Clinical trial results:
A Phase IIB Randomized, Placebo-Controlled Study to Evaluate the Clinical Efficacy and Safety of Induction and Maintenance Therapy with BMS-936557 in Subjects with Active Ulcerative Colitis

Summary

EudraCT number	2010-022506-41
Trial protocol	DE AT HU BE PL IT
Global end of trial date	05 January 2015

Results information

Result version number	v1 (current)
This version publication date	31 August 2016
First version publication date	31 August 2016

Trial information

Trial identification

Sponsor protocol code	IM129-005

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01294410
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Bristol-Myers Squibb International Corporation, Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, 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	05 January 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 January 2015
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to compare the efficacy of BMS-936557 vs placebo for induction of clinical remission (defined as Mayo score <=2 points with no individual subscore >1 point) at Week 11.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 March 2011
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 33
Country: Number of subjects enrolled	Brazil: 22
Country: Number of subjects enrolled	Canada: 21
Country: Number of subjects enrolled	Mexico: 37
Country: Number of subjects enrolled	South Africa: 10
Country: Number of subjects enrolled	United States: 114
Country: Number of subjects enrolled	Netherlands: 10
Country: Number of subjects enrolled	Poland: 50
Country: Number of subjects enrolled	Austria: 12
Country: Number of subjects enrolled	Belgium: 4
Country: Number of subjects enrolled	France: 42
Country: Number of subjects enrolled	Germany: 11
Country: Number of subjects enrolled	Hungary: 31
Country: Number of subjects enrolled	Italy: 14
Worldwide total number of subjects	411
EEA total number of subjects	174

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)	384
From 65 to 84 years	27
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 411 subjects were enrolled at 75 sites in 14 countries.

Pre-assignment

Screening details:

A total of 411 subjects were enrolled, 305 subjects were randomised and treated in the induction period. Reasons for 106 subjects not randomised were: Adverse event-1; Subject withdrew consent-15; Lost to follow up-5; Poor/Non-compliance-2; Study criteria not met-74; Administrative reason by sponsor-1; other-8.

Period 1

Period 1 title	Induction Phase
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects received BMS-936557 matching placebo, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.

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

Dosage and administration details:

Subjects received placebo matching with BMS 936557 via intravenous infusion over 90 minutes once a week for first two weeks and every other week thereafter, up to 11 weeks.

Arm title	BMS-936557 15 mg/kg

Arm description:

Subjects received BMS-936557 15 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.

Arm type	Experimental
Investigational medicinal product name	BMS-936557
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received BMS-936557 15 mg/kg via intravenous infusion over 90 minutes, once a week for first two weeks and every other week thereafter, up to 11 weeks.

Arm title	BMS-936557 25 mg/kg

Arm description:

Subjects received BMS-936557 25 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.

Arm type	Experimental

Investigational medicinal product name	BMS-936557
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received BMS-936557 25 mg/kg via intravenous infusion over 90 minutes, once a week for first two weeks and every other week thereafter, up to 11 weeks.

Number of subjects in period 1[1]	Placebo	BMS-936557 15 mg/kg	BMS-936557 25 mg/kg
Started	100	102	103
Completed	85	90	90
Not completed	15	12	13
Consent withdrawn by subject	3	1	3
Adverse event, non-fatal	1	5	5
Subject request to discontinue study treatment	3	2	1
Other reasons	1	-	-
Lost to follow-up	-	1	1
Subject no longer meets study criteria	-	-	1
Lack of efficacy	7	3	2

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial as out of total 411 subjects who were enrolled, 305 subjects were randomised and treated in the induction period. Reasons for 106 subjects not randomised were: Adverse event-1; Subject withdrew consent-15; Lost to follow up-5; Poor/Non-compliance-2; Study criteria not met-74; Administrative reason by sponsor-1; other-8.

Period 2

Period 2 title	Maintenance Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Carer, Assessor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo to Placebo

Arm description:

Subjects who received placebo in the induction period received placebo intravenous infusion over 90 minutes, every other week for up to 108 weeks.

Arm type	Placebo

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

Dosage and administration details:

Subjects received placebo via intravenous infusion over 90 minutes, every other week for up to 108 weeks.

Arm title	BMS-936557 to Placebo

Arm description:

Subjects who received any dose of BMS-936557 in the induction period received placebo via intravenous infusion over 90 minutes, every other week for up to 108 weeks.

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

Dosage and administration details:

Subjects received placebo via intravenous infusion over 90 minutes, every other week for up to 108 weeks.

Arm title	BMS-936557 5 mg/kg

Arm description:

Subjects received BMS-936557 5 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks.

Arm type	Experimental
Investigational medicinal product name	BMS-936557
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received BMS-936557 5 mg/kg via intravenous infusion over 90 minutes, every other week for up to 108 weeks.

Arm title	BMS-936557 10 mg/kg

Arm description:

Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks.

Arm type	Experimental
Investigational medicinal product name	BMS-936557
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received BMS-936557 10 mg/kg via intravenous infusion over 90 minutes, every other week for up to 108 weeks.

Arm title	BMS-936557 20 mg/kg

Arm description:

Subjects received BMS-936557 20 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks.

Arm type	Experimental

Investigational medicinal product name	BMS-936557
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received BMS-936557 20 mg/kg via intravenous infusion over 90 minutes, every other week for up to 108 weeks.

Number of subjects in period 2[2]	Placebo to Placebo	BMS-936557 to Placebo	BMS-936557 5 mg/kg
Started	30	22	24
Completed	7	4	5
Not completed	23	18	19
Consent withdrawn by subject	1	1	-
Adverse event, non-fatal	-	-	-
Subject request to discontinue study treatment	2	1	2
Pregnancy	-	1	-
Other reasons	-	1	-
Lost to follow-up	-	-	1
Lack of efficacy	20	14	16

Number of subjects in period 2[2]	BMS-936557 10 mg/kg	BMS-936557 20 mg/kg
Started	22	21
Completed	5	5
Not completed	17	16
Consent withdrawn by subject	-	1
Adverse event, non-fatal	2	2
Subject request to discontinue study treatment	2	1
Pregnancy	-	-
Other reasons	-	-
Lost to follow-up	-	-
Lack of efficacy	13	12

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Out of 265 subjects who completed the induction period, only 119 subjects entered the maintenance period. 142 subjects discontinued and moved directly into the open label period.

Period 3

Period 3 title	Open-Label Period
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Arms

Arm title	BMS-936557 10 mg/kg

Arm description:

Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, every other week for up to 41 months.

Arm type	Experimental
Investigational medicinal product name	BMS-936557
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects were adminstered BMS-936557 ~10 mg/kg via intravenous infusion over 90 minutes, every other week for up to 41 months.

Number of subjects in period 3[3]	BMS-936557 10 mg/kg
Started	23
Completed	0
Not completed	237
Consent withdrawn by subject	20
Adverse event, non-fatal	15
Subject request to discontinue study treatment	16
Death	1
Poor/Non-compliance	1
Other reasons	7
Lost to follow-up	2
Subject no longer meets study criteria	1
Lack of efficacy	95
Administrative reason by sponsor	79
Joined	214
Continued from IP and MP	214

Notes:

[3] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Among the 119 subjects treated in the maintenance phase, 26 subjects completed and entered the open label period. 142 subjects moved directly into open label period from the induction

period. A total of 238 subjects entered the open label period of whom 237 subjects were treated and 1 subject from the induction period was not treated. 214 subjects continued from IP and MP.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Subjects received BMS-936557 matching placebo, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.	
Reporting group title	BMS-936557 15 mg/kg
Reporting group description:	
Subjects received BMS-936557 15 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.	
Reporting group title	BMS-936557 25 mg/kg
Reporting group description:	
Subjects received BMS-936557 25 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.	

Reporting group values	Placebo	BMS-936557 15 mg/kg	BMS-936557 25 mg/kg
Number of subjects	100	102	103
Age categorical Units: Subjects			
18 - <40 years	42	54	55
40 - <65 years	51	42	42
>=65 - <75 years	7	5	5
>=75 years	0	1	1
Gender categorical Units: Subjects			
Female	47	36	47
Male	53	66	56

Reporting group values	Total		
Number of subjects	305		
Age categorical Units: Subjects			
18 - <40 years	151		
40 - <65 years	135		
>=65 - <75 years	17		
>=75 years	2		
Gender categorical Units: Subjects			
Female	130		
Male	175		

Subject analysis sets	
Subject analysis set title	IP - Placebo
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received BMS-936557 matching placebo, intravenously, once weekly for the first two weeks and every other week thereafter up to 11 weeks (Post-amendment 4).	

Subject analysis set title	IP- BMS-936557 15 mg/kg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received BMS 936557 15 mg/kg intravenous infusion, once a week for the first two weeks and every other week thereafter, up to 11 weeks (Post-amendment 4).

Subject analysis set title	IP BMS-936557 25 mg/kg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Subjects received BMS 936557 25 mg/kg intravenous infusion, once a week for the first two weeks and every other week thereafter, up to 11 weeks (Post-amendment 4).

Reporting group values	IP - Placebo	IP- BMS-936557 15 mg/kg	IP BMS-936557 25 mg/kg
Number of subjects	83	84	85
Age categorical Units: Subjects			
18 - <40 years	38	45	48
40 - <65 years	39	33	34
>=65 - <75 years	6	5	2
>=75 years	0	1	1
Gender categorical Units: Subjects			
Female	40	30	41
Male	43	54	44

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Subjects received BMS-936557 matching placebo, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.	
Reporting group title	BMS-936557 15 mg/kg
Reporting group description:	
Subjects received BMS-936557 15 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.	
Reporting group title	BMS-936557 25 mg/kg
Reporting group description:	
Subjects received BMS-936557 25 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.	
Reporting group title	Placebo to Placebo
Reporting group description:	
Subjects who received placebo in the induction period received placebo intravenous infusion over 90 minutes, every other week for up to 108 weeks.	
Reporting group title	BMS-936557 to Placebo
Reporting group description:	
Subjects who received any dose of BMS-936557 in the induction period received placebo via intravenous infusion over 90 minutes, every other week for up to 108 weeks.	
Reporting group title	BMS-936557 5 mg/kg
Reporting group description:	
Subjects received BMS-936557 5 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks.	
Reporting group title	BMS-936557 10 mg/kg
Reporting group description:	
Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks.	
Reporting group title	BMS-936557 20 mg/kg
Reporting group description:	
Subjects received BMS-936557 20 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks.	
Reporting group title	BMS-936557 10 mg/kg
Reporting group description:	
Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, every other week for up to 41 months.	
Subject analysis set title	IP - Placebo
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received BMS-936557 matching placebo, intravenously, once weekly for the first two weeks and every other week thereafter up to 11 weeks (Post-amendment 4).	

Subject analysis set title	IP- BMS-936557 15 mg/kg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received BMS 936557 15 mg/kg intravenous infusion, once a week for the first two weeks and every other week thereafter, up to 11 weeks (Post-amendment 4).	
Subject analysis set title	IP BMS-936557 25 mg/kg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Subjects received BMS 936557 25 mg/kg intravenous infusion, once a week for the first two weeks and every other week thereafter, up to 11 weeks (Post-amendment 4).	

Primary: Percentage of Subjects Who Achieved Clinical Remission at Week 11 (Induction period)

End point title	Percentage of Subjects Who Achieved Clinical Remission at Week 11 (Induction period)

End point description:

Clinical remission was defined as a total Mayo score of at least 2 and no individual sub-score greater than 1. The Mayo scoring system is a composite index consisting of 4 disease variables (each scored on a scale of 0 to 3, with higher scores indicating greater frequency or severity): stool frequency, rectal bleeding, findings on endoscopy, and the physician's global assessment. Mayo scores range from 0 to 12 points and utilize all 4 disease variables, with higher scores indicating more severe disease. The analysis was performed in all treated subjects who received any study drug.

End point type	Primary

End point timeframe:

Start of induction period (Day 1) up to Week 11

End point values	IP - Placebo	IP- BMS-936557 15 mg/kg	IP BMS-936557 25 mg/kg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	83	84	85	
Units: Percentage of subjects				
number (confidence interval 95%)	9.6 (3.3 to 16)	13.1 (5.9 to 20.3)	17.6 (9.5 to 25.8)	

Statistical analyses

Statistical analysis title	BMS-936557 15mg/kg vs Placebo
Comparison groups	IP- BMS-936557 15 mg/kg v IP - Placebo
Number of subjects included in analysis	167
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.515
Method	Cochran-Mantel-Haenszel Chi-square test
Parameter estimate	Absolute treatment difference
Point estimate	3.1
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-8.3
upper limit	14.5

Statistical analysis title	BMS-936557 25mg/kg vs Placebo
Comparison groups	IP - Placebo v IP BMS-936557 25 mg/kg

Number of subjects included in analysis	168
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.158
Method	Cochran-Mantel-Haenszel Chi-square test
Parameter estimate	Absolute treatment difference
Point estimate	7.6
Confidence interval	
level	Other: 97.5 %
sides	2-sided
lower limit	-3.9
upper limit	19.2

Secondary: Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Total and Subscale Scores (Bowel, Systemic, Social, and emotional Symptoms) at Week 11

End point title	Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Total and Subscale Scores (Bowel, Systemic, Social, and emotional Symptoms) at Week 11

End point description:

IBDQ was used to measure disease specific quality of life (QoL). The IBDQ consists of a self-administered 32-item questionnaire that evaluates QoL across 4 dimensional scores: Bowel, Systemic, Social and Emotional. The response to each question can range from 1 to 7, with 1 indicating severe problem and 7 indicating normal health. The total IBDQ is computed as the sum of the responses to the individual IBDQ questions. The total score can range between 32 to 224 with higher scores indicating a better QoL. The analysis was performed in all treated subjects who received the study drug. Here "n" refers to the number of treated subjects with non-missing baseline and post-baseline values.

End point type	Secondary

End point timeframe:

Baseline, Week 11

End point values	IP - Placebo	IP- BMS-936557 15 mg/kg	IP BMS-936557 25 mg/kg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	83	84	85	
Units: Score on a scale				
arithmetic mean (standard deviation)				
Bowel symptoms (n=78, 75, 74)	4.18 (± 13.551)	8.41 (± 10.205)	11.16 (± 13.673)	
Systemic symptoms (n=78, 75, 74)	2.08 (± 6.326)	3.95 (± 5.46)	4.3 (± 6.957)	
Emotional symptoms (n=78, 75, 74)	4.98 (± 14.601)	7.75 (± 11.722)	9.65 (± 16.686)	
Social symptoms (n=78, 75, 74)	1.93 (± 7.903)	3.92 (± 6.594)	3.82 (± 8.744)	
Total Score (n=78, 75, 74)	13.17 (± 38.955)	24.03 (± 30.082)	28.93 (± 43.136)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Inflammatory Bowel Disease Questionnaire (IBDQ) Response at Week 11 (IP-78)

End point title	Percentage of Subjects With Inflammatory Bowel Disease Questionnaire (IBDQ) Response at Week 11 (IP-78)

End point description:

IBDQ response was defined as change from baseline in IBDQ score of >=16 points. The analysis was performed in all treated subjects who received the study drug.

End point type	Secondary

End point timeframe:

Week 11

End point values	IP - Placebo	IP- BMS-936557 15 mg/kg	IP BMS-936557 25 mg/kg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	83	84	85	
Units: Percentage of subjects				
number (confidence interval 95%)	38.6 (28.1 to 49)	45.2 (34.6 to 55.9)	51.8 (41.1 to 62.4)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Clinical Response at Week 11

End point title	Percentage of Subjects Who Achieved Clinical Response at Week 11

End point description:

Clinical response was defined as reduction from baseline in Mayo score of at least 3 points and at least 30%, with an accompanying decrease in the subscore for rectal bleeding of at least 1 point or an absolute subscore for rectal bleeding of 0 or 1. The Mayo scoring system is a composite index consisting of 4 disease variables (each scored on a scale of 0 to 3, with higher scores indicating greater frequency or severity): stool frequency, rectal bleeding, findings on endoscopy, and the physician's global assessment. Mayo scores range from 0 to 12 points and utilize all 4 disease variables, with higher scores indicating more severe disease. The analysis was performed in all treated subjects who received any study drug.

End point type	Secondary

End point timeframe:

Start of induction period (Day 1) up to Week 11

End point values	IP - Placebo	IP- BMS-936557 15 mg/kg	IP BMS-936557 25 mg/kg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	83	84	85	
Units: Percentage of subjects				
number (confidence interval 95%)	31.3 (21.3 to 41.3)	44 (33.4 to 54.7)	47.1 (36.4 to 57.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects Who Achieved Mucosal Healing at Week 11

End point title	Percentage of Subjects Who Achieved Mucosal Healing at Week 11

End point description:

Mucosal healing was defined as endoscopic subscore <=1 point. Endoscopy was performed using Sigmoidoscopy. Findings of flexible proctosigmoidoscopy were rated as: 0 = Normal or inactive disease, 1 = Mild disease (erythema, decreased vascular pattern, mild friability), 2 = Moderate disease (marked erythema, absent vascular pattern, friability, erosions), and 3 = Severe disease (spontaneous bleeding, ulceration). The analysis was performed in all the subjects who were randomised and received any study drug.

End point type	Secondary

End point timeframe:

Start of induction period (Day 1) up to Week 11

End point values	IP - Placebo	IP- BMS-936557 15 mg/kg	IP BMS-936557 25 mg/kg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	83	84	85	
Units: Percentage of subjects				
number (confidence interval 95%)	27.7 (18.1 to 37.3)	29.8 (20 to 39.5)	31.8 (21.9 to 41.7)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Adverse Events (AEs), Drug related AEs, Discontinuation due to AEs, Serious Adverse Events (SAEs), Drug related SAEs, Discontinuation Due to SAEs, and Who Died

End point title	Number of Subjects With Adverse Events (AEs), Drug related AEs, Discontinuation due to AEs, Serious Adverse Events (SAEs), Drug related SAEs, Discontinuation Due to SAEs, and Who Died

End point description:

An AE is any new unfavorable symptom, sign, or disease or worsening of a preexisting condition that may not have a causal relationship with treatment. An SAE is a medical event that at any dose results in death, persistent or significant disability/incapacity, or drug dependency/abuse; is life-threatening, an important medical event, or a congenital anomaly/birth defect; or requires or prolongs hospitalization. The analysis was performed in all the subjects who received any study medication.

End point type	Secondary

End point timeframe:

Baseline (Day 1) up to 56 days after the last dose in the induction period/start of the subsequent phase treatment, which ever occurred first.

End point values	IP - Placebo	IP- BMS-936557 15 mg/kg	IP BMS-936557 25 mg/kg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	83	84	85	
Units: Subjects				
AEs	57	56	60	
Drug related AEs	16	27	33	
Discontinuation due to AEs	4	5	4	
SAEs	8	4	4	
Drug related SAEs	0	1	2	
Discontinuation Due to SAEs	4	2	2	
Death	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Marked Hematology Laboratory Abnormalities During Induction period

End point title	Number of Subjects With Marked Hematology Laboratory Abnormalities During Induction period

End point description:

Erythrocytes, Low: if value <0.75*baseline value (PRE) and < lower limit of normal (LLN); Hematocrit, Low: if value <0.75*PRE and <LLN; Hemoglobin, Low: <PRE –30 and <LLN; Platelet Count, Low: if LLN <= PRE <= upper limit of normal (ULN) and value <0.67*LLN, or if PRE <LLN and value <0.5*PRE and value <100; Platelet Count, High: if LLN <=PRE <=ULN and value >1.5*ULN; Total White Blood Cells (WBC) count, Low: if LLN <=PRE <=limit of normal (ULN) and value <0.75*LLN, or if PRE <LLN and Value <0.8*PRE, or if PRE >ULN and value <LLN; Total WBC Count, High: if LLN <=PRE <=ULN and value >1.25*ULN, or if PRE <LLN and value >ULN, or if PRE >ULN and value >1.2*PRE. Lymphocytes, Low (absolute): if value <0.75 and <LLN; Lymphocytes, High (absolute): if value >7.5 and >ULN; Neutrophils, Low (absolute): if value <1.0 and <LLN. The analysis was performed in all the subjects who received any study drug. Here, 'n' signifies evaluable subjects for specified categories in respective treatment arms.

End point type	Secondary

End point timeframe:

Baseline (Day 1) up to 56 days after the last dose in the induction period/start of the subsequent phase treatment, which ever occurred first.

End point values	IP - Placebo	IP- BMS-936557 15 mg/kg	IP BMS-936557 25 mg/kg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	83	84	85	
Units: Subjects				
Erythrocytes, Low (n=83, 82, 84)	1	1	0	
Hematocrit, Low (n=83, 82, 84)	2	0	1	
Hemoglobin, Low (n=83, 82, 84)	3	0	1	
Platelet Count, Low (n=83, 82, 84)	0	0	0	
Platelet Count, High (n=83, 82, 84)	2	0	1	
Total WBC count, Low (n=83, 82, 84)	1	0	1	
Total WBC count, High (n=83, 82, 84)	3	6	2	
Lymphocytes, Low (absolute) (n=83, 82, 84)	17	15	19	
Lymphocytes, High (absolute) (n=83, 82, 84)	1	0	0	
Neutrophils, Low (absolute) (n=83, 82, 84)	0	0	1	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Marked Liver and Kidney Function Laboratory Abnormalities During Induction Period

End point title	Number of Subjects With Marked Liver and Kidney Function Laboratory Abnormalities During Induction Period

End point description:

Alanine Aminotransferase (ALT), High: if lower limit of normal (LLN) <= baseline value (PRE) <=upper limit of normal (ULN) and value >3*ULN, or if PRE >ULN and value >4*PRE; Alkaline Phosphatase (ALP), High: if LLN <=PRE <=ULN and value >2*ULN, or if PRE >ULN and value >3*PRE; Aspartate Aminotransferase (AST), High: if LLN <=PRE <=ULN and value >3*ULN, or if PRE >ULN and value >4*PRE; Bilirubin, Total, High: if LLN <=PRE <=ULN and value >2*ULN, or if PRE >ULN and value >4*PRE; G-Glutamyl Transferase (GGT), High: if LLN <=PRE <=ULN and value >2*ULN, or if PRE >ULN and value >3*PRE; Creatinine, High: if value >1.5*PRE and >ULN. The analysis was performed in all the subjects who received any study drug. Here, 'n' signifies evaluable subjects for specified categories in respective treatment arms.

End point type	Secondary

End point timeframe:

Baseline (Day 1) up to 56 days after the last dose in the induction period/start of the subsequent phase treatment, which ever occurred first.

End point values	IP - Placebo	IP- BMS-936557 15 mg/kg	IP BMS-936557 25 mg/kg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	83	84	85	
Units: Subjects				
ALT, High (n=83, 82, 84)	0	0	1	
ALP, High (n=83, 82, 84)	0	0	0	
AST, High (n=83, 82, 84)	0	1	1	
Total Bilirubin,High (n=83, 82, 84)	0	0	0	
GGT, High (n=83, 82, 84)	2	1	1	
Creatinine, High (n=83, 82, 84)	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Marked Chemistry Laboratory Abnormalities During Induction period

End point title	Number of Subjects With Marked Chemistry Laboratory Abnormalities During Induction period

End point description:

Glucose (fasting serum), Low: if lower limit of normal (LLN) <=baseline value (PRE) <=upper limit of normal (ULN) and value <0.8*LLN, or if PRE <LLN and value <0.8*PRE, or if PRE >ULN and value <LLN; Glucose (fasting serum), High: if LLN <=PRE <=ULN and value >1.5*ULN, or if PRE <LLN and value >ULN, or if PRE >ULN and value >2.0*PRE; Albumin, Low: if LLN <=PRE <=ULN and value <0.9*LLN, or if PRE <LLN and value <0.75*PRE. The analysis was performed in all the subjects who received any study drug. Here, 'n' signifies evaluable subjects for specified categories in respective treatment arms.

End point type	Secondary

End point timeframe:

Baseline (Day 1) up to 56 days after the last dose in the induction period/start of the subsequent phase treatment, which ever occurred first.

End point values	IP - Placebo	IP- BMS-936557 15 mg/kg	IP BMS-936557 25 mg/kg	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	83	84	85	
Units: Subjects				
Glucose (fasting serum) Low (n=63, 66, 62)	1	2	0	
Glucose (fasting serum) High (n=63, 66, 62)	2	0	0	
Albumin, Low (n=83, 82, 84)	2	0	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

On-Treatment period (up to 56 days after the last dose of the study drug)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	IP: Placebo

Reporting group description:

Subjects received BMS-936557 matching placebo, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.

Reporting group title	IP: BMS-936557 15 mg/kg

Reporting group description:

Subjects received BMS-936557 15 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.

Reporting group title	IP: BMS-936557 25 mg/kg

Reporting group description:

Subjects received BMS-936557 25 mg/kg, intravenous infusion, once a week for first two weeks and every other week thereafter, up to 11 weeks.

Reporting group title	MP: Placebo to Placebo

Reporting group description:

Subjects who received placebo in the induction period received placebo intravenous infusion over 90 minutes, every other week for up to 108 weeks.

Reporting group title	MP: BMS-936557 to Placebo

Reporting group description:

Subjects who received any dose of BMS-936557 in the induction period received placebo via intravenous infusion over 90 minutes, every other week for up to 108 weeks.

Reporting group title	MP: BMS-936557 5 mg/kg

Reporting group description:

Subjects received BMS-936557 5 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks.

Reporting group title	MP: BMS-936557 10 mg/kg

Reporting group description:

Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks.

Reporting group title	MP: BMS-936557 20 mg/kg

Reporting group description:

Subjects received BMS-936557 20 mg/kg, intravenous infusion over 90 minutes, every other week for up to 108 weeks.

Reporting group title	OL: BMS-936557 10 mg/kg

Reporting group description:

Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, every other week for up to 41 months.

Serious adverse events	IP: Placebo	IP: BMS-936557 15 mg/kg	IP: BMS-936557 25 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	9 / 100 (9.00%)	6 / 102 (5.88%)	5 / 103 (4.85%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 103 (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
Prostate cancer			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 103 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 103 (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
Peripheral artery thrombosis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
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			
Chills			

subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
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 / 100 (0.00%)	0 / 102 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Prostatitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
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			
Pulmonary embolism			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 103 (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
Psychiatric disorders			
Disorientation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			

subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Cytomegalovirus test positive			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	1 / 103 (0.97%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute coronary syndrome			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 103 (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
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
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 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	5 / 100 (5.00%)	5 / 102 (4.90%)	2 / 103 (1.94%)
occurrences causally related to treatment / all	0 / 5	1 / 5	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon dysplasia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			

subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis chronic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Urticaria			

subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
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			
Calculus ureteric			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 103 (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 failure acute			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
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 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
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 pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
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			
Abscess limb			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic tonsillitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus colitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			

subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycotic aneurysm			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
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 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal endocarditis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 103 (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
Tonsillitis streptococcal			

subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
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	MP: Placebo to Placebo	MP: BMS-936557 to Placebo	MP: BMS-936557 5 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 30 (6.67%)	1 / 22 (4.55%)	2 / 24 (8.33%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 30 (3.33%)	0 / 22 (0.00%)	0 / 24 (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
Prostate cancer			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			

subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
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			
Deep vein thrombosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
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			
Chills			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
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 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
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			
Prostatitis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Pulmonary embolism			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
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			
Disorientation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicidal ideation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Cytomegalovirus test positive			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			

Infusion related reaction			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
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			
Acute coronary syndrome			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
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 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
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 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			

subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon dysplasia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematochezia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			

subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis chronic			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Urticaria			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
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			
Calculus ureteric			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
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 failure acute			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			

Goitre			
subjects affected / exposed	0 / 30 (0.00%)	1 / 22 (4.55%)	0 / 24 (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
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	1 / 24 (4.17%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
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 pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
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			
Abscess limb			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Catheter site infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic tonsillitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus colitis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycotic aneurysm			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
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 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal abscess			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal endocarditis			
subjects affected / exposed	1 / 30 (3.33%)	0 / 22 (0.00%)	0 / 24 (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
Subcutaneous abscess			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis streptococcal			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
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 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	1 / 30 (3.33%)	0 / 22 (0.00%)	0 / 24 (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

Serious adverse events	MP: BMS-936557 10	MP: BMS-936557 20	OL: BMS-936557 10

	mg/kg	mg/kg	mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 22 (13.64%)	2 / 21 (9.52%)	45 / 237 (18.99%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate cancer			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral artery thrombosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous thrombosis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chills			

subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oedema			
subjects affected / exposed	0 / 22 (0.00%)	1 / 21 (4.76%)	0 / 237 (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 / 22 (0.00%)	0 / 21 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Prostatitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 237 (0.00%)
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			
Pulmonary embolism			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 237 (0.00%)
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			
Disorientation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Major depression			

subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	0 / 237 (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
Suicidal ideation			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	0 / 237 (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
Investigations			
Cytomegalovirus test positive			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 237 (0.00%)
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			
Acute coronary syndrome			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 21 (4.76%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ulcerative			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	21 / 237 (8.86%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 22
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colon dysplasia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticular perforation			

subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Faecaloma			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 21 (4.76%)	0 / 237 (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
Haematochezia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis chronic			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Proctitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Urticaria			

subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus ureteric			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure acute			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Goitre			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 237 (0.00%)
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 / 22 (0.00%)	0 / 21 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intervertebral disc protrusion			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
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 pain			
subjects affected / exposed	0 / 22 (0.00%)	1 / 21 (4.76%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Catheter site infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic tonsillitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus colitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis salmonella			

subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Influenza			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mycotic aneurysm			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
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 / 22 (0.00%)	1 / 21 (4.76%)	0 / 237 (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
Rectal abscess			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Streptococcal endocarditis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tonsillitis streptococcal			

subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 237 (0.00%)
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 / 22 (0.00%)	0 / 21 (0.00%)	2 / 237 (0.84%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Type 1 diabetes mellitus			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 237 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	IP: Placebo	IP: BMS-936557 15 mg/kg	IP: BMS-936557 25 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	44 / 100 (44.00%)	42 / 102 (41.18%)	53 / 103 (51.46%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 100 (1.00%)	2 / 102 (1.96%)	3 / 103 (2.91%)
occurrences (all)	1	2	7
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 100 (1.00%)	3 / 102 (2.94%)	3 / 103 (2.91%)
occurrences (all)	2	3	3
Headache			

subjects affected / exposed	6 / 100 (6.00%)	12 / 102 (11.76%)	18 / 103 (17.48%)
occurrences (all)	10	19	25
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 100 (1.00%)	4 / 102 (3.92%)	5 / 103 (4.85%)
occurrences (all)	1	4	5
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	6 / 100 (6.00%)	2 / 102 (1.96%)	5 / 103 (4.85%)
occurrences (all)	6	2	9
Fatigue			
subjects affected / exposed	1 / 100 (1.00%)	4 / 102 (3.92%)	3 / 103 (2.91%)
occurrences (all)	1	5	3
Influenza like illness			
subjects affected / exposed	2 / 100 (2.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences (all)	4	0	0
Pyrexia			
subjects affected / exposed	4 / 100 (4.00%)	4 / 102 (3.92%)	4 / 103 (3.88%)
occurrences (all)	4	4	5
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	2 / 100 (2.00%)	6 / 102 (5.88%)	7 / 103 (6.80%)
occurrences (all)	2	7	7
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences (all)	1	0	0
Abdominal pain			
subjects affected / exposed	6 / 100 (6.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences (all)	6	0	0
Abdominal pain upper			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 103 (0.00%)
occurrences (all)	0	3	0
Constipation			
subjects affected / exposed	1 / 100 (1.00%)	1 / 102 (0.98%)	0 / 103 (0.00%)
occurrences (all)	1	1	0

Diarrhoea			
subjects affected / exposed	1 / 100 (1.00%)	1 / 102 (0.98%)	0 / 103 (0.00%)
occurrences (all)	1	1	0
Dyspepsia			
subjects affected / exposed	3 / 100 (3.00%)	1 / 102 (0.98%)	3 / 103 (2.91%)
occurrences (all)	3	1	3
Nausea			
subjects affected / exposed	6 / 100 (6.00%)	6 / 102 (5.88%)	7 / 103 (6.80%)
occurrences (all)	7	7	8
Vomiting			
subjects affected / exposed	0 / 100 (0.00%)	3 / 102 (2.94%)	5 / 103 (4.85%)
occurrences (all)	0	3	5
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 100 (4.00%)	2 / 102 (1.96%)	5 / 103 (4.85%)
occurrences (all)	4	2	10
Nasal congestion			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	1 / 103 (0.97%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 100 (1.00%)	1 / 102 (0.98%)	2 / 103 (1.94%)
occurrences (all)	1	1	2
Depression			
subjects affected / exposed	0 / 100 (0.00%)	1 / 102 (0.98%)	0 / 103 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	2 / 100 (2.00%)	2 / 102 (1.96%)	2 / 103 (1.94%)
occurrences (all)	3	2	2

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	6 / 100 (6.00%)	3 / 102 (2.94%)	4 / 103 (3.88%)
occurrences (all)	6	3	5
Back pain			
subjects affected / exposed	2 / 100 (2.00%)	2 / 102 (1.96%)	4 / 103 (3.88%)
occurrences (all)	2	2	5
Musculoskeletal pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	2 / 103 (1.94%)
occurrences (all)	0	0	2
Myalgia			
subjects affected / exposed	2 / 100 (2.00%)	2 / 102 (1.96%)	2 / 103 (1.94%)
occurrences (all)	2	3	2
Pain in extremity			
subjects affected / exposed	1 / 100 (1.00%)	0 / 102 (0.00%)	1 / 103 (0.97%)
occurrences (all)	1	0	1
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 100 (1.00%)	1 / 102 (0.98%)	0 / 103 (0.00%)
occurrences (all)	1	1	0
Genital candidiasis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	2 / 103 (1.94%)
occurrences (all)	0	0	2
Nasopharyngitis			
subjects affected / exposed	5 / 100 (5.00%)	4 / 102 (3.92%)	10 / 103 (9.71%)
occurrences (all)	8	4	11
Oral herpes			
subjects affected / exposed	2 / 100 (2.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences (all)	2	0	0
Pharyngitis			
subjects affected / exposed	0 / 100 (0.00%)	2 / 102 (1.96%)	0 / 103 (0.00%)
occurrences (all)	0	2	0
Rhinitis			

subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	1 / 103 (0.97%)
occurrences (all)	0	0	5
Sinusitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	1 / 103 (0.97%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	2 / 103 (1.94%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	3 / 100 (3.00%)	1 / 102 (0.98%)	2 / 103 (1.94%)
occurrences (all)	3	1	2
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 102 (0.00%)	0 / 103 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	MP: Placebo to Placebo	MP: BMS-936557 to Placebo	MP: BMS-936557 5 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	14 / 30 (46.67%)	13 / 22 (59.09%)	16 / 24 (66.67%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	2 / 30 (6.67%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 30 (3.33%)	0 / 22 (0.00%)	2 / 24 (8.33%)
occurrences (all)	1	0	2
Headache			
subjects affected / exposed	0 / 30 (0.00%)	3 / 22 (13.64%)	5 / 24 (20.83%)
occurrences (all)	0	3	28
Blood and lymphatic system disorders			
Anaemia			

subjects affected / exposed	0 / 30 (0.00%)	2 / 22 (9.09%)	0 / 24 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 30 (10.00%)	1 / 22 (4.55%)	0 / 24 (0.00%)
occurrences (all)	6	2	0
Fatigue			
subjects affected / exposed	1 / 30 (3.33%)	0 / 22 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Influenza like illness			
subjects affected / exposed	3 / 30 (10.00%)	2 / 22 (9.09%)	2 / 24 (8.33%)
occurrences (all)	7	2	3
Pyrexia			
subjects affected / exposed	1 / 30 (3.33%)	4 / 22 (18.18%)	3 / 24 (12.50%)
occurrences (all)	1	8	3
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Abdominal pain			
subjects affected / exposed	4 / 30 (13.33%)	0 / 22 (0.00%)	2 / 24 (8.33%)
occurrences (all)	9	0	2
Abdominal pain upper			
subjects affected / exposed	1 / 30 (3.33%)	0 / 22 (0.00%)	1 / 24 (4.17%)
occurrences (all)	1	0	1
Constipation			
subjects affected / exposed	1 / 30 (3.33%)	2 / 22 (9.09%)	0 / 24 (0.00%)
occurrences (all)	2	6	0
Diarrhoea			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Dyspepsia			

subjects affected / exposed	2 / 30 (6.67%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Nausea			
subjects affected / exposed	1 / 30 (3.33%)	0 / 22 (0.00%)	2 / 24 (8.33%)
occurrences (all)	1	0	7
Vomiting			
subjects affected / exposed	1 / 30 (3.33%)	1 / 22 (4.55%)	0 / 24 (0.00%)
occurrences (all)	1	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 30 (0.00%)	1 / 22 (4.55%)	6 / 24 (25.00%)
occurrences (all)	0	1	7
Nasal congestion			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 30 (3.33%)	1 / 22 (4.55%)	1 / 24 (4.17%)
occurrences (all)	1	1	1
Depression			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Insomnia			
subjects affected / exposed	0 / 30 (0.00%)	1 / 22 (4.55%)	2 / 24 (8.33%)
occurrences (all)	0	2	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 30 (16.67%)	3 / 22 (13.64%)	5 / 24 (20.83%)
occurrences (all)	6	3	6

Back pain			
subjects affected / exposed	2 / 30 (6.67%)	0 / 22 (0.00%)	2 / 24 (8.33%)
occurrences (all)	3	0	2
Musculoskeletal pain			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Pain in extremity			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 30 (0.00%)	2 / 22 (9.09%)	3 / 24 (12.50%)
occurrences (all)	0	2	4
Genital candidiasis			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2
Influenza			
subjects affected / exposed	0 / 30 (0.00%)	1 / 22 (4.55%)	6 / 24 (25.00%)
occurrences (all)	0	1	8
Nasopharyngitis			
subjects affected / exposed	4 / 30 (13.33%)	1 / 22 (4.55%)	2 / 24 (8.33%)
occurrences (all)	7	1	4
Oral herpes			
subjects affected / exposed	1 / 30 (3.33%)	0 / 22 (0.00%)	0 / 24 (0.00%)
occurrences (all)	2	0	0
Pharyngitis			
subjects affected / exposed	2 / 30 (6.67%)	2 / 22 (9.09%)	0 / 24 (0.00%)
occurrences (all)	3	2	0
Rhinitis			
subjects affected / exposed	2 / 30 (6.67%)	0 / 22 (0.00%)	1 / 24 (4.17%)
occurrences (all)	2	0	1
Sinusitis			

subjects affected / exposed	1 / 30 (3.33%)	2 / 22 (9.09%)	0 / 24 (0.00%)
occurrences (all)	3	2	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 30 (3.33%)	1 / 22 (4.55%)	2 / 24 (8.33%)
occurrences (all)	1	1	2
Urinary tract infection			
subjects affected / exposed	1 / 30 (3.33%)	1 / 22 (4.55%)	0 / 24 (0.00%)
occurrences (all)	1	2	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 30 (0.00%)	0 / 22 (0.00%)	2 / 24 (8.33%)
occurrences (all)	0	0	2

Non-serious adverse events	MP: BMS-936557 10 mg/kg	MP: BMS-936557 20 mg/kg	OL: BMS-936557 10 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 22 (77.27%)	13 / 21 (61.90%)	149 / 237 (62.87%)
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	2 / 237 (0.84%)
occurrences (all)	0	0	2
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	13 / 237 (5.49%)
occurrences (all)	0	0	16
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	7 / 237 (2.95%)
occurrences (all)	0	0	9
Headache			
subjects affected / exposed	6 / 22 (27.27%)	3 / 21 (14.29%)	23 / 237 (9.70%)
occurrences (all)	16	4	51
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	13 / 237 (5.49%)
occurrences (all)	0	0	13
General disorders and administration site conditions			

Asthenia			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	8 / 237 (3.38%)
occurrences (all)	1	0	18
Fatigue			
subjects affected / exposed	2 / 22 (9.09%)	0 / 21 (0.00%)	11 / 237 (4.64%)
occurrences (all)	2	0	12
Influenza like illness			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	8 / 237 (3.38%)
occurrences (all)	1	0	10
Pyrexia			
subjects affected / exposed	2 / 22 (9.09%)	2 / 21 (9.52%)	20 / 237 (8.44%)
occurrences (all)	3	2	21
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 22 (4.55%)	3 / 21 (14.29%)	7 / 237 (2.95%)
occurrences (all)	1	5	11
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	2 / 22 (9.09%)	0 / 21 (0.00%)	3 / 237 (1.27%)
occurrences (all)	2	0	3
Abdominal pain			
subjects affected / exposed	0 / 22 (0.00%)	1 / 21 (4.76%)	15 / 237 (6.33%)
occurrences (all)	0	1	20
Abdominal pain upper			
subjects affected / exposed	0 / 22 (0.00%)	2 / 21 (9.52%)	6 / 237 (2.53%)
occurrences (all)	0	3	6
Constipation			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	2 / 237 (0.84%)
occurrences (all)	0	0	2
Diarrhoea			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	7 / 237 (2.95%)
occurrences (all)	1	0	9
Dyspepsia			
subjects affected / exposed	2 / 22 (9.09%)	0 / 21 (0.00%)	16 / 237 (6.75%)
occurrences (all)	2	0	19
Nausea			

subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	15 / 237 (6.33%)
occurrences (all)	1	0	24
Vomiting			
subjects affected / exposed	2 / 22 (9.09%)	0 / 21 (0.00%)	8 / 237 (3.38%)
occurrences (all)	2	0	13
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	3 / 22 (13.64%)	2 / 21 (9.52%)	12 / 237 (5.06%)
occurrences (all)	4	2	13
Nasal congestion			
subjects affected / exposed	0 / 22 (0.00%)	2 / 21 (9.52%)	4 / 237 (1.69%)
occurrences (all)	0	2	5
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	2 / 22 (9.09%)	0 / 21 (0.00%)	0 / 237 (0.00%)
occurrences (all)	2	0	0
Rash erythematous			
subjects affected / exposed	2 / 22 (9.09%)	0 / 21 (0.00%)	1 / 237 (0.42%)
occurrences (all)	2	0	2
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 22 (9.09%)	0 / 21 (0.00%)	6 / 237 (2.53%)
occurrences (all)	2	0	7
Depression			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	3 / 237 (1.27%)
occurrences (all)	1	0	4
Insomnia			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	3 / 237 (1.27%)
occurrences (all)	0	0	5
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 22 (13.64%)	0 / 21 (0.00%)	21 / 237 (8.86%)
occurrences (all)	4	0	35
Back pain			
subjects affected / exposed	1 / 22 (4.55%)	1 / 21 (4.76%)	14 / 237 (5.91%)
occurrences (all)	1	1	19

Musculoskeletal pain			
subjects affected / exposed	1 / 22 (4.55%)	2 / 21 (9.52%)	1 / 237 (0.42%)
occurrences (all)	3	2	1
Myalgia			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	6 / 237 (2.53%)
occurrences (all)	1	0	6
Pain in extremity			
subjects affected / exposed	1 / 22 (4.55%)	0 / 21 (0.00%)	4 / 237 (1.69%)
occurrences (all)	1	0	4
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	2 / 22 (9.09%)	1 / 21 (4.76%)	12 / 237 (5.06%)
occurrences (all)	2	1	16
Genital candidiasis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0
Influenza			
subjects affected / exposed	1 / 22 (4.55%)	1 / 21 (4.76%)	9 / 237 (3.80%)
occurrences (all)	2	2	12
Nasopharyngitis			
subjects affected / exposed	3 / 22 (13.64%)	0 / 21 (0.00%)	39 / 237 (16.46%)
occurrences (all)	5	0	65
Oral herpes			
subjects affected / exposed	2 / 22 (9.09%)	0 / 21 (0.00%)	5 / 237 (2.11%)
occurrences (all)	5	0	7
Pharyngitis			
subjects affected / exposed	1 / 22 (4.55%)	2 / 21 (9.52%)	5 / 237 (2.11%)
occurrences (all)	1	2	7
Rhinitis			
subjects affected / exposed	0 / 22 (0.00%)	1 / 21 (4.76%)	3 / 237 (1.27%)
occurrences (all)	0	1	5
Sinusitis			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	9 / 237 (3.80%)
occurrences (all)	0	0	12
Upper respiratory tract infection			

subjects affected / exposed	3 / 22 (13.64%)	2 / 21 (9.52%)	24 / 237 (10.13%)
occurrences (all)	5	2	31
Urinary tract infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	14 / 237 (5.91%)
occurrences (all)	0	0	17
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 22 (0.00%)	0 / 21 (0.00%)	0 / 237 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 June 2011	• Added Drug-induced liver injury language. • Deleted 84 and 112 days post dosing visits. • Deleted requirement for male contraception. • Exclusion Criteria were modified to be more specific, Added ''Lichtiger score of >=10 and Subjects with evidence of active CMV (cytomegalovirus) infection or CMV colitis should also be excluded from the study''. • Added vital signs to each clinic and infusion visit in the T&E. • Added storage time for biopsy and exploratory biomarkers samples. • Revised to indicate a Physician's Assistant can perform the Complete Physical Exam and the PGA for the Full Mayo Score. • Deleted creatinine from the urinalysis testing. • Added information that the diary entries should be collected prior to the preparation day for the endoscopy. • Added two secondary endpoints to match secondary objectives.
20 October 2011	• Changed the duration of the Induction Period (IP) to be 11 weeks and the primary endpoint to IP-78 throughout the protocol. • Changed Post Dosing Follow-up Visit from 14 days post last dose to 28 days. • Specified criteria for dose decrease and limited the option to decrease the dose to 10 mg/kg only during Open-Label. • Clarified requirements and procedures for drug administration.
19 March 2013	• Added severe and/or serious acute infusion reactions as a reason for discontinuation. • Clarified the infusion rate for induction period, maintenance Phase, and open label period.
16 December 2013	• Allowed all subjects to enter open label period regardless of clinical remission or relapse.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

The sponsor decided not to pursue further clinical development of BMS-936557 due to an insufficient demonstration of efficacy across studies in Inflammatory Bowel Disease .

Notes: