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

Summary

EudraCT number	2018-001925-24
Trial protocol	GB FR CZ ES HU PL FI IT
Global end of trial date	30 November 2020

Results information

Result version number	v1 (current)
This version publication date	25 October 2022
First version publication date	25 October 2022

Trial information

Trial identification

Sponsor protocol code	IM011-047

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	22 December 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	30 November 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Assess whether BMS-986165 is superior to placebo at Week 16 in the treatment of subjects with moderate-to severe plaque 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	26 July 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	Australia: 58
Country: Number of subjects enrolled	Canada: 95
Country: Number of subjects enrolled	Czechia: 60
Country: Number of subjects enrolled	Finland: 9
Country: Number of subjects enrolled	France: 10
Country: Number of subjects enrolled	Germany: 34
Country: Number of subjects enrolled	Hungary: 68
Country: Number of subjects enrolled	Israel: 5
Country: Number of subjects enrolled	New Zealand: 7
Country: Number of subjects enrolled	Poland: 267
Country: Number of subjects enrolled	Puerto Rico: 7
Country: Number of subjects enrolled	Spain: 16
Country: Number of subjects enrolled	Sweden: 15
Country: Number of subjects enrolled	United Kingdom: 47
Country: Number of subjects enrolled	United States: 322
Worldwide total number of subjects	1020
EEA total number of subjects	479

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)	912
From 65 to 84 years	108
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

1020 participants randomized and 1018 treated.1 Participant stopped treatment after Week 16 and re-entered in treatment period Week 24-52.

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:

Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.

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 receive Placebo by oral administration once daily (QD). Participants originally randomized to placebo switch to BMS-986165 at Week 16.

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:

Placebo to match

Arm title	Apremilast

Arm description:

Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards. Participants originally randomized to apremilast who are PASI 75 responders at Week 24 are switched to placebo at Week 24. Nonresponders at Week 24 are switched to BMS-986165 at Week 24.

Arm type	Active comparator

Investigational medicinal product name	Apremalist
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	511	255	254
Completed	510	254	254
Not completed	1	1	0
Randomized but not treated	1	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:

Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.

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 receive Placebo by oral administration once daily (QD). Participants originally randomized to placebo switch to BMS-986165 at Week 16.

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:

Placebo to match

Arm title	Apremilast

Arm description:

Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards. Participants originally randomized to apremilast who are PASI 75 responders at Week 24 are switched to placebo at Week 24. Nonresponders at Week 24 are switched to BMS-986165 at Week 24.

Arm type	Active comparator
Investigational medicinal product name	Apremalist
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	510	254	254
Completed	456	212	217
Not completed	54	42	37
Adverse event, serious fatal	-	-	1
Consent withdrawn by subject	14	9	9
Adverse event, non-fatal	11	7	12
Pregnancy	-	-	1
Non-compliance with protocol	5	2	1
Other reasons	13	9	7
Lost to follow-up	5	6	2
Lack of efficacy	6	9	4

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:

Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.

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:

Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards. Participants originally randomized to apremilast who are PASI 75 responders at Week 24 are switched to placebo at Week 24. Nonresponders at Week 24 are switched to BMS-986165 at Week 24.

Arm type	Active comparator
Investigational medicinal product name	Apremalist
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	668	217
Discontinued (re-entered at Week 24-52)	1 [1]	0 [2]
Completed	643	208
Not completed	25	9
Consent withdrawn by subject	2	1
Adverse event, non-fatal	7	2
Pregnancy	1	1
Non-compliance with protocol	3	1
Other reasons	2	3
Lost to follow-up	2	-
Lack of efficacy	8	1

Notes:

[1] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 1 Participant stopped treatment after week 16 and re-entered in treatment period Week 24-52

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: 1 Participant stopped treatment after week 16 and re-entered in treatment period Week 24-52.

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:

Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.

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 receive Placebo by oral administration once daily (QD). Participants originally randomized to placebo switch to BMS-986165 at Week 16.

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:

Placebo to match

Number of subjects in period 4	BMS-986165	Placebo
Started	604	247
Completed	535	214
Not completed	69	33
Consent withdrawn by subject	8	6
Adverse event, non-fatal	14	7
Pregnancy	-	1
Non-compliance with protocol	2	-
Other reasons	28	7
Lost to follow-up	9	4
Lack of efficacy	8	8

Baseline characteristics

Reporting groups	
Reporting group title	BMS-986165
Reporting group description:	
Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.	
Reporting group title	Placebo
Reporting group description:	
Participants receive Placebo by oral administration once daily (QD). Participants originally randomized to placebo switch to BMS-986165 at Week 16.	
Reporting group title	Apremilast
Reporting group description:	
Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards. Participants originally randomized to apremilast who are PASI 75 responders at Week 24 are switched to placebo at Week 24. Nonresponders at Week 24 are switched to BMS-986165 at Week 24.	

Reporting group values	BMS-986165	Placebo	Apremilast
Number of subjects	511	255	254
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)	457	229	226
From 65-84 years	54	26	28
85 years and over	0	0	0
Age Continuous Units: Years			
median	46.9	47.3	46.4
standard deviation	± 13.37	± 13.57	± 13.28
Sex: Female, Male Units: Participants			
Female	175	74	97
Male	336	181	157
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	58	29	29
Not Hispanic or Latino	445	226	223
Unknown or Not Reported	8	0	2
Race/Ethnicity, Customized Units: Subjects			
White	474	232	229

Black or African American	8	9	9
Asian	24	8	12
American Indian or Alaska Native	2	2	3
Native Hawaiian or Other Pacific Islander	0	0	0
Other	3	4	1

Reporting group values	Total		
Number of subjects	1020		
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)	912		
From 65-84 years	108		
85 years and over	0		
Age Continuous			
Units: Years			
median			
standard deviation	-		
Sex: Female, Male			
Units: Participants			
Female	346		
Male	674		
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	116		
Not Hispanic or Latino	894		
Unknown or Not Reported	10		
Race/Ethnicity, Customized			
Units: Subjects			
White	935		
Black or African American	26		
Asian	44		
American Indian or Alaska Native	7		
Native Hawaiian or Other Pacific Islander	0		
Other	8		

End points

End points reporting groups

Reporting group title	BMS-986165
Reporting group description:	
Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.	
Reporting group title	Placebo
Reporting group description:	
Participants receive Placebo by oral administration once daily (QD). Participants originally randomized to placebo switch to BMS-986165 at Week 16.	
Reporting group title	Apremilast
Reporting group description:	
Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards. Participants originally randomized to apremilast who are PASI 75 responders at Week 24 are switched to placebo at Week 24. Nonresponders at Week 24 are switched to BMS-986165 at Week 24.	
Reporting group title	BMS-986165
Reporting group description:	
Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.	
Reporting group title	Placebo
Reporting group description:	
Participants receive Placebo by oral administration once daily (QD). Participants originally randomized to placebo switch to BMS-986165 at Week 16.	
Reporting group title	Apremilast
Reporting group description:	
Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards. Participants originally randomized to apremilast who are PASI 75 responders at Week 24 are switched to placebo at Week 24. Nonresponders at Week 24 are switched to BMS-986165 at Week 24.	
Reporting group title	BMS-986165
Reporting group description:	
Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.	
Reporting group title	Apremilast
Reporting group description:	
Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards. Participants originally randomized to apremilast who are PASI 75 responders at Week 24 are switched to placebo at Week 24. Nonresponders at Week 24 are switched to BMS-986165 at Week 24.	
Reporting group title	BMS-986165
Reporting group description:	
Participants receive 6 mg of BMS-986165 by oral administration once daily (QD). Participants originally randomized to BMS-986165 who are PASI 75 responders at Week 24 are re-randomized to BMS-986165 or placebo. Nonresponders at Week 24 will continue to receive BMS-986165 at Week 24.	
Reporting group title	Placebo
Reporting group description:	
Participants receive Placebo by oral administration once daily (QD). Participants originally randomized to placebo switch to BMS-986165 at Week 16.	

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 average assessment of all psoriatic lesions graded for erythema, scale, and induration. The sPGA measure determines psoriasis severity at a single point in time (without taking into account the baseline disease condition) as: clear (0), almost clear (1), mild (2), moderate (3), or severe (4). 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. 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 a 2-point improvement from baseline using the non-responder imputation (NRI) method.

Non-responder imputation (NRI) 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	511	255		
Units: Participants	253	22		

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	766
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	10.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.54
upper limit	17

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:

The Psoriasis Area and Severity Index (PASI) is a quantitative rating scale for measuring the severity of psoriatic lesions based on area coverage and plaque appearance.

The PASI is a measure of the average erythema (redness), infiltration (thickness), and desquamation (scaling) of psoriatic skin lesions (each graded on a 0-4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to top of buttocks). 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. Baseline is defined as the measurement at the randomization visit (Week 0).

Non-responder imputation (NRI) 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:

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	511	255		
Units: Participants	271	24		

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	766
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	10.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.65
upper limit	16.55

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

End point description:

The Psoriasis Area and Severity Index (PASI) is a quantitative rating scale for measuring the severity of psoriatic lesions based on area coverage and plaque appearance.

The PASI is a measure of the average erythema (redness), infiltration (thickness), and desquamation (scaling) of psoriatic skin lesions (each graded on a 0-4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to top of buttocks). 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. Baseline is defined as the measurement at the randomization visit (Week 0).

Non-responder imputation (NRI) 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:

Baseline and Week 16

End point values	BMS-986165	Placebo	Apremilast	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	511	255	254	
Units: Participants	138	7	46	

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	766
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	11.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.45
upper limit	23.93

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Apremilast

Number of subjects included in analysis	765
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0046
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.18
upper limit	2.56

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

End point description:

The Psoriasis Area and Severity Index (PASI) is a quantitative rating scale for measuring the severity of psoriatic lesions based on area coverage and plaque appearance.

The PASI is a measure of the average erythema (redness), infiltration (thickness), and desquamation (scaling) of psoriatic skin lesions (each graded on a 0-4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to top of buttocks). 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. Baseline is defined as the measurement at the randomization visit (Week 0).

Non-responder imputation (NRI) 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:

Baseline and Week 16

End point values	BMS-986165	Placebo	Apremilast	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	511	255	254	
Units: Participants	52	3	11	

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Placebo

Number of subjects included in analysis	766
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	9.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.89
upper limit	29.4

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	765
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0051
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.3
upper limit	5

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

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

End point description:

The sPGA is a 5-point scale average assessment of all psoriatic lesions graded for erythema, scale, and induration. The sPGA measure determines psoriasis severity at a single point in time (without taking into account the baseline disease condition) as: clear (0), almost clear (1), mild (2), moderate (3), or severe (4). The average of the 3 scales, which is rounded to the nearest whole number, is the final sPGA score. 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.

Non-responder imputation (NRI) 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	511	255	254	
Units: Participants	80	3	16	

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	766
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	14.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.62
upper limit	45.11

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	765
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0002
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.61
upper limit	5.03

Secondary: Change from Baseline in Psoriasis Symptoms and Signs Diary (PSSD) Symptom Score at Week 16

End point title	Change from Baseline in Psoriasis Symptoms and Signs Diary (PSSD) Symptom Score at Week 16

End point description:

The PSSD is an 11-item participant-reported instrument that assesses severity of symptoms and participant-observed signs commonly associated in plaque psoriasis. The PSSD assesses severity of 5 symptoms (itch, pain, stinging, burning, skin tightness) and 6 participant-observed signs (skin dryness,

cracking, scaling, shedding or flaking, redness, bleeding) using 0 to10 numerical ratings. The severity of each item is rated on an 11-point numeric rating scale ranging from 0 (absent) to 10 (worst imaginable) where the symptoms summary score is derived from an average of the scores. A higher score indicates more severe disease. Baseline is defined as the measurement at the randomization visit (Week 0).

A modified baseline observation carried forward (mBOCF) approach will be used in participants with missing data. Missing values will have the last valid observation carried forward (including the baseline value as applicable).

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	466	239	233	
Units: Score on a scale				
arithmetic mean (standard deviation)	-28.9 (± 25.22)	-4.2 (± 19.58)	-21.5 (± 25.44)	

Statistical analyses

Statistical analysis title	ANCOVA
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	705
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-23.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.9
upper limit	-20.3
Variability estimate	Standard error of the mean
Dispersion value	1.67

Statistical analysis title	ANCOVA
Comparison groups	BMS-986165 v Apremilast

Number of subjects included in analysis	699
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	ANCOVA
Parameter estimate	Mean difference (net)
Point estimate	-7.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.5
upper limit	-3.9
Variability estimate	Standard error of the mean
Dispersion value	1.68

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

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

End point description:

Psoriasis Symptoms and Signs Diary (PSSD) is an 11-item participant-reported instrument that assesses severity of symptoms and participant-observed signs commonly associated in plaque psoriasis. The PSSD assesses severity of 5 symptoms (itch, pain, stinging, burning, skin tightness) and 6 participant-observed signs (skin dryness, cracking, scaling, shedding or flaking, redness, bleeding) using 0 to 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) where the symptoms summary score is derived from the average of the scores. A higher score indicates more severe disease. PSSD 0 is the response as a number of participants who experience a PSSD symptom score that determines psoriasis severity as 0 among participants with a baseline PSSD symptom score >= 1 using the non-responder imputation (NRI) method.

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	466	238	232	
Units: Participants	35	3	10	

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Placebo

Number of subjects included in analysis	704
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0005
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	6.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.94
upper limit	21.15

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	698
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0928
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.89
upper limit	3.71

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:

The scalp specific Physician's Global Assessment (ss-PGA) evaluates scalp lesions in terms of clinical signs of redness, thickness, and scaliness and scored on the following 5-point ss-PGA scale: 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 of 0 or 1 with at least a 2-point improvement from baseline among participants with a baseline ss-PGA score ≥3 .

Non-responder imputation (NRI) 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	305	173	166	
Units: Participants	182	30	61	

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	478
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	6.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.34
upper limit	10.81

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	471
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	1.77
upper limit	3.91

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)[3]

End point description:

The DLQI is a participant-reported quality of life index which consists of 10 questions concerning how

much skin problems affect 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 where 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 number of participants with a score of 0 or 1 among participants with a baseline DLQI score ≥2.

Non-responder imputation (NRI) 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:

[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	495	246		
Units: Participants	186	24		

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	741
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	5.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.42
upper limit	8.47

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

End point title	The Number of Participants with a Physician Global Assessment- Fingernails (PGA-F) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Placebo at Week 16 (PGA-F 0/1)[4]

End point description:

The Physician Global Assessment- Fingernails (PGA-F) evaluates the overall condition of the fingernails and 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.

Non-responder imputation (NRI) 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:

[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	Placebo		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	69	38		
Units: Participants	14	3		

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	107
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0621
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	3.21
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.88
upper limit	11.79

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

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

End point description:

The palmoplantar Physician's Global Assessment (pp-PGA) score evaluates palmoplantar (including finger and toe surfaces) psoriasis lesions based on overall severity by investigator, then scored on the following 5-point scale: 0 = clear; 1 = almost clear; 2 = mild; 3 = moderate; and 4 = severe. pp-PGA 0/1 is the number of participants with a score of 0 or 1 among participants with a baseline pp-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	39	17	20	
Units: Participants	18	4	8	

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	59
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3793
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.02
upper limit	5.56

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	56
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.6692
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.06
upper limit	7.46

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)[5]

End point description:

The Psoriasis Area and Severity Index (PASI) is a quantitative rating scale for measuring the severity of psoriatic lesions based on area coverage and plaque appearance.

The PASI is a measure of the average erythema (redness), infiltration (thickness), and desquamation (scaling) of psoriatic skin lesions (each graded on a 0-4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to top of buttocks). 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. Baseline is defined as the measurement at the randomization visit (Week 0).

Non-responder imputation (NRI) 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:

Baseline and 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	Apremilast		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	511	254		
Units: Participants	271	101		

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	765
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0004
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.29
upper limit	2.41

Secondary: The Number of Participants with a static Physician 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 Global Assessment (sPGA) Score of 0 or 1 in Participants Receiving BMS-986165 Compared to Apremilast at Week 16 (sPGA 0/1)[6]

End point description:

The sPGA is a 5-point scale average assessment of all psoriatic lesions graded for erythema, scale, and induration. The sPGA measure determines psoriasis severity at a single point in time (without taking into account the baseline disease condition) as: clear (0), almost clear (1), mild (2), moderate (3), or severe (4). The average of the 3 scales, which is rounded to the nearest whole number, is the final sPGA score. sPGA 0/1 is the number of participants with a sPGA score of 0 or 1 with at least a 2-point improvement from baseline.

Non-responder imputation (NRI) 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:

[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	Apremilast		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	511	254		
Units: Participants	253	86		

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	765
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.45
upper limit	2.78

Secondary: Time to Relapse Until Week 52 Among Week 24 PASI 75 Responders

End point title	Time to Relapse Until Week 52 Among Week 24 PASI 75 Responders

End point description:

Relapse is defined as 50% loss or greater of Week 24 PASI percent improvement from baseline.

The PASI is a measure of the average redness, thickness, and scaliness of psoriatic skin lesions (each graded on a 0 -4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to

top of buttocks). PASI produces a numeric score that can range from 0 to 72, with higher PASI scores denoting more severe disease activity. Note: 99999 = N/A (Insufficient number of participants with events)

End point type	Secondary

End point timeframe:

From Week 24 to Week 52 (up to approximately 28 weeks)

End point values	BMS-986165	Placebo	Apremilast	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	145	150	95	
Units: Days				
median (confidence interval 95%)	99999 (99999 to 99999)	99999 (99999 to 99999)	197.0 (125.0 to 99999)	

Statistical analyses

Statistical analysis title	Log Rank
Comparison groups	BMS-986165 v Placebo
Number of subjects included in analysis	295
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Logrank

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

End point title	The Number of Participants with a static Physician Global Assessment (sPGA) score of 0 or 1 in Participants Receiving BMS-986165 Compared to Apremalist at Week 24 (sPGA 0/1)[7]

End point description:

The sPGA is a 5-point scale average assessment of all psoriatic lesions graded for erythema, scale, and induration. The sPGA measure determines psoriasis severity at a single point in time (without taking into account the baseline disease condition) as: clear (0), almost clear (1), mild (2), moderate (3), or severe (4). The average of the 3 scales, which is rounded to the nearest whole number, is the final sPGA score. sPGA 0/1 is the number of participants with a sPGA score of 0 or 1.

Non-responder imputation (NRI) 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:

[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	504	254		
Units: Participants	251	75		

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	758
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.78
upper limit	3.43

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 Apremalist 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 Apremalist at Week 24 (PASI 75)[8]

End point description:

The Psoriasis Area and Severity Index (PASI) is a quantitative rating scale for measuring the severity of psoriatic lesions based on area coverage and plaque appearance.

The PASI is a measure of the average erythema (redness), infiltration (thickness), and desquamation (scaling) of psoriatic skin lesions (each graded on a 0-4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to top of buttocks). 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. Baseline is defined as the measurement at the randomization visit (Week 0).

Non-responder imputation (NRI) 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:

Baseline and Week 24

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	504	254		
Units: Participants	296	96		

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	758
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.78
upper limit	3.36

Secondary: The Number of Participants who Achieve a 90% Improvement from Baseline in the Psoriasis Area and Severity Index 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 Score in Participants Receiving BMS-986165 Compared to Apremilast at Week 24 (PASI 90)[9]

End point description:

The Psoriasis Area and Severity Index (PASI) is a quantitative rating scale for measuring the severity of psoriatic lesions based on area coverage and plaque appearance.

The PASI is a measure of the average erythema (redness), infiltration (thickness), and desquamation (scaling) of psoriatic skin lesions (each graded on a 0-4 scale), weighted by the area of involvement (head, arms, trunk to groin, and legs to top of buttocks). 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. Baseline is defined as the measurement at the randomization visit (Week 0).

Non-responder imputation (NRI) 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:

Baseline and 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	504	254		
Units: Participants	164	50		

Statistical analyses

Statistical analysis title	Odds Ratio
Comparison groups	BMS-986165 v Apremilast
Number of subjects included in analysis	758
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.07
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.43
upper limit	3.01

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Participants were assessed for Death (all causes) from their first dose until the study was completed (up to approximately 60 weeks). SAEs and NSAEs were assessed from first dose to 30 days following last dose (up to approximately 56 weeks)

Adverse event reporting additional description:

The 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	23.1

Reporting groups

Reporting group title	BMS-986165 (Week 0 up to Week 16)

Reporting group description:

Participants receive 6 mg of BMS-986165 by oral administration once daily (QD).

Reporting group title	Placebo (Week 0 up to Week 16)

Reporting group description:

Participants receive Placebo by oral administration once daily (QD).

Reporting group title	Apremilast (Week 0 up to Week 16)

Reporting group description:

Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards.

Reporting group title	BMS-986165 (Week 0 up to Week 52)

Reporting group description:

Participants receive 6 mg of BMS-986165 by oral administration once daily (QD).

Reporting group title	Placebo (Week 0 up to Week 52)

Reporting group description:

Participants receive Placebo by oral administration once daily (QD).

Reporting group title	Apremilast (Week 0 up to Week 52)

Reporting group description:

Participants receive 30 mg of Apremilast by oral administration twice daily (BID) (with initial titration per label) -10 mg used for titration Day 1 through Day 3 morning dose -20 mg used for titration Day 3 evening dose through Day 5 morning dose. -30 mg from Day 5 evening dose onwards.

Serious adverse events	BMS-986165 (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	8 / 510 (1.57%)	3 / 254 (1.18%)	1 / 254 (0.39%)
number of deaths (all causes)	1	0	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			

subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (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
Lung adenocarcinoma			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	1 / 254 (0.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vascular disorders			
Malignant hypertension			
subjects affected / exposed	1 / 510 (0.20%)	0 / 254 (0.00%)	0 / 254 (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
Peripheral artery occlusion			
subjects affected / exposed	0 / 510 (0.00%)	1 / 254 (0.39%)	0 / 254 (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
Shock			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (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
Thrombosis			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 510 (0.20%)	0 / 254 (0.00%)	0 / 254 (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
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 510 (0.00%)	1 / 254 (0.39%)	0 / 254 (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
Nasal septum deviation			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (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			
Major depression			
subjects affected / exposed	0 / 510 (0.00%)	1 / 254 (0.39%)	0 / 254 (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
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (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
Congenital, familial and genetic disorders			
Gastrointestinal arteriovenous malformation			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	1 / 254 (0.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			

Arteriosclerosis coronary artery			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (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 arrest			
subjects affected / exposed	1 / 510 (0.20%)	0 / 254 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 510 (0.20%)	0 / 254 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (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
Pericardial effusion			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (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
Ischaemic stroke			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	1 / 254 (0.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

Retinal detachment			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (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			
Anal polyp			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (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 haemorrhage			
subjects affected / exposed	1 / 510 (0.20%)	0 / 254 (0.00%)	1 / 254 (0.39%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic mass			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (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
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (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			
Excessive granulation tissue			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (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			
Anal abscess			

subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (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			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (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 / 510 (0.00%)	1 / 254 (0.39%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 510 (0.20%)	0 / 254 (0.00%)	0 / 254 (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
Mycoplasma infection			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (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
Purulence			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	1 / 510 (0.20%)	0 / 254 (0.00%)	0 / 254 (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
Streptococcal bacteraemia			

subjects affected / exposed	1 / 510 (0.20%)	0 / 254 (0.00%)	0 / 254 (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
Upper respiratory tract infection			
subjects affected / exposed	1 / 510 (0.20%)	0 / 254 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular graft infection			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 510 (0.20%)	0 / 254 (0.00%)	0 / 254 (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
Diabetes mellitus			
subjects affected / exposed	0 / 510 (0.00%)	0 / 254 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	BMS-986165 (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	24 / 833 (2.88%)	5 / 501 (1.00%)	3 / 254 (1.18%)
number of deaths (all causes)	2	0	1
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hepatocellular carcinoma			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Lung adenocarcinoma			

subjects affected / exposed	0 / 833 (0.00%)	0 / 501 (0.00%)	1 / 254 (0.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Vascular disorders			
Malignant hypertension			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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
Peripheral artery occlusion			
subjects affected / exposed	0 / 833 (0.00%)	1 / 501 (0.20%)	0 / 254 (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
Shock			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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
Thrombosis			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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
Reproductive system and breast disorders			
Ovarian cyst			
subjects affected / exposed	0 / 833 (0.00%)	0 / 501 (0.00%)	1 / 254 (0.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			

subjects affected / exposed	0 / 833 (0.00%)	1 / 501 (0.20%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 833 (0.00%)	1 / 501 (0.20%)	0 / 254 (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
Nasal septum deviation			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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
Respiratory failure			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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			
Major depression			
subjects affected / exposed	0 / 833 (0.00%)	1 / 501 (0.20%)	0 / 254 (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
Injury, poisoning and procedural complications			
Post procedural haemorrhage			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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
Congenital, familial and genetic disorders			
Gastrointestinal arteriovenous malformation			
subjects affected / exposed	0 / 833 (0.00%)	0 / 501 (0.00%)	1 / 254 (0.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Arteriosclerosis coronary artery			

subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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
Atrial fibrillation			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac arrest			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Myocardial ischaemia			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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
Pericardial effusion			
subjects affected / exposed	0 / 833 (0.00%)	1 / 501 (0.20%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebrovascular accident			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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
Ischaemic stroke			
subjects affected / exposed	0 / 833 (0.00%)	0 / 501 (0.00%)	1 / 254 (0.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

Retinal detachment			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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			
Anal polyp			
subjects affected / exposed	0 / 833 (0.00%)	1 / 501 (0.20%)	0 / 254 (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
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	1 / 254 (0.39%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatic mass			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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
Hepatobiliary disorders			
Hepatitis			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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			
Excessive granulation tissue			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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			
Anal abscess			

subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 833 (0.00%)	1 / 501 (0.20%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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
Mycoplasma infection			
subjects affected / exposed	0 / 833 (0.00%)	0 / 501 (0.00%)	1 / 254 (0.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	3 / 833 (0.36%)	0 / 501 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Purulence			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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
Sepsis			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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
Streptococcal bacteraemia			

subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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
Upper respiratory tract infection			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular graft infection			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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
Diabetes mellitus			
subjects affected / exposed	1 / 833 (0.12%)	0 / 501 (0.00%)	0 / 254 (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-986165 (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	114 / 510 (22.35%)	61 / 254 (24.02%)	86 / 254 (33.86%)
Nervous system disorders			
Headache			
subjects affected / exposed	22 / 510 (4.31%)	14 / 254 (5.51%)	28 / 254 (11.02%)
occurrences (all)	27	17	31
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	24 / 510 (4.71%)	19 / 254 (7.48%)	33 / 254 (12.99%)
occurrences (all)	26	20	36
Nausea			

subjects affected / exposed	7 / 510 (1.37%)	3 / 254 (1.18%)	23 / 254 (9.06%)
occurrences (all)	7	3	23
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	55 / 510 (10.78%)	29 / 254 (11.42%)	23 / 254 (9.06%)
occurrences (all)	66	33	24
Upper respiratory tract infection			
subjects affected / exposed	25 / 510 (4.90%)	11 / 254 (4.33%)	14 / 254 (5.51%)
occurrences (all)	28	12	14

Non-serious adverse events	BMS-986165 (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	249 / 833 (29.89%)	97 / 501 (19.36%)	98 / 254 (38.58%)
Nervous system disorders			
Headache			
subjects affected / exposed	45 / 833 (5.40%)	16 / 501 (3.19%)	30 / 254 (11.81%)
occurrences (all)	53	19	38
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	39 / 833 (4.68%)	22 / 501 (4.39%)	35 / 254 (13.78%)
occurrences (all)	50	23	38
Nausea			
subjects affected / exposed	13 / 833 (1.56%)	6 / 501 (1.20%)	26 / 254 (10.24%)
occurrences (all)	13	6	27
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	133 / 833 (15.97%)	47 / 501 (9.38%)	28 / 254 (11.02%)
occurrences (all)	172	55	33
Upper respiratory tract infection			
subjects affected / exposed	74 / 833 (8.88%)	27 / 501 (5.39%)	21 / 254 (8.27%)
occurrences (all)	89	31	23

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
14 May 2019	1) Randomization in each country will be targeted to approximately 35% or less of the total sample size. 2) Added the 'Time to relapse until Week 52' endpoint

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported