesothelioma	BMS-986148 Ovarian	BMS-986148+Nivolumab Ovarian
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	25	13	22	0[75]
Units: Percentage of participants				
number (confidence interval 95%)				
4 months	0.35 (0.15 to 0.54)	0.65 (0.37 to 0.93)	0.40 (0.18 to 0.62)	(to)
6 months	0.30 (0.11 to 0.49)	0.47 (0.17 to 0.76)	99999 (99999 to 99999)	(to)

Notes:

[75] - 0 subjects analyzed

End point values	BMS-986148 Pancreatic	BMS-986148+Nivolumab Pancreatic	BMS-986148 NSCLC	BMS-986148+Nivolumab NSCLC
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	0[76]	0[77]	0[78]	0[79]
Units: Percentage of participants				
number (confidence interval 95%)				

4 months	(to)	(to)	(to)	(to)
6 months	(to)	(to)	(to)	(to)

Notes:

[76] - 0 subjects analyzed

[77] - 0 subjects analyzed

[78] - 0 subjects analyzed

[79] - 0 subjects analyzed

End point values	BMS-986148 Gastric	BMS-986148+Nivolumab Gastric		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[80]	0[81]		
Units: Percentage of participants				
number (confidence interval 95%)				
4 months	(to)	(to)		
6 months	(to)	(to)		

Notes:

[80] - 0 subjects analyzed

[81] - 0 subjects analyzed

Statistical analyses

No statistical analyses for this end point

Secondary: Changes in QT Corrected by the Fridericia Formula (QTcF) from Baseline, at Selected Times

End point title	Changes in QT Corrected by the Fridericia Formula (QTcF) from Baseline, at Selected Times[82]

End point description:

Changes of participants in QT corrected by the fridericia formula (QTcF) Interval from baseline at <= 30 msec, >30 - <= 60 msec, and > 60 msec grouped by dose + dose regimen

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[82] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Baseline period arm is reported within the subject analysis set

End point values	BMS-986148 0.1MG/KG Q3W	BMS-986148 0.2MG/KG Q3W	BMS-986148 0.4MG/KG Q3W	BMS-986148 0.8MG/KG Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	3	8
Units: Participants				
<= 30 msec,	1	2	2	6
>30 - <= 60 msec	1	0	1	2
> 60 msec	0	0	0	0

End point values	BMS-986148	BMS-986148	BMS-986148	BMS-986148

	1.2MG/KG Q3W Es	1.6MG/KG Q3W	0.4MG/KG QW	0.6MG/KG QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	10	8	4
Units: Participants				
<= 30 msec,	8	9	5	3
>30 - <= 60 msec	0	1	3	1
> 60 msec	0	0	0	0

End point values	BMS-986148 0.8MG/KG Q3W+Nivolumab	BMS 1.2MG/KG Q3W Ex		
Subject group type	Reporting group	Subject analysis set		
Number of subjects analysed	30	51		
Units: Participants				
<= 30 msec,	23	37		
>30 - <= 60 msec	7	12		
> 60 msec	0	2		

Statistical analyses

No statistical analyses for this end point

Secondary: Incidence of Participants with Anti-Drug Antibody (ADA)

End point title	Incidence of Participants with Anti-Drug Antibody (ADA)[83]

End point description:

Incidence of participants with anti-drug antibody (ADA) status grouped by dose + dose regimen

End point type	Secondary

End point timeframe:

Up to 58 months

Notes:

[83] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Baseline period arm is reported within the subject analysis set

End point values	BMS-986148 0.1MG/KG Q3W	BMS-986148 0.2MG/KG Q3W	BMS-986148 0.4MG/KG Q3W	BMS-986148 0.8MG/KG Q3W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[84]	0[85]	0[86]	0[87]
Units: Participants				
ADA positive				
ADA negative				

Notes:

[84] - 0 subjects analyzed

[85] - 0 subjects analyzed

[86] - 0 subjects analyzed

[87] - 0 subjects analyzed

End point values	BMS-986148 1.2MG/KG Q3W Es	BMS-986148 1.6MG/KG Q3W	BMS-986148 0.4MG/KG QW	BMS-986148 0.6MG/KG QW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[88]	0[89]	0[90]	0[91]
Units: Participants				
ADA positive ADA negative				

Notes:

[88] - 0 subjects analyzed

[89] - 0 subjects analyzed

[90] - 0 subjects analyzed

[91] - 0 subjects analyzed

End point values	BMS-986148 0.8MG/KG Q3W+Nivolumab			
Subject group type	Reporting group			
Number of subjects analysed	0[92]			
Units: Participants				
ADA positive ADA negative				

Notes:

[92] - 0 subjects analyzed

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All adverse events were collected from the first dose up to 60 days (inclusive) after the last dose of BMS-986148

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	BMS 0.2MG/KG Q3W

Reporting group description:

Subjects were intravenously administered with monotherapy of 0.2 mg/kg BMS-986148 every 3 weeks.

Reporting group title	BMS 0.1MG/KG Q3W

Reporting group description:

Subjects were intravenously administered with monotherapy of 0.1 milligrams per kilograms (mg/kg) BMS-986148 every 3 weeks.

Reporting group title	BMS 0.8MG/KG Q3W

Reporting group description:

Subjects were intravenously administered with monotherapy of 0.8 mg/kg BMS-986148 every 3 weeks.

Reporting group title	BMS 0.4MG/KG Q3W

Reporting group description:

Subjects were intravenously administered with monotherapy of 0.4 mg/kg BMS-986148 every 3 weeks.

Reporting group title	BMS 1.6MG/KG Q3W

Reporting group description:

Subjects were intravenously administered with monotherapy of 1.6 mg/kg BMS-986148 every 3 weeks.

Reporting group title	BMS 0.4MG/KG QW

Reporting group description:

Subjects were intravenously administered with monotherapy of 0.4 mg/kg BMS-986148 weekly for 3 weeks with one week off.

Reporting group title	BMS 1.2MG/KG Q3W

Reporting group description:

Subjects were intravenously administered with monotherapy of 1.2 mg/kg BMS-986148 every 3 weeks.

Reporting group title	BMS 0.6MG/KG QW

Reporting group description:

Subjects were intravenously administered with monotherapy of 0.6 mg/kg BMS-986148 weekly for 3 weeks with one week off.

Reporting group title	BMS 0.8MG/KG Q3W+N

Reporting group description:

Subjects were intravenously administered with combination therapy of BMS-986148 and nivolumab. The starting dose of 0.8 mg/kg BMS-986148 to be combined with nivolumab at 360 mg every 3 weeks. Followed by escalation to 1.2 mg/kg of BMS-986148 in combination with nivolumab 360 mg every 3 weeks.

Serious adverse events	BMS 0.2MG/KG Q3W	BMS 0.1MG/KG Q3W	BMS 0.8MG/KG Q3W
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	6 / 8 (75.00%)
number of deaths (all causes)	2	1	5

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	3 / 8 (37.50%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 3
Neoplasm malignant			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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			
Venous thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion site extravasation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial necrosis marker increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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			
Subdural haematoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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			
Depressed level of consciousness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Neuralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 8 (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
Duodenal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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 paralytic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haematoma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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			
Bile duct obstruction			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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			
Urinary tract obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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			

Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 8 (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
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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			
Abdominal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphangitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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 / 2 (0.00%)	1 / 2 (50.00%)	0 / 8 (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	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
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	BMS 0.4MG/KG Q3W	BMS 1.6MG/KG Q3W	BMS 0.4MG/KG QW
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 3 (33.33%)	4 / 10 (40.00%)	6 / 8 (75.00%)
number of deaths (all causes)	3	7	7
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	2 / 8 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Neoplasm malignant			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neoplasm progression			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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			
Venous thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion site extravasation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Interstitial lung disease			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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 / 3 (0.00%)	1 / 10 (10.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial necrosis marker increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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			
Subdural haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardio-respiratory arrest			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericardial effusion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (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
Pericarditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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			
Depressed level of consciousness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Syncope			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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 / 3 (0.00%)	2 / 10 (20.00%)	0 / 8 (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
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
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 obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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 paralytic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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 perforation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	0 / 8 (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
Subileus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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			
Bile duct obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Drug-induced liver injury			

subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (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
Hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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			
Urinary tract obstruction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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			
Abdominal infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphangitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
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	BMS 1.2MG/KG Q3W	BMS 0.6MG/KG QW	BMS 0.8MG/KG Q3W+N
Total subjects affected by serious adverse events			
subjects affected / exposed	34 / 59 (57.63%)	3 / 4 (75.00%)	22 / 30 (73.33%)
number of deaths (all causes)	38	4	22
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	14 / 59 (23.73%)	2 / 4 (50.00%)	10 / 30 (33.33%)
occurrences causally related to treatment / all	0 / 14	0 / 2	0 / 10
deaths causally related to treatment / all	0 / 14	0 / 2	0 / 8
Neoplasm malignant			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Neoplasm progression			
subjects affected / exposed	1 / 59 (1.69%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vascular disorders			
Venous thrombosis			

subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion site extravasation			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malaise			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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
Non-cardiac chest pain			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Performance status decreased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	2 / 59 (3.39%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Interstitial lung disease			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
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 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleurisy			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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
Pleuritic pain			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
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	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Blood creatinine increased			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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
Myocardial necrosis marker increased			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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

Transaminases increased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	2 / 30 (6.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Subdural haematoma			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial flutter			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardio-respiratory arrest			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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
Pericardial effusion			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
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	2 / 59 (3.39%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tachycardia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Depressed level of consciousness			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Neuralgia			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraparesis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			

subjects affected / exposed	3 / 59 (5.08%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Ascites			
subjects affected / exposed	4 / 59 (6.78%)	0 / 4 (0.00%)	3 / 30 (10.00%)
occurrences causally related to treatment / all	0 / 5	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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
Duodenal obstruction			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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
Ileus paralytic			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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
Impaired gastric emptying			

subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
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 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haemorrhage			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 59 (1.69%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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
Subileus			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			

subjects affected / exposed	2 / 59 (3.39%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haematoma			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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
Pancreatitis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Bile duct obstruction			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bile duct stenosis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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
Cholangitis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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
Drug-induced liver injury			
subjects affected / exposed	2 / 59 (3.39%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			

subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
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	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Urinary tract obstruction			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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			
Arthralgia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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 chest pain			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
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			
Abdominal infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymphangitis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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
Peritonitis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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	2 / 59 (3.39%)	0 / 4 (0.00%)	4 / 30 (13.33%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 5
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (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

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

Non-serious adverse events	BMS 0.2MG/KG Q3W	BMS 0.1MG/KG Q3W	BMS 0.8MG/KG Q3W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	1 / 2 (50.00%)	8 / 8 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Systolic hypertension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypotension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Chest discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Chills			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Fatigue			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	5 / 8 (62.50%)
occurrences (all)	2	0	19
Influenza like illness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Testicular pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	3 / 8 (37.50%)
occurrences (all)	0	0	3
Dysphonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	1 / 8 (12.50%)
occurrences (all)	1	1	1
Dyspnoea exertional			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pleuritic pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Productive cough			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rales			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hiccups			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Delirium			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hallucination, auditory			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2

Depression			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	4
Hallucination			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	3 / 8 (37.50%)
occurrences (all)	0	0	3
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	1	0	1
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Platelet count decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Weight decreased			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	3 / 8 (37.50%)
occurrences (all)	0	0	5
Blood sodium increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Head injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Mitral valve incompetence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pericarditis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	2 / 8 (25.00%)
occurrences (all)	2	0	3
Dysarthria			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Horner's syndrome			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	2	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Strabismus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chalazion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Lacrimation increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Narrow anterior chamber angle			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Swelling of eyelid			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Visual impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Gastrointestinal disorders			

Abdominal distension			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	3 / 8 (37.50%)
occurrences (all)	1	0	5
Abdominal pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	3 / 8 (37.50%)
occurrences (all)	1	0	4
Abdominal pain lower			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Ascites			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	5
Breath odour			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	3 / 8 (37.50%)
occurrences (all)	1	0	4
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	3 / 8 (37.50%)
occurrences (all)	0	0	4
Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nausea			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	5 / 8 (62.50%)
occurrences (all)	1	1	7
Rectal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Swollen tongue			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	4 / 8 (50.00%)
occurrences (all)	2	0	4
Abdominal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Impaired gastric emptying			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Retching			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin odour abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash macular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nocturia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Proteinuria			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urine odour abnormal			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Back pain			
subjects affected / exposed	1 / 2 (50.00%)	1 / 2 (50.00%)	2 / 8 (25.00%)
occurrences (all)	1	1	3
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Musculoskeletal pain			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Myalgia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 2 (50.00%)	0 / 2 (0.00%)	6 / 8 (75.00%)
occurrences (all)	1	0	8
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Hyperuricaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	3 / 8 (37.50%)
occurrences (all)	0	0	4
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 2 (50.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Increased appetite			

subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 2 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	BMS 0.4MG/KG Q3W	BMS 1.6MG/KG Q3W	BMS 0.4MG/KG QW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	10 / 10 (100.00%)	8 / 8 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Systolic hypertension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Flushing			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	2 / 10 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Chest pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Chills			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	1 / 3 (33.33%)	8 / 10 (80.00%)	3 / 8 (37.50%)
occurrences (all)	1	15	4
Influenza like illness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Malaise			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Non-cardiac chest pain			
subjects affected / exposed	1 / 3 (33.33%)	1 / 10 (10.00%)	3 / 8 (37.50%)
occurrences (all)	1	1	6
Oedema peripheral			
subjects affected / exposed	0 / 3 (0.00%)	2 / 10 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	3 / 10 (30.00%)	1 / 8 (12.50%)
occurrences (all)	0	3	1
Early satiety			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			

Testicular pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 3 (33.33%)	2 / 10 (20.00%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Dysphonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	5 / 10 (50.00%)	1 / 8 (12.50%)
occurrences (all)	0	5	1
Dyspnoea exertional			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Epistaxis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Oropharyngeal pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pleural effusion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	2 / 8 (25.00%)
occurrences (all)	0	0	2
Pleuritic pain			
subjects affected / exposed	0 / 3 (0.00%)	3 / 10 (30.00%)	2 / 8 (25.00%)
occurrences (all)	0	4	5
Productive cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Rales			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Throat irritation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hiccups			
subjects affected / exposed	0 / 3 (0.00%)	2 / 10 (20.00%)	0 / 8 (0.00%)
occurrences (all)	0	2	0
Hypoxia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Nasal congestion			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Anxiety			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Confusional state			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Delirium			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Hallucination, auditory			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Insomnia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1

Depression			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	6 / 10 (60.00%)	3 / 8 (37.50%)
occurrences (all)	0	10	5
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	5 / 10 (50.00%)	2 / 8 (25.00%)
occurrences (all)	0	12	2
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 3 (0.00%)	5 / 10 (50.00%)	2 / 8 (25.00%)
occurrences (all)	0	7	2
Blood bilirubin increased			
subjects affected / exposed	0 / 3 (0.00%)	2 / 10 (20.00%)	2 / 8 (25.00%)
occurrences (all)	0	5	2
Blood creatinine increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Lymphocyte count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	2
Platelet count decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	3
Weight decreased			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood sodium increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Liver function test increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Head injury			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Mitral valve incompetence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Pericarditis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Sinus bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 3 (0.00%)	3 / 10 (30.00%)	0 / 8 (0.00%)
occurrences (all)	0	4	0
Dysarthria			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Dysgeusia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	0 / 3 (0.00%)	3 / 10 (30.00%)	0 / 8 (0.00%)
occurrences (all)	0	3	0
Neuropathy peripheral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Horner's syndrome			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Seizure			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	2 / 8 (25.00%)
occurrences (all)	0	1	3
Lymphopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cataract			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Dry eye			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Strabismus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Vision blurred			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Chalazion			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Eye pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Narrow anterior chamber angle			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Swelling of eyelid			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Visual impairment			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal distension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Abdominal pain			
subjects affected / exposed	0 / 3 (0.00%)	3 / 10 (30.00%)	4 / 8 (50.00%)
occurrences (all)	0	4	6
Abdominal pain lower			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Ascites			
subjects affected / exposed	0 / 3 (0.00%)	3 / 10 (30.00%)	0 / 8 (0.00%)
occurrences (all)	0	5	0
Breath odour			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	4 / 10 (40.00%)	3 / 8 (37.50%)
occurrences (all)	0	4	3
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	8 / 10 (80.00%)	1 / 8 (12.50%)
occurrences (all)	0	11	2
Dry mouth			
subjects affected / exposed	0 / 3 (0.00%)	3 / 10 (30.00%)	1 / 8 (12.50%)
occurrences (all)	0	3	1
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Dysphagia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Eructation			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Flatulence			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 8 (12.50%)
occurrences (all)	0	1	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 3 (100.00%)	7 / 10 (70.00%)	3 / 8 (37.50%)
occurrences (all)	4	15	4
Rectal haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Stomatitis			
subjects affected / exposed	0 / 3 (0.00%)	3 / 10 (30.00%)	0 / 8 (0.00%)
occurrences (all)	0	4	0
Swollen tongue			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	2 / 3 (66.67%)	4 / 10 (40.00%)	0 / 8 (0.00%)
occurrences (all)	2	7	0
Abdominal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Retching			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Umbilical hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	3	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Rash papular			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin odour abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	1 / 3 (33.33%)	2 / 10 (20.00%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Rash macular			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Chromaturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Nocturia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Proteinuria			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urine odour abnormal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Flank pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	2 / 8 (25.00%)
occurrences (all)	0	4	3
Muscle spasms			
subjects affected / exposed	1 / 3 (33.33%)	3 / 10 (30.00%)	0 / 8 (0.00%)
occurrences (all)	1	5	0
Muscular weakness			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 10 (20.00%)	1 / 8 (12.50%)
occurrences (all)	0	2	1
Myalgia			

subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Pain in extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	1 / 8 (12.50%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	1 / 3 (33.33%)	5 / 10 (50.00%)	2 / 8 (25.00%)
occurrences (all)	1	8	2
Dehydration			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hyperglycaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	2 / 8 (25.00%)
occurrences (all)	3	0	3
Hyperuricaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Hypokalaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypomagnesaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hyponatraemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	1	0	0
Hypophosphataemia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 10 (20.00%)	0 / 8 (0.00%)
occurrences (all)	1	2	0
Increased appetite			

subjects affected / exposed	0 / 3 (0.00%)	0 / 10 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 10 (10.00%)	0 / 8 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	BMS 1.2MG/KG Q3W	BMS 0.6MG/KG QW	BMS 0.8MG/KG Q3W+N
Total subjects affected by non-serious adverse events			
subjects affected / exposed	58 / 59 (98.31%)	4 / 4 (100.00%)	27 / 30 (90.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	2 / 59 (3.39%)	0 / 4 (0.00%)	2 / 30 (6.67%)
occurrences (all)	2	0	2
Systolic hypertension			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Hypotension			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 59 (0.00%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	10 / 59 (16.95%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	12	0	3

Chills			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	3 / 30 (10.00%)
occurrences (all)	0	0	4
Fatigue			
subjects affected / exposed	32 / 59 (54.24%)	3 / 4 (75.00%)	15 / 30 (50.00%)
occurrences (all)	60	7	21
Influenza like illness			
subjects affected / exposed	2 / 59 (3.39%)	1 / 4 (25.00%)	2 / 30 (6.67%)
occurrences (all)	3	1	2
Malaise			
subjects affected / exposed	1 / 59 (1.69%)	2 / 4 (50.00%)	1 / 30 (3.33%)
occurrences (all)	1	2	1
Non-cardiac chest pain			
subjects affected / exposed	5 / 59 (8.47%)	1 / 4 (25.00%)	5 / 30 (16.67%)
occurrences (all)	7	1	7
Oedema peripheral			
subjects affected / exposed	9 / 59 (15.25%)	0 / 4 (0.00%)	2 / 30 (6.67%)
occurrences (all)	11	0	4
Pyrexia			
subjects affected / exposed	14 / 59 (23.73%)	2 / 4 (50.00%)	3 / 30 (10.00%)
occurrences (all)	25	4	5
Early satiety			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	2 / 59 (3.39%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	3	0	0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Testicular pain			
subjects affected / exposed	0 / 59 (0.00%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Pelvic pain			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	13 / 59 (22.03%)	0 / 4 (0.00%)	5 / 30 (16.67%)
occurrences (all)	18	0	5
Dysphonia			
subjects affected / exposed	1 / 59 (1.69%)	1 / 4 (25.00%)	1 / 30 (3.33%)
occurrences (all)	1	1	1
Dyspnoea			
subjects affected / exposed	20 / 59 (33.90%)	1 / 4 (25.00%)	5 / 30 (16.67%)
occurrences (all)	31	1	6
Dyspnoea exertional			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	3 / 59 (5.08%)	0 / 4 (0.00%)	2 / 30 (6.67%)
occurrences (all)	3	0	2
Oropharyngeal pain			
subjects affected / exposed	1 / 59 (1.69%)	1 / 4 (25.00%)	1 / 30 (3.33%)
occurrences (all)	2	1	1
Pleural effusion			
subjects affected / exposed	4 / 59 (6.78%)	0 / 4 (0.00%)	3 / 30 (10.00%)
occurrences (all)	4	0	3
Pleuritic pain			
subjects affected / exposed	7 / 59 (11.86%)	1 / 4 (25.00%)	3 / 30 (10.00%)
occurrences (all)	10	2	4
Productive cough			
subjects affected / exposed	7 / 59 (11.86%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	9	0	1
Rales			

subjects affected / exposed	0 / 59 (0.00%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	0	3	0
Throat irritation			
subjects affected / exposed	0 / 59 (0.00%)	1 / 4 (25.00%)	1 / 30 (3.33%)
occurrences (all)	0	1	1
Haemoptysis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Hiccups			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Hypoxia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Nasal congestion			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Abnormal dreams			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Anxiety			
subjects affected / exposed	3 / 59 (5.08%)	1 / 4 (25.00%)	1 / 30 (3.33%)
occurrences (all)	3	1	1
Confusional state			
subjects affected / exposed	2 / 59 (3.39%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Delirium			
subjects affected / exposed	0 / 59 (0.00%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Hallucination, auditory			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	4 / 59 (6.78%)	0 / 4 (0.00%)	6 / 30 (20.00%)
occurrences (all)	4	0	6

Depression			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Hallucination			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	33 / 59 (55.93%)	3 / 4 (75.00%)	10 / 30 (33.33%)
occurrences (all)	94	12	24
Aspartate aminotransferase increased			
subjects affected / exposed	35 / 59 (59.32%)	3 / 4 (75.00%)	12 / 30 (40.00%)
occurrences (all)	111	7	31
Blood alkaline phosphatase increased			
subjects affected / exposed	18 / 59 (30.51%)	2 / 4 (50.00%)	5 / 30 (16.67%)
occurrences (all)	31	3	11
Blood bilirubin increased			
subjects affected / exposed	8 / 59 (13.56%)	2 / 4 (50.00%)	2 / 30 (6.67%)
occurrences (all)	15	2	5
Blood creatinine increased			
subjects affected / exposed	0 / 59 (0.00%)	1 / 4 (25.00%)	1 / 30 (3.33%)
occurrences (all)	0	1	2
Electrocardiogram QT prolonged			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	4 / 59 (6.78%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	7	0	0
Lymphocyte count decreased			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	1	0	3
Platelet count decreased			
subjects affected / exposed	3 / 59 (5.08%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	5	0	0
Weight decreased			

subjects affected / exposed	5 / 59 (8.47%)	0 / 4 (0.00%)	5 / 30 (16.67%)
occurrences (all)	8	0	8
Blood sodium increased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Liver function test increased			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	1	0	1
Head injury			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Mitral valve incompetence			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Pericarditis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Sinus bradycardia			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Tachycardia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	2 / 30 (6.67%)
occurrences (all)	0	0	2
Nervous system disorders			
Dizziness			
subjects affected / exposed	5 / 59 (8.47%)	1 / 4 (25.00%)	1 / 30 (3.33%)
occurrences (all)	8	1	1
Dysarthria			

subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	6 / 59 (10.17%)	2 / 4 (50.00%)	4 / 30 (13.33%)
occurrences (all)	6	2	7
Headache			
subjects affected / exposed	6 / 59 (10.17%)	1 / 4 (25.00%)	4 / 30 (13.33%)
occurrences (all)	8	2	4
Neuropathy peripheral			
subjects affected / exposed	4 / 59 (6.78%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	9	1	0
Peripheral sensory neuropathy			
subjects affected / exposed	3 / 59 (5.08%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	5	0	1
Horner's syndrome			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Seizure			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	6 / 59 (10.17%)	1 / 4 (25.00%)	2 / 30 (6.67%)
occurrences (all)	7	4	3
Lymphopenia			
subjects affected / exposed	0 / 59 (0.00%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Thrombocytopenia			
subjects affected / exposed	3 / 59 (5.08%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	3	2	0
Eye disorders			
Blepharitis			

subjects affected / exposed	2 / 59 (3.39%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	2	1	0
Cataract			
subjects affected / exposed	3 / 59 (5.08%)	0 / 4 (0.00%)	3 / 30 (10.00%)
occurrences (all)	4	0	4
Dry eye			
subjects affected / exposed	5 / 59 (8.47%)	0 / 4 (0.00%)	2 / 30 (6.67%)
occurrences (all)	6	0	2
Strabismus			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	6 / 59 (10.17%)	0 / 4 (0.00%)	3 / 30 (10.00%)
occurrences (all)	8	0	3
Vitreous floaters			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Chalazion			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Narrow anterior chamber angle			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Swelling of eyelid			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Visual impairment			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			

Abdominal distension			
subjects affected / exposed	5 / 59 (8.47%)	0 / 4 (0.00%)	2 / 30 (6.67%)
occurrences (all)	5	0	3
Abdominal pain			
subjects affected / exposed	15 / 59 (25.42%)	1 / 4 (25.00%)	5 / 30 (16.67%)
occurrences (all)	28	1	9
Abdominal pain lower			
subjects affected / exposed	2 / 59 (3.39%)	0 / 4 (0.00%)	4 / 30 (13.33%)
occurrences (all)	4	0	4
Abdominal pain upper			
subjects affected / exposed	4 / 59 (6.78%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	4	0	1
Ascites			
subjects affected / exposed	5 / 59 (8.47%)	0 / 4 (0.00%)	6 / 30 (20.00%)
occurrences (all)	5	0	16
Breath odour			
subjects affected / exposed	0 / 59 (0.00%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	16 / 59 (27.12%)	1 / 4 (25.00%)	10 / 30 (33.33%)
occurrences (all)	26	1	14
Diarrhoea			
subjects affected / exposed	13 / 59 (22.03%)	1 / 4 (25.00%)	5 / 30 (16.67%)
occurrences (all)	21	2	7
Dry mouth			
subjects affected / exposed	5 / 59 (8.47%)	0 / 4 (0.00%)	5 / 30 (16.67%)
occurrences (all)	6	0	5
Dyspepsia			
subjects affected / exposed	5 / 59 (8.47%)	1 / 4 (25.00%)	3 / 30 (10.00%)
occurrences (all)	6	1	3
Dysphagia			
subjects affected / exposed	0 / 59 (0.00%)	1 / 4 (25.00%)	1 / 30 (3.33%)
occurrences (all)	0	1	1
Eructation			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	2 / 30 (6.67%)
occurrences (all)	2	0	2

Flatulence			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 59 (5.08%)	0 / 4 (0.00%)	2 / 30 (6.67%)
occurrences (all)	4	0	3
Haemorrhoids			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	2 / 30 (6.67%)
occurrences (all)	1	0	2
Nausea			
subjects affected / exposed	30 / 59 (50.85%)	1 / 4 (25.00%)	13 / 30 (43.33%)
occurrences (all)	55	1	24
Rectal haemorrhage			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	1	0	2
Swollen tongue			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	17 / 59 (28.81%)	1 / 4 (25.00%)	9 / 30 (30.00%)
occurrences (all)	35	1	11
Abdominal discomfort			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Impaired gastric emptying			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Retching			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Umbilical hernia			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0

Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	3 / 30 (10.00%)
occurrences (all)	1	0	3
Pruritus			
subjects affected / exposed	2 / 59 (3.39%)	0 / 4 (0.00%)	6 / 30 (20.00%)
occurrences (all)	2	0	10
Rash			
subjects affected / exposed	4 / 59 (6.78%)	1 / 4 (25.00%)	4 / 30 (13.33%)
occurrences (all)	6	2	5
Rash papular			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	3 / 30 (10.00%)
occurrences (all)	0	0	4
Skin odour abnormal			
subjects affected / exposed	0 / 59 (0.00%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	0	2	0
Night sweats			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	4
Rash macular			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 59 (1.69%)	1 / 4 (25.00%)	1 / 30 (3.33%)
occurrences (all)	1	1	1
Chromaturia			
subjects affected / exposed	1 / 59 (1.69%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	1	2	0
Nocturia			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Proteinuria			

subjects affected / exposed	1 / 59 (1.69%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	1	1	0
Urine odour abnormal			
subjects affected / exposed	0 / 59 (0.00%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	0	3	0
Urinary retention			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	1	0	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	2 / 30 (6.67%)
occurrences (all)	1	0	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 59 (3.39%)	0 / 4 (0.00%)	4 / 30 (13.33%)
occurrences (all)	2	0	6
Back pain			
subjects affected / exposed	10 / 59 (16.95%)	1 / 4 (25.00%)	2 / 30 (6.67%)
occurrences (all)	11	1	2
Flank pain			
subjects affected / exposed	3 / 59 (5.08%)	1 / 4 (25.00%)	3 / 30 (10.00%)
occurrences (all)	6	5	7
Muscle spasms			
subjects affected / exposed	5 / 59 (8.47%)	0 / 4 (0.00%)	2 / 30 (6.67%)
occurrences (all)	9	0	3
Muscular weakness			
subjects affected / exposed	2 / 59 (3.39%)	0 / 4 (0.00%)	2 / 30 (6.67%)
occurrences (all)	3	0	2
Musculoskeletal chest pain			
subjects affected / exposed	4 / 59 (6.78%)	1 / 4 (25.00%)	4 / 30 (13.33%)
occurrences (all)	4	1	8
Musculoskeletal pain			
subjects affected / exposed	7 / 59 (11.86%)	2 / 4 (50.00%)	3 / 30 (10.00%)
occurrences (all)	11	4	5
Myalgia			

subjects affected / exposed	3 / 59 (5.08%)	0 / 4 (0.00%)	2 / 30 (6.67%)
occurrences (all)	5	0	2
Pain in extremity			
subjects affected / exposed	4 / 59 (6.78%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	4	1	0
Groin pain			
subjects affected / exposed	2 / 59 (3.39%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	2	0	0
Musculoskeletal discomfort			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	3 / 59 (5.08%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	3	0	2
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	2 / 59 (3.39%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	2	1	0
Pneumonia			
subjects affected / exposed	3 / 59 (5.08%)	0 / 4 (0.00%)	4 / 30 (13.33%)
occurrences (all)	3	0	6
Upper respiratory tract infection			
subjects affected / exposed	2 / 59 (3.39%)	0 / 4 (0.00%)	4 / 30 (13.33%)
occurrences (all)	2	0	4
Urinary tract infection			
subjects affected / exposed	3 / 59 (5.08%)	1 / 4 (25.00%)	2 / 30 (6.67%)
occurrences (all)	4	1	3
Conjunctivitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Cystitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0
Lower respiratory tract infection			
subjects affected / exposed	0 / 59 (0.00%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	0	0	0

Oral herpes			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	5	0	1
Respiratory tract infection			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	1	0	1
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	26 / 59 (44.07%)	2 / 4 (50.00%)	11 / 30 (36.67%)
occurrences (all)	47	2	19
Dehydration			
subjects affected / exposed	2 / 59 (3.39%)	1 / 4 (25.00%)	1 / 30 (3.33%)
occurrences (all)	2	2	1
Hyperglycaemia			
subjects affected / exposed	1 / 59 (1.69%)	1 / 4 (25.00%)	2 / 30 (6.67%)
occurrences (all)	1	1	2
Hyperuricaemia			
subjects affected / exposed	0 / 59 (0.00%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	4 / 59 (6.78%)	0 / 4 (0.00%)	4 / 30 (13.33%)
occurrences (all)	4	0	4
Hypokalaemia			
subjects affected / exposed	6 / 59 (10.17%)	0 / 4 (0.00%)	0 / 30 (0.00%)
occurrences (all)	6	0	0
Hypomagnesaemia			
subjects affected / exposed	4 / 59 (6.78%)	1 / 4 (25.00%)	1 / 30 (3.33%)
occurrences (all)	4	1	1
Hyponatraemia			
subjects affected / exposed	2 / 59 (3.39%)	0 / 4 (0.00%)	2 / 30 (6.67%)
occurrences (all)	3	0	5
Hypophosphataemia			
subjects affected / exposed	5 / 59 (8.47%)	1 / 4 (25.00%)	1 / 30 (3.33%)
occurrences (all)	6	1	1
Increased appetite			

subjects affected / exposed	0 / 59 (0.00%)	1 / 4 (25.00%)	0 / 30 (0.00%)
occurrences (all)	0	1	0
Hypoglycaemia			
subjects affected / exposed	1 / 59 (1.69%)	0 / 4 (0.00%)	1 / 30 (3.33%)
occurrences (all)	1	0	2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 July 2015	Added exclusion criteria for troponin. Added additional guidance on the collection of triplicate ECGs.
02 February 2016	Added details for flat dosing, Added IHC scoring details for Part 2 of the study. Clarified eligibility criteria.
12 April 2016	Updated eligibility criteria
21 July 2016	Removed flat dosing option. Added BMS-986148 and Nivolumab combination therapy arm (Part 3).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported