Clinical trial results:
A Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Phase 2 Study to Evaluate the Clinical Efficacy and Safety of BMS-986165 in Subjects With Moderate to Severe Psoriasis

Summary

EudraCT number	2016-002481-31
Trial protocol	LV
Global end of trial date	16 November 2017

Results information

Result version number	v1 (current)
This version publication date	01 December 2018
First version publication date	01 December 2018

Trial information

Trial identification

Sponsor protocol code	IM011-011

Additional study identifiers

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

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	16 November 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 November 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main study objectives were to compare the proportion of subjects with moderate to severe psoriasis in experiencing a 75% improvement as measured by reduction in Psoriasis Area and Severity Index (PASI) score after 12 weeks of treatment between doses of BMS-986165 and placebo and to assess the safety and tolerability of multiple oral doses of BMS-986165 in subjects with moderate to severe psoriasis.

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	16 November 2016
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	Germany: 32
Country: Number of subjects enrolled	Latvia: 21
Country: Number of subjects enrolled	Poland: 98
Country: Number of subjects enrolled	Canada: 39
Country: Number of subjects enrolled	United States: 37
Country: Number of subjects enrolled	Australia: 16
Country: Number of subjects enrolled	Mexico: 2
Country: Number of subjects enrolled	Japan: 22
Worldwide total number of subjects	267
EEA total number of subjects	151

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)	248
From 65 to 84 years	19
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

340 subjects were enrolled, 268 subjects were randomized in the study; One subject was randomized but did not receive study drug due to being lost to follow-up

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Placebo for BMS-986165

Arm type	Placebo
Investigational medicinal product name	BMS-986165 Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

0 mg

Arm title	BMS-986165 3MG QOD

Arm description:

BMS-986165 3mg capsules Every Other Day

Arm type	Experimental
Investigational medicinal product name	BMS-986165 3 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

3mg Every Other Day

Arm title	BMS-986165 3MG QD

Arm description:

BMS-986165 3mg capsules Every Day

Arm type	Experimental
Investigational medicinal product name	BMS-986165 3 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details: 3mg Every Day	
Arm title	BMS-986165 3MG BID
Arm description: BMS-986165 3mg capsules Twice Daily	
Arm type	Experimental
Investigational medicinal product name	BMS-986165 3 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: 3mg Twice Daily	
Arm title	BMS-986165 6MG BID
Arm description: BMS-986165 6mg capsules Twice Daily	
Arm type	Experimental
Investigational medicinal product name	BMS-986165 6 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: 6mg Twice Daily	
Arm title	BMS-986165 12MG QD
Arm description: BMS-986165 12mg capsules Every Day	
Arm type	Experimental
Investigational medicinal product name	BMS-986165 12 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details: 12 mg Every Day	

Number of subjects in period 1	Placebo	BMS-986165 3MG QOD	BMS-986165 3MG QD
Started	45	44	44
Completed	31	34	36
Not completed	14	10	8
Reason not provided by investigator	1	-	1
Subject request to discontinue treatment	4	3	3

Consent withdrawn by subject	1	2	-
Adverse event, non-fatal	2	1	2
Lost to follow-up	1	-	1
Poor/non-compliance	-	-	1
Lack of efficacy	5	4	-

Number of subjects in period 1	BMS-986165 3MG BID	BMS-986165 6MG BID	BMS-986165 12MG QD
Started	45	45	44
Completed	42	39	42
Not completed	3	6	2
Reason not provided by investigator	-	-	-
Subject request to discontinue treatment	-	1	-
Consent withdrawn by subject	1	-	-
Adverse event, non-fatal	1	3	1
Lost to follow-up	1	2	-
Poor/non-compliance	-	-	-
Lack of efficacy	-	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Placebo for BMS-986165	
Reporting group title	BMS-986165 3MG QOD
Reporting group description:	
BMS-986165 3mg capsules Every Other Day	
Reporting group title	BMS-986165 3MG QD
Reporting group description:	
BMS-986165 3mg capsules Every Day	
Reporting group title	BMS-986165 3MG BID
Reporting group description:	
BMS-986165 3mg capsules Twice Daily	
Reporting group title	BMS-986165 6MG BID
Reporting group description:	
BMS-986165 6mg capsules Twice Daily	
Reporting group title	BMS-986165 12MG QD
Reporting group description:	
BMS-986165 12mg capsules Every Day	

Reporting group values	Placebo	BMS-986165 3MG QOD	BMS-986165 3MG QD
Number of subjects	45	44	44
Age categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	43	44	40
From 65-84 years	2	0	4
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	46.4	41.0	45.0
standard deviation	± 11.93	± 11.8	± 13.77
Sex: Female, Male Units: Subjects			
Female	8	8	14
Male	37	36	30
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	5	6	5

Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	1	0
White	40	35	39
More than one race	0	0	0
Unknown or Not Reported	0	1	0

Reporting group values	BMS-986165 3MG BID	BMS-986165 6MG BID	BMS-986165 12MG QD
Number of subjects	45	45	44
Age categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	38	44	39
From 65-84 years	7	1	5
85 years and over	0	0	0
Age Continuous			
Units: Years			
arithmetic mean	45.6	42.8	46.6
standard deviation	± 15.10	± 12.90	± 11.62
Sex: Female, Male			
Units: Subjects			
Female	19	10	14
Male	26	35	30
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	1	1
Asian	5	9	6
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	1	0	0
White	39	35	37
More than one race	0	0	0
Unknown or Not Reported	0	0	0

Reporting group values	Total		
Number of subjects	267		
Age categorical			
Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	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)	248		
From 65-84 years	19		
85 years and over	0		
Age Continuous Units: Years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: Subjects			
Female	73		
Male	194		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	3		
Asian	36		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	2		
White	225		
More than one race	0		
Unknown or Not Reported	1		

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description: Placebo for BMS-986165	
Reporting group title	BMS-986165 3MG QOD
Reporting group description: BMS-986165 3mg capsules Every Other Day	
Reporting group title	BMS-986165 3MG QD
Reporting group description: BMS-986165 3mg capsules Every Day	
Reporting group title	BMS-986165 3MG BID
Reporting group description: BMS-986165 3mg capsules Twice Daily	
Reporting group title	BMS-986165 6MG BID
Reporting group description: BMS-986165 6mg capsules Twice Daily	
Reporting group title	BMS-986165 12MG QD
Reporting group description: BMS-986165 12mg capsules Every Day	

Primary: The percentage of subjects with moderate to severe psoriasis experiencing a 75% improvement (reduction from baseline) in PASI score (PASI-75 response rate) on Day 85 (Week 12)

End point title	The percentage of subjects with moderate to severe psoriasis experiencing a 75% improvement (reduction from baseline) in PASI score (PASI-75 response rate) on Day 85 (Week 12)
End point description: Psoriasis Area and Severity Index (PASI) 75 response: patients who achieved ≥ 75% improvement (reduction) in PASI score compared to baseline were defined as PASI 75 responders. PASI scores can range from 0, corresponding to no signs of psoriasis up to theoretical maximum of 72.0, which means a higher PASI score reflects a higher psoriasis activity.	
End point type	Primary
End point timeframe: Day 1 to Day 85	

End point values	Placebo	BMS-986165 3MG QOD	BMS-986165 3MG QD	BMS-986165 3MG BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	44	44	45
Units: Percentage				
number (confidence interval 95%)				
% of subjects with PASI-75 response rate on Day 85	6.7 (1.4 to 18.3)	9.1 (2.5 to 21.7)	38.6 (24.4 to 54.5)	68.9 (53.4 to 81.8)

End point values	BMS-986165 6MG BID	BMS-986165 12MG QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	44		
Units: Percentage				
number (confidence interval 95%)				
% of subjects with PASI-75 response rate on Day 85	66.7 (51.0 to 80.0)	75.0 (59.7 to 86.8)		

Statistical analyses

Statistical analysis title	P-value (Chi-Squared) BMS-986165 3MG QOD vs pbo
Comparison groups	Placebo v BMS-986165 3MG QOD
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.4873 [1]
Method	Chi-squared

Notes:

[1] - P-value is from the Fishers Exact if at least one cell count is <5. Otherwise, p-value is from the Chi-Square test.

Statistical analysis title	P-value (Chi-Squared) BMS-986165 3MG QD vs pbo
Comparison groups	Placebo v BMS-986165 3MG QD
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0003 [2]
Method	Chi-squared

Notes:

[2] - P-value is from the Fishers Exact if at least one cell count is <5. Otherwise, p-value is from the Chi-Square test.

Statistical analysis title	P-value (Chi-Squared) BMS-986165 3 MG BID vs pbo
Comparison groups	Placebo v BMS-986165 3MG BID
Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Chi-squared

Statistical analysis title	P-value (Chi-Squared) BMS-986165 6MG BID vs pbo
Comparison groups	Placebo v BMS-986165 6MG BID

Number of subjects included in analysis	90
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [3]
Method	Chi-squared

Notes:

[3] - P-value is from the Fishers Exact if at least one cell count is <5. Otherwise, p-value is from the Chi-Square test.

Statistical analysis title	P-value (Chi-Squared) BMS-986165 12MG QD vs pbo
Comparison groups	Placebo v BMS-986165 12MG QD
Number of subjects included in analysis	89
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001 [4]
Method	Chi-squared

Notes:

[4] - P-value is from the Fishers Exact if at least one cell count is <5. Otherwise, p-value is from the Chi-Square test.

Primary: Number of subjects with Adverse Events

End point title	Number of subjects with Adverse Events[5]

End point description:

The safety and tolerability of BMS-986195 as assessed by the number of subjects with adverse events (AEs); number of subjects with serious adverse events (SAEs); number of subjects with adverse events leading to discontinuation

End point type	Primary

End point timeframe:

Day 1 to day 115

Notes:

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

End point values	Placebo	BMS-986165 3MG QOD	BMS-986165 3MG QD	BMS-986165 3MG BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	44	44	45
Units: Subjects				
No. of subjects with SAEs	1	1	1	1
No. of subjects with AEs|	24	26	25	29
No. of subjects who discontinued due to AEs|	2	1	2	1

End point values	BMS-986165 6MG BID	BMS-986165 12MG QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	44		
Units: Subjects				
No. of subjects with SAEs	0	0		
No. of subjects with AEs|	36	34		

No. of subjects who discontinued due to AEs|	3	1		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects on Day 85 with PASI-50, PASI-90, PASI-100.

End point title	Percentage of subjects on Day 85 with PASI-50, PASI-90, PASI-100.

End point description:

Percentage of patients achieving Psoriasis Area and Severity Index (PASI) 50, PASI 90 and PASI 100 responses on Day 85. PASI 50 response: patients who achieved ≥ 50% improvement (reduction) in PASI score compared to baseline were defined as PASI 50 responders. PASI 90 response: patients who achieved ≥ 90% improvement (reduction) in PASI score compared to baseline were defined as PASI 90 responders. PASI 100 response: patients who achieved ≥ 100% improvement (reduction) in PASI score compared to baseline were defined as PASI 100 responders. PASI scores can range from 0, corresponding to no signs of psoriasis up to theoretical maximum of 72.0, which means a higher PASI score reflects a higher psoriasis activity.

End point type	Secondary

End point timeframe:

Day 1 to Day 85

End point values	Placebo	BMS-986165 3MG QOD	BMS-986165 3MG QD	BMS-986165 3MG BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	44	44	45
Units: Percentage				
number (confidence interval 95%)				
% of subjects with PASI-50 at Day 85|	31.1 (18.2 to 46.6)	43.2 (28.3 to 59.0)	68.2 (52.4 to 81.4)	91.1 (78.8 to 97.5)
% of subjects with PASI-90 at Day 85|	2.2 (0.1 to 11.8)	6.8 (1.4 to 18.7)	15.9 (6.6 to 30.1)	44.4 (29.6 to 60.0)
% of subjects with PASI-100 at Day 85|	0 (0.0 to 7.9)	2.3 (0.1 to 12.0)	0 (0.0 to 8.0)	8.9 (2.5 to 21.2)

End point values	BMS-986165 6MG BID	BMS-986165 12MG QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	44		
Units: Percentage				
number (confidence interval 95%)				
% of subjects with PASI-50 at Day 85|	77.8 (62.9 to 88.8)	88.6 (75.4 to 96.2)		
% of subjects with PASI-90 at Day 85|	44.4 (29.6 to 60.0)	43.2 (28.3 to 59.0)		

% of subjects with PASI-100 at Day 85|	17.8 (8.0 to 32.1)	25.0 (13.2 to 40.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of subjects on Day 85 with sPGA score of 0 or 1 (sPGA0/1 response rate).

End point title	Percentage of subjects on Day 85 with sPGA score of 0 or 1 (sPGA0/1 response rate).

End point description:

Percentage of subjects achieving a clear (0) or almost clear (1) status on the Static Physician Global Assessment (sPGA) on Day 85. This index evaluates the physician's global assessment of the participant's psoriasis based on severity of induration, scaling, and erythema. The assessment was scored on a scale of 0 to 5, where 0 = clear, with no evidence of plaque elevation, erythema, or scale, and 5 = severe induration, erythema, and scaling.

End point type	Secondary

End point timeframe:

Day 1 to Day 85

End point values	Placebo	BMS-986165 3MG QOD	BMS-986165 3MG QD	BMS-986165 3MG BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	45	44	44	45
Units: Percentage				
number (confidence interval 95%)				
% of subjects on Day 85 with sPGA 0/1 response	6.7 (1.4 to 18.3)	20.5 (9.8 to 35.3)	38.6 (24.4 to 54.5)	75.6 (60.5 to 87.1)

End point values	BMS-986165 6MG BID	BMS-986165 12MG QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	45	44		
Units: Percentage				
number (confidence interval 95%)				
% of subjects on Day 85 with sPGA 0/1 response	64.4 (48.8 to 78.1)	75.0 (59.7 to 86.8)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in DLQI scores on Day 85

End point title	Change from baseline in DLQI scores on Day 85

End point description:

The DLQI is a subject reported quality of life index which consists of 10 questions concerning symptoms and feelings, daily activities, leisure, work, school, personal relationships, and treatment during the last week. Each question is scored on a scale of 0 to 3 by a tick box: "not at all", "a little", "a lot", or "very much". The scores are summed, giving a range from 0 (no impairment of life quality) to 30 (maximum impairment)

End point type	Secondary

End point timeframe:

Day 1 to Day 85

End point values	Placebo	BMS-986165 3MG QOD	BMS-986165 3MG QD	BMS-986165 3MG BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	38	41	43
Units: Score				
arithmetic mean (confidence interval 95%)				
Change from baseline in DLQI scores on Day 85	-2.85 (-4.33 to -1.37)	-3.76 (-5.15 to -2.38)	-6.07 (-8.07 to -4.08)	-9.67 (-11.42 to -7.93)

End point values	BMS-986165 6MG BID	BMS-986165 12MG QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	43		
Units: Score				
arithmetic mean (confidence interval 95%)				
Change from baseline in DLQI scores on Day 85	-8.38 (-10.72 to -6.03)	-10.16 (-12.27 to -8.06)		

Statistical analyses

No statistical analyses for this end point

Secondary: Change from baseline in BSA on Day 85

End point title	Change from baseline in BSA on Day 85

End point description:

Measurement of psoriasis body surface area (BSA) involvement is estimated using the handprint method with the size of a patient’s handprint representing ~1% of body surface area involved.The total BSA = 100% with breakdown by body region as follows: head and neck = 10% (10 handprints), upper extremities = 20% (20 handprints), trunk including axillae and groin = 30% (30 handprints), lower extremities including buttocks = 40% (40 handprints). A decrease from Baseline indicates improvement. Change from Baseline was calculated as Baseline score - Day 85 score; a positive change from Baseline therefore indicates improvement.

End point type	Secondary

End point timeframe:

Day 1 to Day 85

End point values	Placebo	BMS-986165 3MG QOD	BMS-986165 3MG QD	BMS-986165 3MG BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	34	38	41	43
Units: Percentage				
arithmetic mean (confidence interval 95%)				
Change from baseline in BSA on Day 85	-7.71 (-11.88 to -3.54)	-5.50 (-8.17 to -2.83)	-12.59 (-18.28 to -6.89)	-18.60 (-23.69 to -13.52)

End point values	BMS-986165 6MG BID	BMS-986165 12MG QD		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	40	43		
Units: Percentage				
arithmetic mean (confidence interval 95%)				
Change from baseline in BSA on Day 85	-17.23 (-20.85 to -13.60)	-15.16 (-18.64 to -11.69)		

Statistical analyses

No statistical analyses for this end point

Secondary: Trough observed plasma concentration of BMS-986165 (Ctrough)

End point title	Trough observed plasma concentration of BMS-986165 (Ctrough)[6]

End point description:

Pharmacokinetics of BMS-986165 were derived from plasma concentration versus time data. Ctrough= Trough observed plasma concentration

End point type	Secondary

End point timeframe:

Days 8, 15, 29, 57, 85

Notes:

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

End point values	BMS-986165 3MG QOD	BMS-986165 3MG QD	BMS-986165 3MG BID	BMS-986165 6MG BID
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	44	44	44	45
Units: ng/mL				
arithmetic mean (standard deviation)				
Ctrough of BMS-986165	2.024 (± 3.7061)	3.145 (± 3.1588)	14.819 (± 9.1410)	26.257 (± 14.6483)

End point values	BMS-986165 12MG QD			
Subject group type	Reporting group			
Number of subjects analysed	44			
Units: ng/mL				
arithmetic mean (standard deviation)				
Ctrough of BMS-986165	17.824 (± 22.7536)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: First dose of study therapy and within 30 days of the last dose.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups	
Reporting group title	Placebo
Reporting group description: Subjects received placebo capsules orally for 12 weeks.	
Reporting group title	BMS 3 mg QOD
Reporting group description: Subjects received BMS-986165 3 milligram (mg) capsules orally once every other day (QOD) for 12 weeks.	
Reporting group title	BMS 3 mg QD
Reporting group description: Subjects received BMS-986165 3 mg capsules orally once daily (QD) for 12 weeks.	
Reporting group title	BMS 3 mg BID
Reporting group description: Subjects received BMS-986165 3 mg capsules orally twice daily (BID) for 12 weeks.	
Reporting group title	BMS 6 mg BID
Reporting group description: Subjects received BMS-986165 6 mg capsules orally BID for 12 weeks.	
Reporting group title	BMS 12 mg QD
Reporting group description: Subjects received BMS-986165 12 mg capsules orally QD for 12 weeks.	

Serious adverse events	Placebo	BMS 3 mg QOD	BMS 3 mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 45 (2.22%)	1 / 44 (2.27%)	1 / 44 (2.27%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Eye injury			
subjects affected / exposed	0 / 45 (0.00%)	0 / 44 (0.00%)	1 / 44 (2.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Dizziness			

subjects affected / exposed	0 / 45 (0.00%)	0 / 44 (0.00%)	0 / 44 (0.00%)
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			
Haemorrhagic anaemia			
subjects affected / exposed	1 / 45 (2.22%)	0 / 44 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Haemorrhoidal haemorrhage			
subjects affected / exposed	1 / 45 (2.22%)	0 / 44 (0.00%)	0 / 44 (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
Infections and infestations			
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 45 (0.00%)	1 / 44 (2.27%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	BMS 3 mg BID	BMS 6 mg BID	BMS 12 mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 45 (2.22%)	0 / 45 (0.00%)	0 / 44 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Eye injury			
subjects affected / exposed	0 / 45 (0.00%)	0 / 45 (0.00%)	0 / 44 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Dizziness			
subjects affected / exposed	1 / 45 (2.22%)	0 / 45 (0.00%)	0 / 44 (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
Blood and lymphatic system disorders			

Haemorrhagic anaemia			
subjects affected / exposed	0 / 45 (0.00%)	0 / 45 (0.00%)	0 / 44 (0.00%)
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			
Haemorrhoidal haemorrhage			
subjects affected / exposed	0 / 45 (0.00%)	0 / 45 (0.00%)	0 / 44 (0.00%)
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			
Gastroenteritis rotavirus			
subjects affected / exposed	0 / 45 (0.00%)	0 / 45 (0.00%)	0 / 44 (0.00%)
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	Placebo	BMS 3 mg QOD	BMS 3 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	12 / 45 (26.67%)	14 / 44 (31.82%)	18 / 44 (40.91%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 45 (2.22%)	0 / 44 (0.00%)	1 / 44 (2.27%)
occurrences (all)	1	0	1
Blood immunoglobulin E increased			
subjects affected / exposed	1 / 45 (2.22%)	3 / 44 (6.82%)	2 / 44 (4.55%)
occurrences (all)	1	3	2
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 45 (4.44%)	4 / 44 (9.09%)	4 / 44 (9.09%)
occurrences (all)	2	4	5
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 45 (0.00%)	0 / 44 (0.00%)	0 / 44 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			

subjects affected / exposed	2 / 45 (4.44%)	1 / 44 (2.27%)	1 / 44 (2.27%)
occurrences (all)	2	2	1
Nausea			
subjects affected / exposed	2 / 45 (4.44%)	4 / 44 (9.09%)	0 / 44 (0.00%)
occurrences (all)	2	4	0
Toothache			
subjects affected / exposed	1 / 45 (2.22%)	1 / 44 (2.27%)	1 / 44 (2.27%)
occurrences (all)	1	1	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	0 / 45 (0.00%)	1 / 44 (2.27%)	0 / 44 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	2 / 45 (4.44%)	0 / 44 (0.00%)	1 / 44 (2.27%)
occurrences (all)	2	0	1
Psoriasis			
subjects affected / exposed	2 / 45 (4.44%)	1 / 44 (2.27%)	3 / 44 (6.82%)
occurrences (all)	2	1	3
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	2 / 45 (4.44%)	1 / 44 (2.27%)	5 / 44 (11.36%)
occurrences (all)	2	1	6
Upper respiratory tract infection			
subjects affected / exposed	0 / 45 (0.00%)	2 / 44 (4.55%)	3 / 44 (6.82%)
occurrences (all)	0	2	3

Non-serious adverse events	BMS 3 mg BID	BMS 6 mg BID	BMS 12 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	15 / 45 (33.33%)	25 / 45 (55.56%)	18 / 44 (40.91%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 45 (0.00%)	3 / 45 (6.67%)	5 / 44 (11.36%)
occurrences (all)	0	3	6
Blood immunoglobulin E increased			
subjects affected / exposed	0 / 45 (0.00%)	2 / 45 (4.44%)	2 / 44 (4.55%)
occurrences (all)	0	2	2
Nervous system disorders			

Headache			
subjects affected / exposed	3 / 45 (6.67%)	3 / 45 (6.67%)	2 / 44 (4.55%)
occurrences (all)	3	3	2
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	3 / 45 (6.67%)	0 / 45 (0.00%)	1 / 44 (2.27%)
occurrences (all)	3	0	1
Diarrhoea			
subjects affected / exposed	2 / 45 (4.44%)	2 / 45 (4.44%)	4 / 44 (9.09%)
occurrences (all)	3	2	5
Nausea			
subjects affected / exposed	1 / 45 (2.22%)	1 / 45 (2.22%)	2 / 44 (4.55%)
occurrences (all)	1	1	2
Toothache			
subjects affected / exposed	1 / 45 (2.22%)	3 / 45 (6.67%)	1 / 44 (2.27%)
occurrences (all)	1	3	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 45 (2.22%)	2 / 45 (4.44%)	4 / 44 (9.09%)
occurrences (all)	1	2	4
Pruritus			
subjects affected / exposed	1 / 45 (2.22%)	3 / 45 (6.67%)	2 / 44 (4.55%)
occurrences (all)	1	3	2
Psoriasis			
subjects affected / exposed	2 / 45 (4.44%)	0 / 45 (0.00%)	0 / 44 (0.00%)
occurrences (all)	2	0	0
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	5 / 45 (11.11%)	7 / 45 (15.56%)	3 / 44 (6.82%)
occurrences (all)	6	8	3
Upper respiratory tract infection			
subjects affected / exposed	1 / 45 (2.22%)	4 / 45 (8.89%)	1 / 44 (2.27%)
occurrences (all)	2	4	1

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

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 limitations of this phase 2 trial include its small sample size and short duration; these results warrant confirmation in a larger trial of longer duration

Notes: