Clinical trial results:
A Phase 2 Randomized, Double-Blind, Placebo-Controlled Study of the Safety, Efficacy, and Biomarker Response of BMS-986165 in Subjects with Moderate to Severe Ulcerative Colitis

Summary

EudraCT number	2019-004878-26
Trial protocol	DE NL PL
Global end of trial date	29 November 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	IM011-127

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04613518
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	24 January 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	31 May 2023
Global end of trial reached?	Yes
Global end of trial date	29 November 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective is to estimate the effect of BMS-986165 on clinical response at Week 12.

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	15 March 2021
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Netherlands: 5
Country: Number of subjects enrolled	Poland: 17
Country: Number of subjects enrolled	United Kingdom: 3
Country: Number of subjects enrolled	United States: 5
Worldwide total number of subjects	38
EEA total number of subjects	25

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)	38
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

BMS-986165 6 mg BID arm was removed under Protocol Amendment 02.

Period 1

Period 1 title	Double-Blind Treatment Period
Is this the baseline period?	Yes
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	BMS-986165 12 mg BID

Arm description:

Participants receive BMS-986165 12 mg BID for a 12-week double-blind treatment period, then if eligible, move into the 40-week open-label extension period and receive BMS-986165 6 mg BID PO.

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:

12 mg twice daily

Arm title	BMS-986165 6 mg BID

Arm description:

Participants were randomized to the 6 mg BID arm under the Original Protocol or Protocol Amendment 01 receive 6 mg BID for the 12-week double-blind treatment period and 6 mg BID in the open-label extension period.

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:

12 mg twice daily

Arm title	Placebo BID PO

Arm description:

Participants receive placebo for a 12-week double-blind treatment period, then if eligible, move into the 40-week open-label extension period and receive BMS-986165 6 mg BID PO.

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 matching BMS-986165 twice daily

Number of subjects in period 1	BMS-986165 12 mg BID	BMS-986165 6 mg BID	Placebo BID PO
Started	26	4	8
Completed	19	3	7
Not completed	7	1	1
Participant request to discontinue treatment	1	-	-
Participant withdrew consent	1	1	-
Adverse event, non-fatal	2	-	1
Other Reasons	2	-	-
Lack of efficacy	1	-	-

Period 2

Period 2 title	Open-Label Treatment Period
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	BMS-986165 12 mg BID

Arm description:

Participants receive BMS-986165 12 mg BID for a 12-week double-blind treatment period, then if eligible, move into the 40-week open-label extension period and receive BMS-986165 6 mg BID PO.

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:

12 mg twice daily

Arm title	BMS-986165 6 mg BID

Arm description:

Participants were randomized to the 6 mg BID arm under the Original Protocol or Protocol Amendment 01 receive 6 mg BID for the 12-week double-blind treatment period and 6 mg BID in the open-label extension period.

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:

12 mg twice daily

Arm title	Placebo BID PO

Arm description:

Participants receive placebo for a 12-week double-blind treatment period, then if eligible, move into the 40-week open-label extension period and receive BMS-986165 6 mg BID PO.

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 matching BMS-986165 twice daily

Number of subjects in period 2	BMS-986165 12 mg BID	BMS-986165 6 mg BID	Placebo BID PO
Started	19	3	7
Completed	11	0	1
Not completed	8	3	6
Participant request to discontinue treatment	1	-	-
Participant withdrew consent	1	-	3
Adverse event, non-fatal	1	-	3
Other Reasons	1	-	-
Administrative reason by sponsor	4	-	-
Lack of efficacy	-	3	-

Baseline characteristics

Reporting groups	
Reporting group title	BMS-986165 12 mg BID
Reporting group description:	
Participants receive BMS-986165 12 mg BID for a 12-week double-blind treatment period, then if eligible, move into the 40-week open-label extension period and receive BMS-986165 6 mg BID PO.	
Reporting group title	BMS-986165 6 mg BID
Reporting group description:	
Participants were randomized to the 6 mg BID arm under the Original Protocol or Protocol Amendment 01 receive 6 mg BID for the 12-week double-blind treatment period and 6 mg BID in the open-label extension period.	
Reporting group title	Placebo BID PO
Reporting group description:	
Participants receive placebo for a 12-week double-blind treatment period, then if eligible, move into the 40-week open-label extension period and receive BMS-986165 6 mg BID PO.	

Reporting group values	BMS-986165 12 mg BID	BMS-986165 6 mg BID	Placebo BID PO
Number of subjects	26	4	8
Age categorical Units: Subjects			
Adults (18-64 years)	26	4	8
Age Continuous Units: Years			
arithmetic mean	41.8	28.8	38.0
standard deviation	± 14.4	± 6.7	± 15.1
Sex: Female, Male Units: Participants			
Female	12	2	2
Male	14	2	6
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	1	0	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	25	3	7
More than one race	0	0	0
Unknown or Not Reported	0	0	0
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0	0	0
Not Hispanic or Latino	24	3	6
Unknown or Not Reported	2	1	2

Reporting group values	Total		
Number of subjects	38		

Age categorical Units: Subjects			
Adults (18-64 years)	38		
Age Continuous Units: Years arithmetic mean standard deviation	 -		
Sex: Female, Male Units: Participants			
Female	16		
Male	22		
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	1		
Asian	2		
Native Hawaiian or Other Pacific Islander	0		
Black or African American	0		
White	35		
More than one race	0		
Unknown or Not Reported	0		
Ethnicity (NIH/OMB) Units: Subjects			
Hispanic or Latino	0		
Not Hispanic or Latino	33		
Unknown or Not Reported	5		

End points

End points reporting groups

Reporting group title	BMS-986165 12 mg BID
Reporting group description:	
Participants receive BMS-986165 12 mg BID for a 12-week double-blind treatment period, then if eligible, move into the 40-week open-label extension period and receive BMS-986165 6 mg BID PO.	
Reporting group title	BMS-986165 6 mg BID
Reporting group description:	
Participants were randomized to the 6 mg BID arm under the Original Protocol or Protocol Amendment 01 receive 6 mg BID for the 12-week double-blind treatment period and 6 mg BID in the open-label extension period.	
Reporting group title	Placebo BID PO
Reporting group description:	
Participants receive placebo for a 12-week double-blind treatment period, then if eligible, move into the 40-week open-label extension period and receive BMS-986165 6 mg BID PO.	
Reporting group title	BMS-986165 12 mg BID
Reporting group description:	
Participants receive BMS-986165 12 mg BID for a 12-week double-blind treatment period, then if eligible, move into the 40-week open-label extension period and receive BMS-986165 6 mg BID PO.	
Reporting group title	BMS-986165 6 mg BID
Reporting group description:	
Participants were randomized to the 6 mg BID arm under the Original Protocol or Protocol Amendment 01 receive 6 mg BID for the 12-week double-blind treatment period and 6 mg BID in the open-label extension period.	
Reporting group title	Placebo BID PO
Reporting group description:	
Participants receive placebo for a 12-week double-blind treatment period, then if eligible, move into the 40-week open-label extension period and receive BMS-986165 6 mg BID PO.	

Primary: Percentage of Participants in Clinical Response at Week 12

End point title	Percentage of Participants in Clinical Response at Week 12[1]
End point description:	
Clinical response is defined as achieving the following changes in the modified Mayo score (excludes the physicians' global assessment) -A decrease from baseline in the modified Mayo score of ≥ 2 points, and - A decrease from baseline in the modified Mayo score ≥ 30%, and - A decrease in rectal bleeding (RB) subscore of ≥ 1 point or absolute RB subscore ≤ 1 Note: The modified Mayo score calculated to determine eligibility will also be used as the baseline disease activity score. The modified Mayo score is a 9-point scale (a score of 5 to 9 points denotes moderate to severe disease). The modified Mayo score is a sum of the following 3 components: - Stool frequency (SF) subscore (0 to 3) - Rectal bleeding (RB) subscore (0 to 3) - Endoscopic (ES) subscore (0 to 3) Analyzed for all randomized participants.	
End point type	Primary
End point timeframe:	
At week 12	

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: BMS-986165 6 mg BID was removed from the protocol and not in scope of the endpoints.

End point values	BMS-986165 12 mg BID	Placebo BID PO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	8		
Units: Percentage of participants				
number (confidence interval 95%)	53.8 (33.4 to 73.4)	50.0 (15.7 to 84.3)		

Statistical analyses

Statistical analysis title	DIFFERENCE VS PLACEBO
Comparison groups	BMS-986165 12 mg BID v Placebo BID PO
Number of subjects included in analysis	34
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Mean difference (final values)
Point estimate	3.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.7
upper limit	43.4

Primary: Number of Participants Experiencing Adverse Events (AEs)

End point title	Number of Participants Experiencing Adverse Events (AEs)[2][3]

End point description:

An AE is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment. Analyzed for all randomized participants who receive at least 1 dose of double-blind study treatment.

Note: the first dose of study treatment in the open-label period may be the same as the last dose date of study treatment in double-blind treatment period.

End point type	Primary

End point timeframe:

From first dose up to the last dose in the double-blind period or 30 days post the last dose date if not treated in the open-label period and from the first dose in open-label period up to 30 days post the last dose date (up to approximately 402 days)

Notes:

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

[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: BMS-986165 6 mg BID was removed from the protocol and not in scope of the endpoints.

End point values	BMS-986165 12 mg BID	Placebo BID PO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	8		
Units: Participants				
Double-Blind Treatment Period	21	6		
Open-Label Treatment Period	15	6		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants Experiencing Serious Adverse Events (SAEs)

End point title	Number of Participants Experiencing Serious Adverse Events (SAEs)[4][5]

End point description:

An SAE is defined as any untoward medical occurrence that, at any dose: results in death, is life-threatening, requires inpatient hospitalization or causes prolongation of existing hospitalization, results in persistent or significant disability or permanent damage, is a congenital anomaly/birth defect, is an important medical event. Analyzed for all randomized participants who receive at least 1 dose of double-blind study treatment.

Note: the first dose of study treatment in the open-label period may be the same as the last dose date of study treatment in double-blind treatment period.

End point type	Primary

End point timeframe:

From first dose up to the last dose in the double-blind period or 30 days post the last dose date if not treated in the open-label period and from the first dose in open-label period up to 30 days post the last dose date (up to approximately 402 days)

Notes:

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

[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: BMS-986165 6 mg BID was removed from the protocol and not in scope of the endpoints.

End point values	BMS-986165 12 mg BID	Placebo BID PO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	8		
Units: Participants				
Double-Blind Treatment Period	4	1		
Open-Label Treatment Period	1	1		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants Experiencing Adverse Events (AEs) Leading to Discontinuation

End point title	Number of Participants Experiencing Adverse Events (AEs) Leading to Discontinuation[6][7]

End point description:

An AE is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment.Analyzed for all randomized participants who receive at least 1 dose of double-blind study treatment.

Note: the first dose of study treatment in the open-label period may be the same as the last dose date of study treatment in double-blind treatment period.

End point type	Primary

End point timeframe:

From first dose up to the last dose in the double-blind period or 30 days post the last dose date if not treated in the open-label period and from the first dose in open-label period up to 30 days post the last dose date (up to approximately 402 days)

Notes:

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

[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: BMS-986165 6 mg BID was removed from the protocol and not in scope of the endpoints.

End point values	BMS-986165 12 mg BID	Placebo BID PO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	8		
Units: Participants				
Double-Blind Treatment Period	2	0		
Open-Label Treatment Period	1	3		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants Experiencing Adverse Events of Special Interest (AEIs)

End point title	Number of Participants Experiencing Adverse Events of Special Interest (AEIs)[8][9]

End point description:

An AE is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study drug and that does not necessarily have a causal relationship with this treatment. AEs of special interest include: skin events, influenza, herpes viral infections, opportunistic infections, tuberculosis, cardiovascular events, malignancy, and COVID-19. Analyzed for all randomized participants who receive at least 1 dose of double-blind study treatment.

End point type	Primary

End point timeframe:

From first dose to 52 weeks after first dose

Notes:

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

[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: BMS-986165 6 mg BID was removed from the protocol and not in scope of the endpoints.

End point values	BMS-986165 12 mg BID	Placebo BID PO		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	26	8		
Units: Participants				
Skin Events	15	5		
Influenza	1	2		
Herpes Viral Infections	0	0		
Opportunistic Infections	0	0		
Tuberculosis	0	0		
Cardiovascular events	1	0		
Malignancy	0	0		
COVID-19	3	0		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality was assessed from first dose to study completion (up to approximately 420 days). SAEs and Other AEs were assessed from first dose to 30 days following last dose (up to approximately 402 days)

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	BMS-986165 12 mg BID (Double-Blind Treatment Period)

Reporting group description:

Participants receive BMS-986165 12 mg BID for a 12-week double-blind treatment period.

Reporting group title	Placebo BID PO (Double-Blind Treatment Period)

Reporting group description:

Participants receive placebo for a 12-week double-blind treatment period.

Reporting group title	BMS-986165 6 mg BID (Open-Label Treatment Period)

Reporting group description:

Eligible participants that move into the 40-week open-label extension period receive BMS-986165 6 mg BID PO.

Reporting group title	BMS-986165 6 mg BID (Double-Blind Treatment Period)

Reporting group description:

Participants were randomized to the 6 mg BID arm under the Original Protocol or Protocol Amendment 01 receive 6 mg BID for the 12-week double-blind treatment period.

Serious adverse events	BMS-986165 12 mg BID (Double-Blind Treatment Period)	Placebo BID PO (Double-Blind Treatment Period)	BMS-986165 6 mg BID (Open-Label Treatment Period)
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 26 (15.38%)	1 / 8 (12.50%)	2 / 29 (6.90%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 8 (0.00%)	0 / 29 (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
Gastrointestinal disorders			
Anal fissure			
subjects affected / exposed	0 / 26 (0.00%)	0 / 8 (0.00%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Colitis ulcerative			
subjects affected / exposed	2 / 26 (7.69%)	1 / 8 (12.50%)	1 / 29 (3.45%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrolithiasis			
subjects affected / exposed	1 / 26 (3.85%)	0 / 8 (0.00%)	0 / 29 (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			
Bacteroides bacteraemia			
subjects affected / exposed	1 / 26 (3.85%)	0 / 8 (0.00%)	0 / 29 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	BMS-986165 6 mg BID (Double-Blind Treatment Period)		
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Anal fissure			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Colitis ulcerative			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			

Nephrolithiasis			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bacteroides bacteraemia			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	BMS-986165 12 mg BID (Double-Blind Treatment Period)	Placebo BID PO (Double-Blind Treatment Period)	BMS-986165 6 mg BID (Open-Label Treatment Period)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 26 (73.08%)	6 / 8 (75.00%)	20 / 29 (68.97%)
Investigations			
Weight increased			
subjects affected / exposed	0 / 26 (0.00%)	1 / 8 (12.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 26 (0.00%)	1 / 8 (12.50%)	1 / 29 (3.45%)
occurrences (all)	0	1	1
Injury, poisoning and procedural complications			
Wrist fracture			
subjects affected / exposed	0 / 26 (0.00%)	1 / 8 (12.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 26 (0.00%)	0 / 8 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	2
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	3 / 26 (11.54%)	0 / 8 (0.00%)	0 / 29 (0.00%)
occurrences (all)	3	0	0
Non-cardiac chest pain			

subjects affected / exposed	0 / 26 (0.00%)	0 / 8 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	2
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 26 (0.00%)	1 / 8 (12.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	2 / 26 (7.69%)	0 / 8 (0.00%)	0 / 29 (0.00%)
occurrences (all)	2	0	0
Abdominal pain			
subjects affected / exposed	1 / 26 (3.85%)	1 / 8 (12.50%)	0 / 29 (0.00%)
occurrences (all)	1	1	0
Abdominal distension			
subjects affected / exposed	0 / 26 (0.00%)	0 / 8 (0.00%)	2 / 29 (6.90%)
occurrences (all)	0	0	2
Colitis ulcerative			
subjects affected / exposed	0 / 26 (0.00%)	1 / 8 (12.50%)	1 / 29 (3.45%)
occurrences (all)	0	1	1
Nausea			
subjects affected / exposed	1 / 26 (3.85%)	1 / 8 (12.50%)	0 / 29 (0.00%)
occurrences (all)	1	1	0
Mouth ulceration			
subjects affected / exposed	2 / 26 (7.69%)	0 / 8 (0.00%)	2 / 29 (6.90%)
occurrences (all)	2	0	2
Haemorrhoids			
subjects affected / exposed	0 / 26 (0.00%)	1 / 8 (12.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorder			
subjects affected / exposed	0 / 26 (0.00%)	1 / 8 (12.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Gastritis			
subjects affected / exposed	0 / 26 (0.00%)	1 / 8 (12.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Tongue dry			

subjects affected / exposed	0 / 26 (0.00%)	1 / 8 (12.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 26 (7.69%)	0 / 8 (0.00%)	2 / 29 (6.90%)
occurrences (all)	2	0	2
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	8 / 26 (30.77%)	1 / 8 (12.50%)	5 / 29 (17.24%)
occurrences (all)	8	1	5
Dermatitis acneiform			
subjects affected / exposed	0 / 26 (0.00%)	1 / 8 (12.50%)	1 / 29 (3.45%)
occurrences (all)	0	1	1
Rash			
subjects affected / exposed	4 / 26 (15.38%)	0 / 8 (0.00%)	1 / 29 (3.45%)
occurrences (all)	4	0	1
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 26 (0.00%)	0 / 8 (0.00%)	1 / 29 (3.45%)
occurrences (all)	0	0	1
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	2 / 26 (7.69%)	0 / 8 (0.00%)	1 / 29 (3.45%)
occurrences (all)	2	0	1
Respiratory tract infection			
subjects affected / exposed	0 / 26 (0.00%)	1 / 8 (12.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Pharyngitis			
subjects affected / exposed	2 / 26 (7.69%)	0 / 8 (0.00%)	1 / 29 (3.45%)
occurrences (all)	2	0	1
Oral herpes			
subjects affected / exposed	0 / 26 (0.00%)	1 / 8 (12.50%)	2 / 29 (6.90%)
occurrences (all)	0	1	2
Influenza			
subjects affected / exposed	1 / 26 (3.85%)	0 / 8 (0.00%)	2 / 29 (6.90%)
occurrences (all)	1	0	2

COVID-19			
subjects affected / exposed	1 / 26 (3.85%)	0 / 8 (0.00%)	2 / 29 (6.90%)
occurrences (all)	1	0	2
Nasopharyngitis			
subjects affected / exposed	3 / 26 (11.54%)	1 / 8 (12.50%)	2 / 29 (6.90%)
occurrences (all)	3	1	2
Metabolism and nutrition disorders			
Magnesium deficiency			
subjects affected / exposed	0 / 26 (0.00%)	1 / 8 (12.50%)	0 / 29 (0.00%)
occurrences (all)	0	1	0
Diabetes mellitus inadequate control			
subjects affected / exposed	0 / 26 (0.00%)	1 / 8 (12.50%)	1 / 29 (3.45%)
occurrences (all)	0	1	1

Non-serious adverse events	BMS-986165 6 mg BID (Double-Blind Treatment Period)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)		
Investigations			
Weight increased			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Wrist fracture			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		

Non-cardiac chest pain			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Aphthous ulcer			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Colitis ulcerative			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Mouth ulceration			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorder			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Tongue dry			

subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	3 / 4 (75.00%)		
occurrences (all)	3		
Dermatitis acneiform			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Rash			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 4 (25.00%)		
occurrences (all)	1		
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Respiratory tract infection			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		
Influenza			
subjects affected / exposed	0 / 4 (0.00%)		
occurrences (all)	0		

COVID-19 subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0		
Metabolism and nutrition disorders Magnesium deficiency subjects affected / exposed occurrences (all) Diabetes mellitus inadequate control subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0 0 / 4 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 May 2021	Added instructions and measures to be taken in relation to SARS-CoV-2 infection. Added clarification regarding additional research sample collection and use. Removed prohibition of medical marijuana. Added additional hematology laboratory tests to be conducted. Removed the endoscopic global severity score. Clarified the definitions and male contraception requirements.
24 February 2022	Removed the BMS-986165 6 mg BID treatment arm and Clarified future treatment regimen. Replaced mandatory corticosteroid taper by Week 24 with instruction that subjects should attempt to initiate a taper at least once by Week 24 and removed criterion for treatment failure if a subject is not corticosteroid-free by Week 24.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported