Clinical trial results:
An Open Label, Single Group, Long Term Safety Extension Trial of BI 655066/ABBV-066 (Risankizumab), in Patients With Moderately to Severely Active Crohn's Disease

Summary

EudraCT number	2015-001834-15
Trial protocol	ES BE NL DE
Global end of trial date	19 June 2019

Results information

Result version number	v2 (current)
This version publication date	24 December 2020
First version publication date	28 May 2020
Version creation reason	• New data added to full data set Addition of NCT Number in section Trial Information / Additional Trial Identifier.

Trial information

Trial identification

Sponsor protocol code	1311.20

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02513459
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Boehringer Ingelheim
Sponsor organisation address	Binger Strasse 173, Ingelheim am Rhein, Germany, Binger Strasse 173
Public contact	Boehringer Ingelheim, Boehringer Ingelheim, Call Center, 001 18002430127, clintriage.rdg@boehringer-ingelheim.com
Scientific contact	Boehringer Ingelheim, Call Center, Boehringer Ingelheim, 001 18002430127, clintriage.rdg@boehringer-ingelheim.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	26 September 2019
Is this the analysis of the primary completion data?	Yes
Primary completion date	19 June 2019
Global end of trial reached?	Yes
Global end of trial date	19 June 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study was to investigate long-term safety of risankizumab (BI 655066/ABBV-066) in participants with moderately to severely active Crohn's disease who showed a clinical response or remission on previous treatment with risankizumab in Study NCT02031276 (BI trial 1311.6/ AbbVie M15-993) and were now receiving long-term treatment. Additional objectives of this study were to further investigate long-term efficacy, tolerability, pharmacokinetics, pharmacodynamics and immunogenicity of risankizumab.

Protection of trial subjects:

Only subjects that met all the study inclusion and none of the exclusion criteria were to be entered in the study. All subjects were free to withdraw from the clinical trial at any time for any reason given. Close monitoring of all subjects was adhered to throughout the trial conduct. Rescue medication was allowed for all subjects as required.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	16 September 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Belgium: 19
Country: Number of subjects enrolled	Canada: 1
Country: Number of subjects enrolled	Germany: 6
Country: Number of subjects enrolled	Korea, Republic of: 9
Country: Number of subjects enrolled	Netherlands: 6
Country: Number of subjects enrolled	Poland: 5
Country: Number of subjects enrolled	Spain: 7
Country: Number of subjects enrolled	United Kingdom: 9
Country: Number of subjects enrolled	United States: 3
Worldwide total number of subjects	65
EEA total number of subjects	52

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)	63
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This trial was an open label, single group, long term safety extension trial of Risankizumab, in patients with moderately to severely active Crohn's Disease.

Pre-assignment

Screening details:

All subjects were screened for eligibility prior to participation in the trial. Subjects attended a specialist site which ensured that they (the subjects) strictly met all inclusion and none of the exclusion criteria. Subjects were no to be entered in the trial if any of the entry criteria were violated.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

This trial was an open label trial.

Arms

Arm title	All Risankizumab

Arm description:

Participants who received at least one dose of risankizumab in the current study

Arm type	Experimental
Investigational medicinal product name	Risankizumab 600 mg IV
Investigational medicinal product code	
Other name	BI 655066 / ABBV-066
Pharmaceutical forms	Concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants with clinical response or remission at the end of Study NCT02031276 (Boehringer Ingelheim trial 1311.6/
AbbVie M15-993) or at screening for this study were rolled over directly into this study and received maintenance therapy
of risankizumab 180 mg administered subcutaneously (SC) every 8 weeks (q8w) from Visit 2 through the end of trial (EOT) visit. Participants who lost response or remission between the completion of Study NCT02031276 and enrollment in this study received open-label intravenous (IV) re-induction treatment with risankizumab consisting of 3 infusions of 600 mg (10 mg/ml) IV every 4 weeks (q4w), after which eligibility was assessed if clinical response was re-gained. If clinical response or remission was achieved, participants continued with maintenance treatment of risankizumab 180 mg SC q8w beginning at Visit 5.

Investigational medicinal product name	Risankizumab 180 mg SC
Investigational medicinal product code	
Other name	BI 655066 / ABBV-066
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants with clinical response or remission at the end of Study NCT02031276 (Boehringer Ingelheim trial 1311.6/
AbbVie M15-993) or at screening for this study were rolled over directly into this study and received maintenance therapy
of risankizumab 180 mg (90 mg/ml) administered subcutaneously (SC) every 8 weeks (q8w) from Visit 2 through the end of trial (EOT) visit. Participants who lost response or remission between the completion of Study NCT02031276 and enrollment in this study received open-label intravenous (IV) re-induction treatment with risankizumab consisting of 3 infusions of 600 mg (10 mg/ml) IV every 4 weeks (q4w), after which eligibility was assessed if clinical response was re-gained. If clinical response or remission was achieved, participants continued with maintenance treatment of risankizumab 180 mg SC

q8w beginning at Visit 5.

Number of subjects in period 1	All Risankizumab
Started	65
Completed	44
Not completed	21
Subject decision	2
Loss of efficacy	2
Reproductive plans	1
Lack of response	1
Pregnancy	2
Withdrew consent	5
Adverse event, non-fatal	7
Surgery planned-- not done	1

Baseline characteristics

Reporting groups	
Reporting group title	All Risankizumab
Reporting group description:	
Participants who received at least one dose of risankizumab in the current study	

Reporting group values	All Risankizumab	Total	
Number of subjects	65	65	
Age categorical			
Analysis Population: All participants who received at least one dose of risankizumab in the current study			
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)	63	63	
From 65-84 years	2	2	
85 years and over	0	0	
Age Continuous			
Analysis Population: All participants who received at least one dose of risankizumab in the current study			
Units: years			
arithmetic mean	37.1		
standard deviation	± 12.97	-	
Sex: Female, Male			
Analysis Population: All participants who received at least one dose of risankizumab in the current study			
Units:			
Female	36	36	
Male	29	29	
Race (NIH/OMB)			
Analysis Population: All participants who received at least one dose of risankizumab in the current study			
Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	10	10	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	55	55	
More than one race	0	0	
Unknown or Not Reported	0	0	
Baseline Corticosteroid Use			
Analysis Population: All participants who received at least one dose of risankizumab in the current study			
Units: Subjects			
Yes	21	21	
No.	44	44	
Missing	0	0	

Tumor Necrosis Factor (TNF) Antagonist Exposure			
Analysis Population: All participants who received at least one dose of risankizumab in the current study			
Units: Subjects			
Anti-TNF Experienced	60	60	
Anti-TNF Naive	5	5	
Missing	0	0	
Crohn’s Disease Activity Index (CDAI)			
The Crohn's Disease Activity Index (CDAI) is a composite score that includes participant symptoms evaluated over 7 days (abdominal pain, stool frequency and general well-being), as well as physical and laboratory findings. Items are scored individually, weighted, and do not contribute equally to the overall score. The CDAI is derived from summing up the weighted individual scores of eight items. CDAI approximately ranges from 0 to 600 with higher scores indicating more severe disease. Analysis Population: All participants who received at least one dose of risankizumab in the current study			
Units: units on a scale			
arithmetic mean	304.771		
standard deviation	± 77.9832	-	
High-sensitivity C-Reactive Protein (hs-CRP)			
Analysis Population: All participants who received at least one dose of risankizumab in the current study			
Units: mg/L			
arithmetic mean	20.315		
standard deviation	± 23.1676	-	

End points

End points reporting groups

Reporting group title	All Risankizumab

Reporting group description:

Participants who received at least one dose of risankizumab in the current study

Subject analysis set title	Risankizumab 600 mg IV
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Re-induction treatment; 3 infusions every 4 weeks, after which eligibility was assessed if clinical response was re-gained

Subject analysis set title	Risankizumab 180 mg SC
Subject analysis set type	Intention-to-treat

Subject analysis set description:

Maintenance treatment every 8 weeks (q8w) from Visit 2 through the end of trial (EOT) visit. Participants who re-gained their clinical response following the re-induction treatment could continue with maintenance treatment beginning at Visit 5.

Primary: Number of Participants with Adverse Events

End point title	Number of Participants with Adverse Events[1]

End point description:

A treatment emergent adverse event was defined as an event that occurred or worsened on or after the first dose of study drug through 140 days after the last dose in the current study for participants not rolling over into M16-000 Sub-study 3 or until the first dose of study drug in NCT03105102. All treatment-emergent serious and nonserious adverse events were collected, whether elicited or spontaneously reported by the participant.

Analysis Population: All participants who received at least one dose of risankizumab in the current study

End point type	Primary

End point timeframe:

From the time of study drug administration until 140 days after the last dose of study drug in the current study or until the first dose of study drug in NCT03105102 (AbbVie M16-000 Sub-study 3), up to 4 years for participants who rolled-over

Notes:

[1] - 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: This endpoint was evaluated only descriptively. Thus, no statistical hypothesis were tested.

End point values	All Risankizumab	Risankizumab 600 mg IV	Risankizumab 180 mg SC	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	65	4	65	
Units: Participants	60	2	60	

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Crohn's Disease Activity Index (CDAI) Clinical Remission by Visit

End point title	Percentage of Participants Achieving Crohn's Disease Activity Index (CDAI) Clinical Remission by Visit

End point description:

The Crohn's Disease Activity Index (CDAI) is a composite instrument that includes participant symptoms evaluated over 7 days (abdominal pain, stool frequency and general well-being), as well as physical and laboratory findings. These items are scored individually, weighted, and do not contribute equally to the overall score. The CDAI is derived from summing up the weighted individual scores of eight items. CDAI approximately ranges from 0 to 600 with higher scores indicating more severe disease. Clinical remission is defined as CDAI score < 150.

Analysis Population: Observed case (OC) analysis was performed on the intent-to-treat (ITT) analysis sets. The ITT set for IV consisted of all participants who received at least one dose of risankizumab IV in the current study, and the ITT set for SC consisted of all participants who received at least one dose of risankizumab SC in the current study.

9999 stands for 'not available'.

End point type	Secondary

End point timeframe:

Weeks 0, 4, 8, 16, 24, 32, 40, 48, 56, 64, 72, 80, 88, 96, 104, 112, 120, 128, 136, 144, 152, 160, 168, 176, and 184

End point values	Risankizumab 600 mg IV	Risankizumab 180 mg SC		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	65		
Units: percentage of participants				
number (not applicable)				
Week 0	25.00	72.31		
Week 4	25.00	9999		
Week 8	25.00	73.85		
Week 16	9999	71.88		
Week 24	9999	74.60		
Week 32	9999	78.69		
Week 40	9999	81.67		
Week 48	9999	79.31		
Week 56	9999	80.70		
Week 64	9999	87.27		
Week 72	9999	83.33		
Week 80	9999	79.25		
Week 88	9999	78.43		
Week 96	9999	84.62		
Week 104	9999	85.71		
Week 112	9999	87.50		
Week 120	9999	83.33		
Week 128	9999	86.96		
Week 136	9999	76.92		
Week 144	9999	78.38		
Week 152	9999	76.67		
Week 160	9999	78.26		
Week 168	9999	70.59		
Week 176	9999	60.00		
Week 184	9999	40.00		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Crohn's Disease Activity Index (CDAI) Clinical Response by Visit

End point title	Percentage of Participants Achieving Crohn's Disease Activity Index (CDAI) Clinical Response by Visit

End point description:

CDAI is a composite instrument that includes participant symptoms evaluated over 7 days, as well as physical and laboratory findings. These items are scored individually, weighted, and do not contribute equally to the overall score. The CDAI is derived from summing up the weighted individual scores of eight items. CDAI approximately ranges from 0 to 600 with higher scores indicating more severe disease. Clinical response is defined as CDAI score < 150 or a reduction from baseline of at least 100 points. Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276.

OC analysis was performed on the ITT analysis sets. The ITT set for IV consisted of all participants who received at least one dose of risankizumab IV in the current study, and the ITT set for SC consisted of all participants who received at least one dose of risankizumab SC in the current study.

9999 stands for 'not available'.

End point type	Secondary

End point timeframe:

Weeks 0, 4, 8, 16, 24, 32, 40, 48, 56, 64, 72, 80, 88, 96, 104, 112, 120, 128, 136, 144, 152, 160, 168, 176, and 184

End point values	Risankizumab 600 mg IV	Risankizumab 180 mg SC		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	65		
Units: percentage of participants				
number (not applicable)				
Week 0	50.00	90.77		
Week 4	75.00	9999		
Week 8	100.00	98.46		
Week 16	9999	92.19		
Week 24	9999	95.24		
Week 32	9999	95.08		
Week 40	9999	96.67		
Week 48	9999	94.83		
Week 56	9999	92.98		
Week 64	9999	96.36		
Week 72	9999	94.44		
Week 80	9999	92.45		
Week 88	9999	92.16		
Week 96	9999	92.31		

Week 104	9999	93.88		
Week 112	9999	93.75		
Week 120	9999	93.75		
Week 128	9999	93.48		
Week 136	9999	92.31		
Week 144	9999	91.89		
Week 152	9999	93.33		
Week 160	9999	91.30		
Week 168	9999	82.35		
Week 176	9999	80.00		
Week 184	9999	80.00		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Patient Reported Outcome 2 (PRO-2) Remission by Visit

End point title	Percentage of Participants Achieving Patient Reported Outcome 2 (PRO-2) Remission by Visit

End point description:

The PRO-2 is calculated based on the sum of the weighted patient-reported subscores of CDAI for liquid or soft stool frequency [SF] plus abdominal pain [AP] in the 7 days prior to the study visit. The PRO-2 score is calculated by adding the values of the summed stool frequency scores multiplied by 2 plus the summed abdominal pain scores multiplied by 5. The SF and AP score at an assessment visit was the average of the daily values reported during the 7 days preceding the scheduled assessment visit. PRO-2 scores range from 0 to no upper limit with higher scores indicating more severe disease. Remission is defined as PRO-2 score < 75.

OC analysis was performed on the ITT analysis sets. The ITT set for IV consisted of all participants who received at least one dose of risankizumab IV in the current study, and the ITT set for SC consisted of all participants who received at least one dose of risankizumab SC in the current study.

9999 stands for 'not available'.

End point type	Secondary

End point timeframe:

Weeks 0, 4, 8, 16, 24, 32, 40, 48, 56, 64, 72, 80, 88, 96, 104, 112, 120, 128, 136, 144, 152, 160, 168, 176, and 184

End point values	Risankizumab 600 mg IV	Risankizumab 180 mg SC		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	65		
Units: percentage of participants				
number (not applicable)				
Week 0	25.00	73.85		
Week 4	25.00	9999		
Week 8	50.00	80.00		
Week 16	9999	78.13		
Week 24	9999	77.78		
Week 32	9999	85.25		

Week 40	9999	83.33		
Week 48	9999	82.76		
Week 56	9999	87.72		
Week 64	9999	81.82		
Week 72	9999	81.48		
Week 80	9999	81.13		
Week 88	9999	82.35		
Week 96	9999	84.62		
Week 104	9999	85.71		
Week 112	9999	91.67		
Week 120	9999	85.42		
Week 128	9999	89.13		
Week 136	9999	87.50		
Week 144	9999	86.49		
Week 152	9999	86.67		
Week 160	9999	73.91		
Week 168	9999	77.78		
Week 176	9999	60.00		
Week 184	9999	40.00		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Patient Reported Outcome 2 (PRO-2) Response by Visit

End point title	Percentage of Participants Achieving Patient Reported Outcome 2 (PRO-2) Response by Visit

End point description:

PRO-2 is calculated based on the sum of the weighted patient-reported subscores of CDAI for liquid or soft stool frequency [SF] plus abdominal pain [AP] in last 7 days. PRO-2 score is calculated by adding values of summed stool frequency scores multiplied by 2 plus summed abdominal pain scores multiplied by 5. SF and AP score was the average of the daily values reported during last 7 days. PRO-2 scores range from 0 to no upper limit with higher scores indicating more severe disease. PRO-2 response is defined as a decrease from baseline of 50 points or more. Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276.
analysis performed ITT analysis sets. ITT set for IV consisted of all participants who received at least one dose of risankizumab IV in the current study, and ITT set for SC consisted of all participants who received at least one dose of risankizumab SC in the current study.

9999 stands for 'not available'.

End point type	Secondary

End point timeframe:

Weeks 0, 4, 8, 16, 24, 32, 40, 48, 56, 64, 72, 80, 88, 96, 104, 112, 120, 128, 136, 144, 152, 160, 168, 176, and 184

End point values	Risankizumab 600 mg IV	Risankizumab 180 mg SC		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	65		
Units: percentage of participants				
number (not applicable)				
Week 0	50.00	83.08		
Week 4	50.00	9999		
Week 8	50.00	86.15		
Week 16	9999	90.63		
Week 24	9999	92.06		
Week 32	9999	86.89		
Week 40	9999	98.33		
Week 48	9999	93.10		
Week 56	9999	91.23		
Week 64	9999	90.91		
Week 72	9999	88.89		
Week 80	9999	88.68		
Week 88	9999	86.27		
Week 96	9999	88.46		
Week 104	9999	87.76		
Week 112	9999	87.50		
Week 120	9999	91.67		
Week 128	9999	91.30		
Week 136	9999	92.50		
Week 144	9999	89.19		
Week 152	9999	93.33		
Week 160	9999	86.96		
Week 168	9999	83.33		
Week 176	9999	100.00		
Week 184	9999	100.00		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Crohn's Disease Endoscopic Index of Severity (CDEIS) Remission by Visit

End point title	Percentage of Participants Achieving Crohn's Disease Endoscopic Index of Severity (CDEIS) Remission by Visit

End point description:

CDEIS is an index for determining the severity of Crohn's disease. The CDEIS considers deep ulcerations, superficial ulcerations, ulcerated and non-ulcerated surface, and the presence of ulcerated/non-ulcerated stenosis evaluated in 5 pre-defined segments of the colon (ileum, ascending colon, transverse colon, descending colon and sigmoid loop, and rectum). The score ranges from 0 to 44 where higher scores indicate more severe endoscopic activity. Remission is defined as a score of 4 or less, by visit (or for participants with initial isolated ileitis a score of 2 or less).

Analysis Population: Observed case (OC) analysis was performed on the intent-to-treat (ITT) SC analysis set, which consisted of all participants who received at least one dose of risankizumab SC in the current study.

End point type	Secondary

End point timeframe:

Weeks 0, 48, 104, 152, and 200

End point values	Risankizumab 180 mg SC			
Subject group type	Subject analysis set			
Number of subjects analysed	63			
Units: percentage of participants				
number (not applicable)				
Week 0	42.86			
Week 48	56.45			
Week 104	62.79			
Week 152	58.97			
Week 200	85.71			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Crohn's Disease Endoscopic Index of Severity (CDEIS) Response by Visit

End point title	Percentage of Participants Achieving Crohn's Disease Endoscopic Index of Severity (CDEIS) Response by Visit

End point description:

CDEIS is an index for determining the severity of Crohn's disease. The CDEIS considers deep ulcerations, superficial ulcerations, ulcerated and non-ulcerated surface, and the presence of ulcerated/non-ulcerated stenosis evaluated in 5 pre-defined segments of the colon (ileum, ascending colon, transverse colon, descending colon and sigmoid loop, and rectum). The score ranges from 0 to 44 where higher scores indicate more severe endoscopic activity. Response is defined as a score of 7 or less (or for participants with initial isolated ileitis > 50% reduction from baseline). Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276 (Boehringer Ingelheim trial 1311.6/AbbVie M15-993).

Analysis Population: Observed case (OC) analysis was performed on the intent-to-treat (ITT) SC analysis set, which consisted of all participants who received at least one dose of risankizumab SC in the current study.

End point type	Secondary

End point timeframe:

Weeks 0, 48, 104, 152, and 200

End point values	Risankizumab 180 mg SC			
Subject group type	Subject analysis set			
Number of subjects analysed	63			
Units: percentage of participants				
number (not applicable)				
Week 0	58.73			
Week 48	72.58			

Week 104	81.40			
Week 152	82.05			
Week 200	100.00			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants with Mucosal Healing by Visit

End point title	Percentage of Participants with Mucosal Healing by Visit

End point description:

Mucosal healing is defined as Crohn's Disease Endoscopy Index of Severity (CDEIS) ulcerations sub-score (deep ulceration, superficial ulceration, ulcerated stenosis) of 0 as evaluated in 5 pre-defined segments of the colon (ileum, ascending colon, transverse colon, descending colon and sigmoid loop, and rectum). The overall CDEIS score ranges from 0 to 44 where higher scores indicate more severe endoscopic activity.

Analysis Population: Observed case (OC) analysis was performed on the intent-to-treat (ITT) SC analysis set, which consisted of all participants who received at least one dose of risankizumab SC in the current study.

End point type	Secondary

End point timeframe:

Weeks 0, 48, 104, 152, and 200

End point values	Risankizumab 180 mg SC			
Subject group type	Subject analysis set			
Number of subjects analysed	64			
Units: percentage of participants				
number (not applicable)				
Week 0	29.69			
Week 48	35.48			
Week 104	39.53			
Week 152	43.59			
Week 200	42.86			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Deep Remission by Visit

End point title	Percentage of Participants Achieving Deep Remission by Visit

End point description:

Deep remission is defined as clinical remission (CDAI < 150) and CDEIS remission (CDEIS score of 4 or less, by visit or for participants with initial isolated ileitis a score of 2 or less).

Analysis Population: Observed case (OC) analysis was performed on the intent-to-treat (ITT) SC

analysis set, which consisted of all participants who received at least one dose of risankizumab SC in the current study.

End point type	Secondary

End point timeframe:

Weeks 0, 48, 104, 152, and 200

End point values	Risankizumab 180 mg SC			
Subject group type	Subject analysis set			
Number of subjects analysed	63			
Units: percentage of participants				
number (not applicable)				
Week 0	34.92			
Week 48	47.54			
Week 104	53.49			
Week 152	42.86			
Week 200	0.00			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Inflammatory Bowel Disease Questionnaire (IBDQ) Remission by Visit

End point title	Percentage of Participants Achieving Inflammatory Bowel Disease Questionnaire (IBDQ) Remission by Visit

End point description:

The Inflammatory Bowel Disease Questionnaire (IBDQ) measures the effects of inflammatory bowel disease on daily function and quality of life. The IBDQ consists of 32 questions which address symptoms as a result of Crohn's disease: bowel symptoms (loose stools, abdominal pain), systemic symptoms (fatigue, altered sleep pattern), social function (work attendance, need to cancel social events), and emotional function (anger, depression, irritability). Each question is answered on a scale from 1 (all the time) to 7 (none of the time); the total score ranges from 32 (worst) to 224 (best). IBDQ remission is defined as IBDQ total score > 170 points.

Analysis Population: Observed case (OC) analysis was performed on the intent-to-treat (ITT) SC analysis set, which consisted of all participants who received at least one dose of risankizumab SC in the current study.

End point type	Secondary

End point timeframe:

Weeks 0, 24, 48, 72, 96, 120, 144, 168, and 192

End point values	Risankizumab 180 mg SC			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: percentage of participants				
number (not applicable)				
Week 0	62.50			
Week 24	58.46			
Week 48	70.00			
Week 72	69.23			
Week 96	72.55			
Week 120	70.83			
Week 144	65.00			
Week 168	69.57			
Week 192	66.67			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Inflammatory Bowel Disease Questionnaire (IBDQ) Response by Visit

End point title	Percentage of Participants Achieving Inflammatory Bowel Disease Questionnaire (IBDQ) Response by Visit

End point description:

IBDQ measures the effects of inflammatory bowel disease on daily function and quality of life. IBDQ consists of 32 questions which address symptoms as a result of Crohn's disease: bowel symptoms (loose stools, abdominal pain), systemic symptoms (fatigue, altered sleep pattern), social function (work attendance, need to cancel social events), and emotional function (anger, depression, irritability). Each question is answered on a scale from 1 (all the time) to 7 (none of the time); the total score ranges from 32 (worst) to 224 (best). IBDQ response is defined as increase in IBDQ total score >16 points from baseline. Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276 (Boehringer Ingelheim trial 1311.6/AbbVie M15-993).

OC analysis was performed on the ITT SC analysis set, which consisted of all participants who received at least one dose of risankizumab SC in the current study.

End point type	Secondary

End point timeframe:

Weeks 0, 24, 48, 72, 96, 120, 144, 168, and 192

End point values	Risankizumab 180 mg SC			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: percentage of participants				
number (not applicable)				
Week 0	92.19			
Week 24	89.23			
Week 48	95.00			
Week 72	88.46			

Week 96	90.20			
Week 120	95.83			
Week 144	92.50			
Week 168	86.96			
Week 192	100.00			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Crohn's Disease Activity Index (CDAI) by Visit

End point title	Mean Change From Baseline in Crohn's Disease Activity Index (CDAI) by Visit

End point description:

CDAI is a composite instrument that includes participant symptoms evaluated over 7 days (abdominal pain, stool frequency and general well-being), as well as physical and laboratory findings. These items are scored individually, weighted, and do not contribute equally to the overall score. The CDAI is derived from summing up the weighted individual scores of eight items. CDAI approximately ranges from 0 to 600 with higher scores indicating more severe disease. Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276. A negative change from baseline indicates improvement.

OC analysis was performed on the ITT analysis sets. The ITT set for IV consisted of all participants who received at least one dose of risankizumab IV in the current study, and the ITT set for SC consisted of all participants who received at least one dose of risankizumab SC in the current study.

9999 stands for 'not available'.

End point type	Secondary

End point timeframe:

Weeks 0, 4, 8, 16, 24, 32, 40, 48, 56, 64, 72, 80, 88, 96, 104, 112, 120, 128, 136, 144, 152, 160, 168, 176, and 184

End point values	Risankizumab 600 mg IV	Risankizumab 180 mg SC		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	65		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 0	-50.70 (± 84.565)	-198.47 (± 101.762)		
Week 4	-92.68 (± 40.688)	9999 (± 9999)		
Week 8	-119.40 (± 32.967)	-206.75 (± 83.580)		
Week 16	9999 (± 9999)	-205.93 (± 92.837)		
Week 24	9999 (± 9999)	-194.34 (± 82.840)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change from Baseline in Patient Reported Outcome 2 (PRO-2) Scores by Visit

End point title	Mean Change from Baseline in Patient Reported Outcome 2 (PRO-2) Scores by Visit

End point description:

PRO-2 is calculated based on the sum of weighted patient-reported subscores of CDAI for liquid or soft stool frequency [SF] plus abdominal pain [AP] in last 7 days. The PRO-2 score is calculated by adding values of summed stool frequency scores multiplied by 2 plus summed abdominal pain scores multiplied by 5. The SF and AP score at a visit was the average of the daily values reported during the last 7 days. PRO-2 scores range from 0 to no upper limit with higher scores indicating more severe disease. Baseline is the last measurement prior to first dose of the study drug in the feeder study NCT02031276. A negative change from baseline indicates improvement.
OC analysis was performed on ITT analysis sets. The ITT set for IV consisted of all participants who received at least one dose of risankizumab IV in the current study, and the ITT set for SC consisted of all participants who received at least one dose of risankizumab SC in the current study.
9999 stands for 'not available'.

End point type	Secondary

End point timeframe:

Weeks 0, 4, 8, 16, 24, 32, 40, 48, 56, 64, 72, 80, 88, 96, 104, 112, 120, 128, 136, 144, 152, 160, 168, 176, and 184

End point values	Risankizumab 600 mg IV	Risankizumab 180 mg SC		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	65		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 0	-27.75 (± 48.979)	-105.46 (± 58.807)		
Week 4	-35.25 (± 27.011)	9999 (± 9999)		
Week 8	-53.75 (± 24.405)	-109.53 (± 49.419)		
Week 16	9999 (± 9999)	-108.32 (± 52.848)		
Week 24	9999 (± 9999)	-105.40 (± 50.167)		
Week 32	9999 (± 9999)	-109.41 (± 56.459)		
Week 40	9999 (± 9999)	-116.33 (± 43.511)		
Week 48	9999 (± 9999)	-111.29 (± 48.048)		
Week 56	9999 (± 9999)	-115.54 (± 51.279)		
Week 64	9999 (± 9999)	-113.02 (± 57.338)		
Week 72	9999 (± 9999)	-112.11 (± 56.819)		
Week 80	9999 (± 9999)	-106.42 (± 58.710)		
Week 88	9999 (± 9999)	-108.67 (± 51.214)		

Week 96	9999 (± 9999)	-109.81 (± 50.927)		
Week 104	9999 (± 9999)	-109.10 (± 49.562)		
Week 112	9999 (± 9999)	-109.75 (± 52.951)		
Week 120	9999 (± 9999)	-111.10 (± 47.360)		
Week 128	9999 (± 9999)	-113.02 (± 50.738)		
Week 136	9999 (± 9999)	-113.00 (± 51.575)		
Week 144	9999 (± 9999)	-115.35 (± 53.460)		
Week 152	9999 (± 9999)	-109.17 (± 56.659)		
Week 160	9999 (± 9999)	-96.70 (± 54.018)		
Week 168	9999 (± 9999)	-111.09 (± 55.287)		
Week 176	9999 (± 9999)	-103.06 (± 42.717)		
Week 184	9999 (± 9999)	-129.13 (± 70.484)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Crohn's Disease Endoscopic Index of Severity (CDEIS) by Visit

End point title	Mean Change From Baseline in Crohn's Disease Endoscopic Index of Severity (CDEIS) by Visit

End point description:

CDEIS is an index for determining the severity of Crohn's disease. The CDEIS considers deep ulcerations, superficial ulcerations, ulcerated and non-ulcerated surface, and the presence of ulcerated/non-ulcerated stenosis evaluated in 5 pre-defined segments of the colon (ileum, ascending colon, transverse colon, descending colon and sigmoid loop, and rectum). The score ranges from 0 to 44 where higher scores indicate more severe endoscopic activity. Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276 (Boehringer Ingelheim trial 1311.6/AbbVie M15-993). A negative change from baseline indicates improvement.

Analysis Population: Observed case (OC) analysis was performed on the intent-to-treat (ITT) SC analysis set, which consisted of all participants who received at least one dose of risankizumab SC in the current study.

End point type	Secondary

End point timeframe:

Weeks 0, 48, 104, 152, and 200

End point values	Risankizumab 180 mg SC			
Subject group type	Subject analysis set			
Number of subjects analysed	63			
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 0	-8.08 (± 5.973)			
Week 48	-9.32 (± 6.014)			
Week 104	-9.24 (± 6.035)			
Week 152	-9.75 (± 7.254)			
Week 200	-10.76 (± 5.209)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Simple Endoscopic Score (SES-CD) by Visit

End point title	Mean Change From Baseline in Simple Endoscopic Score (SES-CD) by Visit

End point description:

SES-CD is calculated based the sum of individual segment values for four endoscopic variables (presence and size of ulcers, ulcerated surface, affected surface and presence of narrowing). Each variable in each segment is scored 0 to 3 resulting in SES-CD values ranging from 0 to 56 with higher scores indicating more severe disease. Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276 (Boehringer Ingelheim trial 1311.6/AbbVie M15-993). A negative change from baseline indicates improvement.

Analysis Population: Observed case (OC) analysis was performed on the intent-to-treat (ITT) SC analysis set, which consisted of all participants who received at least one dose of risankizumab SC in the current study.

End point type	Secondary

End point timeframe:

Weeks 0, 48, 104, 152, and 200

End point values	Risankizumab 180 mg SC			
Subject group type	Subject analysis set			
Number of subjects analysed	63			
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 0	-9.63 (± 8.001)			
Week 48	-12.35 (± 7.753)			
Week 104	-11.56 (± 8.060)			

Week 152	-12.63 (± 9.139)			
Week 200	-13.36 (± 7.521)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Stool Frequency (SF) By Visit

End point title	Mean Change From Baseline in Stool Frequency (SF) By Visit

End point description:

Participants were asked to record the frequency of liquid stools on a daily basis. The number of liquid stools in the prior 7 days was summed. Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276 (Boehringer Ingelheim trial 1311.6/AbbVie M15-993). Negative values indicate improvement from baseline.

Analysis Population: Observed case (OC) analysis was performed on the intent-to-treat (ITT) analysis sets. The ITT set for IV consisted of all participants who received at least one dose of risankizumab IV in the current study, and the ITT set for SC consisted of all participants who received at least one dose of risankizumab SC in the current study.

9999 stands for 'not available'.

End point type	Secondary

End point timeframe:

Weeks 0, 4, 8, 16, 24, 32, 40, 48, 56, 64, 72, 80, 88, 96, 104, 112, 120, 128, 136, 144, 152, 160, 168, 176, and 184

End point values	Risankizumab 600 mg IV	Risankizumab 180 mg SC		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	65		
Units: number of liquid stools in prior 7 days				
arithmetic mean (standard deviation)				
Week 0	-0.46 (± 2.319)	-4.13 (± 3.273)		
Week 4	-0.46 (± 1.584)	9999 (± 9999)		
Week 8	-1.07 (± 1.421)	-4.22 (± 3.160)		
Week 16	9999 (± 9999)	-4.10 (± 3.223)		
Week 24	9999 (± 9999)	-4.19 (± 3.209)		
Week 32	9999 (± 9999)	-4.08 (± 3.536)		
Week 40	9999 (± 9999)	-4.58 (± 3.037)		
Week 48	9999 (± 9999)	-4.31 (± 3.278)		
Week 56	9999 (± 9999)	-4.48 (± 3.282)		

Week 64	9999 (± 9999)	-4.41 (± 3.514)		
Week 72	9999 (± 9999)	-4.25 (± 3.513)		
Week 80	9999 (± 9999)	-4.00 (± 3.469)		
Week 88	9999 (± 9999)	-4.04 (± 3.331)		
Week 96	9999 (± 9999)	-4.27 (± 3.037)		
Week 104	9999 (± 9999)	-4.00 (± 2.943)		
Week 112	9999 (± 9999)	-3.91 (± 2.951)		
Week 120	9999 (± 9999)	-3.99 (± 2.840)		
Week 128	9999 (± 9999)	-4.05 (± 3.060)		
Week 136	9999 (± 9999)	-3.95 (± 3.137)		
Week 144	9999 (± 9999)	-4.13 (± 3.308)		
Week 152	9999 (± 9999)	-4.00 (± 3.150)		
Week 160	9999 (± 9999)	-3.71 (± 3.044)		
Week 168	9999 (± 9999)	-4.08 (± 3.353)		
Week 176	9999 (± 9999)	-3.61 (± 2.583)		
Week 184	9999 (± 9999)	-4.50 (± 3.881)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Abdominal Pain (AP) Score By Visit

End point title	Mean Change From Baseline in Abdominal Pain (AP) Score By Visit

End point description:

Participants were asked to rate and record daily abdominal pain on a scale of 0 to 3 [none (0), mild (1), moderate (2) and severe (3)]. The ratings in the prior 7 days were summed. Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276 (Boehringer Ingelheim trial 1311.6/AbbVie M15-993). Negative values indicate improvement from baseline.

Analysis Population: Observed case (OC) analysis was performed on the intent-to-treat (ITT) analysis sets. The ITT set for IV consisted of all participants who received at least one dose of risankizumab IV in the current study, and the ITT set for SC consisted of all participants who received at least one dose of risankizumab SC in the current study.

9999 stands for 'not applicable'.

End point type	Secondary

End point timeframe:

Weeks 0, 4, 8, 16, 24, 32, 40, 48, 56, 64, 72, 80, 88, 96, 104, 112, 120, 128, 136, 144, 152, 160, 168, 176, and 184

End point values	Risankizumab 600 mg IV	Risankizumab 180 mg SC		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	4	65		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 0	-0.61 (± 1.006)	-1.36 (± 0.885)		
Week 4	-0.82 (± 0.768)	9999 (± 9999)		
Week 8	-1.11 (± 0.357)	-1.44 (± 0.746)		
Week 16	9999 (± 9999)	-1.45 (± 0.773)		
Week 24	9999 (± 9999)	-1.33 (± 0.804)		
Week 32	9999 (± 9999)	-1.49 (± 0.760)		
Week 40	9999 (± 9999)	-1.49 (± 0.766)		
Week 48	9999 (± 9999)	-1.46 (± 0.720)		
Week 56	9999 (± 9999)	-1.51 (± 0.815)		
Week 64	9999 (± 9999)	-1.47 (± 0.825)		
Week 72	9999 (± 9999)	-1.50 (± 0.839)		
Week 80	9999 (± 9999)	-1.44 (± 0.816)		
Week 88	9999 (± 9999)	-1.49 (± 0.787)		
Week 96	9999 (± 9999)	-1.43 (± 0.881)		
Week 104	9999 (± 9999)	-1.52 (± 0.861)		
Week 112	9999 (± 9999)	-1.57 (± 0.890)		
Week 120	9999 (± 9999)	-1.58 (± 0.735)		
Week 128	9999 (± 9999)	-1.61 (± 0.776)		
Week 136	9999 (± 9999)	-1.65 (± 0.792)		
Week 144	9999 (± 9999)	-1.64 (± 0.836)		
Week 152	9999 (± 9999)	-1.52 (± 0.833)		
Week 160	9999 (± 9999)	-1.28 (± 0.788)		
Week 168	9999 (± 9999)	-1.54 (± 0.657)		
Week 176	9999 (± 9999)	-1.50 (± 0.670)		
Week 184	9999 (± 9999)	-1.89 (± 0.921)		

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Total Score by Visit

End point title	Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Total Score by Visit

End point description:

IBDQ measures the effects of inflammatory bowel disease on daily function and quality of life. The IBDQ consists of 32 questions which address symptoms as a result of Crohn's disease: bowel symptoms (loose stools, abdominal pain), systemic symptoms (fatigue, altered sleep pattern), social function (work attendance, need to cancel social events), and emotional function (anger, depression, irritability). Each question is answered on a scale from 1 (all the time) to 7 (none of the time); the total score ranges from 32 (worst) to 224 (best). Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276 (Boehringer Ingelheim trial 1311.6/AbbVie M15-993). Positive values indicate improvement from baseline.
OC analysis was performed on the intent-to-treat ITT SC analysis set, which consisted of all participants who received at least one dose of risankizumab SC in the current study.

End point type	Secondary

End point timeframe:

Weeks 0, 24, 48, 72, 96, 120, 144, 168, and 192

End point values	Risankizumab 180 mg SC			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 0	62.48 (± 38.791)			
Week 24	58.72 (± 35.626)			
Week 48	64.03 (± 33.039)			
Week 72	64.14 (± 42.229)			
Week 96	62.38 (± 39.220)			
Week 120	67.28 (± 34.390)			
Week 144	61.34 (± 34.894)			
Week 168	56.36 (± 33.035)			
Week 192	71.17 (± 41.911)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Symptom Domain Score by Visit

End point title	Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Bowel Symptom Domain Score by Visit

End point description:

IBDQ measures the effects of inflammatory bowel disease on daily function and quality of life. The IBDQ consists of 32 questions which address symptoms as a result of Crohn's disease: bowel symptoms (loose stools, abdominal pain), systemic symptoms (fatigue, altered sleep pattern), social function (work attendance, need to cancel social events), and emotional function (anger, depression, irritability). Each question is answered on a scale from 1 (all the time) to 7 (none of the time); the total score ranges from 32 (worst) to 224 (best). Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276 (Boehringer Ingelheim trial 1311.6/AbbVie M15-993). Positive values indicate improvement from baseline.
OC analysis was performed on the ITT SC analysis set, which consisted of all participants who received at least one dose of risankizumab SC in the current study.

End point type	Secondary

End point timeframe:

Weeks 0, 24, 48, 72, 96, 120, 144, 168, and 192

End point values	Risankizumab 180 mg SC			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 0	20.44 (± 11.680)			
Week 24	18.26 (± 11.587)			
Week 48	20.29 (± 10.861)			
Week 72	20.64 (± 12.547)			
Week 96	19.12 (± 13.064)			
Week 120	22.25 (± 10.473)			
Week 144	20.46 (± 10.639)			
Week 168	18.44 (± 10.658)			
Week 192	22.67 (± 14.962)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic System Domain Score by Visit

End point title	Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Systemic System Domain Score by Visit

End point description:

IBDQ measures the effects of inflammatory bowel disease on daily function and quality of life. The IBDQ consists of 32 questions which address symptoms as a result of Crohn's disease: bowel symptoms (loose stools, abdominal pain), systemic symptoms (fatigue, altered sleep pattern), social function (work attendance, need to cancel social events), and emotional function (anger, depression, irritability). Each question is answered on a scale from 1 (all the time) to 7 (none of the time); the total score ranges from 32 (worst) to 224 (best). Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276 (Boehringer Ingelheim trial 1311.6/AbbVie M15-993). Positive values indicate improvement from baseline.
OC analysis was performed on the ITT SC analysis set, which consisted of all participants who received at least one dose of risankizumab SC in the current study.

End point type	Secondary

End point timeframe:

Weeks 0, 24, 48, 72, 96, 120, 144, 168, and 192

End point values	Risankizumab 180 mg SC			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 0	9.9 (± 6.66)			
Week 24	9.1 (± 6.44)			
Week 48	9.6 (± 6.08)			
Week 72	10.1 (± 7.36)			
Week 96	10.3 (± 5.80)			
Week 120	9.8 (± 6.16)			
Week 144	8.9 (± 6.02)			
Week 168	8.2 (± 5.10)			
Week 192	11.8 (± 4.62)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Function Domain Score by Visit

End point title	Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Social Function Domain Score by Visit

End point description:

IBDQ measures the effects of inflammatory bowel disease on daily function and quality of life. The IBDQ consists of 32 questions which address symptoms as a result of Crohn's disease: bowel symptoms (loose stools, abdominal pain), systemic symptoms (fatigue, altered sleep pattern), social function (work attendance, need to cancel social events), and emotional function (anger, depression, irritability). Each question is answered on a scale from 1 (all the time) to 7 (none of the time); the total score ranges from 32 (worst) to 224 (best). Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276 (Boehringer Ingelheim trial 1311.6/AbbVie M15-993). Positive values indicate improvement from baseline.
OC analysis was performed on the ITT SC analysis set, which consisted of all participants who received at least one dose of risankizumab SC in the current study.

End point type	Secondary

End point timeframe:

Weeks 0, 24, 48, 72, 96, 120, 144, 168, and 192

End point values	Risankizumab 180 mg SC			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 0	11.04 (± 8.230)			
Week 24	10.57 (± 7.652)			
Week 48	11.64 (± 7.487)			
Week 72	11.20 (± 8.731)			
Week 96	10.59 (± 8.556)			
Week 120	11.92 (± 7.347)			
Week 144	10.93 (± 8.309)			
Week 168	10.87 (± 9.503)			
Week 192	11.67 (± 9.266)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Function Domain Score by Visit

End point title	Mean Change From Baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) Emotional Function Domain Score by Visit

End point description:

IBDQ measures the effects of inflammatory bowel disease on daily function and quality of life. The IBDQ consists of 32 questions which address symptoms as a result of Crohn's disease: bowel symptoms (loose stools, abdominal pain), systemic symptoms (fatigue, altered sleep pattern), social function (work attendance, need to cancel social events), and emotional function (anger, depression, irritability). Each question is answered on a scale from 1 (all the time) to 7 (none of the time); the total score ranges from 32 (worst) to 224 (best). Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276 (Boehringer Ingelheim trial 1311.6/AbbVie M15-993). Positive values indicate improvement from baseline.
OC analysis was performed on the ITT SC analysis set, which consisted of all participants who received at least one dose of risankizumab SC in the current study.

End point type	Secondary

End point timeframe:

Weeks 0, 24, 48, 72, 96, 120, 144, 168, and 192

End point values	Risankizumab 180 mg SC			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 0	21.09 (± 16.820)			
Week 24	20.79 (± 15.632)			
Week 48	22.55 (± 14.965)			
Week 72	22.23 (± 17.912)			
Week 96	22.41 (± 17.075)			
Week 120	23.35 (± 15.391)			
Week 144	21.03 (± 15.044)			
Week 168	18.87 (± 14.552)			
Week 192	25.00 (± 21.373)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in High-Sensitivity C-reactive Protein (hs-CRP) by Visit

End point title	Mean Change From Baseline in High-Sensitivity C-reactive Protein (hs-CRP) by Visit

End point description:

Concentration of serum high-sensitivity C-reactive Protein (hs-CRP) was analyzed by a central laboratory. It is a general marker of inflammation that is sensitive to acute changes in inflammatory response, and higher levels indicate more inflammation. Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276 (Boehringer Ingelheim trial 1311.6/AbbVie M15-993). Negative values indicate improvement from baseline.

Analysis Population: Observed case (OC) analysis was performed on the intent-to-treat (ITT) SC analysis set, which consisted of all participants who received at least one dose of risankizumab SC in the current study.

End point type	Secondary

End point timeframe:

Weeks 0, 8, 24, 40, 56, 72, 88, 104, 120, 128, 136, 152, 160, 176, and 184

End point values	Risankizumab 180 mg SC			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: milligrams per liter (mg/L)				
arithmetic mean (standard deviation)				
Week 0	-14.64 (± 22.842)			
Week 8	-15.84 (± 22.548)			
Week 24	-12.76 (± 24.457)			
Week 40	-14.32 (± 24.080)			
Week 56	-16.11 (± 24.194)			
Week 72	-14.40 (± 21.878)			
Week 88	-17.07 (± 23.312)			
Week 104	-14.44 (± 20.057)			
Week 120	-13.81 (± 22.667)			
Week 128	-14.87 (± 20.133)			
Week 136	-15.78 (± 20.864)			
Week 152	-17.03 (± 20.998)			
Week 160	-18.43 (± 22.147)			
Week 176	-20.49 (± 25.062)			
Week 184	-25.01 (± 32.459)			

Statistical analyses

No statistical analyses for this end point

Secondary: Mean Change From Baseline in Fecal Calprotectin (FCP) Profile by Visit

End point title	Mean Change From Baseline in Fecal Calprotectin (FCP) Profile by Visit

End point description:

Fecal calprotectin (FCP) is an indicator of inflammation in the colon with higher levels indicative of higher levels of inflammation. Stool samples were analyzed by a central laboratory for fecal calprotectin levels. Baseline is defined as the last measurement prior to the first dose of the study drug in the feeder study NCT02031276 (Boehringer Ingelheim trial 1311.6/AbbVie M15-993). Negative values indicate improvement from baseline.

Analysis Population: Observed case (OC) analysis was performed on the intent-to-treat (ITT) SC analysis set, which consisted of all participants who received at least one dose of risankizumab SC in the current study.

End point type	Secondary

End point timeframe:

Weeks 0, 24, 56, 88, 120, 152, and 184

End point values	Risankizumab 180 mg SC			
Subject group type	Subject analysis set			
Number of subjects analysed	65			
Units: microgram per gram (µg/g)				
arithmetic mean (standard deviation)				
Week 0	-1983.9 (± 3402.12)			
Week 24	-2166.4 (± 4035.66)			
Week 56	-2277.8 (± 4104.19)			
Week 88	-2485.9 (± 4157.37)			
Week 120	-2031.9 (± 5187.92)			
Week 152	-2631.5 (± 4589.62)			
Week 184	-4436.1 (± 7455.55)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

TEAEs and TESAEs were collected from the first dose of study drug until 140 days after the last dose of study drug in the current study or until the first dose of study drug in NCT03105102, up to 4 years for participants who rolled-over.

Adverse event reporting additional description:

Treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs) are defined as any adverse event (AE) with an onset date that is on or after the first dose of study drug until 140 days after the last dose of study drug and were collected whether elicited or spontaneously reported by the participant.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Risankizumab 600 mg IV

Reporting group description:

Re-induction treatment; 3 infusions every 4 weeks, after which eligibility was assessed if clinical response was re-gained.

Reporting group title	All Risankizumab

Reporting group description:

Participants who received at least one dose of risankizumab in the current study.

Reporting group title	Risankizumab 180 mg SC

Reporting group description:

Maintenance treatment every 8 weeks (q8w) from Visit 2 through the end of trial (EOT) visit. Participants who re-gained their clinical response following the re-induction treatment could continue with maintenance treatment beginning at Visit 5.

Serious adverse events	Risankizumab 600 mg IV	All Risankizumab	Risankizumab 180 mg SC
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	23 / 65 (35.38%)	23 / 65 (35.38%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Anastomotic leak			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ankle fracture			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post procedural complication			
subjects affected / exposed	0 / 4 (0.00%)	2 / 65 (3.08%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Procedural pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thermal burn			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Selective abortion			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Nasal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)

occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
Anaphylactic reaction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Iron deficiency anaemia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Carotid sinus syndrome			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cluster headache			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Crohn's disease			
subjects affected / exposed	0 / 4 (0.00%)	2 / 65 (3.08%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dumping syndrome			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileal stenosis			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired gastric emptying			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal stenosis			
subjects affected / exposed	0 / 4 (0.00%)	2 / 65 (3.08%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Umbilical hernia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Reproductive system and breast disorders			
Menorrhagia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian cyst			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Anal abscess			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Campylobacter infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis viral			
subjects affected / exposed	0 / 4 (0.00%)	2 / 65 (3.08%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 4 (0.00%)	2 / 65 (3.08%)	2 / 65 (3.08%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 2

deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subcutaneous abscess			
subjects affected / exposed	0 / 4 (0.00%)	1 / 65 (1.54%)	1 / 65 (1.54%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 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	Risankizumab 600 mg IV	All Risankizumab	Risankizumab 180 mg SC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 4 (50.00%)	52 / 65 (80.00%)	52 / 65 (80.00%)
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 4 (0.00%)	5 / 65 (7.69%)	5 / 65 (7.69%)
occurrences (all)	0	5	5
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 4 (0.00%)	4 / 65 (6.15%)	4 / 65 (6.15%)
occurrences (all)	0	4	4
Weight increased			
subjects affected / exposed	1 / 4 (25.00%)	2 / 65 (3.08%)	2 / 65 (3.08%)
occurrences (all)	1	3	2
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 4 (0.00%)	6 / 65 (9.23%)	6 / 65 (9.23%)
occurrences (all)	0	10	10
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 4 (0.00%)	9 / 65 (13.85%)	9 / 65 (13.85%)
occurrences (all)	0	15	15
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 4 (0.00%)	13 / 65 (20.00%)	13 / 65 (20.00%)
occurrences (all)	0	14	14
Ear and labyrinth disorders			

Ear pain			
subjects affected / exposed	1 / 4 (25.00%)	1 / 65 (1.54%)	0 / 65 (0.00%)
occurrences (all)	1	1	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	0 / 4 (0.00%)	5 / 65 (7.69%)	5 / 65 (7.69%)
occurrences (all)	0	5	5
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 4 (0.00%)	4 / 65 (6.15%)	4 / 65 (6.15%)
occurrences (all)	0	5	5
Abdominal pain			
subjects affected / exposed	0 / 4 (0.00%)	12 / 65 (18.46%)	12 / 65 (18.46%)
occurrences (all)	0	13	13
Abdominal pain upper			
subjects affected / exposed	1 / 4 (25.00%)	5 / 65 (7.69%)	4 / 65 (6.15%)
occurrences (all)	1	7	6
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	4 / 65 (6.15%)	4 / 65 (6.15%)
occurrences (all)	0	4	4
Crohn's disease			
subjects affected / exposed	0 / 4 (0.00%)	10 / 65 (15.38%)	10 / 65 (15.38%)
occurrences (all)	0	11	11
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	8 / 65 (12.31%)	8 / 65 (12.31%)
occurrences (all)	0	9	9
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 4 (0.00%)	4 / 65 (6.15%)	4 / 65 (6.15%)
occurrences (all)	0	4	4
Haematochezia			
subjects affected / exposed	1 / 4 (25.00%)	2 / 65 (3.08%)	2 / 65 (3.08%)
occurrences (all)	1	6	5
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	10 / 65 (15.38%)	10 / 65 (15.38%)
occurrences (all)	0	10	10
Odynophagia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 65 (1.54%)	0 / 65 (0.00%)

occurrences (all)	1	1	0
Vomiting			
subjects affected / exposed	1 / 4 (25.00%)	5 / 65 (7.69%)	4 / 65 (6.15%)
occurrences (all)	1	5	4
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	5 / 65 (7.69%)	5 / 65 (7.69%)
occurrences (all)	0	5	5
Rash			
subjects affected / exposed	0 / 4 (0.00%)	4 / 65 (6.15%)	4 / 65 (6.15%)
occurrences (all)	0	4	4
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	11 / 65 (16.92%)	11 / 65 (16.92%)
occurrences (all)	0	14	14
Back pain			
subjects affected / exposed	0 / 4 (0.00%)	8 / 65 (12.31%)	8 / 65 (12.31%)
occurrences (all)	0	10	10
Myalgia			
subjects affected / exposed	0 / 4 (0.00%)	5 / 65 (7.69%)	5 / 65 (7.69%)
occurrences (all)	0	6	6
Pain in extremity			
subjects affected / exposed	0 / 4 (0.00%)	5 / 65 (7.69%)	5 / 65 (7.69%)
occurrences (all)	0	8	8
Metabolism and nutrition disorders			
Vitamin B12 deficiency			
subjects affected / exposed	1 / 4 (25.00%)	3 / 65 (4.62%)	2 / 65 (3.08%)
occurrences (all)	1	3	2
Vitamin D deficiency			
subjects affected / exposed	0 / 4 (0.00%)	4 / 65 (6.15%)	4 / 65 (6.15%)
occurrences (all)	0	4	4
Infections and infestations			
Ear infection			
subjects affected / exposed	0 / 4 (0.00%)	4 / 65 (6.15%)	4 / 65 (6.15%)
occurrences (all)	0	4	4
Gastroenteritis			

subjects affected / exposed	0 / 4 (0.00%)	15 / 65 (23.08%)	15 / 65 (23.08%)
occurrences (all)	0	19	19
Influenza			
subjects affected / exposed	0 / 4 (0.00%)	8 / 65 (12.31%)	8 / 65 (12.31%)
occurrences (all)	0	11	11
Nasopharyngitis			
subjects affected / exposed	1 / 4 (25.00%)	20 / 65 (30.77%)	20 / 65 (30.77%)
occurrences (all)	2	40	38
Oral herpes			
subjects affected / exposed	0 / 4 (0.00%)	5 / 65 (7.69%)	5 / 65 (7.69%)
occurrences (all)	0	6	6
Pharyngitis			
subjects affected / exposed	0 / 4 (0.00%)	4 / 65 (6.15%)	4 / 65 (6.15%)
occurrences (all)	0	7	7
Rhinitis			
subjects affected / exposed	0 / 4 (0.00%)	6 / 65 (9.23%)	6 / 65 (9.23%)
occurrences (all)	0	7	7
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	5 / 65 (7.69%)	5 / 65 (7.69%)
occurrences (all)	0	6	6
Tooth abscess			
subjects affected / exposed	0 / 4 (0.00%)	5 / 65 (7.69%)	5 / 65 (7.69%)
occurrences (all)	0	7	7
Tracheitis			
subjects affected / exposed	0 / 4 (0.00%)	4 / 65 (6.15%)	4 / 65 (6.15%)
occurrences (all)	0	5	5
Upper respiratory tract infection			
subjects affected / exposed	1 / 4 (25.00%)	7 / 65 (10.77%)	7 / 65 (10.77%)
occurrences (all)	1	9	8
Urinary tract infection			
subjects affected / exposed	0 / 4 (0.00%)	9 / 65 (13.85%)	9 / 65 (13.85%)
occurrences (all)	0	10	10

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
15 October 2015	Amendment 1: Substantive changes from the original protocol to Amendment 1 were to clarify entry criteria for subjects rolling over from Study M15-993 who have lost a previous response/remission, change pregnancy test at screening to be a blood test only if urine test was positive, remove CRP and fecal calprotectin as measured biomarkers, replace numeric rating scale for abdominal pain with categorical pain scale of none, mild, moderate and severe, clarify definitions of SAE and AE relatedness, add possibility of interim analyses as deemed necessary by the Sponsor, administrative changes, and other changes throughout the protocol to accommodate the major design changes.
13 October 2016	Amendment 2: Substantive changes from Amendment 1 to Amendment 2 were to change study sponsorship from Boehringer Ingelheim (BI) only to BI outside the United States and AbbVie in the United States.
28 April 2017	Amendment 3: Substantive changes from Amendment 2 to Amendment 3 were to change the study protocol format to the AbbVie template and add the AbbVie study number of Study M15-989, remove the checklist for drug-induced liver injury, modify description of study team structure, modify AE definition to align with AbbVie procedures, and modify description of statistical analyses.
25 July 2018	Amendment 4: Substantive changes from Amendment 3 to Amendment 4 were to terminate this study and add the option for subjects who complete the EOT visit to enroll into Study M16-000 Sub-study 3, make modifications throughout the protocol to accommodate this design change, change the follow-up period from 15 to 20 weeks after last dose of study drug, and update benefit/risk information.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported