Clinical trial results:
A Phase I/IIa Trial With BMS-986158, a Small Molecule Inhibitor of the Bromodomain and Extra-Terminal (BET) Proteins, as Monotherapy or in Combination with Nivolumab in Subjects with Selected Advanced Solid Tumors or Hematologic Malignancies

Summary

EudraCT number	2015-000324-29
Trial protocol	ES NL BE GB FR
Global end of trial date	17 March 2021

Results information

Result version number	v1 (current)
This version publication date	29 March 2022
First version publication date	29 March 2022

Trial information

Trial identification

Sponsor protocol code	CA011-001

Additional study identifiers

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

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	25 August 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	17 March 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the safety and tolerability and to assess the DLTs, MTD, and recommended Phase 2 dose (RP2D) of BMS-986158 as monotherapy for subjects with advanced solid tumors and hematologic malignancies.

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	Australia: 12
Country: Number of subjects enrolled	Canada: 32
Country: Number of subjects enrolled	France: 13
Country: Number of subjects enrolled	United States: 26
Worldwide total number of subjects	83
EEA total number of subjects	13

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)	63

From 65 to 84 years	19
85 years and over	1

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

83 participants were 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	Part 1 Schedule A - BMS-986158 0.75 mg

Arm description:

Single dose of BMS-986158 at 0.75 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle

Arm type	Experimental
Investigational medicinal product name	BMS-986158-01
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

0.75 mg - single dose at first - approximately 7 days later, same dose QD for 5 days followed by a 2 days rest period

Arm title	Part 1 Schedule A - BMS-986158 1.25 mg

Arm description:

Single dose of BMS-986158 at 1.25 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle

Arm type	Experimental
Investigational medicinal product name	BMS-986158-01
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

1.25 mg - single dose at first - approximately 7 days later, same dose QD for 5 days followed by a 2 days rest period

Arm title	Part 1 Schedule A - BMS-986158 2 mg

Arm description:

Single dose of BMS-986158 at 2 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle

Arm type	Experimental

Investigational medicinal product name	BMS-986158-01
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

2 mg - single dose at first - approximately 7 days later, same dose QD for 5 days followed by a 2 days rest period

Arm title	Part 1 Schedule A - BMS-986158 3 mg

Arm description:

Single dose of BMS-986158 at 3 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle

Arm type	Experimental
Investigational medicinal product name	BMS-986158-01
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

3 mg - single dose at first - approximately 7 days later, same dose QD for 5 days followed by a 2 days rest period

Arm title	Part 1 Schedule A - BMS-986158 4.5 mg

Arm description:

Single dose of BMS-986158 at 4.5 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle

Arm type	Experimental
Investigational medicinal product name	BMS-986158-01
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

4.5 mg - single dose at first - approximately 7 days later, same dose QD for 5 days followed by a 2 days rest period

Arm title	Part 1 Schedule B - BMS-986158 2 mg

Arm description:

Single dose of BMS-986158 at 2 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 14 consecutive days, followed by a 7 days rest period, on a 21 days cycle

Arm type	Experimental
Investigational medicinal product name	BMS-986158-01
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

2 mg - single dose at first - approximately 7 days later, same dose QD for 14 days followed by a 7 days rest period

Arm title	Part 1 Schedule B - BMS-986158 3 mg

Arm description:

Single dose of BMS-986158 at 3 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 14 consecutive days, followed by a 7 days rest period, on a 21 days cycle

Arm type	Experimental

Investigational medicinal product name	BMS-986158-01
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

3 mg - single dose at first - approximately 7 days later, same dose QD for 14 days followed by a 7 days rest period

Arm title	Part 1 Schedule C - BMS-986158 2 mg

Arm description:

Single dose of BMS-986158 at 2 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 7 consecutive days, followed by a 14 days rest period, on a 21 days cycle

Arm type	Experimental
Investigational medicinal product name	BMS-986158-01
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

2 mg - single dose at first - approximately 7 days later, same dose QD for 7 days followed by a 14 days rest period

Arm title	Part 1 Schedule C - BMS-986158 3 mg

Arm description:

Single dose of BMS-986158 at 3 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 7 consecutive days, followed by a 14 days rest period, on a 21 days cycle

Arm type	Experimental
Investigational medicinal product name	BMS-986158-01
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

3 mg - single dose at first - approximately 7 days later, same dose QD for 7 days followed by a 14 days rest period

Arm title	Part 1 Schedule C - BMS-986158 4.5 mg

Arm description:

Single dose of BMS-986158 at 4.5 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 7 consecutive days, followed by a 14 days rest period, on a 21 days cycle

Arm type	Experimental
Investigational medicinal product name	BMS-986158-01
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

4.5 mg - single dose at first - approximately 7 days later, same dose QD for 7 days followed by a 14 days rest period

Arm title	Part 2 Schedule A

Arm description:

BMS-986158 administered at 4.5 mg QD for 5 consecutive days, followed by a 2 days resting period, for a total of 10 doses. Then, BMS-986158 is administered at the 3.75 mg dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle

Arm type	Experimental

Investigational medicinal product name	BMS-986158-01
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

4.5 mg QD 5days on 2 days off for 10 cycles. Later, 3 mg QD 5days on 2 days off

Number of subjects in period 1	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg
Started	5	4	13
Completed	0	0	0
Not completed	5	4	13
Consent withdrawn by subject	-	-	-
Disease progression	5	4	13
Study drug toxicity	-	-	-
Participant request to discontinue	-	-	-
Adverse event unrelated to study drug	-	-	-

Number of subjects in period 1	Part 1 Schedule A - BMS-986158 3 mg	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg
Started	10	13	4
Completed	0	0	0
Not completed	10	13	4
Consent withdrawn by subject	-	-	-
Disease progression	10	10	3
Study drug toxicity	-	1	-
Participant request to discontinue	-	-	-
Adverse event unrelated to study drug	-	2	1

Number of subjects in period 1	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg	Part 1 Schedule C - BMS-986158 3 mg
Started	4	6	13
Completed	0	0	0
Not completed	4	6	13
Consent withdrawn by subject	-	-	-
Disease progression	4	5	13
Study drug toxicity	-	-	-
Participant request to discontinue	-	-	-
Adverse event unrelated to study drug	-	1	-

Number of subjects in period 1	Part 1 Schedule C - BMS-986158 4.5 mg	Part 2 Schedule A
Started	10	1

Completed	0	0
Not completed	10	1
Consent withdrawn by subject	-	1
Disease progression	9	-
Study drug toxicity	-	-
Participant request to discontinue	1	-
Adverse event unrelated to study drug	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Part 1 Schedule A - BMS-986158 0.75 mg
Reporting group description:	
Single dose of BMS-986158 at 0.75 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle	
Reporting group title	Part 1 Schedule A - BMS-986158 1.25 mg
Reporting group description:	
Single dose of BMS-986158 at 1.25 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle	
Reporting group title	Part 1 Schedule A - BMS-986158 2 mg
Reporting group description:	
Single dose of BMS-986158 at 2 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle	
Reporting group title	Part 1 Schedule A - BMS-986158 3 mg
Reporting group description:	
Single dose of BMS-986158 at 3 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle	
Reporting group title	Part 1 Schedule A - BMS-986158 4.5 mg
Reporting group description:	
Single dose of BMS-986158 at 4.5 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle	
Reporting group title	Part 1 Schedule B - BMS-986158 2 mg
Reporting group description:	
Single dose of BMS-986158 at 2 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 14 consecutive days, followed by a 7 days rest period, on a 21 days cycle	
Reporting group title	Part 1 Schedule B - BMS-986158 3 mg
Reporting group description:	
Single dose of BMS-986158 at 3 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 14 consecutive days, followed by a 7 days rest period, on a 21 days cycle	
Reporting group title	Part 1 Schedule C - BMS-986158 2 mg
Reporting group description:	
Single dose of BMS-986158 at 2 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 7 consecutive days, followed by a 14 days rest period, on a 21 days cycle	
Reporting group title	Part 1 Schedule C - BMS-986158 3 mg
Reporting group description:	
Single dose of BMS-986158 at 3 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 7 consecutive days, followed by a 14 days rest period, on a 21 days cycle	
Reporting group title	Part 1 Schedule C - BMS-986158 4.5 mg
Reporting group description:	
Single dose of BMS-986158 at 4.5 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 7 consecutive days, followed by a 14 days rest period, on a 21 days cycle	
Reporting group title	Part 2 Schedule A
Reporting group description:	
BMS-986158 administered at 4.5 mg QD for 5 consecutive days, followed by a 2 days resting period, for a total of 10 doses. Then, BMS-986158 is administered at the 3.75 mg dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle	

Reporting group values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg
Number of subjects	5	4	13

Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	4	4	7
>=65 years	1	0	6
Age Continuous Units: Years			
arithmetic mean	61.4	45.0	63.2
standard deviation	± 7.2	± 9.4	± 12.1
Sex: Female, Male Units: Participants			
Female	5	3	12
Male	0	1	1
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	5	3	11
More than one race	0	0	0
Unknown or Not Reported	0	0	1
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	0	1	6
Unknown or Not Reported	5	3	7

Reporting group values	Part 1 Schedule A - BMS-986158 3 mg	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg
Number of subjects	10	13	4
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	7	10	3
>=65 years	3	3	1
Age Continuous Units: Years			
arithmetic mean	54.3	55.5	61.3
standard deviation	± 16.4	± 15.4	± 3.0
Sex: Female, Male Units: Participants			
Female	7	9	2
Male	3	4	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	0	1	0
White	10	10	4

More than one race	0	0	0
Unknown or Not Reported	0	2	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	6	5	2
Unknown or Not Reported	4	8	2

Reporting group values	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg	Part 1 Schedule C - BMS-986158 3 mg
Number of subjects	4	6	13
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	2	6	12
>=65 years	2	0	1
Age Continuous Units: Years			
arithmetic mean	68.5	58.8	53.6
standard deviation	± 5.4	± 2.7	± 9.1
Sex: Female, Male Units: Participants			
Female	3	5	9
Male	1	1	4
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	4	6	8
More than one race	0	0	0
Unknown or Not Reported	0	0	4
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	1	1
Not Hispanic or Latino	2	4	4
Unknown or Not Reported	2	1	8

Reporting group values	Part 1 Schedule C - BMS-986158 4.5 mg	Part 2 Schedule A	Total
Number of subjects	10	1	83
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	7	1	63
>=65 years	3	0	20
Age Continuous Units: Years			
arithmetic mean	58.1	30.0	
standard deviation	± 9.9	± 99999	-

Sex: Female, Male Units: Participants			
Female	9	0	64
Male	1	1	19
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	1	1	4
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	2
White	8	0	69
More than one race	0	0	0
Unknown or Not Reported	1	0	8
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	1	0	3
Not Hispanic or Latino	6	1	37
Unknown or Not Reported	3	0	43

Subject analysis sets

Subject analysis set title	Schedule A
Subject analysis set type	Sub-group analysis
Subject analysis set description: All participants treated with BMS-986158 at any dose under Schedule A regimen (5 days on treatment, 2 days off treatment).	
Subject analysis set title	Schedule B
Subject analysis set type	Sub-group analysis
Subject analysis set description: All participants treated with BMS-986158 at any dose under Schedule B regimen (14 days on treatment, 7 days off treatment).	
Subject analysis set title	Schedule C
Subject analysis set type	Sub-group analysis
Subject analysis set description: All participants treated with BMS-986158 at any dose under Schedule C regimen (7 days on treatment, 14 days off treatment).	
Subject analysis set title	BMS-986158 0.75 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description: All participants treated with BMS-986158 at 0.75 mg dose, regardless of the dosing schedule.	
Subject analysis set title	BMS-986158 1.25 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description: All participants treated with BMS-986158 at 1.25 mg dose, regardless of the dosing schedule.	
Subject analysis set title	BMS-986158 2 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description: All participants treated with BMS-986158 at 2 mg dose, regardless of the dosing schedule.	
Subject analysis set title	BMS-986158 3 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description: All participants treated with BMS-986158 at 3 mg dose, regardless of the dosing schedule.	

Subject analysis set title	BMS-986158 4.5 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
All participants treated with BMS-986158 at 4.5 mg dose, regardless of the dosing schedule.	
Subject analysis set title	BMS-986158 0.75 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
All participants treated with BMS-986158 at 0.75 mg dose, regardless of the dosing schedule.	
Subject analysis set title	BMS-986158 2 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
All participants treated with BMS-986158 at 2 mg dose, regardless of the dosing schedule.	
Subject analysis set title	BMS-986158 3 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
All participants treated with BMS-986158 at 3 mg dose, regardless of the dosing schedule.	
Subject analysis set title	BMS-986158 4.5 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
All participants treated with BMS-986158 at 4.5 mg dose, regardless of the dosing schedule.	

Reporting group values	Schedule A	Schedule B	Schedule C
Number of subjects	46	8	29
Age Categorical Units: Participants			
<=18 years	0	0	0
Between 18 and 65 years	33	5	25
>=65 years	13	3	4
Age Continuous Units: Years			
arithmetic mean	56.6	64.9	56.2
standard deviation	± 14.5	± 5.6	± 8.6
Sex: Female, Male Units: Participants			
Female	36	5	23
Male	10	3	6
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	0	2
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	2	0	0
White	39	8	22
More than one race	0	0	0
Unknown or Not Reported	3	0	5
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	3
Not Hispanic or Latino	19	4	14
Unknown or Not Reported	27	4	12

Reporting group values	BMS-986158 0.75 mg	BMS-986158 1.25 mg	BMS-986158 2 mg
Number of subjects	5	3	16
Age Categorical Units: Participants			
<=18 years Between 18 and 65 years >=65 years			
Age Continuous Units: Years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units: Participants			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	BMS-986158 3 mg	BMS-986158 4.5 mg	BMS-986158 0.75 mg
Number of subjects	25	17	4
Age Categorical Units: Participants			
<=18 years Between 18 and 65 years >=65 years			
Age Continuous Units: Years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units: Participants			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian			

Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

Reporting group values	BMS-986158 2 mg	BMS-986158 3 mg	BMS-986158 4.5 mg
Number of subjects	11	18	14
Age Categorical Units: Participants			
<=18 years Between 18 and 65 years >=65 years			
Age Continuous Units: Years arithmetic mean standard deviation	±	±	±
Sex: Female, Male Units: Participants			
Female Male			
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported			
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported			

End points

End points reporting groups

Reporting group title	Part 1 Schedule A - BMS-986158 0.75 mg
Reporting group description:	
Single dose of BMS-986158 at 0.75 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle	
Reporting group title	Part 1 Schedule A - BMS-986158 1.25 mg
Reporting group description:	
Single dose of BMS-986158 at 1.25 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle	
Reporting group title	Part 1 Schedule A - BMS-986158 2 mg
Reporting group description:	
Single dose of BMS-986158 at 2 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle	
Reporting group title	Part 1 Schedule A - BMS-986158 3 mg
Reporting group description:	
Single dose of BMS-986158 at 3 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle	
Reporting group title	Part 1 Schedule A - BMS-986158 4.5 mg
Reporting group description:	
Single dose of BMS-986158 at 4.5 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle	
Reporting group title	Part 1 Schedule B - BMS-986158 2 mg
Reporting group description:	
Single dose of BMS-986158 at 2 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 14 consecutive days, followed by a 7 days rest period, on a 21 days cycle	
Reporting group title	Part 1 Schedule B - BMS-986158 3 mg
Reporting group description:	
Single dose of BMS-986158 at 3 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 14 consecutive days, followed by a 7 days rest period, on a 21 days cycle	
Reporting group title	Part 1 Schedule C - BMS-986158 2 mg
Reporting group description:	
Single dose of BMS-986158 at 2 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 7 consecutive days, followed by a 14 days rest period, on a 21 days cycle	
Reporting group title	Part 1 Schedule C - BMS-986158 3 mg
Reporting group description:	
Single dose of BMS-986158 at 3 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 7 consecutive days, followed by a 14 days rest period, on a 21 days cycle	
Reporting group title	Part 1 Schedule C - BMS-986158 4.5 mg
Reporting group description:	
Single dose of BMS-986158 at 4.5 mg. Approximately 7 days later, BMS-986158 is administered at the same dose QD for 7 consecutive days, followed by a 14 days rest period, on a 21 days cycle	
Reporting group title	Part 2 Schedule A
Reporting group description:	
BMS-986158 administered at 4.5 mg QD for 5 consecutive days, followed by a 2 days resting period, for a total of 10 doses. Then, BMS-986158 is administered at the 3.75 mg dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle	
Subject analysis set title	Schedule A
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
All participants treated with BMS-986158 at any dose under Schedule A regimen (5 days on treatment, 2 days off treatment).	
Subject analysis set title	Schedule B
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants treated with BMS-986158 at any dose under Schedule B regimen (14 days on treatment, 7 days off treatment).

Subject analysis set title	Schedule C
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants treated with BMS-986158 at any dose under Schedule C regimen (7 days on treatment, 14 days off treatment).

Subject analysis set title	BMS-986158 0.75 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants treated with BMS-986158 at 0.75 mg dose, regardless of the dosing schedule.

Subject analysis set title	BMS-986158 1.25 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants treated with BMS-986158 at 1.25 mg dose, regardless of the dosing schedule.

Subject analysis set title	BMS-986158 2 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants treated with BMS-986158 at 2 mg dose, regardless of the dosing schedule.

Subject analysis set title	BMS-986158 3 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants treated with BMS-986158 at 3 mg dose, regardless of the dosing schedule.

Subject analysis set title	BMS-986158 4.5 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants treated with BMS-986158 at 4.5 mg dose, regardless of the dosing schedule.

Subject analysis set title	BMS-986158 0.75 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants treated with BMS-986158 at 0.75 mg dose, regardless of the dosing schedule.

Subject analysis set title	BMS-986158 2 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants treated with BMS-986158 at 2 mg dose, regardless of the dosing schedule.

Subject analysis set title	BMS-986158 3 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants treated with BMS-986158 at 3 mg dose, regardless of the dosing schedule.

Subject analysis set title	BMS-986158 4.5 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

All participants treated with BMS-986158 at 4.5 mg dose, regardless of the dosing schedule.

Primary: Number of Participants Experiencing Adverse Events

End point title	Number of Participants Experiencing Adverse Events[1]

End point description:

Number of participants experiencing different types of events, including Adverse Events (AEs), Serious Adverse Events (SAEs), AEs leading to discontinuation and deaths. Events are classified based on the NCI Common Terminology Criteria for Adverse Events (CTCAE) version 4.03.

End point type	Primary

End point timeframe:

From first dose to 30 days following last dose (up to approximately 29 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: No statistical analyses were performed for this endpoint

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	13	10
Units: Participants				
Adverse Events (AEs)	5	4	13	10
Serious Adverse Events (SAEs)	3	3	7	7
AEs leading to discontinuation	0	0	0	1
Deaths	0	1	2	4

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	4	4	6
Units: Participants				
Adverse Events (AEs)	13	4	4	6
Serious Adverse Events (SAEs)	9	2	2	4
AEs leading to discontinuation	3	1	0	1
Deaths	3	0	0	1

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg	Part 2 Schedule A	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	10	1	
Units: Participants				
Adverse Events (AEs)	13	9	1	
Serious Adverse Events (SAEs)	5	3	0	
AEs leading to discontinuation	0	0	0	
Deaths	2	0	0	

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Abnormal Hepatic Test Values

End point title	Number of Participants With Abnormal Hepatic Test Values[2]

End point description:

Number of participants experiencing abnormal hepatic function, as measured by different parameters.
ALT = Alanine aminotransferase AST = Aspartate aminotransferase ULN = Upper Limit of Normal

End point type	Primary

End point timeframe:

From first dose to 30 days following last dose (up to approximately 29 months)

Notes:

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

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	13	10
Units: Participants				
ALT OR AST > 3XULN	2	1	2	2
ALT OR AST > 5XULN	1	0	2	1
ALT OR AST > 10XULN	0	0	1	1
ALT OR AST > 20XULN	0	0	0	0
TOTAL BILIRUBIN > 2XULN	1	0	0	1
ALT OR AST > 3XULN + BILIRUB > 2XULN W/ 1 DAY	1	0	0	1
ALT OR AST > 3XULN + BILIRUB > 2XULN W/ 30 DAYS	1	0	0	1

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	4	4	6
Units: Participants				
ALT OR AST > 3XULN	2	0	1	0
ALT OR AST > 5XULN	2	0	0	0
ALT OR AST > 10XULN	0	0	0	0
ALT OR AST > 20XULN	0	0	0	0
TOTAL BILIRUBIN > 2XULN	4	0	1	0
ALT OR AST > 3XULN + BILIRUB > 2XULN W/ 1 DAY	0	0	0	0
ALT OR AST > 3XULN + BILIRUB > 2XULN W/ 30 DAYS	0	0	1	0

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg	Part 2 Schedule A	

Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	10	1	
Units: Participants				
ALT OR AST > 3XULN	2	2	0	
ALT OR AST > 5XULN	2	1	0	
ALT OR AST > 10XULN	0	0	0	
ALT OR AST > 20XULN	0	0	0	
TOTAL BILIRUBIN > 2XULN	0	1	1	
ALT OR AST > 3XULN + BILIRUB > 2XULN W/ 1 DAY	0	1	0	
ALT OR AST > 3XULN + BILIRUB > 2XULN W/ 30 DAYS	0	1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Best Overall Response (BOR)

End point title	Best Overall Response (BOR)

End point description:

BOR, as assessed by the investigator, is defined as the best response designation, recorded between the dates of first dose and the date of first objectively documented progression (per RECIST v1.1 for solid tumors, Lugano 2014 criteria for hematologic malignancies or PCWG3 for prostate cancer) or the date of subsequent therapy, whichever occurs first.

End point type	Secondary

End point timeframe:

From first dose to date of first documented progression or subsequent therapy (up to approximately 28 months)

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	13	10
Units: Participants				
Complete Response	0	0	0	0
Partial Response	0	0	0	0
Stable Disease	1	1	2	1
Progressive Disease	4	2	8	7
Unable to determine	0	1	3	2

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	4	4	6
Units: Participants				
Complete Response	0	0	0	0
Partial Response	1	0	0	0
Stable Disease	7	2	1	1
Progressive Disease	3	2	2	2
Unable to determine	2	0	1	3

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg	Part 2 Schedule A	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	10	1	
Units: Participants				
Complete Response	0	0	0	
Partial Response	0	0	1	
Stable Disease	4	4	0	
Progressive Disease	9	4	0	
Unable to determine	0	2	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR)

End point description:

ORR is defined as the percentage of participants who achieved a best overall response of Complete Response (CR) or Partial Response (PR)

End point type	Secondary

End point timeframe:

From first dose to date of first documented progression or subsequent therapy (up to approximately 28 months)

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	13	10
Units: Percent of Participants				
number (confidence interval 95%)	0 (0.0 to 52.2)	0 (0.0 to 60.2)	0 (0.0 to 24.7)	0 (0.0 to 30.8)

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	13	4	4	6
Units: Percent of Participants				
number (confidence interval 95%)	7.7 (0.2 to 36.0)	0 (0.0 to 60.2)	0 (0.0 to 60.2)	0 (0.0 to 45.9)

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg	Part 2 Schedule A	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	10	1	
Units: Percent of Participants				
number (confidence interval 95%)	0 (0.0 to 24.7)	0 (0.0 to 30.8)	100.0 (2.5 to 100.0)	

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR)

End point description:

DOR is defined as the time between the date of first response and the date of the first objectively documented disease progression (as determined by RECIST v1.1 for solid tumors, Lugano 2014 criteria for hematologic malignancies, or PCWG3 (including PSA assessments) for prostate cancer [CRPC or NEPC]), or death due to any cause, whichever occurs first.

End point type	Secondary

End point timeframe:

From date of first response to date of first objectively documented disease progression or death (up to approximately 42 weeks)

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[3]	0[4]	0[5]	0[6]
Units: Weeks				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[3] - No responders in this cohort

[4] - No responders in this cohort

[5] - No responders in this cohort

[6] - No responders in this cohort

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0[7]	0[8]	0[9]
Units: Weeks				
arithmetic mean (standard deviation)	22.3 (± 99999)	()	()	()

Notes:

[7] - No responders in this cohort

[8] - No responders in this cohort

[9] - No responders in this cohort

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg	Part 2 Schedule A	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	0[10]	0[11]	1	
Units: Weeks				
arithmetic mean (standard deviation)	()	()	42.4 (± 99999)	

Notes:

[10] - No responders in this cohort

[11] - No responders in this cohort

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS)

End point title	Progression Free Survival (PFS)

End point description:

PFS 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.

End point type	Secondary

End point timeframe:

From first dose to date of first objectively documented disease progression or death (up to approximately 28 months)

End point values	Schedule A	Schedule B	Schedule C	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	46	8	29	
Units: Weeks				
median (confidence interval 95%)	8.29 (7.14 to 9.71)	8.43 (5.57 to 40.14)	9.00 (7.86 to 13.29)	

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival Rate (PFSR)

End point title	Progression Free Survival Rate (PFSR)

End point description:

PFSR is defined as the percentage of participants who remain progression free and surviving at the specified timepoints (12 weeks, 24 weeks, and 48 weeks). Reported values are estimates derived from Kaplan-Meier analyses

End point type	Secondary

End point timeframe:

From first dose to 12 weeks, to 24 weeks, and to 48 weeks after first dose

End point values	Schedule A	Schedule B	Schedule C	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	46	8	29	
Units: Percent of participants				
number (confidence interval 95%)				
12 weeks	31.0 (17.4 to 45.6)	42.9 (9.8 to 73.4)	31.6 (14.2 to 50.6)	
24 weeks	18.1 (8.0 to 31.5)	42.9 (9.8 to 73.4)	13.5 (3.4 to 30.6)	
48 weeks	10.3 (3.3 to 22.1)	14.3 (0.7 to 46.5)	6.8 (0.6 to 24.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (Cmax) - Single Dose Administration

End point title	Maximum Observed Plasma Concentration (Cmax) - Single Dose Administration

End point description:

Values are reported separately for the parent BMS-986158 and its metabolite BMT-161485

End point type	Secondary

End point timeframe:

From drug administration in Cycle 1 Day 1 to 168 hours post drug administration

End point values	BMS-986158 0.75 mg	BMS-986158 1.25 mg	BMS-986158 2 mg	BMS-986158 3 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	3	16	25
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158	68.8 (± 23)	175 (± 36)	269 (± 25)	368 (± 30)
Metabolite BMT-161485	5.00 (± 30)	10.0 (± 29)	18.2 (± 36)	21.6 (± 47)

End point values	BMS-986158 4.5 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	17			
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158	513 (± 25)			
Metabolite BMT-161485	35.6 (± 41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time of Maximum Observed Plasma Concentration (Tmax) - Single Dose Administration

End point title	Time of Maximum Observed Plasma Concentration (Tmax) - Single Dose Administration

End point description:

Values are reported separately for the parent BMS-986158 and its metabolite BMT-161485

End point type	Secondary

End point timeframe:

From drug administration in Cycle 1 Day 1 to 168 hours post drug administration

End point values	BMS-986158 0.75 mg	BMS-986158 1.25 mg	BMS-986158 2 mg	BMS-986158 3 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	3	16	25
Units: Hours				
median (full range (min-max))				
Parent BMS-986158	4.00 (2.00 to 4.02)	1.00 (1.00 to 2.00)	1.04 (0.500 to 4.03)	1.02 (0.500 to 6.15)

Metabolite BMT-161485	24.0 (2.55 to 24.2)	2.00 (2.00 to 24.0)	6.00 (1.00 to 72.0)	3.03 (0.983 to 48.0)

End point values	BMS-986158 4.5 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	17			
Units: Hours				
median (full range (min-max))				
Parent BMS-986158	2.02 (1.00 to 4.03)			
Metabolite BMT-161485	6.27 (1.00 to 48.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-Time Curve in One Dosing Interval (AUC(0-24)) - Single Dose Administration

End point title	Area Under the Plasma Concentration-Time Curve in One Dosing Interval (AUC(0-24)) - Single Dose Administration
End point description:	
Values are reported separately for the parent BMS-986158 and its metabolite BMT-161485	
End point type	Secondary
End point timeframe:	
From drug administration in Cycle 1 Day 1 to 168 hours post drug administration	

End point values	BMS-986158 0.75 mg	BMS-986158 1.25 mg	BMS-986158 2 mg	BMS-986158 3 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	3	16	25
Units: hr*ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158	1027 (± 16)	2309 (± 13)	3533 (± 25)	4989 (± 38)
Metabolite BMT-161485	98.2 (± 34)	188 (± 11)	310 (± 35)	377 (± 44)

End point values	BMS-986158 4.5 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	17			
Units: hr*ng/mL				
geometric mean (geometric coefficient				

of variation)				
Parent BMS-986158	7039 (± 34)			
Metabolite BMT-161485	629 (± 41)			

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Terminal Phase Half-Life (T-HALF) - Single Dose Administration

End point title	Apparent Terminal Phase Half-Life (T-HALF) - Single Dose Administration

End point description:

Values are reported separately for the parent BMS-986158 and its metabolite BMT-161485

End point type	Secondary

End point timeframe:

From drug administration in Cycle 1 Day 1 to 168 hours post drug administration

End point values	BMS-986158 0.75 mg	BMS-986158 1.25 mg	BMS-986158 2 mg	BMS-986158 3 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	3	11	18
Units: hr				
arithmetic mean (standard deviation)				
Parent BMS-986158	33.7 (± 1.41)	48.7 (± 6.66)	54.3 (± 19.87)	42.7 (± 19.56)
Metabolite BMT-161485	35.3 (± 99999)	50.8 (± 6.26)	48.8 (± 18.78)	39.4 (± 13.80)

End point values	BMS-986158 4.5 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	14			
Units: hr				
arithmetic mean (standard deviation)				
Parent BMS-986158	43.8 (± 15.75)			
Metabolite BMT-161485	38.7 (± 13.66)			

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-Time Curve From Time Zero Extrapolated to Infinite Time (AUC(INF)) - Single Dose Administration

End point title	Area Under the Plasma Concentration-Time Curve From Time Zero Extrapolated to Infinite Time (AUC(INF)) - Single Dose Administration

End point description:

Values are reported separately for the parent BMS-986158 and its metabolite BMT-161485

End point type	Secondary

End point timeframe:

From drug administration in Cycle 1 Day 1 to 168 hours post drug administration

End point values	BMS-986158 0.75 mg	BMS-986158 1.25 mg	BMS-986158 2 mg	BMS-986158 3 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	4	3	11	18
Units: hr*ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158	2479 (± 18)	7013 (± 17)	9775 (± 56)	11677 (± 44)
Metabolite BMT-161485	409 (± 99999)	892 (± 13)	944 (± 73)	1128 (± 46)

End point values	BMS-986158 4.5 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	14			
Units: hr*ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158	18974 (± 40)			
Metabolite BMT-161485	2231 (± 67)			

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Total Body Clearance (CLT/F) - Single Dose Administration

End point title	Apparent Total Body Clearance (CLT/F) - Single Dose Administration

End point description:

Values are reported only for the parent BMS-986158

End point type	Secondary

End point timeframe:

From drug administration in Cycle 1 Day 1 to 168 hours post drug administration

End point values	BMS-986158 0.75 mg	BMS-986158 1.25 mg	BMS-986158 2 mg	BMS-986158 3 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	5	3	16	25
Units: mL/min				
geometric mean (geometric coefficient of variation)	5.04 (± 17)	2.97 (± 18)	3.41 (± 56)	4.28 (± 62)

End point values	BMS-986158 4.5 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	17			
Units: mL/min				
geometric mean (geometric coefficient of variation)	3.95 (± 33)			

Statistical analyses

No statistical analyses for this end point

Secondary: Apparent Volume of Distribution of Terminal Phase (Vz/F) - Single Dose Administration

End point title	Apparent Volume of Distribution of Terminal Phase (Vz/F) - Single Dose Administration

End point description:

Values are reported only for the parent BMS-986158

End point type	Secondary

End point timeframe:

From drug administration in Cycle 1 Day 1 to 168 hours post drug administration

End point values	BMS-986158 1.25 mg	BMS-986158 0.75 mg	BMS-986158 2 mg	BMS-986158 3 mg
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	3	4	11	18
Units: Liters				
geometric mean (geometric coefficient of variation)	12.5 (± 18)	14.7 (± 21)	14.8 (± 27)	14.4 (± 28)

End point values	BMS-986158 4.5 mg			
Subject group type	Subject analysis set			
Number of subjects analysed	14			
Units: Liters				
geometric mean (geometric coefficient	14.1 (± 31)			

of variation)

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Plasma Concentration (Cmax) - Multiple Dose Administration

End point title	Maximum Observed Plasma Concentration (Cmax) - Multiple Dose Administration[12]

End point description:

Values are reported separately for the parent BMS-986158 and its metabolite BMT-161485. Values are also reported separately for Cycle 1 Day 1 and the latest collection timepoint available (Cycle 2 Day 5 for Schedule A, Cycle 2 day 14 for Schedule B, Cycle 2 Day 7 for Schedule C)

End point type	Secondary

End point timeframe:

From Cycle 1 Day 1 to Cycle 2 Day 5 (Schedule A) or to Cycle 2 Day 14 (Schedule B) or to Cycle 2 Day 7 (Schedule C)

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Not all the arms were assessed for this endpoint

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	9	10
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Cycle 1 Day 1	68.8 (± 23)	175 (± 36)	260 (± 20)	328 (± 36)
Parent BMS-986158 - Latest timepoint	136 (± 43)	284 (± 16)	442 (± 29)	624 (± 44)
Metabolite BMT-161485 - Cycle 1 Day 1	5.00 (± 30)	10.0 (± 29)	16.9 (± 32)	22.5 (± 38)
Metabolite BMT-161485 -Latest timepoint	25.8 (± 82)	31.0 (± 25)	49.4 (± 46)	83.3 (± 57)

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	1	4	6
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Cycle 1 Day 1	478 (± 24)	207 (± 99999)	481 (± 25)	295 (± 29)

Parent BMS-986158 - Latest timepoint	898 (± 39)	279 (± 99999)	855 (± 99999)	520 (± 34)
Metabolite BMT-161485 - Cycle 1 Day 1	30.0 (± 41)	13.6 (± 99999)	26.3 (± 63)	21.1 (± 35)
Metabolite BMT-161485 -Latest timepoint	126 (± 50)	32.7 (± 99999)	127 (± 99999)	80.7 (± 53)

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	7		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Cycle 1 Day 1	370 (± 22)	567 (± 24)		
Parent BMS-986158 - Latest timepoint	588 (± 47)	901 (± 62)		
Metabolite BMT-161485 - Cycle 1 Day 1	19.4 (± 44)	45.5 (± 32)		
Metabolite BMT-161485 -Latest timepoint	64.5 (± 55)	146 (± 83)		

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Maximum Observed Plasma Concentration (Tmax) - Multiple Dose Administration

End point title	Time to Maximum Observed Plasma Concentration (Tmax) - Multiple Dose Administration[13]

End point description:

Values are reported separately for the parent BMS-986158 and its metabolite BMT-161485. Values are also reported separately for Cycle 1 Day 1 and the latest collection timepoint available (Cycle 2 Day 5 for Schedule A, Cycle 2 day 14 for Schedule B, Cycle 2 Day 7 for Schedule C)

End point type	Secondary

End point timeframe:

From Cycle 1 Day 1 to Cycle 2 Day 5 (Schedule A) or to Cycle 2 Day 14 (Schedule B) or to Cycle 2 Day 7 (Schedule C)

Notes:

[13] - 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: Not all the arms were assessed for this endpoint

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	9	10
Units: Hours				
median (full range (min-max))				
Parent BMS-986158 - Cycle 1 day 1	4.00 (2.00 to 4.02)	1.00 (1.00 to 2.00)	2.00 (1.00 to 4.03)	2.00 (0.983 to 6.15)

Parent BMS-986158 - Latest timepoint	3.14 (2.00 to 6.05)	1.50 (0.500 to 2.00)	2.00 (0.500 to 4.02)	2.01 (0.500 to 2.10)
Metabolite BMT-161485 - Cycle 1 Day 1	24.0 (2.55 to 24.2)	2.00 (2.00 to 24.0)	5.08 (2.00 to 72.0)	23.9 (0.983 to 48.0)
Metabolite BMT-161485 -Latest timepoint	24.0 (24.0 to 24.0)	4.00 (1.50 to 6.00)	2.07 (0 to 4.02)	2.01 (1.00 to 6.10)

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	1	4	6
Units: Hours				
median (full range (min-max))				
Parent BMS-986158 - Cycle 1 day 1	2.04 (1.00 to 4.03)	1.00 (1.00 to 1.00)	1.03 (1.00 to 4.03)	1.00 (0.500 to 2.03)
Parent BMS-986158 - Latest timepoint	2.00 (1.00 to 4.05)	1.00 (1.00 to 1.00)	1.00 (1.00 to 1.00)	1.00 (0.833 to 4.00)
Metabolite BMT-161485 - Cycle 1 Day 1	15.1 (1.00 to 48.0)	1.00 (1.00 to 1.00)	1.52 (1.00 to 47.4)	14.9 (1.00 to 71.5)
Metabolite BMT-161485 -Latest timepoint	4.00 (1.00 to 24.0)	1.00 (1.00 to 1.00)	1.00 (1.00 to 1.00)	4.08 (3.83 to 24.0)

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	7		
Units: Hours				
median (full range (min-max))				
Parent BMS-986158 - Cycle 1 day 1	1.00 (0.500 to 2.02)	2.02 (1.00 to 4.00)		
Parent BMS-986158 - Latest timepoint	1.66 (0.967 to 2.03)	2.00 (0.167 to 2.03)		
Metabolite BMT-161485 - Cycle 1 Day 1	2.02 (1.00 to 48.0)	6.27 (1.00 to 45.6)		
Metabolite BMT-161485 -Latest timepoint	4.00 (0 to 6.32)	4.00 (1.00 to 27.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-Time Curve From Time Zero to Time of Last Quantifiable Concentration (AUC(0-T)) - Multiple Dose Administration

End point title	Area Under the Plasma Concentration-Time Curve From Time Zero to Time of Last Quantifiable Concentration (AUC(0-T)) - Multiple Dose Administration[14]

End point description:

Values are reported separately for the parent BMS-986158 and its metabolite BMT-161485. Values are also reported separately for Cycle 1 Day 1 and the latest collection timepoint available (Cycle 2 Day 5 for Schedule A, Cycle 2 day 14 for Schedule B, Cycle 2 Day 7 for Schedule C)

End point type	Secondary

End point timeframe:

From Cycle 1 Day 1 to Cycle 2 Day 5 (Schedule A) or to Cycle 2 Day 14 (Schedule B) or to Cycle 2 Day 7 (Schedule C)

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Not all the arms were assessed for this endpoint

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	9	10
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Cycle 1 day 1	2150 (± 15)	6372 (± 14)	8564 (± 48)	10452 (± 50)
Parent BMS-986158 - Latest timepoint	3449 (± 93)	4961 (± 73)	7612 (± 71)	13378 (± 77)
Metabolite BMT-161485 - Cycle 1 day 1	314 (± 32)	790 (± 14)	992 (± 65)	1305 (± 48)
Metabolite BMT-161485 -Latest timepoint	1474 (± 89)	691 (± 73)	1110 (± 89)	2925 (± 85)

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	1	4	6
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Cycle 1 day 1	19124 (± 46)	5202 (± 99999)	25852 (± 41)	10931 (± 43)
Parent BMS-986158 - Latest timepoint	29517 (± 36)	6321 (± 99999)	33978 (± 99999)	19868 (± 45)
Metabolite BMT-161485 - Cycle 1 day 1	2748 (± 64)	424 (± 99999)	2467 (± 61)	1895 (± 58)
Metabolite BMT-161485 -Latest timepoint	6691 (± 49)	1000 (± 99999)	7339 (± 99999)	5022 (± 62)

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	7		
Units: h*ng/mL				

geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Cycle 1 day 1	11493 (± 54)	17220 (± 84)		
Parent BMS-986158 - Latest timepoint	18266 (± 97)	19995 (± 135)		
Metabolite BMT-161485 - Cycle 1 day 1	1219 (± 73)	2645 (± 77)		
Metabolite BMT-161485 -Latest timepoint	3458 (± 96)	5719 (± 134)		

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Plasma Concentration-Time Curve in One Dosing Interval (AUC(0-24)) - Multiple Dose Administration

End point title	Area Under the Plasma Concentration-Time Curve in One Dosing Interval (AUC(0-24)) - Multiple Dose Administration[15]

End point description:

Values are reported separately for the parent BMS-986158 and its metabolite BMT-161485. Values are also reported separately for Cycle 1 Day 1 and the latest collection timepoint available (Cycle 2 Day 5 for Schedule A, Cycle 2 day 14 for Schedule B, Cycle 2 Day 7 for Schedule C)

End point type	Secondary

End point timeframe:

From Cycle 1 Day 1 to Cycle 2 Day 5 (Schedule A) or to Cycle 2 Day 14 (Schedule B) or to Cycle 2 Day 7 (Schedule C)

Notes:

[15] - 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: Not all the arms were assessed for this endpoint

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	9	10
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Cycle 1 day 1	1027 (± 16)	2309 (± 13)	3610 (± 22)	4942 (± 43)
Parent BMS-986158 - Latest timepoint	2716 (± 51)	3852 (± 99999)	99999 (± 99999)	9817 (± 56)
Metabolite BMT-161485 - Cycle 1 Day 1	98.2 (± 34)	188 (± 11)	290 (± 22)	404 (± 39)
Metabolite BMT-161485 -Latest timepoint	550 (± 81)	500 (± 99999)	99999 (± 99999)	1746 (± 64)

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	1	4	6

Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Cycle 1 day 1	6786 (± 24)	2358 (± 99999)	6921 (± 28)	3660 (± 27)
Parent BMS-986158 - Latest timepoint	14551 (± 32)	3430 (± 99999)	13305 (± 99999)	8561 (± 36)
Metabolite BMT-161485 - Cycle 1 Day 1	560 (± 42)	191 (± 99999)	439 (± 52)	367 (± 36)
Metabolite BMT-161485 -Latest timepoint	2649 (± 48)	505 (± 99999)	2551 (± 99999)	1765 (± 51)

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	7		
Units: h*ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Cycle 1 day 1	4468 (± 29)	7418 (± 43)		
Parent BMS-986158 - Latest timepoint	8637 (± 71)	11286 (± 104)		
Metabolite BMT-161485 - Cycle 1 Day 1	337 (± 46)	741 (± 38)		
Metabolite BMT-161485 -Latest timepoint	1299 (± 63)	2616 (± 102)		

Statistical analyses

No statistical analyses for this end point

Secondary: Minimum Observed Concentration Within a Dosing Interval (Cmin) - Multiple Dose Administration

End point title	Minimum Observed Concentration Within a Dosing Interval (Cmin) - Multiple Dose Administration[16]

End point description:

Values are reported separately for the parent BMS-986158 and its metabolite BMT-161485. Values are reported only for the latest collection timepoint available (Cycle 2 Day 5 for Schedule A, Cycle 2 day 14 for Schedule B, Cycle 2 Day 7 for Schedule C)

End point type	Secondary

End point timeframe:

From Cycle 1 Day 1 to Cycle 2 Day 5 (Schedule A) or to Cycle 2 Day 14 (Schedule B) or to Cycle 2 Day 7 (Schedule C)

Notes:

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

Justification: Not all the arms were assessed for this endpoint

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	7	8
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Latest timepoint	73.7 (± 45)	141 (± 17)	208 (± 53)	227 (± 76)
Metabolite BMT-161485 -Latest timepoint	16.4 (± 91)	22.3 (± 22)	33.7 (± 55)	54.0 (± 73)

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	1	1	5
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Latest timepoint	428 (± 41)	85.1 (± 99999)	435 (± 99999)	270 (± 42)
Metabolite BMT-161485 -Latest timepoint	89.6 (± 55)	14.4 (± 99999)	79.5 (± 99999)	59.7 (± 54)

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	7		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Latest timepoint	238 (± 94)	253 (± 125)		
Metabolite BMT-161485 -Latest timepoint	44.2 (± 74)	71.1 (± 115)		

Statistical analyses

No statistical analyses for this end point

Secondary: Concentration at the End of Dosing Interval (C24) - Multiple Dose Administration

End point title	Concentration at the End of Dosing Interval (C24) - Multiple Dose Administration[17]

End point description:

Values are reported separately for the parent BMS-986158 and its metabolite BMT-161485. Values are

also reported separately for Cycle 1 Day 1 and the latest collection timepoint available (Cycle 2 Day 5 for Schedule A, Cycle 2 day 14 for Schedule B, Cycle 2 Day 7 for Schedule C)

End point type	Secondary

End point timeframe:

From Cycle 1 Day 1 to Cycle 2 Day 5 (Schedule A) or to Cycle 2 Day 14 (Schedule B) or to Cycle 2 Day 7 (Schedule C)

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: Not all the arms were assessed for this endpoint

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	9	10
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Cycle 1 Day 1	33.5 (± 18)	67.4 (± 12)	108 (± 36)	143 (± 50)
Parent BMS-986158 - Latest timepoint	87.9 (± 63)	116 (± 99999)	99999 (± 99999)	280 (± 64)
Metabolite BMT-161485 - Cycle 1 Day 1	4.85 (± 29)	7.92 (± 8)	12.0 (± 37)	18.8 (± 40)
Metabolite BMT-161485 -Latest timepoint	16.4 (± 91)	22.3 (± 22)	33.7 (± 55)	54.0 (± 73)

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	1	4	6
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Cycle 1 Day 1	210 (± 32)	66.1 (± 99999)	232 (± 30)	112 (± 33)
Parent BMS-986158 - Latest timepoint	461 (± 36)	85.1 (± 99999)	463 (± 99999)	276 (± 45)
Metabolite BMT-161485 - Cycle 1 Day 1	27.0 (± 44)	5.23 (± 99999)	19.0 (± 42)	16.3 (± 37)
Metabolite BMT-161485 -Latest timepoint	89.6 (± 55)	14.4 (± 99999)	104 (± 99999)	69.4 (± 62)

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	7		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				

Parent BMS-986158 - Cycle 1 Day 1	125 (± 43)	185 (± 68)		
Parent BMS-986158 - Latest timepoint	244 (± 93)	263 (± 131)		
Metabolite BMT-161485 - Cycle 1 Day 1	12.9 (± 58)	29.1 (± 53)		
Metabolite BMT-161485 -Latest timepoint	47.8 (± 74)	84.5 (± 120)		

Statistical analyses

No statistical analyses for this end point

Secondary: Trough Observed Plasma Concentration (Ctrough) - Multiple Dose Administration

End point title	Trough Observed Plasma Concentration (Ctrough) - Multiple Dose Administration[18]

End point description:

Values are reported separately for the parent BMS-986158 and its metabolite BMT-161485. Values are also reported separately for the first and last collection

End point type	Secondary

End point timeframe:

From Cycle (C)2 Day (D)2 to C2D5 (Schedule A) or from C2D14 to C4D8 (Schedule B) or from C2D7 to C8D8 (Schedule C)

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Not all the arms were assessed for this endpoint

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	4	8
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - First collection	35.7 (± 25)	79.6 (± 10)	142 (± 51)	138 (± 48)
Parent BMS-986158 -Last collection	87.9 (± 63)	116 (± 99999)	99999 (± 99999)	280 (± 64)
Metabolite BMT-161485 - First collection	7.78 (± 36)	9.42 (± 19)	11.4 (± 51)	22.2 (± 48)
Metabolite BMT-161485 - Last collection	25.8 (± 82)	20.1 (± 99999)	99999 (± 99999)	65.8 (± 63)

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	1	1	3
Units: ng/mL				
geometric mean (geometric coefficient of variation)				

Parent BMS-986158 - First collection	257 (± 27)	109 (± 99999)	435 (± 99999)	242 (± 58)
Parent BMS-986158 -Last collection	461 (± 36)	289 (± 99999)	99999 (± 99999)	69.1 (± 99999)
Metabolite BMT-161485 - First collection	36.5 (± 44)	16.9 (± 99999)	79.5 (± 99999)	51.2 (± 68)
Metabolite BMT-161485 - Last collection	108 (± 47)	36.4 (± 99999)	99999 (± 99999)	10.8 (± 99999)

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	7		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - First collection	282 (± 98)	284 (± 119)		
Parent BMS-986158 -Last collection	370 (± 99999)	99999 (± 99999)		
Metabolite BMT-161485 - First collection	49.4 (± 81)	75.3 (± 110)		
Metabolite BMT-161485 - Last collection	24.5 (± 99999)	99999 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Accumulation Index (AI) - Multiple Dose Administration

End point title	Accumulation Index (AI) - Multiple Dose Administration[19]

End point description:

AI is defined as the ratio of an exposure measure at steady-state to that after the first dose. Reported exposure measures include Cmax, C24 and AUC24. Values are reported separately for the parent BMS-986158 and its metabolite BMT-161485.

End point type	Secondary

End point timeframe:

Cycle 2 Day 5 (Schedule A) or Cycle 2 Day 14 (Schedule B) or Cycle 2 Day 7 (Schedule C)

Notes:

[19] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Not all the arms were assessed for this endpoint

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	3	7	8
Units: Ratio				
geometric mean (geometric coefficient of variation)				

Parent BMS-986158 - Cmax	1.89 (± 20)	1.72 (± 20)	1.76 (± 34)	1.94 (± 42)
Parent BMS-986158 - C24	2.58 (± 51)	99999 (± 99999)	99999 (± 99999)	1.79 (± 38)
Parent BMS-986158 - AUC24	2.60 (± 35)	99999 (± 99999)	99999 (± 99999)	1.95 (± 38)
Metabolite BMT-161485 - Cmax	4.53 (± 54)	3.44 (± 38)	2.91 (± 27)	3.46 (± 33)
Metabolite BMT-161485 - C24	4.63 (± 58)	99999 (± 99999)	99999 (± 99999)	3.18 (± 38)
Metabolite BMT-161485 - AUC24	5.06 (± 45)	99999 (± 99999)	99999 (± 99999)	4.20 (± 55)

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	1	1	5
Units: Ratio				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Cmax	1.79 (± 29)	1.35 (± 99999)	2.37 (± 99999)	1.65 (± 13)
Parent BMS-986158 - C24	2.24 (± 29)	1.29 (± 99999)	3.05 (± 99999)	2.55 (± 24)
Parent BMS-986158 - AUC24	2.15 (± 23)	1.45 (± 99999)	2.78 (± 99999)	2.34 (± 22)
Metabolite BMT-161485 - Cmax	4.45 (± 30)	2.40 (± 99999)	6.35 (± 99999)	4.12 (± 36)
Metabolite BMT-161485 - C24	4.33 (± 39)	2.76 (± 99999)	6.23 (± 99999)	4.46 (± 31)
Metabolite BMT-161485 - AUC24	5.03 (± 34)	2.64 (± 99999)	6.85 (± 99999)	4.66 (± 25)

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	7		
Units: Ratio				
geometric mean (geometric coefficient of variation)				
Parent BMS-986158 - Cmax	1.50 (± 38)	1.59 (± 47)		
Parent BMS-986158 - C24	1.98 (± 54)	1.42 (± 72)		
Parent BMS-986158 - AUC24	1.90 (± 46)	1.52 (± 59)		
Metabolite BMT-161485 - Cmax	3.08 (± 59)	3.21 (± 64)		
Metabolite BMT-161485 - C24	4.02 (± 42)	2.91 (± 79)		
Metabolite BMT-161485 - AUC24	3.87 (± 54)	3.53 (± 87)		

Statistical analyses

No statistical analyses for this end point

Secondary: Effective Elimination Half-Life (Effective T-HALF) - Multiple Dose

Administration

End point title	Effective Elimination Half-Life (Effective T-HALF) - Multiple Dose Administration[20]

End point description:

Values are reported separately for the parent BMS-986158 and its metabolite BMT-161485.

End point type	Secondary

End point timeframe:

Cycle 2 Day 5 (Schedule A) or Cycle 2 Day 14 (Schedule B) or Cycle 2 Day 7 (Schedule C)

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Not all the arms were assessed for this endpoint

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	0[21]	0[22]	7
Units: Hours				
arithmetic mean (standard deviation)				
Parent BMS-986158	36.0 (± 15.99)	()	()	25.7 (± 14.86)
Metabolite BMT-161485	80.9 (± 40.42)	()	()	72.1 (± 47.11)

Notes:

[21] - No participants analyzed in this cohort

[22] - No participants analyzed in this cohort

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	8	1	1	5
Units: Hours				
arithmetic mean (standard deviation)				
Parent BMS-986158	27.3 (± 8.72)	14.4 (± 99999)	37.3 (± 99999)	31.6 (± 10.48)
Metabolite BMT-161485	80.4 (± 29.59)	35.2 (± 99999)	105 (± 99999)	72.7 (± 19.42)

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	7		
Units: Hours				
arithmetic mean (standard deviation)				
Parent BMS-986158	27.3 (± 15.15)	27.6 (± 19.11)		
Metabolite BMT-161485	63.5 (± 39.53)	72.8 (± 74.17)		

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of Metabolite (BMT-161485) Maximum Observed Plasma Concentration (Cmax) to Parent (BMS-986158) Cmax - Multiple Dose Administration

End point title	Ratio of Metabolite (BMT-161485) Maximum Observed Plasma Concentration (Cmax) to Parent (BMS-986158) Cmax - Multiple Dose Administration[23]

End point description:

Values are reported separately for Cycle 1 Day 1 and the latest collection timepoint available (Cycle 2 Day 5 for Schedule A, Cycle 2 day 14 for Schedule B, Cycle 2 Day 7 for Schedule C)

End point type	Secondary

End point timeframe:

From Cycle 1 Day 1 to Cycle 2 Day 5 (Schedule A) or to Cycle 2 Day 14 (Schedule B) or to Cycle 2 Day 7 (Schedule C)

Notes:

[23] - 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: Not all the arms were assessed for this endpoint

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	8	9
Units: Ratio				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	0.073 (± 0.0104)	0.057 (± 0.0052)	0.068 (± 0.0204)	0.078 (± 0.0268)
Latest timepoint	0.179 (± 0.0726)	0.112 (± 0.0329)	0.115 (± 0.0290)	0.144 (± 0.0528)

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	1	4	6
Units: Ratio				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	0.068 (± 0.0303)	0.066 (± 99999)	0.059 (± 0.0247)	0.077 (± 0.0373)
Latest timepoint	0.142 (± 0.0260)	0.117 (± 99999)	0.149 (± 99999)	0.163 (± 0.0536)

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg		

Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	7		
Units: Ratio				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	0.056 (± 0.0187)	0.083 (± 0.0209)		
Latest timepoint	0.115 (± 0.0371)	0.173 (± 0.0576)		

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of Metabolite (BMT-161485) Area Under the Plasma Concentration-Time Curve From Time Zero to Time of Last Quantifiable Concentration (AUC(0-T)) to Parent (BMS-986158) AUC(0-T) - Multiple Dose Administration

End point title	Ratio of Metabolite (BMT-161485) Area Under the Plasma Concentration-Time Curve From Time Zero to Time of Last Quantifiable Concentration (AUC(0-T)) to Parent (BMS-986158) AUC(0-T) - Multiple Dose Administration[24]

End point description:

Values are reported separately for Cycle 1 Day 1 and the latest collection timepoint available (Cycle 2 Day 5 for Schedule A, Cycle 2 day 14 for Schedule B, Cycle 2 Day 7 for Schedule C)

End point type	Secondary

End point timeframe:

From Cycle 1 Day 1 to Cycle 2 Day 5 (Schedule A) or to Cycle 2 Day 14 (Schedule B) or to Cycle 2 Day 7 (Schedule C)

Notes:

[24] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Not all the arms were assessed for this endpoint

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	4	8	9
Units: Ratio				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	0.154 (± 0.0504)	0.127 (± 0.0369)	0.125 (± 0.0262)	0.152 (± 0.0572)
Latest timepoint	0.247 (± 0.1000)	0.141 (± 0.0248)	0.150 (± 0.0377)	0.234 (± 0.0787)

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg

Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	1	4	6
Units: Ratio				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	0.151 (± 0.0558)	0.081 (± 99999)	0.099 (± 0.0279)	0.182 (± 0.0632)
Latest timepoint	0.233 (± 0.0558)	0.158 (± 99999)	0.216 (± 99999)	0.274 (± 0.1184)

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	7		
Units: Ratio				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	0.114 (± 0.0473)	0.170 (± 0.0821)		
Latest timepoint	0.203 (± 0.0788)	0.320 (± 0.1552)		

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of Metabolite (BMT-161485) Area Under the Plasma Concentration-Time Curve From Time Zero Extrapolated to Infinite Time (AUC(INF)) to Parent (BMS-986158) AUC(INF) - Multiple Dose Administration

End point title	Ratio of Metabolite (BMT-161485) Area Under the Plasma Concentration-Time Curve From Time Zero Extrapolated to Infinite Time (AUC(INF)) to Parent (BMS-986158) AUC(INF) - Multiple Dose Administration[25]

End point description:

End point type	Secondary

End point timeframe:

Cycle 1 Day 1

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Not all the arms were assessed for this endpoint

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	3	4	4
Units: Ratio				

arithmetic mean (standard deviation)	0.177 (± 99999)	0.131 (± 0.0426)	0.120 (± 0.0286)	0.158 (± 0.0307)

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	1	1	3
Units: Ratio				
arithmetic mean (standard deviation)	0.164 (± 0.0809)	0.080 (± 99999)	0.106 (± 99999)	0.139 (± 0.0401)

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	6	5		
Units: Ratio				
arithmetic mean (standard deviation)	0.103 (± 0.0357)	0.184 (± 0.0947)		

Statistical analyses

No statistical analyses for this end point

Secondary: Ratio of Metabolite (BMT-161485) Area Under the Plasma Concentration-Time Curve in One Dosing Interval (AUC(0-24)) to Parent (BMS-986158) AUC(0-24) - Multiple Dose Administration

End point title	Ratio of Metabolite (BMT-161485) Area Under the Plasma Concentration-Time Curve in One Dosing Interval (AUC(0-24)) to Parent (BMS-986158) AUC(0-24) - Multiple Dose Administration[26]

End point description:

Values are reported separately for Cycle 1 Day 1 and the latest collection timepoint available (Cycle 2 Day 5 for Schedule A, Cycle 2 day 14 for Schedule B, Cycle 2 Day 7 for Schedule C)

End point type	Secondary

End point timeframe:

From Cycle 1 Day 1 to Cycle 2 Day 5 (Schedule A) or to Cycle 2 Day 14 (Schedule B) or to Cycle 2 Day 7 (Schedule C)

Notes:

[26] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Not all the arms were assessed for this endpoint

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	3	8	9
Units: Ratio				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	0.099 (± 0.0290)	0.081 (± 0.0055)	0.086 (± 0.0208)	0.097 (± 0.0425)
Latest timepoint	0.213 (± 0.0786)	0.130 (± 99999)	99999 (± 99999)	0.192 (± 0.0697)

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	1	4	6
Units: Ratio				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	0.087 (± 0.0347)	0.081 (± 99999)	0.066 (± 0.0221)	0.102 (± 0.0178)
Latest timepoint	0.187 (± 0.0475)	0.147 (± 99999)	0.192 (± 99999)	0.218 (± 0.0770)

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	11	7		
Units: Ratio				
arithmetic mean (standard deviation)				
Cycle 1 Day 1	0.080 (± 0.0283)	0.108 (± 0.0445)		
Latest timepoint	0.160 (± 0.0561)	0.253 (± 0.1151)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change From Baseline in Electrocardiogram Parameter QTcF

End point title	Change From Baseline in Electrocardiogram Parameter QTcF[27]

End point description:

QT Interval corrected for Fridericia's Formula. Change from baseline is calculated from pre-dose at the indicated timepoints.

End point type	Secondary

End point timeframe:

From Cycle 1 Day 1 to last dosing day in Cycle 2 (C2D8 for Schedule A, C2D14 for Schedule B, C2D7 for Schedule C).

Notes:

[27] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Not all the arms were assessed for this endpoint

End point values	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule A - BMS-986158 3 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	1	9	8
Units: msec				
arithmetic mean (standard deviation)	-6.8 (± 11.63)	-5.3 (± 99999)	-3.3 (± 22.48)	-5.4 (± 18.45)

End point values	Part 1 Schedule A - BMS-986158 4.5 mg	Part 1 Schedule B - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	3	1	4
Units: msec				
arithmetic mean (standard deviation)	-10.2 (± 22.43)	-10.7 (± 15.10)	-16.7 (± 99999)	-7.7 (± 10.98)

End point values	Part 1 Schedule C - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 4.5 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	8	8		
Units: msec				
arithmetic mean (standard deviation)	14.3 (± 14.03)	-0.6 (± 10.75)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Serious Adverse events and other adverse events were assessed from date of first dose to 30 days following date of last dose (up to approximately 29 months).

Adverse event reporting additional description:

All treated participants

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	Part 1 Schedule A - BMS-986158 0.75 mg

Reporting group description:

Single dose of BMS-986158 at 0.75 mg.
Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle

Reporting group title	Part 1 Schedule A - BMS-986158 1.25 mg

Reporting group description:

Single dose of BMS-986158 at 1.25 mg.
Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle

Reporting group title	Part 1 Schedule A - BMS-986158 4.5 mg

Reporting group description:

Single dose of BMS-986158 at 4.5 mg.
Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle

Reporting group title	Part 1 Schedule A - BMS-986158 3 mg

Reporting group description:

Single dose of BMS-986158 at 3 mg.
Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle

Reporting group title	Part 1 Schedule A - BMS-986158 2 mg

Reporting group description:

Single dose of BMS-986158 at 2 mg.
Approximately 7 days later, BMS-986158 is administered at the same dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle

Reporting group title	Part 1 Schedule B - BMS-986158 2 mg

Reporting group description:

Single dose of BMS-986158 at 2 mg.
Approximately 7 days later, BMS-986158 is administered at the same dose QD for 14 consecutive days, followed by a 7 days rest period, on a 21 days cycle

Reporting group title	Part 1 Schedule B - BMS-986158 3 mg

Reporting group description:

Single dose of BMS-986158 at 3 mg.
Approximately 7 days later, BMS-986158 is administered at the same dose QD for 14 consecutive days, followed by a 7 days rest period, on a 21 days cycle

Reporting group title	Part 1 Schedule C - BMS-986158 2 mg

Reporting group description:

Single dose of BMS-986158 at 2 mg.
Approximately 7 days later, BMS-986158 is administered at the same dose QD for 7 consecutive days, followed by a 14 days rest period, on a 21 days cycle

Reporting group title	Part 1 Schedule C - BMS-986158 3 mg

Reporting group description:

Single dose of BMS-986158 at 3 mg.
Approximately 7 days later, BMS-986158 is administered at the same dose QD for 7 consecutive days, followed by a 14 days rest period, on a 21 days cycle

Reporting group title	Part 1 Schedule C - BMS-986158 4.5 mg

Reporting group description:

Single dose of BMS-986158 at 4.5 mg.
Approximately 7 days later, BMS-986158 is administered at the same dose QD for 7 consecutive days, followed by a 14 days rest period, on a 21 days cycle

Reporting group title	Part 2 Schedule A

Reporting group description:

BMS-986158 administered at 4.5 mg QD for 5 consecutive days, followed by a 2 days resting period, for a total of 10 doses.
Then, BMS-986158 is administered at the 3.75 mg dose QD for 5 consecutive days, followed by a 2 days rest period, on a 28 days cycle

Serious adverse events	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 4.5 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 5 (60.00%)	3 / 4 (75.00%)	9 / 13 (69.23%)
number of deaths (all causes)	5	3	12
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Malignant pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
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 malignant			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			

Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
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			
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Vaginal fistula			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dyspnoea			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 13 (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
Pneumothorax			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
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			
Femur fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
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			
Myocardial infarction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	2 / 13 (15.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Haemorrhage intracranial			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	0 / 4 (0.00%)	2 / 13 (15.38%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	1 / 4 (25.00%)	2 / 13 (15.38%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
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 cholestatic			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (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
Flank pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
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			
Pneumonia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
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 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (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

Serious adverse events	Part 1 Schedule A - BMS-986158 3 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 2 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 10 (70.00%)	7 / 13 (53.85%)	2 / 4 (50.00%)
number of deaths (all causes)	8	10	3
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	3 / 10 (30.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 3	0 / 1	0 / 0
Malignant pleural effusion			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 malignant			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Tumour pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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			
Non-cardiac chest pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (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
Pyrexia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Vaginal fistula			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal pain			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 4 (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
Seizure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (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
Ascites			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (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
Nausea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 10 (10.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 cholestatic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
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 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Flank pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
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			
Pneumonia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 4 (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
Pyelonephritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (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
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg	Part 1 Schedule C - BMS-986158 3 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	4 / 6 (66.67%)	5 / 13 (38.46%)
number of deaths (all causes)	3	4	10

number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Malignant pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 13 (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
Neoplasm malignant			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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			
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			

Vaginal fistula			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vulvovaginal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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			
Femur fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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			
Myocardial infarction			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
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	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombocytopenia			
subjects affected / exposed	2 / 4 (50.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Duodenal obstruction			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 13 (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
Intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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 / 4 (0.00%)	2 / 6 (33.33%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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 cholestatic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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			
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
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 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
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 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 1 Schedule C - BMS-986158 4.5 mg	Part 2 Schedule A	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 10 (30.00%)	0 / 1 (0.00%)	
number of deaths (all causes)	7	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Malignant neoplasm progression			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant pleural effusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm malignant			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Non-cardiac chest pain			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Vaginal fistula			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vulvovaginal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombocytopenia			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			

Biliary obstruction			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Flank pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pathological fracture			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Part 1 Schedule A - BMS-986158 0.75 mg	Part 1 Schedule A - BMS-986158 1.25 mg	Part 1 Schedule A - BMS-986158 4.5 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	5 / 5 (100.00%)	4 / 4 (100.00%)	13 / 13 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Flushing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hot flush			

subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Hypertension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypotension			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Raynaud's phenomenon			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	3 / 13 (23.08%)
occurrences (all)	0	0	4
Catheter site pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Fatigue			
subjects affected / exposed	3 / 5 (60.00%)	4 / 4 (100.00%)	5 / 13 (38.46%)
occurrences (all)	3	5	6
Influenza like illness			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Malaise			
subjects affected / exposed	2 / 5 (40.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Non-cardiac chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	4 / 13 (30.77%)
occurrences (all)	0	0	5
Pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Suprapubic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Intermenstrual bleeding			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Pelvic pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 5 (20.00%)	1 / 4 (25.00%)	4 / 13 (30.77%)
occurrences (all)	1	1	5
Dysphonia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 5 (0.00%)	2 / 4 (50.00%)	5 / 13 (38.46%)
occurrences (all)	0	2	7
Dyspnoea exertional			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	4 / 13 (30.77%)
occurrences (all)	0	0	5
Haemoptysis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Pleural effusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Insomnia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Mood altered			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Amylase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Blood albumin decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	4 / 13 (30.77%)
occurrences (all)	0	0	4
Blood creatinine increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Haemoglobin decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
International normalised ratio increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Lipase increased			
subjects affected / exposed	3 / 5 (60.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Urine output decreased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Weight decreased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	5 / 13 (38.46%)
occurrences (all)	0	1	5
White blood cell count increased			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Eye contusion			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Post procedural haematoma			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Post procedural haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Postoperative ileus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Radiation retinopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Tachycardia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dizziness			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	0 / 5 (0.00%)	2 / 4 (50.00%)	2 / 13 (15.38%)
occurrences (all)	0	2	2
Dysgeusia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	5 / 13 (38.46%)
occurrences (all)	0	0	6
Migraine			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Neuropathy peripheral			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Paraesthesia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Parosmia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	9 / 13 (69.23%)
occurrences (all)	0	0	14
Leukopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Lymphopenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Neutropenia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			
subjects affected / exposed	0 / 5 (0.00%)	2 / 4 (50.00%)	8 / 13 (61.54%)
occurrences (all)	0	3	13
Ear and labyrinth disorders			
External ear pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Meniere's disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Vertigo			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Eye pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Eyelid oedema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Vision blurred			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	1 / 5 (20.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Abdominal distension			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Abdominal pain			
subjects affected / exposed	1 / 5 (20.00%)	1 / 4 (25.00%)	1 / 13 (7.69%)
occurrences (all)	2	3	1
Abdominal pain upper			
subjects affected / exposed	3 / 5 (60.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	3	0	1
Constipation			
subjects affected / exposed	2 / 5 (40.00%)	2 / 4 (50.00%)	4 / 13 (30.77%)
occurrences (all)	2	2	5
Diarrhoea			
subjects affected / exposed	3 / 5 (60.00%)	1 / 4 (25.00%)	10 / 13 (76.92%)
occurrences (all)	4	1	15
Dry mouth			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	3 / 13 (23.08%)
occurrences (all)	0	1	3
Dyspepsia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Dysphagia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0

Flatulence			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Melaena			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 5 (60.00%)	2 / 4 (50.00%)	6 / 13 (46.15%)
occurrences (all)	7	4	8
Small intestinal obstruction			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	3 / 5 (60.00%)	3 / 4 (75.00%)	6 / 13 (46.15%)
occurrences (all)	5	5	10
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	1 / 5 (20.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Hepatomegaly			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Jaundice			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Decubitus ulcer			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dermatitis acneiform			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Dry skin			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Photosensitivity reaction			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1

Rash			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	3 / 13 (23.08%)
occurrences (all)	0	0	4
Rash maculo-papular			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Skin disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Chromaturia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hydronephrosis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Arthritis			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	2 / 5 (40.00%)	1 / 4 (25.00%)	3 / 13 (23.08%)
occurrences (all)	2	1	3
Flank pain			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Muscle spasms			
subjects affected / exposed	1 / 5 (20.00%)	1 / 4 (25.00%)	3 / 13 (23.08%)
occurrences (all)	1	1	3
Musculoskeletal chest pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Myalgia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Neck pain			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Pain in extremity			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Pain in jaw			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1

Candida infection			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Enteritis infectious			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Localised infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Pyuria			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	1 / 5 (20.00%)	1 / 4 (25.00%)	3 / 13 (23.08%)
occurrences (all)	1	1	3

Urosepsis			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Viral infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Appetite disorder			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	2 / 5 (40.00%)	3 / 4 (75.00%)	7 / 13 (53.85%)
occurrences (all)	2	5	8
Dehydration			
subjects affected / exposed	0 / 5 (0.00%)	1 / 4 (25.00%)	1 / 13 (7.69%)
occurrences (all)	0	3	1
Gout			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			

subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypokalaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypomagnesaemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	3 / 13 (23.08%)
occurrences (all)	0	0	3
Hyponatraemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypophosphataemia			
subjects affected / exposed	0 / 5 (0.00%)	0 / 4 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2

Non-serious adverse events	Part 1 Schedule A - BMS-986158 3 mg	Part 1 Schedule A - BMS-986158 2 mg	Part 1 Schedule B - BMS-986158 2 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	10 / 10 (100.00%)	12 / 13 (92.31%)	4 / 4 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Flushing			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hot flush			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypotension			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	2 / 10 (20.00%)	2 / 13 (15.38%)	0 / 4 (0.00%)
occurrences (all)	2	2	0
Catheter site pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Chest pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	3 / 10 (30.00%)	8 / 13 (61.54%)	3 / 4 (75.00%)
occurrences (all)	3	8	3
Influenza like illness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Non-cardiac chest pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 10 (0.00%)	2 / 13 (15.38%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Pain			
subjects affected / exposed	2 / 10 (20.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	2	0	1
Pyrexia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Suprapubic pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Intermenstrual bleeding			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal discharge			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			

Cough			
subjects affected / exposed	2 / 10 (20.00%)	3 / 13 (23.08%)	2 / 4 (50.00%)
occurrences (all)	2	3	5
Dysphonia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	1 / 10 (10.00%)	3 / 13 (23.08%)	2 / 4 (50.00%)
occurrences (all)	1	3	2
Dyspnoea exertional			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Epistaxis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Haemoptysis			
subjects affected / exposed	0 / 10 (0.00%)	2 / 13 (15.38%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Nasal congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Sinus congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Wheezing			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	2 / 4 (50.00%)
occurrences (all)	0	0	2
Mood altered			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Amylase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	2 / 13 (15.38%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Blood albumin decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Haemoglobin decreased			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	2 / 4 (50.00%)
occurrences (all)	1	2	2
White blood cell count increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Eye contusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post procedural haematoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Postoperative ileus			

subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Radiation retinopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Transfusion reaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Sinus tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Ventricular extrasystoles			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	2 / 4 (50.00%)
occurrences (all)	0	1	2
Headache			
subjects affected / exposed	0 / 10 (0.00%)	4 / 13 (30.77%)	1 / 4 (25.00%)
occurrences (all)	0	4	3
Dysgeusia			

subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	2 / 4 (50.00%)
occurrences (all)	1	0	2
Migraine			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuralgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neuropathy peripheral			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Paraesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Presyncope			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Somnolence			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 10 (10.00%)	3 / 13 (23.08%)	1 / 4 (25.00%)
occurrences (all)	1	4	1
Leukopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0

Thrombocytopenia			
subjects affected / exposed	6 / 10 (60.00%)	3 / 13 (23.08%)	2 / 4 (50.00%)
occurrences (all)	6	5	2
Ear and labyrinth disorders			
External ear pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Meniere's disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Tinnitus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Lacrimation increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Vitreous floaters			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			

Abdominal discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Abdominal distension			
subjects affected / exposed	0 / 10 (0.00%)	2 / 13 (15.38%)	0 / 4 (0.00%)
occurrences (all)	0	2	0
Abdominal pain			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Abdominal pain upper			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Constipation			
subjects affected / exposed	0 / 10 (0.00%)	5 / 13 (38.46%)	1 / 4 (25.00%)
occurrences (all)	0	6	1
Diarrhoea			
subjects affected / exposed	7 / 10 (70.00%)	6 / 13 (46.15%)	3 / 4 (75.00%)
occurrences (all)	9	8	7
Dry mouth			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	1 / 4 (25.00%)
occurrences (all)	1	1	1
Dyspepsia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	2
Dysphagia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eructation			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Flatulence			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Gingival pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	3 / 10 (30.00%)	8 / 13 (61.54%)	1 / 4 (25.00%)
occurrences (all)	3	14	1
Small intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 10 (20.00%)	7 / 13 (53.85%)	1 / 4 (25.00%)
occurrences (all)	2	10	2
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Dry skin			
subjects affected / exposed	4 / 10 (40.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	4	1	0
Erythema			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Nail disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	2 / 10 (20.00%)	1 / 13 (7.69%)	1 / 4 (25.00%)
occurrences (all)	2	1	1
Rash			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Rash maculo-papular			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Skin disorder			

subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chromaturia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Chronic kidney disease			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Dysuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hydronephrosis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pollakiuria			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Urinary retention			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
Arthritis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	2 / 4 (50.00%)
occurrences (all)	0	1	2
Flank pain			

subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Muscle spasms			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 10 (0.00%)	2 / 13 (15.38%)	0 / 4 (0.00%)
occurrences (all)	0	3	0
Myalgia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Neck pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Bronchitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Enteritis infectious			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

Herpes zoster			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Localised infection			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Oral herpes			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Paronychia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Tooth infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
Urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
Urosepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Vaginal infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Viral infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Appetite disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Decreased appetite			
subjects affected / exposed	3 / 10 (30.00%)	6 / 13 (46.15%)	2 / 4 (50.00%)
occurrences (all)	3	9	2
Dehydration			
subjects affected / exposed	1 / 10 (10.00%)	2 / 13 (15.38%)	1 / 4 (25.00%)
occurrences (all)	1	2	1
Gout			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hyperkalaemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Hypoalbuminaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Hypocalcaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
Hypokalaemia			
subjects affected / exposed	2 / 10 (20.00%)	0 / 13 (0.00%)	0 / 4 (0.00%)
occurrences (all)	2	0	0
Hypomagnesaemia			

subjects affected / exposed	2 / 10 (20.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Hyponatraemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	2	1	0
Hypophosphataemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 13 (7.69%)	0 / 4 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Part 1 Schedule B - BMS-986158 3 mg	Part 1 Schedule C - BMS-986158 2 mg	Part 1 Schedule C - BMS-986158 3 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	6 / 6 (100.00%)	13 / 13 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Flushing			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	1	0	2
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Raynaud's phenomenon			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	2 / 4 (50.00%)	1 / 6 (16.67%)	3 / 13 (23.08%)
occurrences (all)	2	1	3
Catheter site pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chest discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Chills			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Early satiety			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Fatigue			
subjects affected / exposed	1 / 4 (25.00%)	2 / 6 (33.33%)	5 / 13 (38.46%)
occurrences (all)	1	2	7
Influenza like illness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Malaise			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Mucosal inflammation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 4 (50.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1

Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Suprapubic pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Reproductive system and breast disorders			
Intermenstrual bleeding			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pelvic pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Vaginal discharge			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Vaginal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Vulvovaginal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 4 (0.00%)	2 / 6 (33.33%)	3 / 13 (23.08%)
occurrences (all)	0	2	3
Dysphonia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Dyspnoea			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	6 / 13 (46.15%)
occurrences (all)	1	0	6
Dyspnoea exertional			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Epistaxis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pleural effusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Sinus congestion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Wheezing			
subjects affected / exposed	0 / 4 (0.00%)	2 / 6 (33.33%)	0 / 13 (0.00%)
occurrences (all)	0	2	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Mood altered			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Amylase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Blood albumin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Blood uric acid increased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Haemoglobin decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
International normalised ratio increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lipase increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Lymphocyte count decreased			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urine output decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	3 / 13 (23.08%)
occurrences (all)	0	1	3
White blood cell count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eye contusion			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Post procedural haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Post procedural haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Postoperative ileus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Radiation retinopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Transfusion reaction			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Cardiac disorders			

Atrial flutter			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cardiomyopathy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Sinus tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Ventricular extrasystoles			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Migraine			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Neuralgia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Parosmia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Presyncope			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Somnolence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 6 (16.67%)	4 / 13 (30.77%)
occurrences (all)	1	1	5
Leukopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	8
Thrombocytopenia			
subjects affected / exposed	4 / 4 (100.00%)	0 / 6 (0.00%)	5 / 13 (38.46%)
occurrences (all)	10	0	6
Ear and labyrinth disorders			
External ear pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Meniere's disease			

subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Tinnitus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eye pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eyelid oedema			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Lacrimation increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vision blurred			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vitreous floaters			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			

subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	3 / 13 (23.08%)
occurrences (all)	1	0	4
Abdominal pain upper			
subjects affected / exposed	2 / 4 (50.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	2	0	2
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	2 / 6 (33.33%)	3 / 13 (23.08%)
occurrences (all)	0	3	4
Diarrhoea			
subjects affected / exposed	2 / 4 (50.00%)	4 / 6 (66.67%)	8 / 13 (61.54%)
occurrences (all)	2	5	11
Dry mouth			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dysphagia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Eructation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gingival pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Melaena			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nausea			

subjects affected / exposed	0 / 4 (0.00%)	6 / 6 (100.00%)	7 / 13 (53.85%)
occurrences (all)	0	6	12
Small intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Stomatitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	1 / 4 (25.00%)	5 / 6 (83.33%)	5 / 13 (38.46%)
occurrences (all)	1	6	9
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hepatomegaly			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperbilirubinaemia			
subjects affected / exposed	3 / 4 (75.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Jaundice			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Decubitus ulcer			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Dermatitis acneiform			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dry skin			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hyperkeratosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nail disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Night sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Photosensitivity reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Pruritus			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Rash			
subjects affected / exposed	2 / 4 (50.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Rash maculo-papular			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Skin disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Chromaturia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Chronic kidney disease			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Hydronephrosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urinary retention			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Arthritis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Flank pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Groin pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Muscle spasms			

subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	1 / 13 (7.69%)
occurrences (all)	0	1	1
Neck pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pain in jaw			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Candida infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Enteritis infectious			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Localised infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Paronychia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Pyuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Urinary tract infection			
subjects affected / exposed	1 / 4 (25.00%)	2 / 6 (33.33%)	2 / 13 (15.38%)
occurrences (all)	1	2	2
Urosepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vaginal infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Viral infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Metabolism and nutrition disorders			
Appetite disorder			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Decreased appetite			
subjects affected / exposed	2 / 4 (50.00%)	3 / 6 (50.00%)	3 / 13 (23.08%)
occurrences (all)	2	4	3
Dehydration			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gout			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Hyperglycaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Hypocalcaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypokalaemia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 6 (16.67%)	2 / 13 (15.38%)
occurrences (all)	1	1	3
Hypomagnesaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	2 / 13 (15.38%)
occurrences (all)	0	0	2
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hypophosphataemia			

subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1

Non-serious adverse events	Part 1 Schedule C - BMS-986158 4.5 mg	Part 2 Schedule A	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 10 (90.00%)	1 / 1 (100.00%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Flushing			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hot flush			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypertension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypotension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Raynaud's phenomenon			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Catheter site pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

Chest discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Chills			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Early satiety			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	5 / 10 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	7	0	
Influenza like illness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Malaise			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Mucosal inflammation			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Non-cardiac chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	

Suprapubic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Reproductive system and breast disorders			
Intermenstrual bleeding			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pelvic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Vaginal discharge			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Vaginal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dysphonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	3 / 10 (30.00%)	0 / 1 (0.00%)	
occurrences (all)	3	0	
Dyspnoea exertional			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Epistaxis			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Haemoptysis			

subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Nasal congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Oropharyngeal pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pleural effusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Sinus congestion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Wheezing			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Insomnia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Mood altered			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Amylase increased			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	4	
Aspartate aminotransferase increased			

subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)		
occurrences (all)	2	0		
Blood albumin decreased				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Blood bilirubin increased				
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)		
occurrences (all)	0	8		
Blood creatinine increased				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Blood uric acid increased				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Gamma-glutamyltransferase increased				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Haemoglobin decreased				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
International normalised ratio increased				
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)		
occurrences (all)	0	1		
Lipase increased				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Lymphocyte count decreased				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Urine output decreased				
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)		
occurrences (all)	0	0		
Weight decreased				

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
White blood cell count increased			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Eye contusion			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Post procedural haematoma			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Post procedural haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Postoperative ileus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Radiation retinopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Transfusion reaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Atrial flutter			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Cardiomyopathy			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Sinus tachycardia			

subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Tachycardia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Ventricular extrasystoles			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Balance disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dizziness			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Headache			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dysgeusia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Migraine			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Neuralgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Neuropathy peripheral			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Paraesthesia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Parosmia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

Presyncope			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Somnolence			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Leukopenia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	3	
Lymphopenia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Neutropenia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	3	
Thrombocytopenia			
subjects affected / exposed	3 / 10 (30.00%)	1 / 1 (100.00%)	
occurrences (all)	4	1	
Ear and labyrinth disorders			
External ear pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Meniere's disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Tinnitus			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Vertigo			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Eye disorders			

Dry eye			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Eye pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Eyelid oedema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Lacrimation increased			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Vision blurred			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Vitreous floaters			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal discomfort			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Abdominal distension			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Abdominal pain			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Abdominal pain upper			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Constipation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Diarrhoea			

subjects affected / exposed	7 / 10 (70.00%)	1 / 1 (100.00%)	
occurrences (all)	8	1	
Dry mouth			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Dyspepsia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Dysphagia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Eructation			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Flatulence			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Gingival pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Melaena			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Nausea			
subjects affected / exposed	5 / 10 (50.00%)	0 / 1 (0.00%)	
occurrences (all)	7	0	
Small intestinal obstruction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Stomatitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Vomiting			

subjects affected / exposed	3 / 10 (30.00%)	0 / 1 (0.00%)	
occurrences (all)	5	0	
Hepatobiliary disorders			
Hepatic pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hepatomegaly			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Hyperbilirubinaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	3	0	
Jaundice			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Decubitus ulcer			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dermatitis acneiform			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	2	
Dry skin			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Erythema			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hyperhidrosis			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Hyperkeratosis			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Nail disorder			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Night sweats			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Photosensitivity reaction			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Rash			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Rash maculo-papular			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Skin disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Chromaturia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Chronic kidney disease			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Dysuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	

Hydronephrosis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pollakiuria			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Urinary retention			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Arthritis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	2 / 10 (20.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Flank pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Groin pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Muscle spasms			
subjects affected / exposed	2 / 10 (20.00%)	0 / 1 (0.00%)	
occurrences (all)	2	0	
Musculoskeletal chest pain			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Myalgia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Neck pain			

subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pain in extremity			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pain in jaw			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Abdominal infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Candida infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Enteritis infectious			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Herpes zoster			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Influenza			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Localised infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Oral herpes			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Paronychia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	

Pneumonia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Pyuria			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Tooth infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Urosepsis			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Vaginal infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Viral infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Metabolism and nutrition disorders			
Appetite disorder			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Decreased appetite			
subjects affected / exposed	3 / 10 (30.00%)	0 / 1 (0.00%)	
occurrences (all)	7	0	
Dehydration			

subjects affected / exposed	2 / 10 (20.00%)	0 / 1 (0.00%)	
occurrences (all)	3	0	
Gout			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hyperglycaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hyperkalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypoalbuminaemia			
subjects affected / exposed	1 / 10 (10.00%)	0 / 1 (0.00%)	
occurrences (all)	1	0	
Hypocalcaemia			
subjects affected / exposed	0 / 10 (0.00%)	1 / 1 (100.00%)	
occurrences (all)	0	1	
Hypokalaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypomagnesaemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hyponatraemia			
subjects affected / exposed	0 / 10 (0.00%)	0 / 1 (0.00%)	
occurrences (all)	0	0	
Hypophosphataemia			
subjects affected / exposed	1 / 10 (10.00%)	1 / 1 (100.00%)	
occurrences (all)	1	1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 April 2016	Study design updates
06 September 2017	Study design updates
01 March 2018	Updates to Exclusion Criteria
17 July 2018	PK Sample collection schedule updates
18 March 2019	Study design updates

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported