Clinical trial results:
A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of BMS-986165 in Subjects with Moderate to Severe Crohn's Disease

Summary

EudraCT number	2017-001976-48
Trial protocol	GB HU FR ES PL DE DK PT NL BE IT RO
Global end of trial date	23 October 2023

Results information

Result version number	v1 (current)
This version publication date	15 June 2024
First version publication date	15 June 2024

Trial information

Trial identification

Sponsor protocol code	IM011-023

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	Chaussee de la Hulpe 185, Brussels, Belgium, 1170
Public contact	Bristol-Myers Squibb International Corporation, EU Study Start-Up Unit, 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	28 November 2023
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	23 October 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To assess the effect of BMS-986165 on clinical remission and endoscopic response at the end of the Induction Period (Week 12 [Day 85]).

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	16 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: 7
Country: Number of subjects enrolled	Belgium: 2
Country: Number of subjects enrolled	Brazil: 7
Country: Number of subjects enrolled	Canada: 3
Country: Number of subjects enrolled	China: 12
Country: Number of subjects enrolled	Czechia: 6
Country: Number of subjects enrolled	Denmark: 1
Country: Number of subjects enrolled	France: 3
Country: Number of subjects enrolled	Germany: 11
Country: Number of subjects enrolled	Hungary: 8
Country: Number of subjects enrolled	Ireland: 1
Country: Number of subjects enrolled	Israel: 1
Country: Number of subjects enrolled	Italy: 9
Country: Number of subjects enrolled	Japan: 20
Country: Number of subjects enrolled	Korea, Republic of: 1
Country: Number of subjects enrolled	Mexico: 4
Country: Number of subjects enrolled	Netherlands: 2
Country: Number of subjects enrolled	Poland: 37
Country: Number of subjects enrolled	Portugal: 1
Country: Number of subjects enrolled	Romania: 3

Country: Number of subjects enrolled	Russian Federation: 15
Country: Number of subjects enrolled	Spain: 5
Country: Number of subjects enrolled	Taiwan: 4
Country: Number of subjects enrolled	United Kingdom: 10
Country: Number of subjects enrolled	United States: 66
Worldwide total number of subjects	239
EEA total number of subjects	89

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)	222
From 65 to 84 years	17
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

239 participants were randomized to a study treatment, 235 participants were treated.

Pre-assignment

Screening details:

Enrollment into the 12 mg BMS-986165 arm was discontinued. Participants who were randomized to 12 mg BMS-986165 were continued on their originally assigned double-blind study treatment. These participants completed all study procedures and assessments outlined in the current version of the protocol.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Placebo was taken twice per day over 12 weeks. Participants who achieved a clinical response after the 12 week induction period continued to take placebo twice daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to receive open-label BMS-986165 6 mg twice per day until week 52. Week 12 responders (Placebo) and week 12 non-responders (BMS-986165 6 mg OL) who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the OLE Period and began/continued to receive BMS986165 6 mg twice daily.

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

Dosage and administration details:

6mg taken twice per day

Investigational medicinal product name	Placebo matching BMS-986165 oral capsule
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

1 capsule taken twice per day.

Arm title	3 mg BMS-986165

Arm description:

BMS-986165 3 mg was taken orally twice per day over 12 weeks. Participants who achieved a clinical response after the 12 week induction period continued to take BMS-986165 3 mg orally twice daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to receive BMS-986165 6 mg twice per day until week 52. Week 12 responders (BMS-986165 3 mg) and week 12 non-responders (BMS-986165 6 mg OL) who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the open-label extension period and began/continued to receive open label BMS-986165 6 mg twice daily.

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

Dosage and administration details:

6mg taken twice per day

Investigational medicinal product name	BMS-986165 oral capsule
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

3mg taken twice per day

Arm title	6 mg BMS-986165

Arm description:

BMS-986165 6 mg was taken orally twice per day over 12 weeks. Participants who achieved a clinical response after the 12-week induction period continued to take BMS-986165 6 mg orally twice daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to enter the open label period and continued to receive BMS-986165 6 mg twice per day until week 52. Week 12 responders and week 12 non-responders who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the open label extension period and continued to receive open label BMS-986165 6 mg twice daily.

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

Dosage and administration details:

6mg taken twice per day

Arm title	12 mg BMS-986165

Arm description:

BMS-986165 12 mg was taken orally once per day over 12 weeks. Participants who achieved a clinical response after the 12-week induction period continued to take BMS-986165 12 mg orally once daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response prior to protocol v 3 but had an appropriate safety profile were eligible to enter the open label period and received BMS-986165 12 mg once per day. Participants who were randomized prior to the implementation of Protocol v3.0 who had not yet reached Week 12 but had an appropriate safety profile could switch to open-label BMS-986165 6 mg for the Maintenance Period, if they did not achieve a clinical response at Week 12. Week 12 responders and week 12 non-responders who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the open label extension period to receive open label BMS-986165 6 mg twice daily.

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

Dosage and administration details:

6mg taken twice per day

Investigational medicinal product name	BMS-986165 oral capsule
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

12 mg taken once per day

Number of subjects in period 1	Placebo	3 mg BMS-986165	6 mg BMS-986165
Started	60	86	84
Completed	59	84	83
Not completed	1	2	1
Consent withdrawn by subject	-	1	-
Other reasons	1	1	1

Number of subjects in period 1	12 mg BMS-986165
Started	9
Completed	9
Not completed	0
Consent withdrawn by subject	-
Other reasons	-

Period 2

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Placebo was taken twice per day over 12 weeks. Participants who achieved a clinical response after the 12 week induction period continued to take placebo twice daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to receive open-label BMS-986165 6 mg twice per day until week 52. Week 12 responders (Placebo) and week 12 non-responders (BMS-986165 6 mg OL) who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the OLE Period and began/continued to receive BMS986165 6 mg twice daily.

Arm type	Placebo

Investigational medicinal product name	BMS-986165 oral capsule
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

6mg taken twice per day

Investigational medicinal product name	Placebo matching BMS-986165 oral capsule
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

1 capsule taken twice per day.

Arm title	3 mg BMS-986165

Arm description:

BMS-986165 3 mg was taken orally twice per day over 12 weeks. Participants who achieved a clinical response after the 12 week induction period continued to take BMS-986165 3 mg orally twice daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to receive BMS-986165 6 mg twice per day until week 52. Week 12 responders (BMS-986165 3 mg) and week 12 non-responders (BMS-986165 6 mg OL) who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the open-label extension period and began/continued to receive open label BMS-986165 6 mg twice daily.

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

Dosage and administration details:

6mg taken twice per day

Investigational medicinal product name	BMS-986165 oral capsule
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

3mg taken twice per day

Arm title	6 mg BMS-986165

Arm description:

BMS-986165 6 mg was taken orally twice per day over 12 weeks. Participants who achieved a clinical response after the 12-week induction period continued to take BMS-986165 6 mg orally twice daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to enter the open label period and continued to receive BMS-986165 6 mg twice per day until week 52. Week 12 responders and week 12 non-responders who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the open label extension period and continued to receive open label BMS-986165 6 mg twice daily.

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

Dosage and administration details:

6mg taken twice per day

Arm title	12 mg BMS-986165

Arm description:

BMS-986165 12 mg was taken orally once per day over 12 weeks. Participants who achieved a clinical response after the 12-week induction period continued to take BMS-986165 12 mg orally once daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response prior to protocol v 3 but had an appropriate safety profile were eligible to enter the open label period and received BMS-986165 12 mg once per day. Participants who were randomized prior to the implementation of Protocol v3.0 who had not yet reached Week 12 but had an appropriate safety profile could switch to open-label BMS-986165 6 mg for the Maintenance Period, if they did not achieve a clinical response at Week 12. Week 12 responders and week 12 non-responders who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the open label extension period to receive open label BMS-986165 6 mg twice daily.

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

Dosage and administration details:

6mg taken twice per day

Investigational medicinal product name	BMS-986165 oral capsule
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

12 mg taken once per day

Number of subjects in period 2	Placebo	3 mg BMS-986165	6 mg BMS-986165
Started	59	84	83
Completed	13	14	14
Not completed	46	70	69
Consent withdrawn by subject	5	11	16
Adverse event, non-fatal	11	20	18
Site terminated by sponsor	-	1	-
Study terminated by sponsor	7	20	15
Other reasons	4	6	7
Lost to follow-up	1	-	-
Lack of efficacy	18	12	13

Number of subjects in period 2	12 mg BMS-986165
Started	9

Completed	4
Not completed	5
Consent withdrawn by subject	1
Adverse event, non-fatal	2
Site terminated by sponsor	-
Study terminated by sponsor	-
Other reasons	-
Lost to follow-up	-
Lack of efficacy	2

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Placebo was taken twice per day over 12 weeks. Participants who achieved a clinical response after the 12 week induction period continued to take placebo twice daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to receive open-label BMS-986165 6 mg twice per day until week 52. Week 12 responders (Placebo) and week 12 non-responders (BMS-986165 6 mg OL) who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the OLE Period and began/continued to receive BMS986165 6 mg twice daily.	
Reporting group title	3 mg BMS-986165
Reporting group description:	
BMS-986165 3 mg was taken orally twice per day over 12 weeks. Participants who achieved a clinical response after the 12 week induction period continued to take BMS-986165 3 mg orally twice daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to receive BMS-986165 6 mg twice per day until week 52. Week 12 responders (BMS-986165 3 mg) and week 12 non-responders (BMS-986165 6 mg OL) who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the open-label extension period and began/continued to receive open label BMS-986165 6 mg twice daily.	
Reporting group title	6 mg BMS-986165
Reporting group description:	
BMS-986165 6 mg was taken orally twice per day over 12 weeks. Participants who achieved a clinical response after the 12-week induction period continued to take BMS-986165 6 mg orally twice daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to enter the open label period and continued to receive BMS-986165 6 mg twice per day until week 52. Week 12 responders and week 12 non-responders who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the open label extension period and continued to receive open label BMS-986165 6 mg twice daily.	
Reporting group title	12 mg BMS-986165
Reporting group description:	
BMS-986165 12 mg was taken orally once per day over 12 weeks. Participants who achieved a clinical response after the 12-week induction period continued to take BMS-986165 12 mg orally once daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response prior to protocol v 3 but had an appropriate safety profile were eligible to enter the open label period and received BMS-986165 12 mg once per day. Participants who were randomized prior to the implementation of Protocol v3.0 who had not yet reached Week 12 but had an appropriate safety profile could switch to open-label BMS-986165 6 mg for the Maintenance Period, if they did not achieve a clinical response at Week 12. Week 12 responders and week 12 non-responders who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the open label extension period to receive open label BMS-986165 6 mg twice daily.	

Reporting group values	Placebo	3 mg BMS-986165	6 mg BMS-986165
Number of subjects	60	86	84
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)	52	81	80

From 65-84 years	8	5	4
85 years and over	0	0	0

Age Continuous			
Units: Years			
arithmetic mean	39.1	39.5	37.9
standard deviation	± 16.7	± 15.2	± 14.6
Sex: Female, Male			
Units: Participants			
Female	22	38	34
Male	38	48	50
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	2	7	2
Not Hispanic or Latino	58	78	80
Unknown or Not Reported	0	1	2
Race/Ethnicity, Customized			
Race			
Units: Subjects			
Asian	11	13	12
Black or African American	1	1	3
White	48	70	68
Other	0	2	0
Not Reported	0	0	1

Reporting group values	12 mg BMS-986165	Total	
Number of subjects	9	239	
Age categorical			
Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	9	222	
From 65-84 years	0	17	
85 years and over	0	0	
Age Continuous			
Units: Years			
arithmetic mean	37.4		
standard deviation	± 13.7	-	
Sex: Female, Male			
Units: Participants			
Female	3	97	
Male	6	142	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	0	11	
Not Hispanic or Latino	9	225	

Unknown or Not Reported	0	3	
Race/Ethnicity, Customized			
Race			
Units: Subjects			
Asian	1	37	
Black or African American	0	5	
White	8	194	
Other	0	2	
Not Reported	0	1	

End points reporting groups

Reporting group title	Placebo

Reporting group description:

Placebo was taken twice per day over 12 weeks. Participants who achieved a clinical response after the 12 week induction period continued to take placebo twice daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to receive open-label BMS-986165 6 mg twice per day until week 52. Week 12 responders (Placebo) and week 12 non-responders (BMS-986165 6 mg OL) who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the OLE Period and began/continued to receive BMS986165 6 mg twice daily.

Reporting group title	3 mg BMS-986165

Reporting group description:

BMS-986165 3 mg was taken orally twice per day over 12 weeks. Participants who achieved a clinical response after the 12 week induction period continued to take BMS-986165 3 mg orally twice daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to receive BMS-986165 6 mg twice per day until week 52. Week 12 responders (BMS-986165 3 mg) and week 12 non-responders (BMS-986165 6 mg OL) who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the open-label extension period and began/continued to receive open label BMS-986165 6 mg twice daily.

Reporting group title	6 mg BMS-986165

Reporting group description:

BMS-986165 6 mg was taken orally twice per day over 12 weeks. Participants who achieved a clinical response after the 12-week induction period continued to take BMS-986165 6 mg orally twice daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to enter the open label period and continued to receive BMS-986165 6 mg twice per day until week 52. Week 12 responders and week 12 non-responders who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the open label extension period and continued to receive open label BMS-986165 6 mg twice daily.

Reporting group title	12 mg BMS-986165

Reporting group description:

BMS-986165 12 mg was taken orally once per day over 12 weeks. Participants who achieved a clinical response after the 12-week induction period continued to take BMS-986165 12 mg orally once daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response prior to protocol v 3 but had an appropriate safety profile were eligible to enter the open label period and received BMS-986165 12 mg once per day. Participants who were randomized prior to the implementation of Protocol v3.0 who had not yet reached Week 12 but had an appropriate safety profile could switch to open-label BMS-986165 6 mg for the Maintenance Period, if they did not achieve a clinical response at Week 12. Week 12 responders and week 12 non-responders who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the open label extension period to receive open label BMS-986165 6 mg twice daily.

Reporting group title	Placebo

Reporting group description:

Placebo was taken twice per day over 12 weeks. Participants who achieved a clinical response after the 12 week induction period continued to take placebo twice daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to receive open-label BMS-986165 6 mg twice per day until week 52. Week 12 responders (Placebo) and week 12 non-responders (BMS-986165 6 mg OL) who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the OLE Period and began/continued to receive BMS986165 6 mg twice daily.

Reporting group title	3 mg BMS-986165

Reporting group description:

BMS-986165 3 mg was taken orally twice per day over 12 weeks. Participants who achieved a clinical response after the 12 week induction period continued to take BMS-986165 3 mg orally twice daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to receive BMS-986165 6 mg twice per day until week 52. Week 12 responders (BMS-986165 3 mg) and week 12 non-responders (BMS-986165 6 mg OL) who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the open-label extension period and began/continued to receive

open label BMS-986165 6 mg twice daily.

Reporting group title	6 mg BMS-986165

Reporting group description:

BMS-986165 6 mg was taken orally twice per day over 12 weeks. Participants who achieved a clinical response after the 12-week induction period continued to take BMS-986165 6 mg orally twice daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to enter the open label period and continued to receive BMS-986165 6 mg twice per day until week 52. Week 12 responders and week 12 non-responders who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the open label extension period and continued to receive open label BMS-986165 6 mg twice daily.

Reporting group title	12 mg BMS-986165

Reporting group description:

BMS-986165 12 mg was taken orally once per day over 12 weeks. Participants who achieved a clinical response after the 12-week induction period continued to take BMS-986165 12 mg orally once daily until the end of the maintenance period (week 52). Participants who did not achieve clinical response prior to protocol v 3 but had an appropriate safety profile were eligible to enter the open label period and received BMS-986165 12 mg once per day. Participants who were randomized prior to the implementation of Protocol v3.0 who had not yet reached Week 12 but had an appropriate safety profile could switch to open-label BMS-986165 6 mg for the Maintenance Period, if they did not achieve a clinical response at Week 12. Week 12 responders and week 12 non-responders who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to enter the open label extension period to receive open label BMS-986165 6 mg twice daily.

Primary: Percent of participants achieving clinical remission at Week 12

End point title	Percent of participants achieving clinical remission at Week 12

End point description:

Percent of participants achieving clinical remission at Week 12. Clinical remission is defined as achieving a Crohn's Disease Activity Index (CDAI) Score below 150. CDAI is a tool that helps doctors measure how severe someone's Crohn's disease is. It uses questions about symptoms experienced over a week to calculate a score. The scores range from 0 to 600 and are classified into different categories. Scores from 0 to 149 suggest the disease may be in remission. Scores from 150 to 220 indicate mild activity. Scores from 220 to 450 mean the disease is moderate to severe. Scores from 451 to 600 indicate severe disease. Higher scores mean more severe symptoms.
Risk Difference and Odds Ratio prespecified to be collected for 3 mg and 6 mg BMS-986165 arms only.

End point type	Primary

End point timeframe:

12 weeks after first dose

End point values	Placebo	3 mg BMS-986165	6 mg BMS-986165	12 mg BMS-986165
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	86	84	9
Units: Percent of Participants				
number (confidence interval 95%)	28.3 (16.9 to 39.7)	32.6 (22.7 to 42.5)	21.4 (12.7 to 30.2)	22.2 (0.0 to 49.4)

Statistical analyses

Statistical analysis title	Risk Difference (RD) Placebo vs 3 mg BMS-986165
Comparison groups	3 mg BMS-986165 v Placebo

Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5812 [1]
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	4.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11
upper limit	19.5

Notes:

[1] - Based on a 2-sided test at a significance level of 0.025.

Statistical analysis title	Odds Ratio (OR) Placebo vs 6 mg BMS-986165
Comparison groups	Placebo v 6 mg BMS-986165
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.372 [2]
Method	Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	1.5

Notes:

[2] - Based on a 2-sided test at a significance level of 0.025.

Statistical analysis title	Risk Difference (RD) Placebo vs 6 mg BMS-986165
Comparison groups	Placebo v 6 mg BMS-986165
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.372 [3]
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	-6.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.2
upper limit	7.6

Notes:

[3] - Based on a 2-sided test at a significance level of 0.025.

Statistical analysis title	Odds Ratio (OR) Placebo vs 3 mg BMS-986165

Comparison groups	Placebo v 3 mg BMS-986165
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5812 [4]
Method	Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6
upper limit	2.5

Notes:

[4] - Based on a 2-sided test at a significance level of 0.025.

Primary: Percent of participants achieving endoscopic response at Week 12

End point title	Percent of participants achieving endoscopic response at Week 12

End point description:

Endoscopic Response is defined as >= 50% decrease from baseline in the Simple Endoscopic Score for Crohn’s Disease (SES-CD). The SES-CD score is a way to measure how severe a person's bowel disease is. It looks at five different parts of the bowel and checks for things like ulcers and inflammation. Each part is given a score from 0 to 3 based on how bad the disease is. These scores are then added together for a total score ranging from 0 to 60. Higher scores indicate more severe disease. Baseline refers to the initial set of before data collected from participants before starting study treatment.
Risk Difference and Odds Ratio prespecified to be collected for 3 mg and 6 mg BMS-986165 arms only.

End point type	Primary

End point timeframe:

12 weeks after first dose

End point values	Placebo	3 mg BMS-986165	6 mg BMS-986165	12 mg BMS-986165
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	86	84	9
Units: Percent of Participants				
number (confidence interval 95%)	8.3 (1.3 to 15.3)	23.3 (14.3 to 32.2)	16.7 (8.7 to 24.6)	33.3 (2.5 to 64.1)

Statistical analyses

Statistical analysis title	Risk Difference (RD) Placebo vs 3 mg BMS-986165
Comparison groups	Placebo v 3 mg BMS-986165

Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0198 [5]
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	15
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.7
upper limit	26.3

Notes:

[5] - Based on a 2-sided test at a significance level of 0.025.

Statistical analysis title	Odds Ratio (OR) Placebo vs 6 mg BMS-986165
Comparison groups	Placebo v 6 mg BMS-986165
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1584 [6]
Method	Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	6.1

Notes:

[6] - Based on a 2-sided test at a significance level of 0.025.

Statistical analysis title	Risk Difference (RD) Placebo vs 6 mg BMS-986165
Comparison groups	Placebo v 6 mg BMS-986165
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.1584 [7]
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	8.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.6
upper limit	19

Notes:

[7] - Based on a 2-sided test at a significance level of 0.025.

Statistical analysis title	Odds Ratio (OR) Placebo vs 3 mg BMS-986165

Comparison groups	Placebo v 3 mg BMS-986165
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0198 [8]
Method	Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	3.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.2
upper limit	9.8

Notes:

[8] - Based on a 2-sided test at a significance level of 0.025.

Secondary: Percent of participants achieving clinical response at Week 12

End point title	Percent of participants achieving clinical response at Week 12

End point description:

Clinical response is defined as a reduction from baseline in the Crohn's Disease Activity Index (CDAI) score of ≥ 100 points or a total CDAI score < 150. CDAI is a tool that helps doctors measure how severe someone's Crohn's disease is. It uses questions about symptoms experienced over a week to calculate a score. The scores range from 0 to 600 and are classified into different categories. Scores from 0 to 149 suggest the disease may be in remission. Scores from 150 to 220 indicate mild activity. Scores from 220 to 450 mean the disease is moderate to severe. Scores from 451 to 600 indicate severe disease. Higher scores mean more severe symptoms. Baseline refers to the initial set of before data collected from participants before starting study treatment.
Risk Difference and Odds Ratio prespecified to be collected for 3 mg and 6 mg BMS-986165 arms only.

End point type	Secondary

End point timeframe:

12 weeks after first dose

End point values	Placebo	3 mg BMS-986165	6 mg BMS-986165	12 mg BMS-986165
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	86	84	9
Units: Percent of Participants				
number (confidence interval 95%)	40.0 (27.6 to 52.4)	47.7 (37.1 to 58.2)	38.1 (27.7 to 48.5)	55.6 (23.1 to 88.0)

Statistical analyses

Statistical analysis title	Risk Difference (RD) Placebo vs 3 mg BMS-986165
Comparison groups	Placebo v 3 mg BMS-986165

Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3464 [9]
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	7.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.2
upper limit	23.6

Notes:

[9] - Based on a 2-sided test at a significance level of 0.025.

Statistical analysis title	Odds Ratio (OR) Placebo vs 3 mg BMS-986165
Comparison groups	Placebo v 3 mg BMS-986165
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.3464 [10]
Method	Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	2.8

Notes:

[10] - Based on a 2-sided test at a significance level of 0.025.

Statistical analysis title	Risk Difference (RD) Placebo vs 6 mg BMS-986165
Comparison groups	Placebo v 6 mg BMS-986165
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8857 [11]
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	1.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17
upper limit	14.7

Notes:

[11] - Based on a 2-sided test at a significance level of 0.025.

Statistical analysis title	Odds Ratio (OR) Placebo vs 6 mg BMS-986165

Comparison groups	Placebo v 6 mg BMS-986165
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.8857 [12]
Method	Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5
upper limit	1.9

Notes:

[12] - Based on a 2-sided test at a significance level of 0.025.

Secondary: Percent of participants who achieving Patient Reported Outcomes 2 (PRO2) remission at Week 12

End point title	Percent of participants who achieving Patient Reported Outcomes 2 (PRO2) remission at Week 12

End point description:

The Patient Reported Outcomes 2 (PRO2) is a way for patients to report how they're feeling. It focuses on two things: how often they have loose or liquid stools, and how much abdominal pain they have. They keep track of these things every day for a week. Stool frequency is rated on a scale from 0 to 3, with 0 being the normal number of stools per day to 3 which is >/=5 stools more than normal per day. The pain is rated on a scale from 0 to 3, with 0 being no pain and 3 being severe pain. The scores for these two things are added up to get a total score ranging from 0-6. If the average daily score for abdominal pain is 1 or less, and the average number of loose or liquid stools is 3 or less, then the disease might be in remission.
Risk Difference and Odds Ratio prespecified to be collected for 3 mg and 6 mg BMS-986165 arms only.

End point type	Secondary

End point timeframe:

12 weeks after first dose

End point values	Placebo	3 mg BMS-986165	6 mg BMS-986165	12 mg BMS-986165
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	86	84	9
Units: Percent of Participants				
number (confidence interval 95%)	25.0 (14.0 to 36.0)	32.6 (22.7 to 42.5)	20.2 (11.6 to 28.8)	33.3 (2.5 to 64.1)

Statistical analyses

Statistical analysis title	Risk Difference (RD) Placebo vs 3 mg BMS-986165
Comparison groups	Placebo v 3 mg BMS-986165

Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2841 [13]
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.7
upper limit	22.9

Notes:

[13] - Based on a 2-sided test at a significance level of 0.025.

Statistical analysis title	Odds Ratio (OR) Placebo vs 3 mg BMS-986165
Comparison groups	Placebo v 3 mg BMS-986165
Number of subjects included in analysis	146
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.2841 [14]
Method	Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	3.1

Notes:

[14] - Based on a 2-sided test at a significance level of 0.025.

Statistical analysis title	Risk Difference (RD) Placebo vs 6 mg BMS-986165
Comparison groups	Placebo v 6 mg BMS-986165
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5417 [15]
Method	Mantel-Haenszel
Parameter estimate	Risk difference (RD)
Point estimate	-4.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.6
upper limit	9.2

Notes:

[15] - Based on a 2-sided test at a significance level of 0.025.

Statistical analysis title	Odds Ratio (OR) Placebo vs 6 mg BMS-986165

Comparison groups	Placebo v 6 mg BMS-986165
Number of subjects included in analysis	144
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.5417 [16]
Method	Mantel-Haenszel
Parameter estimate	Odds ratio (OR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	1.8

Notes:

[16] - Based on a 2-sided test at a significance level of 0.025.

Secondary: Change from baseline in Simple Endoscopic Score for Crohn’s Disease (SES-CD) at Week 12

End point title	Change from baseline in Simple Endoscopic Score for Crohn’s Disease (SES-CD) at Week 12

End point description:

The SES-CD score is a way to measure how severe a person's bowel disease is. It looks at five different parts of the bowel and checks for ulcer size, ulcerated surface, inflamed surface, and stenosis. Each is given a score from 0 to 3 based on how bad the disease is. These scores are then added together for a total score ranging from 0 to 60. Higher scores indicate more severe disease. Baseline refers to the initial set of before data collected from participants starting study treatment.

End point type	Secondary

End point timeframe:

12 weeks after first dose

End point values	Placebo	3 mg BMS-986165	6 mg BMS-986165	12 mg BMS-986165
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	50	70	58	7
Units: Change in Score on a Scale				
arithmetic mean (standard deviation)	-1.5 (± 4.3)	-2.5 (± 6.5)	-3.7 (± 5.5)	-5.6 (± 8.5)

Statistical analyses

Statistical analysis title	ANCOVA Placebo vs 6 mg BMS-986165
Comparison groups	Placebo v 6 mg BMS-986165
Number of subjects included in analysis	108
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0177 [17]
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-2.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.1
upper limit	-0.4
Variability estimate	Standard error of the mean
Dispersion value	0.95

Notes:

[17] - Based on a 2-sided test at a significance level of 0.025.

Statistical analysis title	ANCOVA Placebo vs 3 mg BMS-986165
Comparison groups	Placebo v 3 mg BMS-986165
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	
P-value	= 0.0428 [18]
Method	ANCOVA
Parameter estimate	Mean difference (final values)
Point estimate	-1.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.7
upper limit	-0.1
Variability estimate	Standard error of the mean
Dispersion value	0.92

Notes:

[18] - Based on a 2-sided test at a significance level of 0.025.

Adverse events information

Timeframe for reporting adverse events:

Serious Adverse Events (SAEs) and Other Non-Serious Adverse Events (NSAEs) were assessed from first dose to 30 days after last dose of study therapy (assessed up to approximately 63 months).

Adverse event reporting additional description:

The number at risk for SAEs and NSAEs represents all participants that received at least 1 dose of study therapy or similar.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.0

Reporting groups

Reporting group title	Placebo

Reporting group description:

Placebo was taken twice per day over 12 weeks. Participants who achieved a clinical response after week 12 continued to take placebo twice daily until the end of week 52.

Reporting group title	3 mg BMS-986165

Reporting group description:

BMS-986165 3 mg was taken orally twice per day over 12 weeks. Participants who achieved a clinical response after the week 12 continued to take BMS-986165 3 mg orally twice daily until the end of week 52.

Reporting group title	12 mg BMS-986165

Reporting group description:

Participants who took 12 mg BMS-986165 up to week 12/52 who did not achieve clinical response prior to protocol v 3 but had an appropriate safety profile were eligible to enter the open label period and received BMS-986165 12 mg once per day until week 104.

Reporting group title	12 mg BMS-986165

Reporting group description:

BMS-986165 12 mg was taken orally once per day over 12 weeks. Participants who achieved a clinical response after week 12 continued to take BMS-986165 12 mg orally once daily until the end of week 52. Participants who did not achieve clinical response prior to protocol v 3 but had an appropriate safety profile were eligible to receive BMS-986165 12 mg once per day.

Reporting group title	6 mg BMS-986165

Reporting group description:

Participants from the Placebo, 3 mg BMS-986165, and 6 mg BMS-986165 arms who did not achieve clinical response at week 12 but had an appropriate safety profile were eligible to receive open-label BMS-986165 6 mg twice per day until week 52. Week 12 responders and week 12 non-responders who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to begin/continue to receive BMS986165 6 mg twice daily. Participants who were randomized to the 12 mg BMS-986165 arm prior to Protocol v3.0 who had not yet reached Week 12 but had an appropriate safety profile could switch to open-label BMS-986165 6 mg if they did not achieve a clinical response at Week 12. Week 12 responders and week 12 non-responders from this arm who continued to derive a clinical benefit from their respective treatments at week 26/52 and week 52 respectively were eligible to receive open label BMS-986165 6 mg twice daily until week 104.

Reporting group title	6 mg BMS-986165

Reporting group description:

BMS-986165 6 mg was taken orally twice per day over 12 weeks. Participants who achieved a clinical response after the week 12 continued to take BMS-986165 6 mg orally twice daily until the end of week 52.

Serious adverse events	Placebo	3 mg BMS-986165	12 mg BMS-986165
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 59 (10.17%)	11 / 84 (13.10%)	1 / 6 (16.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Accidental exposure to product			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (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
Accidental overdose			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (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
Craniofacial injury			
subjects affected / exposed	0 / 59 (0.00%)	1 / 84 (1.19%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (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
Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (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			
Microcytic anaemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (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
Ear and labyrinth disorders			
Vertigo			

subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (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			
Ileal perforation			
subjects affected / exposed	0 / 59 (0.00%)	1 / 84 (1.19%)	0 / 6 (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
Gastritis			
subjects affected / exposed	0 / 59 (0.00%)	1 / 84 (1.19%)	0 / 6 (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
Enteritis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	3 / 59 (5.08%)	5 / 84 (5.95%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 5	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 59 (0.00%)	1 / 84 (1.19%)	0 / 6 (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
Subileus			
subjects affected / exposed	1 / 59 (1.69%)	0 / 84 (0.00%)	0 / 6 (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
Stomatitis necrotising			
subjects affected / exposed	0 / 59 (0.00%)	1 / 84 (1.19%)	0 / 6 (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
Small intestinal obstruction			

subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (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
Large intestinal obstruction			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (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			
Hepatic cytolysis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (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
Cholecystitis acute			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (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
Acute hepatic failure			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (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			
Tracheal stenosis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (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			
Depression			
subjects affected / exposed	1 / 59 (1.69%)	0 / 84 (0.00%)	0 / 6 (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
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			

subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	1 / 59 (1.69%)	0 / 84 (0.00%)	0 / 6 (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
Anal abscess			
subjects affected / exposed	1 / 59 (1.69%)	0 / 84 (0.00%)	0 / 6 (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
Breast abscess			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mediastinitis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung abscess			
subjects affected / exposed	1 / 59 (1.69%)	0 / 84 (0.00%)	0 / 6 (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
Infectious pleural effusion			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	1 / 6 (16.67%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic foot infection			
subjects affected / exposed	0 / 59 (0.00%)	1 / 84 (1.19%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Norovirus infection			

subjects affected / exposed	0 / 59 (0.00%)	1 / 84 (1.19%)	0 / 6 (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
Peritonsillar abscess			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (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
Urosepsis			
subjects affected / exposed	0 / 59 (0.00%)	1 / 84 (1.19%)	0 / 6 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (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
Hypophosphataemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (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	12 mg BMS-986165	6 mg BMS-986165	6 mg BMS-986165
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 9 (22.22%)	15 / 161 (9.32%)	5 / 83 (6.02%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Accidental exposure to product			
subjects affected / exposed	0 / 9 (0.00%)	1 / 161 (0.62%)	0 / 83 (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
Accidental overdose			

subjects affected / exposed	0 / 9 (0.00%)	1 / 161 (0.62%)	0 / 83 (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
Craniofacial injury			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (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			
Haematoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Ectopic pregnancy			
subjects affected / exposed	0 / 9 (0.00%)	1 / 161 (0.62%)	0 / 83 (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
Blood and lymphatic system disorders			
Microcytic anaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 161 (0.62%)	0 / 83 (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
Ear and labyrinth disorders			
Vertigo			
subjects affected / exposed	0 / 9 (0.00%)	1 / 161 (0.62%)	0 / 83 (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 disorders			
Ileal perforation			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (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
Enteritis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 161 (0.62%)	0 / 83 (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
Crohn's disease			
subjects affected / exposed	1 / 9 (11.11%)	6 / 161 (3.73%)	2 / 83 (2.41%)
occurrences causally related to treatment / all	0 / 1	0 / 9	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (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
Subileus			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (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
Stomatitis necrotising			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	1 / 161 (0.62%)	0 / 83 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 9 (0.00%)	1 / 161 (0.62%)	0 / 83 (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			
Hepatic cytolysis			

subjects affected / exposed	1 / 9 (11.11%)	0 / 161 (0.00%)	0 / 83 (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
Cholecystitis acute			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute hepatic failure			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Tracheal stenosis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Depression			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral disc protrusion			
subjects affected / exposed	0 / 9 (0.00%)	1 / 161 (0.62%)	0 / 83 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			

subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (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
Breast abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (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
Mediastinitis			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (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 abscess			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (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
Infectious pleural effusion			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (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
Diabetic foot infection			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (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
Norovirus infection			
subjects affected / exposed	0 / 9 (0.00%)	1 / 161 (0.62%)	0 / 83 (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
Peritonsillar abscess			
subjects affected / exposed	0 / 9 (0.00%)	1 / 161 (0.62%)	0 / 83 (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
Urosepsis			

subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (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			
Hypoglycaemia			
subjects affected / exposed	0 / 9 (0.00%)	1 / 161 (0.62%)	0 / 83 (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
Hypophosphataemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	1 / 83 (1.20%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Placebo	3 mg BMS-986165	12 mg BMS-986165
Total subjects affected by non-serious adverse events			
subjects affected / exposed	33 / 59 (55.93%)	55 / 84 (65.48%)	3 / 6 (50.00%)
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 59 (5.08%)	2 / 84 (2.38%)	0 / 6 (0.00%)
occurrences (all)	3	3	0
Pyrexia			
subjects affected / exposed	4 / 59 (6.78%)	4 / 84 (4.76%)	0 / 6 (0.00%)
occurrences (all)	4	5	0
Reproductive system and breast disorders			
Breast haematoma			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	4 / 59 (6.78%)	2 / 84 (2.38%)	0 / 6 (0.00%)
occurrences (all)	4	2	0
Cough			

subjects affected / exposed	1 / 59 (1.69%)	3 / 84 (3.57%)	1 / 6 (16.67%)
occurrences (all)	1	3	2
Injury, poisoning and procedural complications			
Traumatic haemothorax			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Thoracic vertebral fracture			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Rib fracture			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	1 / 6 (16.67%)
occurrences (all)	0	0	1
Cardiac disorders			
Ventricular extrasystoles			
subjects affected / exposed	1 / 59 (1.69%)	0 / 84 (0.00%)	1 / 6 (16.67%)
occurrences (all)	1	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 59 (6.78%)	6 / 84 (7.14%)	0 / 6 (0.00%)
occurrences (all)	4	7	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 59 (0.00%)	2 / 84 (2.38%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Iron deficiency anaemia			
subjects affected / exposed	3 / 59 (5.08%)	1 / 84 (1.19%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Lymphopenia			
subjects affected / exposed	0 / 59 (0.00%)	2 / 84 (2.38%)	0 / 6 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	3 / 59 (5.08%)	6 / 84 (7.14%)	0 / 6 (0.00%)
occurrences (all)	3	6	0
Aphthous ulcer			

subjects affected / exposed	2 / 59 (3.39%)	3 / 84 (3.57%)	0 / 6 (0.00%)
occurrences (all)	2	3	0
Dyspepsia			
subjects affected / exposed	3 / 59 (5.08%)	1 / 84 (1.19%)	0 / 6 (0.00%)
occurrences (all)	3	1	0
Mouth ulceration			
subjects affected / exposed	0 / 59 (0.00%)	6 / 84 (7.14%)	0 / 6 (0.00%)
occurrences (all)	0	9	0
Nausea			
subjects affected / exposed	4 / 59 (6.78%)	4 / 84 (4.76%)	0 / 6 (0.00%)
occurrences (all)	4	4	0
Proctalgia			
subjects affected / exposed	1 / 59 (1.69%)	1 / 84 (1.19%)	0 / 6 (0.00%)
occurrences (all)	1	1	0
Vomiting			
subjects affected / exposed	5 / 59 (8.47%)	2 / 84 (2.38%)	0 / 6 (0.00%)
occurrences (all)	5	2	0
Crohn's disease			
subjects affected / exposed	9 / 59 (15.25%)	10 / 84 (11.90%)	0 / 6 (0.00%)
occurrences (all)	9	10	0
Hepatobiliary disorders			
Hepatic cytolysis			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash papular			
subjects affected / exposed	0 / 59 (0.00%)	1 / 84 (1.19%)	0 / 6 (0.00%)
occurrences (all)	0	1	0
Rash			
subjects affected / exposed	2 / 59 (3.39%)	5 / 84 (5.95%)	0 / 6 (0.00%)
occurrences (all)	2	6	0
Skin lesion			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0
Acne			

subjects affected / exposed	2 / 59 (3.39%)	9 / 84 (10.71%)	0 / 6 (0.00%)
occurrences (all)	2	10	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	5 / 59 (8.47%)	5 / 84 (5.95%)	0 / 6 (0.00%)
occurrences (all)	7	6	0
Back pain			
subjects affected / exposed	3 / 59 (5.08%)	1 / 84 (1.19%)	0 / 6 (0.00%)
occurrences (all)	3	2	0
Myalgia			
subjects affected / exposed	0 / 59 (0.00%)	4 / 84 (4.76%)	0 / 6 (0.00%)
occurrences (all)	0	5	0
Infections and infestations			
COVID-19			
subjects affected / exposed	6 / 59 (10.17%)	5 / 84 (5.95%)	1 / 6 (16.67%)
occurrences (all)	6	6	1
Folliculitis			
subjects affected / exposed	0 / 59 (0.00%)	5 / 84 (5.95%)	0 / 6 (0.00%)
occurrences (all)	0	5	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 59 (3.39%)	9 / 84 (10.71%)	1 / 6 (16.67%)
occurrences (all)	2	9	2
Nasopharyngitis			
subjects affected / exposed	3 / 59 (5.08%)	6 / 84 (7.14%)	1 / 6 (16.67%)
occurrences (all)	4	8	2
Metabolism and nutrition disorders			
Hypophosphataemia			
subjects affected / exposed	0 / 59 (0.00%)	0 / 84 (0.00%)	0 / 6 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	12 mg BMS-986165	6 mg BMS-986165	6 mg BMS-986165
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 9 (77.78%)	86 / 161 (53.42%)	55 / 83 (66.27%)
General disorders and administration site conditions			
Asthenia			

subjects affected / exposed	1 / 9 (11.11%)	3 / 161 (1.86%)	1 / 83 (1.20%)
occurrences (all)	1	4	1
Pyrexia			
subjects affected / exposed	0 / 9 (0.00%)	9 / 161 (5.59%)	7 / 83 (8.43%)
occurrences (all)	0	13	9
Reproductive system and breast disorders			
Breast haematoma			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	0 / 9 (0.00%)	4 / 161 (2.48%)	6 / 83 (7.23%)
occurrences (all)	0	4	7
Cough			
subjects affected / exposed	0 / 9 (0.00%)	1 / 161 (0.62%)	3 / 83 (3.61%)
occurrences (all)	0	1	4
Injury, poisoning and procedural complications			
Traumatic haemothorax			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Rib fracture			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Ventricular extrasystoles			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	0 / 83 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 9 (0.00%)	4 / 161 (2.48%)	5 / 83 (6.02%)
occurrences (all)	0	4	5
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	1 / 9 (11.11%)	2 / 161 (1.24%)	4 / 83 (4.82%)
occurrences (all)	1	2	4
Iron deficiency anaemia			
subjects affected / exposed	0 / 9 (0.00%)	0 / 161 (0.00%)	1 / 83 (1.20%)
occurrences (all)	0	0	1
Lymphopenia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 161 (0.62%)	0 / 83 (0.00%)
occurrences (all)	2	1	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 9 (0.00%)	10 / 161 (6.21%)	7 / 83 (8.43%)
occurrences (all)	0	10	8
Aphthous ulcer			
subjects affected / exposed	0 / 9 (0.00%)	7 / 161 (4.35%)	8 / 83 (9.64%)
occurrences (all)	0	8	11
Dyspepsia			
subjects affected / exposed	1 / 9 (11.11%)	2 / 161 (1.24%)	0 / 83 (0.00%)
occurrences (all)	1	2	0
Mouth ulceration			
subjects affected / exposed	0 / 9 (0.00%)	7 / 161 (4.35%)	4 / 83 (4.82%)
occurrences (all)	0	11	8
Nausea			
subjects affected / exposed	0 / 9 (0.00%)	5 / 161 (3.11%)	2 / 83 (2.41%)
occurrences (all)	0	5	2
Proctalgia			
subjects affected / exposed	1 / 9 (11.11%)	2 / 161 (1.24%)	0 / 83 (0.00%)
occurrences (all)	1	2	0
Vomiting			
subjects affected / exposed	0 / 9 (0.00%)	2 / 161 (1.24%)	2 / 83 (2.41%)
occurrences (all)	0	2	2
Crohn's disease			
subjects affected / exposed	1 / 9 (11.11%)	17 / 161 (10.56%)	10 / 83 (12.05%)
occurrences (all)	1	19	11
Hepatobiliary disorders			

Hepatic cytolysis			
subjects affected / exposed	1 / 9 (11.11%)	0 / 161 (0.00%)	0 / 83 (0.00%)
occurrences (all)	1	0	0
Skin and subcutaneous tissue disorders			
Rash papular			
subjects affected / exposed	1 / 9 (11.11%)	0 / 161 (0.00%)	1 / 83 (1.20%)
occurrences (all)	1	0	1
Rash			
subjects affected / exposed	0 / 9 (0.00%)	6 / 161 (3.73%)	5 / 83 (6.02%)
occurrences (all)	0	8	5
Skin lesion			
subjects affected / exposed	1 / 9 (11.11%)	1 / 161 (0.62%)	1 / 83 (1.20%)
occurrences (all)	1	1	1
Acne			
subjects affected / exposed	0 / 9 (0.00%)	5 / 161 (3.11%)	12 / 83 (14.46%)
occurrences (all)	0	6	12
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 9 (11.11%)	8 / 161 (4.97%)	6 / 83 (7.23%)
occurrences (all)	2	9	6
Back pain			
subjects affected / exposed	0 / 9 (0.00%)	5 / 161 (3.11%)	2 / 83 (2.41%)
occurrences (all)	0	6	2
Myalgia			
subjects affected / exposed	1 / 9 (11.11%)	1 / 161 (0.62%)	2 / 83 (2.41%)
occurrences (all)	1	1	3
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 9 (0.00%)	22 / 161 (13.66%)	11 / 83 (13.25%)
occurrences (all)	0	23	11
Folliculitis			
subjects affected / exposed	0 / 9 (0.00%)	1 / 161 (0.62%)	1 / 83 (1.20%)
occurrences (all)	0	1	1
Upper respiratory tract infection			
subjects affected / exposed	3 / 9 (33.33%)	11 / 161 (6.83%)	5 / 83 (6.02%)
occurrences (all)	3	16	8

Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 9 (0.00%) 0	12 / 161 (7.45%) 18	5 / 83 (6.02%) 5
Metabolism and nutrition disorders Hypophosphataemia subjects affected / exposed occurrences (all)	1 / 9 (11.11%) 1	1 / 161 (0.62%) 2	2 / 83 (2.41%) 2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
24 May 2018	Includes modifications to multiple sections of the protocol to incorporate updated information, provide clarity, and to align with recent communications with FDA.
25 June 2019	Includes the following modifications: Change of co-primary endpoint (clinical remission) definition Removal of 12 mg QD treatment arm Addition of 52-week open-label extension period Clarification of clinical response, loss of response, and treatment failure definitions Clarification of corticosteroid tapering and rescue instructions Revision of the Schedule of Activities and Biomarker sections to provide clarity Update of Multiplicity Adjustment Section (10.4.6) Update of wording in various appendices to be consistent across studies of BMS-986165 Minor grammatical and typographic corrections
20 August 2019	Includes the following modifications: Clarification of the number of subject diary days required to calculate the CDAI Alignment in protocol text and Appendix 7 of washout times for specific treatments Clarification of rescreening requirements for subjects positive for C. difficile
06 August 2021	Includes the following modifications: Added information, instructions, and measures to be taken related to SARS-CoV-2 infection. Reconfigured secondary and exploratory endpoints in response to expert consensus on treatment targets in IBD. Added availability of a long-term extension study, IM011077, for eligible subjects. Removed exclusion criterion that prohibited the participation of subjects who had previously experienced inadequate response or loss of response to ustekinumab. Clarified multiple other inclusion and exclusion criteria. Updated vendor information Added efficacy and safety findings from recent BMS-986165 studies Removed fasting requirement at screening. Clarified procedures for C. difficile testing, endoscopies, unblinding for Week 12 analysis, hematocrit analysis, potential future analyses, and subjects with liver abnormalities and potential DILI AEs. Clarified that pharmacogenomic testing is optional. Clarified that subjects who need rescue treatment must discontinue study treatment during the OLE. Updated language throughout protocol to reflect current BMS procedures, policies, and guidelines.
02 September 2022	Includes the following modifications: Added diary selection rules for Week 0 of CDAI/PRO2 calculation Updated efficacy analyses to reflect updated planned statistical analyses Clarification of assessments and timing for Week 104 visit Clarification of final assessments for subjects rolling to IM011077, and these subjects will not be considered IM011023 study completers Elucidation of treatment failure rules Added open-label 6 mg BID BMS-986165 arm to the Selection and Timing of Dose table Applied minor editorial changes to enhance the clarity of the protocol and update address information

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported