



Clinical trial results:

A Phase IIa, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Clinical Efficacy and Safety of Induction and Maintenance Therapy with BMS-936557 in Subjects with Active Crohn's Disease

Summary

EudraCT number	2011-002981-19
Trial protocol	BE HU PL
Global end of trial date	29 December 2014

Results information

Result version number	v1 (current)
This version publication date	24 August 2016
First version publication date	24 August 2016

Trial information

Trial identification

Sponsor protocol code	IM129-008
-----------------------	-----------

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01466374
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	29 December 2014
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	29 December 2014
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the trial was to assess the efficacy of BMS-936557 for induction of clinical remission (as defined by an absolute Crohn's Disease Activity Index [CDAI] score <150) as determined by the presence of a relationship between exposure (observed steady-state Cmin) and clinical remission 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	11 December 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	Belgium: 10
Country: Number of subjects enrolled	France: 36
Country: Number of subjects enrolled	Hungary: 29
Country: Number of subjects enrolled	Israel: 3
Country: Number of subjects enrolled	Poland: 38
Country: Number of subjects enrolled	Puerto Rico: 1
Country: Number of subjects enrolled	South Africa: 9
Country: Number of subjects enrolled	United States: 69
Worldwide total number of subjects	195
EEA total number of subjects	113

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)	189
From 65 to 84 years	6
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 195 subjects were enrolled at 28 sites in 8 countries.

Pre-assignment

Screening details:

Out of 195 subjects enrolled, 121 were randomised. Of the 74 subjects not randomised, 57 did not meet study criteria, 13 withdrew consent, and 4 experienced an adverse event prior to randomisation.

Period 1

Period 1 title	Induction Period
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 over 90 minutes, once a week for the first week and every other week thereafter up to 11 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 BMS-936557 matching placebo via intravenous infusion over 90 minutes, once a week for the first week and every other week thereafter up to 11 weeks.

Arm title	BMS-936557 10 mg/kg
------------------	---------------------

Arm description:

Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, once a week for the first week 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 10 mg/kg via intravenous infusion over 90 minutes once a week for the first week and every other week thereafter up to 11 weeks.

Arm title	BMS-936557 20 mg/kg
------------------	---------------------

Arm description:

Subjects received BMS-936557 20 mg/kg, intravenous infusion over 90 minutes, once a week for the first week 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 20 mg/kg via intravenous infusion over 90 minutes once a week for the first week and every other week thereafter up to 11 weeks.

Number of subjects in period 1 ^[1]	Placebo	BMS-936557 10 mg/kg	BMS-936557 20 mg/kg
Started	40	40	41
Completed	39	32	35
Not completed	1	8	6
Consent withdrawn by subject	1	1	-
Adverse event, non-fatal	-	5	5
Lack of efficacy	-	2	1

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 195 subjects who were enrolled only 121 were randomised. 57 subjects no longer met study criteria, 13 subjects withdrew consent, and 4 subjects experienced an adverse event prior to randomisation.

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 matching with BMS-936557 in the induction period received placebo matching with BMS-936557 intravenous infusion over 90 minutes, every other week for up to 48 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 BMS-936557 matching placebo via intravenous infusion over 90 minutes, every other week for up to 48 weeks.

Arm title	BMS-936557 to Placebo
-----------	-----------------------

Arm description:

Subjects who received any dose of BMS-936557 in the induction period received BMS-936557 matching placebo via intravenous infusion over 90 minutes, every other week for up to 48 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 BMS-936557 matching placebo via intravenous infusion over 90 minutes, every other week for up to 48 weeks.

Arm title	BMS-936557 7.5 mg/kg
------------------	----------------------

Arm description:

Subjects who received any dose of BMS-936557 in the induction period and achieved a clinical response (CR-100) received BMS-936557 7.5 mg/kg, intravenous infusion over 90 minutes, every other week for up to 48 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 7.5 mg/kg via intravenous infusion over 90 minutes, every other week for up to 48 weeks.

Arm title	BMS-936557 15 mg/kg
------------------	---------------------

Arm description:

Subjects who received any dose of BMS-936557 in the induction period and achieved a clinical response (CR-100) received BMS-936557 15 mg/kg, intravenous infusion over 90 minutes, every other week for up to 48 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, every other week for up to 48 weeks.

Number of subjects in period 2^[2]	Placebo to Placebo	BMS-936557 to Placebo	BMS-936557 7.5 mg/kg
Started	13	11	12
Completed	5	2	3
Not completed	8	9	9
Consent withdrawn by subject	1	-	-
Adverse event, non-fatal	-	1	2

Subject request to discontinue study treatment	-	-	-
Lost to follow-up	-	-	-
Lack of efficacy	5	5	3
Administrative reason by sponsor	2	3	4

Number of subjects in period 2^[2]	BMS-936557 15 mg/kg
Started	11
Completed	7
Not completed	4
Consent withdrawn by subject	-
Adverse event, non-fatal	2
Subject request to discontinue study treatment	1
Lost to follow-up	1
Lack of efficacy	-
Administrative reason by sponsor	-

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 106 subjects who completed the induction period, 57 subjects continued directly into the open label period and only 47 subjects entered the maintenance phase.

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
------------------	------------

Arm description:

Subjects received BMS-936557 15 mg/kg, intravenous infusion over 90 minutes, every other week. Subjects who did not demonstrate clinical response by Open label day 85 (OL-85) were discontinued from the study. Subjects who continued in the study and demonstrated prolonged clinical remission (>3 months) had the option of decreasing the dose to 10 mg/kg.

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 administered with BMS-936557 15 mg/kg via intravenous infusion over 90 minutes, every other week.

Number of subjects in period 3^[3]	BMS-936557
Started	15
Completed	10
Not completed	74
Consent withdrawn by subject	6
Adverse event, non-fatal	9
Subject request to discontinue study treatment	2
Pregnancy	1
Lost to follow-up	1
Poor/non-compliance	1
Lack of efficacy	23
Administrative reason by sponsor	31
Joined	69
Subjects continuing directly from induction period	57
Discontinued and moving from maintenance period	12

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: Out of 106 subjects who completed the induction period, 57 subjects continued directly into the open label period, 47 subjects entered the maintenance phase, and 2 subjects elected not to continue into the maintenance phase.

Baseline characteristics

Reporting groups

Reporting group title	Placebo
-----------------------	---------

Reporting group description:

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

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

Reporting group description:

Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, once a week for the first week and every other week thereafter up to 11 weeks.

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

Reporting group description:

Subjects received BMS-936557 20 mg/kg, intravenous infusion over 90 minutes, once a week for the first week and every other week thereafter up to 11 weeks.

Reporting group values	Placebo	BMS-936557 10 mg/kg	BMS-936557 20 mg/kg
Number of subjects	40	40	41
Age categorical Units: Subjects			
<65 years	39	39	39
>=65 years	1	1	2
Age continuous Units: years			
arithmetic mean	37.3	35.8	35.4
standard deviation	± 13.12	± 12.96	± 13.05
Gender categorical Units: Subjects			
Female	22	17	21
Male	18	23	20

Reporting group values	Total		
Number of subjects	121		
Age categorical Units: Subjects			
<65 years	117		
>=65 years	4		
Age continuous Units: years			
arithmetic mean			
standard deviation	-		
Gender categorical Units: Subjects			
Female	60		
Male	61		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Subjects received BMS-936557 matching placebo, intravenous infusion over 90 minutes, once a week for the first week and every other week thereafter up to 11 weeks.	
Reporting group title	BMS-936557 10 mg/kg
Reporting group description: Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, once a week for the first week and every other week thereafter up to 11 weeks.	
Reporting group title	BMS-936557 20 mg/kg
Reporting group description: Subjects received BMS-936557 20 mg/kg, intravenous infusion over 90 minutes, once a week for the first week and every other week thereafter up to 11 weeks.	
Reporting group title	Placebo to Placebo
Reporting group description: Subjects who received placebo matching with BMS-936557 in the induction period received placebo matching with BMS-936557 intravenous infusion over 90 minutes, every other week for up to 48 weeks.	
Reporting group title	BMS-936557 to Placebo
Reporting group description: Subjects who received any dose of BMS-936557 in the induction period received BMS-936557 matching placebo via intravenous infusion over 90 minutes, every other week for up to 48 weeks.	
Reporting group title	BMS-936557 7.5 mg/kg
Reporting group description: Subjects who received any dose of BMS-936557 in the induction period and achieved a clinical response (CR-100) received BMS-936557 7.5 mg/kg, intravenous infusion over 90 minutes, every other week for up to 48 weeks.	
Reporting group title	BMS-936557 15 mg/kg
Reporting group description: Subjects who received any dose of BMS-936557 in the induction period and achieved a clinical response (CR-100) received BMS-936557 15 mg/kg, intravenous infusion over 90 minutes, every other week for up to 48 weeks.	
Reporting group title	BMS-936557
Reporting group description: Subjects received BMS-936557 15 mg/kg, intravenous infusion over 90 minutes, every other week. Subjects who did not demonstrate clinical response by Open label day 85 (OL-85) were discontinued from the study. Subjects who continued in the study and demonstrated prolonged clinical remission (>3 months) had the option of decreasing the dose to 10 mg/kg.	

Primary: Percentage of Subjects in Clinical Remission at Week 11 (IP-78)

End point title	Percentage of Subjects in Clinical Remission at Week 11 (IP-78)
End point description: Clinical Remission was defined as an absolute Crohn's Disease Activity Index (CDAI) score <150. CDAI is a composite index consisting of a weighted scoring of 8 disease variables: number of liquid stools, extent of abdominal pain, general well-being, occurrence of extra intestinal symptoms, need for anti-diarrheal drugs, presence of abdominal masses, hematocrit, and body weight. CDAI score was based partly on entries (7 days before evaluation) from subject's diary kept while on study. CDAI scores range from 0 to ~600 points. All subjects who prematurely discontinued for any reason were considered as non-responders/remitters. The analysis was performed in Intent-to-Treat population defined as all the subjects who were randomised and received the study treatment.	
End point type	Primary

End point timeframe:

Week 11

End point values	Placebo	BMS-936557 10 mg/kg	BMS-936557 20 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	40	41	
Units: Percentage of subjects				
number (confidence interval 90%)	20 (9.6 to 30.4)	22.5 (11.6 to 33.4)	29.3 (17.6 to 41)	

Statistical analyses

Statistical analysis title	Treatment difference from Placebo - BMS 10 mg/kg
Comparison groups	BMS-936557 10 mg/kg v Placebo
Number of subjects included in analysis	80
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.855
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment difference
Point estimate	0.7
Confidence interval	
level	90 %
sides	2-sided
lower limit	-14.5
upper limit	15.9

Statistical analysis title	Treatment difference from Placebo - BMS 20 mg/kg
Comparison groups	Placebo v BMS-936557 20 mg/kg
Number of subjects included in analysis	81
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.4
Method	Cochran-Mantel-Haenszel
Parameter estimate	Treatment difference
Point estimate	7.6
Confidence interval	
level	90 %
sides	2-sided
lower limit	-8.7
upper limit	23.8

Secondary: Percentage of Subjects With Clinical Response at Week 7 (IP-50) and Week 11 (IP-78)

End point title	Percentage of Subjects With Clinical Response at Week 7 (IP-50) and Week 11 (IP-78)
-----------------	---

End point description:

Clinical response was defined by a reduction in Crohn's Disease Activity Index (CDAI) ≥ 100 points or absolute CDAI < 150 points. The analysis was performed in Intent-to-Treat population defined as all the subjects who were randomised and received the study drug.

End point type	Secondary
----------------	-----------

End point timeframe:

Week 7 and Week 11

End point values	Placebo	BMS-936557 10 mg/kg	BMS-936557 20 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	40	41	
Units: Percentage of subjects				
number (confidence interval 90%)				
IP-50	47.5 (34.5 to 60.5)	45 (32.1 to 57.9)	53.7 (40.8 to 66.5)	
IP-78	35 (22.6 to 47.4)	47.5 (34.5 to 60.5)	41.5 (28.8 to 54.1)	

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ)

End point title	Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ)
-----------------	--

End point description:

IBDQ consists of a self-administered 32-item questionnaire evaluating quality of life across 4 dimensional scores: Bowel – symptoms related to primary bowel disturbance, Systemic, Social and Emotional. Responses 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 ranges between 32 to 224 with higher scores indicating a better quality of life. The analysis was performed in all the subjects who were randomised and received the study drug. Here, 'Number of subjects analysed' signifies subjects evaluable for this outcome measure.

End point type	Secondary
----------------	-----------

End point timeframe:

Week 11

End point values	Placebo	BMS-936557 10 mg/kg	BMS-936557 20 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	37	37	40	
Units: units on a scale				
arithmetic mean (standard deviation)	14.6 (± 33.33)	22.5 (± 37.49)	32.9 (± 30.69)	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Adverse Events (AEs), Related AEs, Discontinuation Due to AEs, Serious Adverse Events (SAEs), Related SAEs, Discontinuation Due to SAEs, and Who Died in the Induction Period

End point title	Number of Subjects With Adverse Events (AEs), Related AEs, Discontinuation Due to AEs, Serious Adverse Events (SAEs), Related SAEs, Discontinuation Due to SAEs, and Who Died in the Induction Period
-----------------	---

End point description:

AE=any new untoward medical occurrence or worsening of a pre-existing medical condition which does not necessarily have a causal relationship with this treatment. Related AE=relationship of certain, probable, possible, or missing. SAE=any untoward medical occurrence that at any dose: results in death, is life-threatening, requires inpatient hospitalization or causes prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, results in development of drug dependency or drug abuse, is an important medical event. The analysis was performed in all the subjects who received the study drug.

End point type	Secondary
----------------	-----------

End point timeframe:

First dose of study drug up to 56 days after the last dose of study drug or until the start of a new study period, whichever occurred earlier.

End point values	Placebo	BMS-936557 10 mg/kg	BMS-936557 20 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	40	41	
Units: Subjects				
AEs	31	26	24	
Related AEs	7	12	16	
Discontinuation Due to AEs	0	5	5	
SAEs	2	3	4	
Related SAEs	0	1	3	
Discontinuation Due to SAEs	0	3	3	
Death	0	0	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Marked Laboratory Abnormalities During Induction Period

End point title	Number of Subjects With Marked Laboratory Abnormalities During Induction Period
-----------------	---

End point description:

Hemoglobin Low: <baseline value (PRE) -30 and <Lower limit of normal (LLN); Leukocytes 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; Leukocytes 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; Creatinine high: if value >1.5*PRE and >ULN; Albumin low: if LLN ≤PRE ≤ULN and value <0.9*LLN. The analysis was performed in all the subjects who received the study drug.

End point type	Secondary
----------------	-----------

End point timeframe:

First dose of study drug up to 56 days after the last dose of study drug or until the start of a new study period, whichever occurred earlier.

End point values	Placebo	BMS-936557 10 mg/kg	BMS-936557 20 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	40	41	
Units: Subjects				
Hemoglobin Low	0	0	1	
Leukocytes Low	1	0	0	
Leukocytes High	3	3	4	
Lymphocytes Low (absolute)	8	8	5	
Neutrophils Low (absolute)	1	0	0	
Creatinine High	0	1	1	
Albumin Low	1	1	0	

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects With Clinically Significant Changes in Vital Signs During Induction Period

End point title	Number of Subjects With Clinically Significant Changes in Vital Signs During Induction Period
-----------------	---

End point description:

Vital signs included body temperature, heart rate, and blood pressure which were to be taken pre-infusion (no more than 30 minutes pre-infusion), end of infusion, and end of observation. The analysis was performed in all the subjects who received the study drug.

End point type	Secondary
----------------	-----------

End point timeframe:

First dose of study drug up to 56 days after the last dose of study drug or until the start of a new study period, whichever occurred earlier.

End point values	Placebo	BMS-936557 10 mg/kg	BMS-936557 20 mg/kg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	40	40	41	
Units: Subjects				
Body temperature	0	0	0	
Heart rate	0	0	0	
Blood pressure	0	0	0	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

On-Treatment period (First dose of study drug up to 56 days after the last dose of 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 over 90 minutes, once a week for the first week and every other week thereafter up to 11 weeks.

Reporting group title	IP: BMS 10 mg/kg
-----------------------	------------------

Reporting group description:

Subjects received BMS-936557 10 mg/kg, intravenous infusion over 90 minutes, once a week for the first week and every other week thereafter up to 11 weeks.

Reporting group title	IP: BMS 20 mg/kg
-----------------------	------------------

Reporting group description:

Subjects received BMS-936557 20 mg/kg, intravenous infusion over 90 minutes, once a week for the first week and every other week thereafter up to 11 weeks.

Reporting group title	MP: PLA->PLA
-----------------------	--------------

Reporting group description:

Subjects who received placebo matching with BMS-936557 in the induction period received placebo matching with BMS-936557 intravenous infusion over 90 minutes, every other week for up to 48 weeks.

Reporting group title	MP: BMS->PLA
-----------------------	--------------

Reporting group description:

Subjects who received any dose of BMS-936557 in the induction period received BMS-936557 matching placebo via intravenous infusion over 90 minutes, every other week for up to 48 weeks.

Reporting group title	MP: BMS 7.5 mg/kg
-----------------------	-------------------

Reporting group description:

Subjects who received any dose of BMS-936557 in the induction period and achieved a clinical response (CR-100) received BMS-936557 7.5 mg/kg, intravenous infusion over 90 minutes, every other week for up to 48 weeks.

Reporting group title	MP: BMS 15 mg/kg
-----------------------	------------------

Reporting group description:

Subjects who received any dose of BMS-936557 in the induction period and achieved a clinical response (CR-100) received BMS-936557 15 mg/kg, intravenous infusion over 90 minutes, every other week for up to 48 weeks.

Reporting group title	OL: BMS-936557
-----------------------	----------------

Reporting group description:

Subjects received BMS-936557 15 mg/kg, intravenous infusion over 90 minutes, every other week. Subjects who did not demonstrate clinical response by Open label day 85 (OL-85) were discontinued from the study. Subjects who continued in the study and demonstrated prolonged clinical remission (>3 months) had the option of decreasing the dose to 10 mg/kg.

Serious adverse events	IP: Placebo	IP: BMS 10 mg/kg	IP: BMS 20 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 40 (5.00%)	3 / 40 (7.50%)	4 / 41 (9.76%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroma			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
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			
Peripheral artery thrombosis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 41 (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
Cardiac disorders			
Cardiac failure congestive			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
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			
Hyperthermia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
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			
Anaphylactic shock			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	2 / 41 (4.88%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			

Abdominal distension			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	2 / 40 (5.00%)	2 / 40 (5.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 2	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver injury			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
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 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
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			
Spondyloarthropathy			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
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 viral			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 41 (2.44%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
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 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
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: PLA->PLA	MP: BMS->PLA	MP: BMS 7.5 mg/kg
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 13 (7.69%)	2 / 11 (18.18%)	2 / 12 (16.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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			
Peripheral artery thrombosis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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			
Cardiac failure congestive			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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			
Hyperthermia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 12 (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
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 distension			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver injury			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Calculus ureteric			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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			
Spondyloarthropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchopneumonia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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 viral			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastoiditis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
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: BMS 15 mg/kg	OL: BMS-936557	
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 11 (9.09%)	13 / 84 (15.48%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Fibroma			
subjects affected / exposed	0 / 11 (0.00%)	1 / 84 (1.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Peripheral artery thrombosis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac failure congestive			
subjects affected / exposed	0 / 11 (0.00%)	1 / 84 (1.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Hyperthermia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic shock			
subjects affected / exposed	0 / 11 (0.00%)	1 / 84 (1.19%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Crohn's disease			
subjects affected / exposed	1 / 11 (9.09%)	7 / 84 (8.33%)	
occurrences causally related to treatment / all	0 / 2	0 / 11	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 11 (0.00%)	1 / 84 (1.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Cholelithiasis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 84 (1.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Renal and urinary disorders			
Calculus ureteric			
subjects affected / exposed	0 / 11 (0.00%)	1 / 84 (1.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Spondyloarthropathy			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 11 (0.00%)	1 / 84 (1.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchopneumonia			
subjects affected / exposed	0 / 11 (0.00%)	1 / 84 (1.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mastoiditis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 11 (0.00%)	1 / 84 (1.19%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Non-serious adverse events	IP: Placebo	IP: BMS 10 mg/kg	IP: BMS 20 mg/kg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 40 (57.50%)	18 / 40 (45.00%)	18 / 41 (43.90%)
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
Fatigue			
subjects affected / exposed	2 / 40 (5.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Influenza like illness			
subjects affected / exposed	4 / 40 (10.00%)	1 / 40 (2.50%)	0 / 41 (0.00%)
occurrences (all)	4	1	0
Infusion site extravasation			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	2 / 40 (5.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Pyrexia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	2 / 41 (4.88%)
occurrences (all)	1	0	2
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	2 / 41 (4.88%)
occurrences (all)	0	2	2
Reproductive system and breast disorders			
Penis disorder			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 40 (2.50%)	2 / 40 (5.00%)	1 / 41 (2.44%)
occurrences (all)	1	2	1
Psychiatric disorders			

Anxiety subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	0 / 40 (0.00%) 0	3 / 41 (7.32%) 3
Injury, poisoning and procedural complications Foot fracture subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	1 / 40 (2.50%) 1	3 / 41 (7.32%) 4
Laceration subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	3 / 40 (7.50%) 4	3 / 40 (7.50%) 5	2 / 41 (4.88%) 2
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Iron deficiency anaemia subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Lymphopenia subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Ear and labyrinth disorders Cerumen impaction subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Ear pain subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Vertigo			

subjects affected / exposed occurrences (all)	2 / 40 (5.00%) 2	0 / 40 (0.00%) 0	1 / 41 (2.44%) 1
Eye disorders Episcleritis subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Gastrointestinal disorders Abdominal distension subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1	1 / 40 (2.50%) 1	0 / 41 (0.00%) 0
Abdominal pain upper subjects affected / exposed occurrences (all)	2 / 40 (5.00%) 2	1 / 40 (2.50%) 1	3 / 41 (7.32%) 3
Abdominal rigidity subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Abdominal tenderness subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1	1 / 40 (2.50%) 1	0 / 41 (0.00%) 0
Anal fistula subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Dental caries subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Dyspepsia subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 1	0 / 40 (0.00%) 0	2 / 41 (4.88%) 4
Flatulence subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Gastritis			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Nausea			
subjects affected / exposed	4 / 40 (10.00%)	0 / 40 (0.00%)	1 / 41 (2.44%)
occurrences (all)	4	0	1
Rectal haemorrhage			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	2 / 40 (5.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	2	0	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Dermatitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Dermatitis psoriasiform			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Erythema			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	3 / 41 (7.32%)
occurrences (all)	0	0	3
Pruritus			
subjects affected / exposed	1 / 40 (2.50%)	2 / 40 (5.00%)	1 / 41 (2.44%)
occurrences (all)	1	3	1
Skin lesion			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 40 (0.00%)	4 / 40 (10.00%)	0 / 41 (0.00%)
occurrences (all)	0	5	0
Bone pain			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Joint stiffness			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Sacroiliitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Tendon disorder			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 40 (7.50%)	1 / 40 (2.50%)	0 / 41 (0.00%)
occurrences (all)	3	1	0
Clostridium difficile infection			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Cystitis			
subjects affected / exposed	0 / 40 (0.00%)	1 / 40 (2.50%)	0 / 41 (0.00%)
occurrences (all)	0	1	0
Ear infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Escherichia urinary tract infection			

subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Furuncle			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Influenza			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	1 / 41 (2.44%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	1 / 40 (2.50%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	1	0	0
Rash pustular			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Skin infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Staphylococcal skin infection			
subjects affected / exposed	0 / 40 (0.00%)	0 / 40 (0.00%)	0 / 41 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	0 / 41 (0.00%)
occurrences (all)	1	1	0
Upper respiratory tract infection			
subjects affected / exposed	1 / 40 (2.50%)	1 / 40 (2.50%)	2 / 41 (4.88%)
occurrences (all)	1	1	3
Urinary tract infection			

subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Urinary tract infection bacterial subjects affected / exposed occurrences (all)	1 / 40 (2.50%) 2	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Vulvovaginal mycotic infection subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	1 / 40 (2.50%) 1	0 / 41 (0.00%) 0
Metabolism and nutrition disorders			
Dehydration subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	0 / 40 (0.00%) 0	0 / 41 (0.00%) 0
Iron deficiency subjects affected / exposed occurrences (all)	0 / 40 (0.00%) 0	2 / 40 (5.00%) 2	0 / 41 (0.00%) 0

Non-serious adverse events	MP: PLA->PLA	MP: BMS->PLA	MP: BMS 7.5 mg/kg
Total subjects affected by non-serious adverse events subjects affected / exposed	7 / 13 (53.85%)	9 / 11 (81.82%)	11 / 12 (91.67%)
General disorders and administration site conditions			
Asthenia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 11 (0.00%) 0	1 / 12 (8.33%) 1
Fatigue subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 11 (0.00%) 0	1 / 12 (8.33%) 1
Influenza like illness subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 11 (9.09%) 1	1 / 12 (8.33%) 1
Infusion site extravasation subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Oedema peripheral subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Pyrexia			

subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Immune system disorders Hypersensitivity subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Reproductive system and breast disorders Penis disorder subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 11 (0.00%) 0	1 / 12 (8.33%) 1
Respiratory, thoracic and mediastinal disorders Cough subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Psychiatric disorders Anxiety subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Injury, poisoning and procedural complications Foot fracture subjects affected / exposed occurrences (all) Infusion related reaction subjects affected / exposed occurrences (all) Laceration subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0 0 / 13 (0.00%) 0 0 / 13 (0.00%) 0	0 / 11 (0.00%) 0 0 / 11 (0.00%) 0 0 / 11 (0.00%) 0	1 / 12 (8.33%) 1 0 / 12 (0.00%) 0 0 / 12 (0.00%) 0
Nervous system disorders Headache subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 2	1 / 11 (9.09%) 1	1 / 12 (8.33%) 2
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0

Iron deficiency anaemia subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Lymphopenia subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0
Ear and labyrinth disorders			
Cerumen impaction subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Ear pain subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Eye disorders			
Episcleritis subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Gastrointestinal disorders			
Abdominal distension subjects affected / exposed occurrences (all)	1 / 13 (7.69%) 1	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Abdominal pain subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 11 (0.00%) 0	2 / 12 (16.67%) 2
Abdominal pain upper subjects affected / exposed occurrences (all)	2 / 13 (15.38%) 2	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0
Abdominal rigidity subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	1 / 11 (9.09%) 1	0 / 12 (0.00%) 0
Abdominal tenderness subjects affected / exposed occurrences (all)	0 / 13 (0.00%) 0	0 / 11 (0.00%) 0	0 / 12 (0.00%) 0
Anal fistula			

subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dental caries			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dyspepsia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Flatulence			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Gastritis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Haemorrhoids			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Rectal haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Dermatitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Dermatitis psoriasiform			
subjects affected / exposed	1 / 13 (7.69%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	2	3	0

Eczema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Erythema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin lesion			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
Bone pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Joint stiffness			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Myalgia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
Sacroiliitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Tendon disorder			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Clostridium difficile infection			

subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	0 / 13 (0.00%)	2 / 11 (18.18%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
Ear infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Erysipelas			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Escherichia urinary tract infection			
subjects affected / exposed	2 / 13 (15.38%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	3	0	0
Furuncle			
subjects affected / exposed	2 / 13 (15.38%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	2	1	0
Gastroenteritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Oral herpes			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Pharyngitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Rash pustular			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin infection			

subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Staphylococcal skin infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Tooth infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	2 / 11 (18.18%)	2 / 12 (16.67%)
occurrences (all)	0	2	3
Urinary tract infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection bacterial			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal mycotic infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Iron deficiency			
subjects affected / exposed	0 / 13 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	MP: BMS 15 mg/kg	OL: BMS-936557	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	9 / 11 (81.82%)	50 / 84 (59.52%)	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 11 (0.00%)	3 / 84 (3.57%)	
occurrences (all)	0	4	
Fatigue			

subjects affected / exposed	0 / 11 (0.00%)	2 / 84 (2.38%)	
occurrences (all)	0	2	
Influenza like illness			
subjects affected / exposed	0 / 11 (0.00%)	1 / 84 (1.19%)	
occurrences (all)	0	1	
Infusion site extravasation			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences (all)	0	0	
Oedema peripheral			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	0 / 11 (0.00%)	6 / 84 (7.14%)	
occurrences (all)	0	10	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 11 (9.09%)	4 / 84 (4.76%)	
occurrences (all)	1	6	
Reproductive system and breast disorders			
Penis disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 11 (0.00%)	2 / 84 (2.38%)	
occurrences (all)	0	2	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	0 / 11 (0.00%)	1 / 84 (1.19%)	
occurrences (all)	0	1	
Injury, poisoning and procedural complications			
Foot fracture			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences (all)	0	0	
Infusion related reaction			

subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	3 / 84 (3.57%) 3	
Laceration subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 84 (0.00%) 0	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	4 / 84 (4.76%) 8	
Blood and lymphatic system disorders Anaemia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 84 (1.19%) 1	
Iron deficiency anaemia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 84 (0.00%) 0	
Lymphopenia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 84 (0.00%) 0	
Ear and labyrinth disorders Cerumen impaction subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 84 (0.00%) 0	
Ear pain subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 84 (1.19%) 2	
Vertigo subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 84 (1.19%) 1	
Eye disorders Episcleritis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 84 (0.00%) 0	
Gastrointestinal disorders Abdominal distension subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 84 (0.00%) 0	

Abdominal pain		
subjects affected / exposed	0 / 11 (0.00%)	5 / 84 (5.95%)
occurrences (all)	0	5
Abdominal pain upper		
subjects affected / exposed	0 / 11 (0.00%)	2 / 84 (2.38%)
occurrences (all)	0	2
Abdominal rigidity		
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0
Abdominal tenderness		
subjects affected / exposed	1 / 11 (9.09%)	1 / 84 (1.19%)
occurrences (all)	1	1
Anal fistula		
subjects affected / exposed	0 / 11 (0.00%)	3 / 84 (3.57%)
occurrences (all)	0	3
Dental caries		
subjects affected / exposed	0 / 11 (0.00%)	2 / 84 (2.38%)
occurrences (all)	0	2
Dyspepsia		
subjects affected / exposed	0 / 11 (0.00%)	6 / 84 (7.14%)
occurrences (all)	0	6
Flatulence		
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0
Gastritis		
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0
Haemorrhoids		
subjects affected / exposed	1 / 11 (9.09%)	1 / 84 (1.19%)
occurrences (all)	1	1
Nausea		
subjects affected / exposed	1 / 11 (9.09%)	7 / 84 (8.33%)
occurrences (all)	1	7
Rectal haemorrhage		
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)
occurrences (all)	0	0

Vomiting subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	5 / 84 (5.95%) 5	
Skin and subcutaneous tissue disorders			
Alopecia subjects affected / exposed occurrences (all)	1 / 11 (9.09%) 1	0 / 84 (0.00%) 0	
Dermatitis subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 84 (0.00%) 0	
Dermatitis psoriasiform subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 84 (0.00%) 0	
Eczema subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	1 / 84 (1.19%) 1	
Erythema subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 84 (0.00%) 0	
Pruritus subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	4 / 84 (4.76%) 5	
Skin lesion subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 84 (0.00%) 0	
Musculoskeletal and connective tissue disorders			
Arthralgia subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	2 / 84 (2.38%) 2	
Bone pain subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 84 (0.00%) 0	
Joint stiffness subjects affected / exposed occurrences (all)	0 / 11 (0.00%) 0	0 / 84 (0.00%) 0	
Myalgia			

subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences (all)	0	0	
Sacroiliitis			
subjects affected / exposed	0 / 11 (0.00%)	2 / 84 (2.38%)	
occurrences (all)	0	2	
Tendon disorder			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 11 (0.00%)	1 / 84 (1.19%)	
occurrences (all)	0	1	
Clostridium difficile infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences (all)	0	0	
Cystitis			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences (all)	0	0	
Ear infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 84 (1.19%)	
occurrences (all)	0	1	
Erysipelas			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences (all)	0	0	
Escherichia urinary tract infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 84 (1.19%)	
occurrences (all)	0	1	
Furuncle			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences (all)	0	0	
Gastroenteritis			
subjects affected / exposed	0 / 11 (0.00%)	2 / 84 (2.38%)	
occurrences (all)	0	2	
Influenza			
subjects affected / exposed	0 / 11 (0.00%)	3 / 84 (3.57%)	
occurrences (all)	0	6	

Nasopharyngitis			
subjects affected / exposed	0 / 11 (0.00%)	4 / 84 (4.76%)	
occurrences (all)	0	4	
Oral herpes			
subjects affected / exposed	0 / 11 (0.00%)	2 / 84 (2.38%)	
occurrences (all)	0	2	
Pharyngitis			
subjects affected / exposed	0 / 11 (0.00%)	3 / 84 (3.57%)	
occurrences (all)	0	3	
Rash pustular			
subjects affected / exposed	1 / 11 (9.09%)	1 / 84 (1.19%)	
occurrences (all)	1	1	
Skin infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 84 (0.00%)	
occurrences (all)	1	0	
Staphylococcal skin infection			
subjects affected / exposed	1 / 11 (9.09%)	0 / 84 (0.00%)	
occurrences (all)	1	0	
Tooth infection			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	4 / 11 (36.36%)	8 / 84 (9.52%)	
occurrences (all)	8	11	
Urinary tract infection			
subjects affected / exposed	0 / 11 (0.00%)	2 / 84 (2.38%)	
occurrences (all)	0	2	
Urinary tract infection bacterial			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal mycotic infection			
subjects affected / exposed	0 / 11 (0.00%)	1 / 84 (1.19%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	1 / 11 (9.09%)	0 / 84 (0.00%)	
occurrences (all)	1	0	
Iron deficiency			
subjects affected / exposed	0 / 11 (0.00%)	0 / 84 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 September 2011	The main purpose of this amendment was to permit collection and storage of blood samples for use in future exploratory pharmacogenetic research.
16 November 2011	The purpose of this amendment was to correct references given in the screening period section, update inclusion criteria and target population, delete and correct the inclusion criteria regarding women of childbearing potential; update exclusion criteria, update the method of assigning subjects; and to revise fourth secondary efficacy endpoint.
19 March 2013	The main purpose of this amendment was to add severe or serious acute infusion reaction as a reason for discontinuation of treatment and to revise the study drug infusion time.
29 May 2013	The main purpose of this amendment was to add interim analysis when approximately 2/3 of subjects are randomised and modification of the induction phase-8 dosing window from -2 to -1 day.
15 November 2013	The main purpose of this amendment was to increase percentage of biologic experienced subjects to be allowed in the study from 50% to a maximum of approximately 70%, excluding subjects who previously had inadequate response and/or intolerance to 3 more approved biologic agents, add a second year of open label in all sections as appropriate.

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 study was terminated as sponsor decided not to pursue further clinical development of BMS-936557 due to an insufficient demonstration of efficacy across studies in inflammatory bowel disease (Crohn's disease and ulcerative colitis).
--

Notes: