Clinical trial results:
A Multi-Center, Randomized, Double-Blind, Placebo- and Active Comparator-Controlled Phase 3 Study to Evaluate the Clinical Efficacy and Safety of BMS-986165 in Subjects with Moderate to Severe Psoriasis

Summary

EudraCT number	2018-001926-25
Trial protocol	GB FR ES DE PL Outside EU/EEA
Global end of trial date	02 September 2020

Results information

Result version number	v1 (current)
This version publication date	22 October 2022
First version publication date	22 October 2022

Trial information

Trial identification

Sponsor protocol code	IM011-046

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	15 October 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	02 September 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Investigate Efficacy and Safety of BMS-986165 versus Placebo and Active Comparator in Subjects with 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 participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	07 August 2018
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	Canada: 62
Country: Number of subjects enrolled	China: 6
Country: Number of subjects enrolled	Germany: 2
Country: Number of subjects enrolled	Japan: 66
Country: Number of subjects enrolled	Poland: 182
Country: Number of subjects enrolled	Russian Federation: 69
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 26
Country: Number of subjects enrolled	Spain: 8
Country: Number of subjects enrolled	Taiwan: 8
Country: Number of subjects enrolled	United Kingdom: 19
Country: Number of subjects enrolled	United States: 218
Worldwide total number of subjects	666
EEA total number of subjects	192

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37	0

wk	
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)	605
From 65 to 84 years	61
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

666 participants randomized and 665 treated

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	BMS-986165

Arm description:

BMS-986165 6 mg daily (QD) week 0 - week 52. At week 16, participants were switched in blinded manner from placebo. At week 24, participants who did not achieve PASI 50 were switched in a blinded manner from Apremilast

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

Dosage and administration details:

6 mg daily

Arm title	Placebo

Arm description:

Participants received placebo week 0 - week 16 and then switched in a blinded manner to BMS-986165 6 mg daily (QD) through week 52

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Twice a day

Arm title	Apremilast

Arm description:

Apremilast titrated from 10 mg daily (QD) to 30 mg twice a day (BID) over the first 5 days of dosing, continuing through week 24. At week 24, participants who achieved Psoriasis Area and Severity Index (PASI) 50 continued with regimen in a blinded manner and participants who did not achieve PASI 50 were switched in a blinded manner to BMS-986165 6 mg QD through week 52

Arm type	Active comparator

Investigational medicinal product name	Apremilast
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg used for titration day 1 through day 3 morning dose. 20 mg used for titration day 3 through day 5 morning dose. 30 mg from day 5 evening dose onwards.

Number of subjects in period 1	BMS-986165	Placebo	Apremilast
Started	332	166	168
Completed	332	165	168
Not completed	0	1	0
d/c study due to incorrect randomization	-	1	-

Period 2

Period 2 title	Treatment Week 0 - Week 16
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	BMS-986165

Arm description:

BMS-986165 6 mg daily (QD) week 0 - week 52. At week 16, participants were switched in blinded manner from placebo. At week 24, participants who did not achieve PASI 50 were switched in a blinded manner from Apremilast

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

Dosage and administration details:

6 mg daily

Arm title	Placebo

Arm description:

Participants received placebo week 0 - week 16 and then switched in a blinded manner to BMS-986165 6 mg daily (QD) through week 52

Arm type	Placebo

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Twice a day

Arm title	Apremilast

Arm description:

Apremilast titrated from 10 mg daily (QD) to 30 mg twice a day (BID) over the first 5 days of dosing, continuing through week 24. At week 24, participants who achieved Psoriasis Area and Severity Index (PASI) 50 continued with regimen in a blinded manner and participants who did not achieve PASI 50 were switched in a blinded manner to BMS-986165 6 mg QD through week 52

Arm type	Active comparator
Investigational medicinal product name	Apremilast
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg used for titration day 1 through day 3 morning dose. 20 mg used for titration day 3 through day 5 morning dose. 30 mg from day 5 evening dose onwards.

Number of subjects in period 2	BMS-986165	Placebo	Apremilast
Started	332	165	168
Completed	307	145	145
Not completed	25	20	23
Adverse event, serious fatal	-	1	-
Consent withdrawn by subject	4	3	3
Adverse event, non-fatal	5	7	10
Other reasons	8	5	3
Lost to follow-up	7	2	4
Protocol deviation	1	1	2
Lack of efficacy	-	1	1

Period 3

Period 3 title	Treatment Week 16 - Week 24
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	BMS-986165

Arm description:

BMS-986165 6 mg daily (QD) week 0 - week 52. At week 16, participants were switched in blinded manner from placebo. At week 24, participants who did not achieve PASI 50 were switched in a blinded manner from Apremilast

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

Dosage and administration details:

6 mg daily

Arm title	Apremilast

Arm description:

Apremilast titrated from 10 mg daily (QD) to 30 mg twice a day (BID) over the first 5 days of dosing, continuing through week 24. At week 24, participants who achieved Psoriasis Area and Severity Index (PASI) 50 continued with regimen in a blinded manner and participants who did not achieve PASI 50 were switched in a blinded manner to BMS-986165 6 mg QD through week 52

Arm type	Active comparator
Investigational medicinal product name	Apremilast
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg used for titration day 1 through day 3 morning dose. 20 mg used for titration day 3 through day 5 morning dose. 30 mg from day 5 evening dose onwards.

Number of subjects in period 3	BMS-986165	Apremilast
Started	452	145
Completed	442	141
Not completed	10	4
Consent withdrawn by subject	2	1
Adverse event, non-fatal	1	1
Other reasons	3	-
Lost to follow-up	-	2
Lack of efficacy	3	-
Protocol deviation	1	-

Period 4

Period 4 title	Treatment Week 24 - Week 52
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer

Arms

Are arms mutually exclusive?	Yes
Arm title	BMS-986165

Arm description:

BMS-986165 6 mg daily (QD) week 0 - week 52. At week 16, participants were switched in blinded manner from placebo. At week 24, participants who did not achieve PASI 50 were switched in a blinded manner from Apremilast

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

Dosage and administration details:

6 mg daily

Arm title	Apremilast

Arm description:

Apremilast titrated from 10 mg daily (QD) to 30 mg twice a day (BID) over the first 5 days of dosing, continuing through week 24. At week 24, participants who achieved Psoriasis Area and Severity Index (PASI) 50 continued with regimen in a blinded manner and participants who did not achieve PASI 50 were switched in a blinded manner to BMS-986165 6 mg QD through week 52

Arm type	Active comparator
Investigational medicinal product name	Apremilast
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

10 mg used for titration day 1 through day 3 morning dose. 20 mg used for titration day 3 through day 5 morning dose. 30 mg from day 5 evening dose onwards.

Number of subjects in period 4	BMS-986165	Apremilast
Started	496	87
Completed	444	83
Not completed	52	4
Consent withdrawn by subject	10	-
Adverse event, non-fatal	8	1
Site terminated by sponsor	2	-
Other reasons	19	2
Lost to follow-up	5	1

Lack of efficacy	6	-
Protocol deviation	2	-

Baseline characteristics

Reporting groups	
Reporting group title	BMS-986165
Reporting group description:	
BMS-986165 6 mg daily (QD) week 0 - week 52. At week 16, participants were switched in blinded manner from placebo. At week 24, participants who did not achieve PASI 50 were switched in a blinded manner from Apremilast	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo week 0 - week 16 and then switched in a blinded manner to BMS-986165 6 mg daily (QD) through week 52	
Reporting group title	Apremilast
Reporting group description:	
Apremilast titrated from 10 mg daily (QD) to 30 mg twice a day (BID) over the first 5 days of dosing, continuing through week 24. At week 24, participants who achieved Psoriasis Area and Severity Index (PASI) 50 continued with regimen in a blinded manner and participants who did not achieve PASI 50 were switched in a blinded manner to BMS-986165 6 mg QD through week 52	

Reporting group values	BMS-986165	Placebo	Apremilast
Number of subjects	332	166	168
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)	306	141	158
From 65-84 years	26	25	10
85 years and over	0	0	0
Age Continuous Units: Years			
arithmetic mean	45.9	47.9	44.7
standard deviation	± 13.71	± 13.98	± 12.06
Sex: Female, Male Units: Participants			
Female	102	53	58
Male	230	113	110
Race/Ethnicity, Customized Units: Subjects			
White	267	128	139
Black or African American	2	3	1
Asian	59	34	28
American Indian or Alaska Native	0	0	0
Native Hawaiian or other Pacific Islander	0	0	0
Other	4	1	0
Ethnicity (NIH/OMB)			

Units: Subjects			
Hispanic or Latino	50	26	30
Not Hispanic or Latino	282	140	138
Unknown or Not Reported	0	0	0

Reporting group values	Total		
Number of subjects	666		
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)	605		
From 65-84 years	61		
85 years and over	0		
Age Continuous Units: Years			
arithmetic mean			
standard deviation	-		
Sex: Female, Male Units: Participants			
Female	213		
Male	453		
Race/Ethnicity, Customized Units: Subjects			
White	534		
Black or African American	6		
Asian	121		
American Indian or Alaska Native	0		
Native Hawaiian or other Pacific Islander	0		
Other	5		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	106		
Not Hispanic or Latino	560		
Unknown or Not Reported	0		

End points

End points reporting groups

Reporting group title	BMS-986165
Reporting group description:	
BMS-986165 6 mg daily (QD) week 0 - week 52. At week 16, participants were switched in blinded manner from placebo. At week 24, participants who did not achieve PASI 50 were switched in a blinded manner from Apremilast	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo week 0 - week 16 and then switched in a blinded manner to BMS-986165 6 mg daily (QD) through week 52	
Reporting group title	Apremilast
Reporting group description:	
Apremilast titrated from 10 mg daily (QD) to 30 mg twice a day (BID) over the first 5 days of dosing, continuing through week 24. At week 24, participants who achieved Psoriasis Area and Severity Index (PASI) 50 continued with regimen in a blinded manner and participants who did not achieve PASI 50 were switched in a blinded manner to BMS-986165 6 mg QD through week 52	
Reporting group title	BMS-986165
Reporting group description:	
BMS-986165 6 mg daily (QD) week 0 - week 52. At week 16, participants were switched in blinded manner from placebo. At week 24, participants who did not achieve PASI 50 were switched in a blinded manner from Apremilast	
Reporting group title	Placebo
Reporting group description:	
Participants received placebo week 0 - week 16 and then switched in a blinded manner to BMS-986165 6 mg daily (QD) through week 52	
Reporting group title	Apremilast
Reporting group description:	
Apremilast titrated from 10 mg daily (QD) to 30 mg twice a day (BID) over the first 5 days of dosing, continuing through week 24. At week 24, participants who achieved Psoriasis Area and Severity Index (PASI) 50 continued with regimen in a blinded manner and participants who did not achieve PASI 50 were switched in a blinded manner to BMS-986165 6 mg QD through week 52	
Reporting group title	BMS-986165
Reporting group description:	
BMS-986165 6 mg daily (QD) week 0 - week 52. At week 16, participants were switched in blinded manner from placebo. At week 24, participants who did not achieve PASI 50 were switched in a blinded manner from Apremilast	
Reporting group title	Apremilast
Reporting group description:	
Apremilast titrated from 10 mg daily (QD) to 30 mg twice a day (BID) over the first 5 days of dosing, continuing through week 24. At week 24, participants who achieved Psoriasis Area and Severity Index (PASI) 50 continued with regimen in a blinded manner and participants who did not achieve PASI 50 were switched in a blinded manner to BMS-986165 6 mg QD through week 52	
Reporting group title	BMS-986165
Reporting group description:	
BMS-986165 6 mg daily (QD) week 0 - week 52. At week 16, participants were switched in blinded manner from placebo. At week 24, participants who did not achieve PASI 50 were switched in a blinded manner from Apremilast	
Reporting group title	Apremilast
Reporting group description:	
Apremilast titrated from 10 mg daily (QD) to 30 mg twice a day (BID) over the first 5 days of dosing, continuing through week 24. At week 24, participants who achieved Psoriasis Area and Severity Index (PASI) 50 continued with regimen in a blinded manner and participants who did not achieve PASI 50 were switched in a blinded manner to BMS-986165 6 mg QD through week 52	

Primary: The Number of Participants with a static Physician's Global Assessment (sPGA) score of 0 or 1 in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (sPGA 0/1)

End point title	The Number of Participants with a static Physician's Global Assessment (sPGA) score of 0 or 1 in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (sPGA 0/1)[1]

End point description:

The sPGA is a 5-point scale of an average assessment of all psoriatic lesions based on erythema, scale, and induration. The average of the 3 scales, which is rounded to the nearest whole number, is the final sPGA score. The higher sPGA score denotes to more severe disease activity (0 = Clear; 1 = Almost clear; 2 = Mild; 3 = Moderate; Severe = 4). sPGA 0/1 is the response as a number of participants who experience a sPGA score that determines psoriasis severity as 0 or 1 with at least 2-point improvement from baseline using the non-responder imputation (NRI) method that will be used for participants who discontinue treatment or study prior to week 16 or who have missing week 16 endpoint data for any reason.

End point type	Primary

End point timeframe:

Week 16

Notes:

[1] - 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 pre-specified arms planned for this end point.

End point values	BMS-986165	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332	166		
Units: Participants	178	12		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	498
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	18.71
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.51
upper limit	36.81

Primary: The Number of Participants who Achieve a 75% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants

Receiving BMS-986165 Compared to Placebo at Week 16 (PASI 75)

End point title	The Number of Participants who Achieve a 75% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (PASI 75)[2]

End point description:

PASI is a measure of the average redness, thickness, and scaliness of psoriatic skin lesions (each graded on a 0 to 4 scale; 0 = none to 4 = very severe), weighted by the area of involvement (head, upper extremities, trunk, and lower extremities). The PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. PASI 75 is the response as a number of participants who experience at least a 75% improvement in PASI score as compared with the baseline value using the non-responder imputation (NRI) method that will be used for participants who discontinue treatment or study prior to week 16 or who have missing week 16 endpoint data for any reason.

Baseline is defined as the measurement at the randomization visit (Week 0).

End point type	Primary

End point timeframe:

Baseline and Week 16

Notes:

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

End point values	BMS-986165	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332	166		
Units: Participants	194	21		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	498
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	11.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.49
upper limit	18.95

Secondary: Psoriasis Symptoms and Signs Diary (PSSD) Symptom Score 0 at Week 16

End point title	Psoriasis Symptoms and Signs Diary (PSSD) Symptom Score 0 at Week 16

End point description:

PSSD with a 24-hour recall period is an 11-item participant-reported instrument that assesses severity of symptoms and participant-observed signs commonly associated in plaque psoriasis. PSSD assesses severity of 5 symptoms (itch, pain, stinging, burning, skin tightness) and 6 participants-observed signs (skin dryness, cracking, scaling, shedding or flaking, redness, bleeding) using 0-10 numerical ratings. The severity of each item is rated on an 11-point numeric rating scale ranging from 0 (absent) to 10 (worst imaginable). PSSD 0 is the response as a number of participants who experience a PSSD symptom score that is derived from the average of the scores and determines psoriasis severity as 0 among participants with a baseline PSSD symptom score >= 1.

End point type	Secondary

End point timeframe:

Week 16

End point values	BMS-986165	Placebo	Apremilast	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	305	149	158	
Units: Participants	24	1	7	

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	454
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0013
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	13.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.77
upper limit	105.5

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	463
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1702
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.84

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.76
upper limit	4.42

Secondary: The Number of Participants who Achieve a 90% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score at Week 16 (PASI 90)

End point title	The Number of Participants who Achieve a 90% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score at Week 16 (PASI 90)

End point description:

PASI is a measure of the average redness, thickness, and scaliness of psoriatic skin lesions (each graded on a 0 to 4 scale; 0 = none to 4 = very severe), weighted by the area of involvement (head, upper extremities, trunk, and lower extremities). The PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. PASI 90 is the response as a number of participants who experience at least a 90% improvement in PASI score as compared with the baseline value using the non-responder imputation (NRI) method that will be used for participants who discontinue treatment or study prior to week 16 or who have missing week 16 endpoint data for any reason.

Baseline is defined as the measurement at the randomization visit (Week 0).

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	BMS-986165	Placebo	Apremilast	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	332	166	168	
Units: Participants	118	7	33	

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	500
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0002
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.4

Confidence interval	
level	95 %
sides	2-sided
lower limit	1.51
upper limit	3.6

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	498
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	16.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.91
upper limit	37.72

Secondary: The Number of Participants with a static Physician's Global Assessment Score of 0 at Week 16 (sPGA 0)

End point title	The Number of Participants with a static Physician's Global Assessment Score of 0 at Week 16 (sPGA 0)

End point description:

The sPGA is a 5-point scale of an average assessment of all psoriatic lesions based on erythema, scale, and induration. The average of the 3 scales, which is rounded to the nearest whole number, is the final sPGA score. The higher sPGA score denotes to more severe disease activity (0 = Clear; 1 = Almost clear; 2 = Mild; 3 = Moderate; 4 = Severe). sPGA 0 is the response as a number of participants who experience a sPGA score that determines psoriasis severity as 0 using the non-responder imputation (NRI) method that will be used for participants who discontinue treatment or study prior to week 16 or who have missing week 16 endpoint data for any reason.

End point type	Secondary

End point timeframe:

Week 16

End point values	BMS-986165	Placebo	Apremilast	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	332	166	168	
Units: Participants	58	1	8	

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	498
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	39.54
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.29
upper limit	295.75

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	500
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	4.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.07
upper limit	9.84

Secondary: The Number of Participants who Achieve a 100% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (PASI 100)

End point title	The Number of Participants who Achieve a 100% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (PASI 100)[3]

End point description:

PASI is a measure of the average redness, thickness, and scaliness of psoriatic skin lesions (each graded on a 0 to 4 scale; 0 = none to 4 = very severe), weighted by the area of involvement (head, upper extremities, trunk, and lower extremities). The PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. PASI 100 is the response as a number of participants who experience at least a 100% improvement in PASI score as compared with the baseline value using the non-responder imputation (NRI) method that will be used for participants who discontinue treatment or study prior to week 16 or who have missing week 16 endpoint data for any reason.

Baseline is defined as the measurement at the randomization visit (Week 0).

End point type	Secondary

End point timeframe:

Baseline and Week 16

Notes:

[3] - 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 pre-specified arms planned for this end point.

End point values	BMS-986165	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332	166		
Units: Participants	47	1		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	498
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	31.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.09
upper limit	239.36

Secondary: Change from Baseline in Psoriasis Symptoms and Signs Diary (PSSD) Symptom Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 16

End point title	Change from Baseline in Psoriasis Symptoms and Signs Diary (PSSD) Symptom Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 16[4]

End point description:

Change from baseline in PSSD score. PSSD with a 24-hour recall period is an 11-item participant-reported instrument that assesses severity of symptoms and participant-observed signs commonly associated in plaque psoriasis. PSSD assesses severity of 5 symptoms (itch, pain, stinging, burning, skin tightness) and 6 participants-observed signs (skin dryness, cracking, scaling, shedding or flaking, redness, bleeding) using 0-10 numerical ratings. PSSD symptom score is derived from the average of the scores. The severity of each item is rated on an 11-point numeric rating scale ranging from 0 (absent) to 10 (worst imaginable). A modified observation carried forward (mBOCF) approach will be used for missing data. the baseline observation will be carried forward for participants who discontinue study treatment for all analysis weeks after the assessment time point of discontinuation due to lack of efficacy and AEs.

Baseline is defined as the measurement at the randomization visit (Week 0).

End point type	Secondary

End point timeframe:

Baseline and Week 16

Notes:

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

End point values	BMS-986165	Apremilast		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	306	158		
Units: Score on a scale				
arithmetic mean (standard deviation)	-29.4 (± 24.43)	-22.8 (± 23.40)		

Statistical analyses

Statistical analysis title	Adjusted Mean Difference
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	464
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Adjusted Mean Difference
Point estimate	-8.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.8
upper limit	-4.9
Variability estimate	Standard error of the mean
Dispersion value	2

Secondary: The Number of Participants with a Dermatology Life Quality Index (DLQI) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (DLQI 0/1)

End point title	The Number of Participants with a Dermatology Life Quality Index (DLQI) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (DLQI 0/1)[5]

End point description:

DLQI is a participant-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 before questionnaire. Each question is scored on a scale of 0 to 3 by a tick box (0 = "not at all"; 1 = "a little"; 2 = "a lot"; or 3 = "very much"). The scores are summed, giving a range from 0 (no impairment of life quality) to 30 (maximum impairment). DLQI 0/1 is the response as a number of participants who experience DLQI score of 0 or 1 among participants with a baseline DLQI score >=2.

End point type	Secondary

End point timeframe:

Week 16

Notes:

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

End point values	BMS-986165	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	322	160		
Units: Participants	132	17		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	482
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	6.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.46
upper limit	10.53

Secondary: Number of Participants with a Physician's Global Assessment-Fingernails (PGA-F) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Placebo at Week 16

End point title	Number of Participants with a Physician's Global Assessment-Fingernails (PGA-F) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Placebo at Week 16[6]

End point description:

PGA-F overall condition of the fingernails is rated on a 5-point scale (0 = clear; 1 = minimal; 2 = mild; 3 = moderate; and 4 = severe). PGA-F 0/1 is the response as a number of participants with a PGA-F score of 0 or 1 with at least a 2-point improvement from baseline among participants with a baseline PGA-F score >=3.

End point type	Secondary

End point timeframe:

Week 16

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 pre-specified arms planned for this end point.

End point values	BMS-986165	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	43	34		
Units: Participants	9	3		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	77
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1049
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	10.96

Secondary: The Number of Participants who Achieve a 75% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 16 (PASI 75)

End point title	The Number of Participants who Achieve a 75% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 16 (PASI 75)[7]

End point description:

PASI is a measure of the average redness, thickness, and scaliness of psoriatic skin lesions (each graded on a 0 to 4 scale; 0 = none to 4 = very severe), weighted by the area of involvement (head, upper extremities, trunk, and lower extremities). The PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. PASI 75 is the response as a number of participants who experience at least a 75% improvement in PASI score as compared with the baseline value using the non-responder imputation (NRI) method that will be used for participants who discontinue treatment or study prior to week 16 or who have missing week 16 endpoint data for any reason.

Baseline is defined as the measurement at the randomization visit (Week 0).

End point type	Secondary

End point timeframe:

Baseline and Week 16

Notes:

[7] - 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 pre-specified arms planned for this end point.

End point values	BMS-986165	Apremilast		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332	168		
Units: Participants	194	59		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	500
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.78
upper limit	3.91

Secondary: The Number of Participants with a Scalp Specific Physician's Global Assessment (ss-PGA) Score 0 or 1 at Week 16 (ss-PGA 0/1)

End point title	The Number of Participants with a Scalp Specific Physician's Global Assessment (ss-PGA) Score 0 or 1 at Week 16 (ss-PGA 0/1)

End point description:

ss-PGA is a 5-point scale that evaluates scalp lesions in terms of clinical signs of redness, thickness, and scaliness. The higher ss-PGA score denotes to more severe disease activity (0 = absence of disease; 1 = very mild disease; 2 = mild disease; 3 = moderate disease; 4 = severe disease). ss-PGA 0/1 is the response as a number of participants who experience a ss-PGA score that determines scalp lesions severity as 0 or 1 with at least a 2-point improvement from baseline among participants with a baseline ss-PGA score >=3.

End point type	Secondary

End point timeframe:

Week 16

End point values	BMS-986165	Placebo	Apremilast	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	209	121	110	
Units: Participants	147	21	43	

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	319
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	3.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.21
upper limit	6.04

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	330
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	11.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.69
upper limit	21.25

Secondary: The Number of Participants with a static Physician's Global Assessment (sPGA) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Apremilast at Week 16 (sPGA 0/1)

End point title	The Number of Participants with a static Physician's Global Assessment (sPGA) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Apremilast at Week 16 (sPGA 0/1)[8]

End point description:

The sPGA is a 5-point scale of an average assessment of all psoriatic lesions based on erythema, scale, and induration. The average of the 3 scales, which is rounded to the nearest whole number, is the final sPGA score. The higher sPGA score denotes to more severe disease activity (0 = Clear; 1 = Almost clear; 2 = Mild; 3 = Moderate; Severe = 4). sPGA 0/1 is the response as a number of participants who experience a sPGA score that determines psoriasis severity as 0 or 1 with at least 2-point improvement from baseline using the non-responder imputation (NRI) method that will be used for participants who discontinue treatment or study prior to week 16 or who have missing week 16 endpoint data for any reason.

End point type	Secondary

End point timeframe:

Week 16

Notes:

[8] - 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 pre-specified arms planned for this end point.

End point values	BMS-986165	Apremilast		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332	168		
Units: Participants	178	54		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	500
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.53
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.7
upper limit	3.78

Secondary: The Number of Participants with a static Physician's Global Assessment (sPGA) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Apremilast at Week 24 (sPGA 0/1)

End point title	The Number of Participants with a static Physician's Global Assessment (sPGA) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Apremilast at Week 24 (sPGA 0/1)[9]

End point description:

The sPGA is a 5-point scale of an average assessment of all psoriatic lesions based on erythema, scale, and induration. The average of the 3 scales, which is rounded to the nearest whole number, is the final sPGA score. The higher sPGA score denotes to more severe disease activity (0 = Clear; 1 = Almost clear; 2 = Mild; 3 = Moderate; Severe = 4). sPGA 0/1 is the response as a number of participants who experience a sPGA score that determines psoriasis severity as 0 or 1 with at least 2-point improvement from baseline using the non-responder imputation (NRI) method that will be used for participants who discontinue treatment or study prior to week 24 or who have missing week 24 endpoint data for any reason.

End point type	Secondary

End point timeframe:

Week 24

Notes:

[9] - 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 pre-specified arms planned for this end point.

End point values	BMS-986165	Apremilast		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332	168		
Units: Participants	195	52		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	500
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	3.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.16
upper limit	4.83

Secondary: The Number of Participants who Achieve a 75% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 24 (PASI 75)

End point title	The Number of Participants who Achieve a 75% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 24 (PASI 75)[10]

End point description:

PASI is a measure of the average redness, thickness, and scaliness of psoriatic skin lesions (each graded on a 0 to 4 scale; 0 = none to 4 = very severe), weighted by the area of involvement (head, upper extremities, trunk, and lower extremities). The PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. PASI 75 is the response as a number of participants who experience at least a 75% improvement in PASI score as compared with the baseline value using the non-responder imputation (NRI) method that will be used for participants who discontinue treatment or study prior to week 24 or who have missing week 24 endpoint data for any reason.

Baseline is defined as the measurement at the randomization visit (Week 0).

End point type	Secondary

End point timeframe:

Baseline and Week 24

Notes:

[10] - 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 pre-specified arms planned for this end point.

End point values	BMS-986165	Apremilast		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332	168		
Units: Participants	230	64		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	500
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	3.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.53
upper limit	5.6

Secondary: The Number of Participants who Achieve a 90% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 24 (PASI 90)

End point title	The Number of Participants who Achieve a 90% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 24 (PASI 90)[11]

End point description:

PASI is a measure of the average redness, thickness, and scaliness of psoriatic skin lesions (each graded on a 0 to 4 scale; 0 = none to 4 = very severe), weighted by the area of involvement (head, upper extremities, trunk, and lower extremities). The PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. PASI 90 is the response as a number of participants who experience at least a 90% improvement in PASI score as compared with the baseline value using the non-responder imputation (NRI) method that will be used for participants who discontinue treatment or study prior to week 24 or who have missing week 24 endpoint data for any reason.

Baseline is defined as the measurement at the randomization visit (Week 0).

End point type	Secondary

End point timeframe:

Baseline and Week 24

Notes:

[11] - 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 pre-specified arms planned for this end point.

End point values	BMS-986165	Apremilast		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332	168		
Units: Participants	140	37		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	500
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.71
upper limit	4.05

Secondary: The Number of Participants with a static Physician's Global Assessment (sPGA) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Apremilast at Week 52 and at Week 24 (sPGA 0/1)

End point title	The Number of Participants with a static Physician's Global Assessment (sPGA) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Apremilast at Week 52 and at Week 24 (sPGA 0/1)[12]

End point description:

The sPGA is a 5-point scale of an average assessment of all psoriatic lesions based on erythema, scale, and induration. The average of the 3 scales, which is rounded to the nearest whole number, is the final sPGA score. The higher sPGA score denotes to more severe disease activity (0 = Clear; 1 = Almost clear; 2 = Mild; 3 = Moderate; Severe = 4). sPGA 0/1 is the response as a number of participants who experience a sPGA score that determines psoriasis severity as 0 or 1 with at least 2-point improvement from baseline using the non-responder imputation (NRI) method that will be used for participants who discontinue treatment or study prior to week 52 or who have missing week 52 endpoint data for any reason.

End point type	Secondary

End point timeframe:

Week 52 and Week 24

Notes:

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

End point values	BMS-986165	Apremilast		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332	167		
Units: Participants	151	37		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	499
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	3.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.96
upper limit	4.69

Secondary: The Number of Participants who Achieve a 75% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 52 and at Week 24 (PASI 75)

End point title	The Number of Participants who Achieve a 75% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 52 and at Week 24 (PASI 75)[13]

End point description:

PASI is a measure of the average redness, thickness, and scaliness of psoriatic skin lesions (each graded on a 0 to 4 scale; 0 = none to 4 = very severe), weighted by the area of involvement (head, upper extremities, trunk, and lower extremities). The PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. PASI 75 is the response as a number of participants who experience at least a 75% improvement in PASI score as compared with the baseline value using the non-responder imputation (NRI) method that will be used for participants who discontinue treatment or study prior to week 52, or who have missing week 52 endpoint data for any reason.

Baseline is defined as the measurement at the randomization visit (Week 0).

End point type	Secondary

End point timeframe:

Baseline, Week 52 and Week 24

Notes:

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

End point values	BMS-986165	Apremilast		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332	167		
Units: Participants	187	51		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	499
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	3.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.06
upper limit	4.69

Secondary: The Number of Participants who Achieve a 90% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 52 and at Week 24 (PASI 90)

End point title	The Number of Participants who Achieve a 90% Improvement from Baseline in the Psoriasis Area and Severity Index (PASI) Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 52 and at Week 24 (PASI 90)[14]

End point description:

PASI is a measure of the average redness, thickness, and scaliness of psoriatic skin lesions (each graded on a 0 to 4 scale; 0 = none to 4 = very severe), weighted by the area of involvement (head, upper extremities, trunk, and lower extremities). The PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. PASI 90 is the response as a number of participants who experience at least a 90% improvement in PASI score as compared with the baseline value using the non-responder imputation (NRI) method that will be used for participants who discontinue treatment or study prior to week 52, or who have missing week 52 endpoint data for any reason.

Baseline is defined as the measurement at the randomization visit (Week 0).

End point type	Secondary

End point timeframe:

Baseline, Week 52 and Week 24

Notes:

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

End point values	BMS-986165	Apremilast		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332	167		
Units: Participants	103	26		

Statistical analyses

Statistical analysis title	Odds Ratio (OR)
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	499
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0002
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.55
upper limit	4.19

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Deaths (all causes) was assessed from first dose to study completion (up to approximately 24 months). SAEs and NSAEs were assessed from first dose to 30 days following last dose (up to approximately 12 months)

Adverse event reporting additional description:

Total number of subjects exposed represents all participants that received at least 1 dose of study medication.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	23.0

Reporting groups

Reporting group title	BMS Week 0 up to Week 16

Reporting group description:

BMS-986165 6 mg daily (QD) week 0 - week 16

Reporting group title	Placebo Week 0 up to Week 16

Reporting group description:

Participants received placebo week 0 - week 16

Reporting group title	Apremilast Week 0 up to Week 16

Reporting group description:

Apremilast titrated from 10 mg daily (QD) to 30 mg twice a day (BID) over the first 5 days of dosing week 0 - week 16

Reporting group title	BMS Week 0 up to Week 52

Reporting group description:

BMS-986165 6 mg daily (QD) week 0 - week 52

Reporting group title	Placebo Week 0 up to Week 52

Reporting group description:

Participants received placebo week 0 - week 52

Reporting group title	Apremilast Week 0 up to Week 52

Reporting group description:

Apremilast titrated from 10 mg daily (QD) to 30 mg twice a day (BID) over the first 5 days of dosing week 0 - week 52

Serious adverse events	BMS Week 0 up to Week 16	Placebo Week 0 up to Week 16	Apremilast Week 0 up to Week 16
Total subjects affected by serious adverse events			
subjects affected / exposed	7 / 332 (2.11%)	9 / 165 (5.45%)	4 / 168 (2.38%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			

subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hodgkin's disease			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
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			
Aortic dissection			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
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			
Hernia perforation			
subjects affected / exposed	0 / 332 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Incarcerated hernia			
subjects affected / exposed	0 / 332 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea exertional			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Organising pneumonia			
subjects affected / exposed	1 / 332 (0.30%)	0 / 165 (0.00%)	0 / 168 (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
Pulmonary embolism			

subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Alcohol withdrawal syndrome			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Clavicle fracture			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fracture displacement			
subjects affected / exposed	0 / 332 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Hand fracture			
subjects affected / exposed	0 / 332 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Lower limb fracture			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tendon injury			
subjects affected / exposed	0 / 332 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Toxicity to various agents			
subjects affected / exposed	1 / 332 (0.30%)	0 / 165 (0.00%)	0 / 168 (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

Wrist fracture			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 332 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Angina unstable			
subjects affected / exposed	0 / 332 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Atrial fibrillation			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive heart disease			
subjects affected / exposed	0 / 332 (0.00%)	1 / 165 (0.61%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 332 (0.30%)	0 / 165 (0.00%)	1 / 168 (0.60%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular tachycardia			

subjects affected / exposed	1 / 332 (0.30%)	0 / 165 (0.00%)	0 / 168 (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
Nervous system disorders			
Ischaemic stroke			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	1 / 332 (0.30%)	0 / 165 (0.00%)	0 / 168 (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
Transient ischaemic attack			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia vitamin B12 deficiency			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	1 / 168 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous fistula			

subjects affected / exposed	0 / 332 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Intra-abdominal fluid collection			
subjects affected / exposed	0 / 332 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Obstructive pancreatitis			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
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 perforation			
subjects affected / exposed	0 / 332 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 332 (0.00%)	1 / 165 (0.61%)	0 / 168 (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			
Acute kidney injury			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Stress urinary incontinence			
subjects affected / exposed	1 / 332 (0.30%)	0 / 165 (0.00%)	0 / 168 (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
Ureterolithiasis			
subjects affected / exposed	1 / 332 (0.30%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
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			
COVID-19			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carbuncle			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	1 / 168 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 332 (0.00%)	1 / 165 (0.61%)	0 / 168 (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

Infectious mononucleosis			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Localised infection			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	1 / 168 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pilonidal cyst			
subjects affected / exposed	0 / 332 (0.00%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 332 (0.30%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	BMS Week 0 up to Week 52	Placebo Week 0 up to Week 52	Apremilast Week 0 up to Week 52
Total subjects affected by serious adverse events			
subjects affected / exposed	31 / 531 (5.84%)	9 / 165 (5.45%)	6 / 168 (3.57%)
number of deaths (all causes)	0	1	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Breast cancer			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
Hodgkin's disease			

subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Aortic dissection			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
General disorders and administration site conditions			
Hernia perforation			
subjects affected / exposed	0 / 531 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Incarcerated hernia			
subjects affected / exposed	0 / 531 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Respiratory, thoracic and mediastinal disorders			
Dyspnoea exertional			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
Organising pneumonia			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
Pulmonary embolism			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
Psychiatric disorders			
Alcohol withdrawal syndrome			

subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Clavicle fracture			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
Fracture displacement			
subjects affected / exposed	0 / 531 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Hand fracture			
subjects affected / exposed	0 / 531 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Lower limb fracture			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
Tendon injury			
subjects affected / exposed	0 / 531 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Toxicity to various agents			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
Wrist fracture			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Acute myocardial infarction			
subjects affected / exposed	0 / 531 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Angina unstable			
subjects affected / exposed	1 / 531 (0.19%)	1 / 165 (0.61%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
Hypertensive heart disease			
subjects affected / exposed	0 / 531 (0.00%)	1 / 165 (0.61%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	1 / 168 (0.60%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pericarditis			
subjects affected / exposed	2 / 531 (0.38%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Supraventricular tachycardia			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
Ventricular tachycardia			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
Nervous system disorders			

Ischaemic stroke			
subjects affected / exposed	0 / 531 (0.00%)	0 / 165 (0.00%)	1 / 168 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
Transient ischaemic attack			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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			
Anaemia vitamin B12 deficiency			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 531 (0.00%)	0 / 165 (0.00%)	1 / 168 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocutaneous fistula			
subjects affected / exposed	0 / 531 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Intra-abdominal fluid collection			

subjects affected / exposed	0 / 531 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Obstructive pancreatitis			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal perforation			
subjects affected / exposed	0 / 531 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Hepatobiliary disorders			
Cholecystitis acute			
subjects affected / exposed	2 / 531 (0.38%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholelithiasis			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 531 (0.00%)	1 / 165 (0.61%)	0 / 168 (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			
Acute kidney injury			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
Stress urinary incontinence			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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

Ureterolithiasis			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Osteoarthritis			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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			
COVID-19			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
COVID-19 pneumonia			
subjects affected / exposed	0 / 531 (0.00%)	0 / 165 (0.00%)	1 / 168 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Carbuncle			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
Cellulitis			
subjects affected / exposed	0 / 531 (0.00%)	0 / 165 (0.00%)	1 / 168 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 531 (0.00%)	1 / 165 (0.61%)	0 / 168 (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
Infectious mononucleosis			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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

Localised infection			
subjects affected / exposed	0 / 531 (0.00%)	0 / 165 (0.00%)	1 / 168 (0.60%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pharyngotonsillitis			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (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
Pilonidal cyst			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	1 / 531 (0.19%)	0 / 165 (0.00%)	0 / 168 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	BMS Week 0 up to Week 16	Placebo Week 0 up to Week 16	Apremilast Week 0 up to Week 16
Total subjects affected by non-serious adverse events			
subjects affected / exposed	76 / 332 (22.89%)	24 / 165 (14.55%)	60 / 168 (35.71%)
Vascular disorders			
Hypertension			
subjects affected / exposed	6 / 332 (1.81%)	0 / 165 (0.00%)	6 / 168 (3.57%)
occurrences (all)	7	0	6
Nervous system disorders			
Headache			
subjects affected / exposed	16 / 332 (4.82%)	5 / 165 (3.03%)	17 / 168 (10.12%)
occurrences (all)	19	5	21
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	13 / 332 (3.92%)	6 / 165 (3.64%)	17 / 168 (10.12%)
occurrences (all)	15	6	21
Nausea			

subjects affected / exposed	7 / 332 (2.11%)	4 / 165 (2.42%)	19 / 168 (11.31%)
occurrences (all)	7	4	20
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	21 / 332 (6.33%)	7 / 165 (4.24%)	14 / 168 (8.33%)
occurrences (all)	22	7	15
Upper respiratory tract infection			
subjects affected / exposed	21 / 332 (6.33%)	6 / 165 (3.64%)	3 / 168 (1.79%)
occurrences (all)	21	6	3

Non-serious adverse events	BMS Week 0 up to Week 52	Placebo Week 0 up to Week 52	Apremilast Week 0 up to Week 52
Total subjects affected by non-serious adverse events			
subjects affected / exposed	197 / 531 (37.10%)	24 / 165 (14.55%)	80 / 168 (47.62%)
Vascular disorders			
Hypertension			
subjects affected / exposed	14 / 531 (2.64%)	0 / 165 (0.00%)	9 / 168 (5.36%)
occurrences (all)	18	0	9
Nervous system disorders			
Headache			
subjects affected / exposed	35 / 531 (6.59%)	5 / 165 (3.03%)	23 / 168 (13.69%)
occurrences (all)	46	5	27
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	30 / 531 (5.65%)	6 / 165 (3.64%)	19 / 168 (11.31%)
occurrences (all)	32	6	25
Nausea			
subjects affected / exposed	7 / 531 (1.32%)	4 / 165 (2.42%)	21 / 168 (12.50%)
occurrences (all)	8	4	23
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	96 / 531 (18.08%)	7 / 165 (4.24%)	26 / 168 (15.48%)
occurrences (all)	123	7	30
Upper respiratory tract infection			
subjects affected / exposed	50 / 531 (9.42%)	6 / 165 (3.64%)	6 / 168 (3.57%)
occurrences (all)	57	6	10

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 June 2018	Clarified Psoriasis Symptoms and Signs Diary Timeline (PSSD)
20 November 2018	Updated Exclusion Criteria
14 May 2019	Updated Randomization target for each country
06 June 2019	Revised the testing order (hierarchy) of key secondary endpoints
17 December 2019	added and updated relevant protocol deviation criteria for the Per Protocol Set

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported