Clinical trial results:
A Multicenter, Randomized, Double-Blind, Placebo Controlled Induction Study of the Efficacy and Safety of Risankizumab in Subjects With Moderately to Severely Active Crohn's Disease

Summary

EudraCT number	2016-003123-32
Trial protocol	SK CZ DE GB PT IE BG AT LV PL BE NL EE SE ES GR NO LT HR IT RO
Global end of trial date	14 April 2021

Results information

Result version number	v1 (current)
This version publication date	14 October 2021
First version publication date	14 October 2021

Trial information

Trial identification

Sponsor protocol code	M16-006

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03105128
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AbbVie Deutschland GmbH & Co. KG
Sponsor organisation address	AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6 4UB
Public contact	Global Medical Services, AbbVie, 001 8006339110, abbvieclinicaltrials@abbvie.com
Scientific contact	Global Medical Services, AbbVie, 001 8006339110, abbvieclinicaltrials@abbvie.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	14 April 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	14 April 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the efficacy and safety of risankizumab versus placebo during induction therapy in participants with moderately to severely active Crohn's disease (CD).

Protection of trial subjects:

Subject and/or legal guardian read and understood the information provided about the study and gave written permission.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 May 2017
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 4
Country: Number of subjects enrolled	Austria: 7
Country: Number of subjects enrolled	Belarus: 1
Country: Number of subjects enrolled	Belgium: 68
Country: Number of subjects enrolled	Bosnia and Herzegovina: 2
Country: Number of subjects enrolled	Brazil: 14
Country: Number of subjects enrolled	Bulgaria: 4
Country: Number of subjects enrolled	Canada: 65
Country: Number of subjects enrolled	Chile: 2
Country: Number of subjects enrolled	China: 75
Country: Number of subjects enrolled	Croatia: 14
Country: Number of subjects enrolled	Czechia: 18
Country: Number of subjects enrolled	Estonia: 3
Country: Number of subjects enrolled	Germany: 74
Country: Number of subjects enrolled	Greece: 12
Country: Number of subjects enrolled	Israel: 22
Country: Number of subjects enrolled	Italy: 38
Country: Number of subjects enrolled	Japan: 75
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 18
Country: Number of subjects enrolled	Latvia: 2
Country: Number of subjects enrolled	Malaysia: 1

Country: Number of subjects enrolled	Mexico: 2
Country: Number of subjects enrolled	Netherlands: 8
Country: Number of subjects enrolled	New Zealand: 6
Country: Number of subjects enrolled	Norway: 10
Country: Number of subjects enrolled	Poland: 63
Country: Number of subjects enrolled	Portugal: 14
Country: Number of subjects enrolled	Romania: 6
Country: Number of subjects enrolled	Russian Federation: 25
Country: Number of subjects enrolled	Serbia: 23
Country: Number of subjects enrolled	Singapore: 1
Country: Number of subjects enrolled	Slovakia: 8
Country: Number of subjects enrolled	South Africa: 27
Country: Number of subjects enrolled	Spain: 18
Country: Number of subjects enrolled	Sweden: 10
Country: Number of subjects enrolled	Switzerland: 4
Country: Number of subjects enrolled	Ukraine: 17
Country: Number of subjects enrolled	United Kingdom: 25
Country: Number of subjects enrolled	United States: 145
Worldwide total number of subjects	931
EEA total number of subjects	377

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)	9
Adults (18-64 years)	880
From 65 to 84 years	42
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were randomized to receive 600mg risankizumab, 1200mg risankizumab or placebo during the double-blind, placebo-controlled Period 1. At Week 12, subjects who do not achieve clinical response were randomized into Period 2 to receive 180mg risankizumab, 360mg risankizumab or 1200mg risankizumab. Subjects who received placebo received 1200mg.

Pre-assignment

Screening details:

A total of 931 subjects were enrolled and included in the intent-to-treat (ITT) population; 850 of those had a baseline eligible Simple Endoscopic Score for Crohn's disease (SES-CD) of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component and were included in the ITT1A population.

Period 1

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

Blinding implementation details:

All AbbVie personnel with direct oversight of the conduct and management of the trial (with the exception of AbbVie's Drug Supply Management Team) the Investigator, study site personnel and the subject remained blinded to each subject's treatment throughout the blinded period of the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Period 1 Placebo IV

Arm description:

Participants randomized to receive Placebo by intravenous (IV) infusion at Baseline, Weeks 4 and 8.

Arm type	Experimental
Investigational medicinal product name	Period 1 Placebo IV
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received placebo intravenously at Baseline, Week 4 and Week 8.

Arm title	Period 1 Risankizumab 600mg IV

Arm description:

Participants randomized to receive risankizumab 600mg by intravenous infusion at Baseline, Weeks 4 and 8.

Arm type	Experimental
Investigational medicinal product name	Period 1 Risankizumab 600mg IV
Investigational medicinal product code	ABBV-066
Other name	BI 655066, SKYRIZI
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received risankizumab 600mg intravenously at Baseline, Week 4 and Week 8.

Arm title	Period 1 Risankizumab 1200mg IV

Arm description:

Participants randomized to receive risankizumab 1200mg by intravenous infusion at Baseline, Weeks 4

and 8.

Arm type	Experimental
Investigational medicinal product name	Period 1 Risankizumab 1200mg IV
Investigational medicinal product code	ABBV-066
Other name	BI 655066, SKYRIZI
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received risankizumab 1200mg intravenously at Baseline, Week 4 and Week 8.

Number of subjects in period 1	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV
Started	186	373	372
Completed	163	365	366
Not completed	23	8	6
Adverse event, non-fatal	13	4	3
Other, not specified	1	1	2
COVID-19 logistical restrictions	2	-	-
Lack of efficacy	3	-	1
Withdrawal by subject	4	3	-

Period 2

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

Blinding implementation details:

All AbbVie personnel with direct oversight of the conduct and management of the trial (with the exception of AbbVie's Drug Supply Management Team) the Investigator, study site personnel and the subject remained blinded to each subject's treatment throughout the blinded period of the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Period 2 Risankizumab 180mg SC

Arm description:

Participants randomized to receive risankizumab 180mg by subcutaneous(SC) injection at Weeks 12 and 20.

Arm type	Experimental

Investigational medicinal product name	Period 2 Risankizumab 180mg SC
Investigational medicinal product code	ABBV-066
Other name	BI 655066, SKYRIZI
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received risankizumab 180mg subcutaneously at Weeks 12 and 20.

Arm title	Period 2 Risankizumab 360mg SC

Arm description:

Participants randomized to receive risankizumab 360mg by subcutaneous injection at Weeks 12 and 20.

Arm type	Experimental
Investigational medicinal product name	Period 2 Risankizumab 360mg SC
Investigational medicinal product code	ABBV-066
Other name	BI 655066, SKYRIZI
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received risankizumab 360mg subcutaneously at Weeks 12 and 20.

Arm title	Period 2 Risankizumab 1200mg IV

Arm description:

Participants randomized to receive risankizumab 1200mg by intravenous infusion at Weeks 12, 16 and 20.

Arm type	Experimental
Investigational medicinal product name	Period 2 Risankizumab 1200mg IV
Investigational medicinal product code	ABBV-066
Other name	BI 655066, SKYRIZI
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants received risankizumab 1200mg intravenously at Weeks 12, 16, and 20.

Arm title	Period 2 Placebo/Risankizumab 1200mg IV

Arm description:

Participants who received placebo in Induction Period 1 received 1200 mg risankizumab by intravenous infusion at Weeks 12, 16, and 20.

Arm type	Experimental
Investigational medicinal product name	Period 2 Placebo/Risankizumab 1200mg IV
Investigational medicinal product code	ABBV-066
Other name	BI 655066, SKYRIZI
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Participants who received placebo in Induction Period 1 received 1200 mg risankizumab intravenously at Weeks 12, 16, and 20.

Number of subjects in period 2[1]	Period 2 Risankizumab 180mg SC	Period 2 Risankizumab 360mg SC	Period 2 Risankizumab 1200mg IV
Started	67	68	67
Completed	62	65	64
Not completed	5	3	3
Adverse event, non-fatal	-	2	-
Other, not specified	-	-	-
COVID-19 logistical restrictions	1	-	2
Lack of efficacy	2	-	1
Withdrawal by subject	2	1	-

Number of subjects in period 2[1]	Period 2 Placebo/Risankizumab 1200mg IV
Started	76
Completed	74
Not completed	2
Adverse event, non-fatal	-
Other, not specified	2
COVID-19 logistical restrictions	-
Lack of efficacy	-
Withdrawal by subject	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: All participants who entered Induction Period 2.

Baseline characteristics

Reporting groups	
Reporting group title	Period 1 Placebo IV
Reporting group description:	
Participants randomized to receive Placebo by intravenous (IV) infusion at Baseline, Weeks 4 and 8.	
Reporting group title	Period 1 Risankizumab 600mg IV
Reporting group description:	
Participants randomized to receive risankizumab 600mg by intravenous infusion at Baseline, Weeks 4 and 8.	
Reporting group title	Period 1 Risankizumab 1200mg IV
Reporting group description:	
Participants randomized to receive risankizumab 1200mg by intravenous infusion at Baseline, Weeks 4 and 8.	

Reporting group values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV
Number of subjects	186	373	372
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	37.5	38.5	37.6
standard deviation	± 13.51	± 13.22	± 13.55
Gender categorical Units: Subjects			
Female	93	168	173
Male	93	205	199
Ethnicity Units: Subjects			
Hispanic or Latino	10	13	18
Not Hispanic or Latino	176	360	354
Race Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	32	68	75
Black or African American	9	10	13
Native Hawaiian or Other Pacific Islander	1	0	1
White	144	291	279
More than one race	0	4	4

Reporting group values	Total		
Number of subjects	931		
Age categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	 -		
Gender categorical Units: Subjects			
Female	434		
Male	497		
Ethnicity Units: Subjects			
Hispanic or Latino	41		
Not Hispanic or Latino	890		
Race Units: Subjects			
American Indian or Alaska Native	0		
Asian	175		
Black or African American	32		
Native Hawaiian or Other Pacific Islander	2		
White	714		
More than one race	8		

End points

End points reporting groups

Reporting group title	Period 1 Placebo IV
Reporting group description:	
Participants randomized to receive Placebo by intravenous (IV) infusion at Baseline, Weeks 4 and 8.	
Reporting group title	Period 1 Risankizumab 600mg IV
Reporting group description:	
Participants randomized to receive risankizumab 600mg by intravenous infusion at Baseline, Weeks 4 and 8.	
Reporting group title	Period 1 Risankizumab 1200mg IV
Reporting group description:	
Participants randomized to receive risankizumab 1200mg by intravenous infusion at Baseline, Weeks 4 and 8.	
Reporting group title	Period 2 Risankizumab 180mg SC
Reporting group description:	
Participants randomized to receive risankizumab 180mg by subcutaneous(SC) injection at Weeks 12 and 20.	
Reporting group title	Period 2 Risankizumab 360mg SC
Reporting group description:	
Participants randomized to receive risankizumab 360mg by subcutaneous injection at Weeks 12 and 20.	
Reporting group title	Period 2 Risankizumab 1200mg IV
Reporting group description:	
Participants randomized to receive risankizumab 1200mg by intravenous infusion at Weeks 12, 16 and 20.	
Reporting group title	Period 2 Placebo/Risankizumab 1200mg IV
Reporting group description:	
Participants who received placebo in Induction Period 1 received 1200 mg risankizumab by intravenous infusion at Weeks 12, 16, and 20.	

Primary: Percentage of Participants With Endoscopic Response at Week 12

End point title	Percentage of Participants With Endoscopic Response at Week 12
End point description:	
Endoscopic response was a decrease in Simplified Endoscopic Score for Crohn's Disease (SES-CD) > 50% from Baseline (or for subjects with isolated ileal disease and a Baseline SES-CD of 4, at least a 2 point reduction from Baseline). Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.	
End point type	Primary
End point timeframe:	
Week 12	

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	336	339	
Units: percentage of participants				
number (not applicable)	12.0	40.3	32.1	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV
Number of subjects included in analysis	511
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	28.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	21.2
upper limit	35.4

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Risankizumab 1200mg IV v Period 1 Placebo IV
Number of subjects included in analysis	514
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	20.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.6
upper limit	27.1

Primary: Percentage of Participants With Clinical Remission at Week 12

End point title	Percentage of Participants With Clinical Remission at Week 12

End point description:

Clinical remission is defined as using the average daily Stool Frequency (SF) ≤ 2.8 and not worse than Baseline AND average daily Abdominal Pain (AP) score ≤ 1 and not worse than Baseline.

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Primary

End point timeframe:

Week 12

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	336	339	
Units: percentage of participants				
number (not applicable)	21.7	43.5	41.0	

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Risk difference = (risankizumab - placebo).

Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV
Number of subjects included in analysis	511
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	21.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.8
upper limit	29.9

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Risk difference = (risankizumab - placebo).

Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 1200mg IV

Number of subjects included in analysis	514
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	18.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.8
upper limit	26.8

Secondary: Percentage of Participants With Crohn's Disease Activity Index (CDAI) Clinical Remission at Week 12

End point title	Percentage of Participants With Crohn's Disease Activity Index (CDAI) Clinical Remission at Week 12

End point description:

Crohn's Disease Activity Index (CDAI) is used to assess the symptoms of participants with Crohn's Disease. Higher CDAI scores indicate more severe disease. Clinical remission of Crohn's disease is defined as CDAI < 150.

Intent to Treat IA Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible Simple Endoscopic Score for Crohn's disease (SES-CD) of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	336	339	
Units: Percentage of participants				
number (not applicable)	24.6	45.2	41.6	

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Risk difference = (risankizumab - placebo).

Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV

Number of subjects included in analysis	511
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	20.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.4
upper limit	29

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Risankizumab 1200mg IV v Period 1 Placebo IV
Number of subjects included in analysis	514
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	16.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	8.5
upper limit	24.9

Secondary: Percentage of Participants With Crohn's Disease Activity Index (CDAI) Clinical Response at Week 12

End point title	Percentage of Participants With Crohn's Disease Activity Index (CDAI) Clinical Response at Week 12

End point description:

Crohn's Disease Activity Index (CDAI) is used to assess the symptoms of participants with Crohn's Disease. Higher CDAI scores indicate more severe disease. Clinical response is defined as reduction of CDAI ≥ 100 points from baseline.

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	336	339	
Units: percentage of participants				
number (not applicable)	36.7	59.7	64.9	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV
Number of subjects included in analysis	511
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	23.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.2
upper limit	31.9

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Risankizumab 1200mg IV v Period 1 Placebo IV
Number of subjects included in analysis	514
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	27.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	19
upper limit	36.4

Secondary: Change From Baseline of Induction in Functional Assessment of Chronic

Illness Therapy (FACIT)-Fatigue at Week 12

End point title	Change From Baseline of Induction in Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue at Week 12

End point description:

The FACIT-Fatigue scale is a 13-item tool that measures an individual's level of fatigue during their usual daily activities over the past 7 days. Each of the fatigue and impact of fatigue items are measured on a four point Likert scale. The FACIT Fatigue Scale is the sum of the individual 13 scores and ranges from 0 to 52 where higher scores indicate better the quality of life. A positive change from baseline indicates improvement.

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	134	302	310	
Units: units on a scale				
least squares mean (standard error)	6.0 (± 0.86)	11.2 (± 0.59)	10.1 (± 0.58)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Mean difference = (risankizumab - placebo).

Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV
Number of subjects included in analysis	436
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed-Effect Model Repeat Measurement
Parameter estimate	LS Mean
Point estimate	5.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.2
upper limit	7.2

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:	
Mean difference = (risankizumab - placebo).	
Comparison groups	Period 1 Risankizumab 1200mg IV v Period 1 Placebo IV
Number of subjects included in analysis	444
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed-Effect Model Repeat Measurement
Parameter estimate	LS Mean
Point estimate	4.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.1
upper limit	6.1

Secondary: Percentage of Participants With Enhanced Clinical Response and Endoscopic Response at Week 12

End point title	Percentage of Participants With Enhanced Clinical Response and Endoscopic Response at Week 12

End point description:

Enhanced clinical response was defined as ≥ 60% decrease in average daily Stool Frequency and/or ≥ 35% decrease in average daily Abdominal Pain score and both not worse than baseline, and/or clinical remission. Endoscopic Response was defined as a decrease in Simplified Endoscopic Score for Crohn's Disease (SES-CD) > 50% from Baseline (or for subjects with isolated ileal disease and a Baseline SES-CD of 4, at least a 2 point reduction from Baseline).

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	336	339	
Units: percentage of participants				
number (not applicable)	8	30.9	23.2	

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:	
Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV
Number of subjects included in analysis	511
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	23.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	16.8
upper limit	29.6

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Risankizumab 1200mg IV v Period 1 Placebo IV
Number of subjects included in analysis	514
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	15.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.3
upper limit	21.2

Secondary: Percentage of Participants With Endoscopic Remission at Week 12

End point title	Percentage of Participants With Endoscopic Remission at Week 12

End point description:

Endoscopic remission was defined as SES-CD ≤ 4 and at least a 2-point reduction versus baseline and no subscore greater than 1 in any individual variable.

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	336	339	
Units: percentage of participants				
number (not applicable)	9.1	24.2	23.9	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV
Number of subjects included in analysis	511
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	15.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	9
upper limit	21.2

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Risankizumab 1200mg IV v Period 1 Placebo IV
Number of subjects included in analysis	514
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	15.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.4
upper limit	21.4

Secondary: Percentage of Participants With Enhanced Clinical Response at Week 12

End point title	Percentage of Participants With Enhanced Clinical Response at Week 12

End point description:

Enhanced clinical response was defined as ≥ 60% decrease in average daily Stool Frequency and/or ≥ 35% decrease in average daily Abdominal Pain score and both not worse than baseline, and/or clinical remission.

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	336	339	
Units: percentage of participants				
number (not applicable)	41.9	62.8	64.3	

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Risk difference = (risankizumab - placebo).

Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV
Number of subjects included in analysis	511
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	21
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.2
upper limit	29.9

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Risankizumab 1200mg IV v Period 1 Placebo IV
Number of subjects included in analysis	514
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	21.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	12.8
upper limit	30.4

Secondary: Percentage of Participants With Ulcer-Free Endoscopy at Week 12

End point title	Percentage of Participants With Ulcer-Free Endoscopy at Week 12

End point description:

Ulcer-free endoscopy was defined as SES-CD ulcerated surface subscore of 0 in subjects with SES-CD ulcerated surface subscore ≥ 1 at baseline.

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	173	336	338	
Units: percentage of participants				
number (not applicable)	7.6	21.0	16.4	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV

Number of subjects included in analysis	509
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	13.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.9
upper limit	19.5

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Risankizumab 1200mg IV v Period 1 Placebo IV
Number of subjects included in analysis	511
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	9.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.7
upper limit	14.5

Secondary: Percentage of Participants With Resolution of Extra-Intestinal Manifestations (EIMs) at Week 12, in Participants With EIMs at Baseline

End point title	Percentage of Participants With Resolution of Extra-Intestinal Manifestations (EIMs) at Week 12, in Participants With EIMs at Baseline

End point description:

Manifestations of Crohn's disease in areas of the body other than the digestive tract, including eyes, skin, joints, mouth, and liver.

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	64	140	158	
Units: percentage of participants				
number (not applicable)	20.5	38.1	43.7	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV
Number of subjects included in analysis	204
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.022
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	14.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.1
upper limit	27

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Risankizumab 1200mg IV v Period 1 Placebo IV
Number of subjects included in analysis	222
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	23.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.1
upper limit	36.3

Secondary: Percentage of Participants With CD-Related Hospitalization through

Week 12

End point title	Percentage of Participants With CD-Related Hospitalization through Week 12

End point description:

Participants with at least one admission to the hospital due to Crohn's Disease

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	336	339	
Units: percentage of participants				
number (not applicable)	12	3.3	1.8	

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Risk difference = (risankizumab - placebo).

Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV
Number of subjects included in analysis	511
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	-8.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.9
upper limit	-3.5

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Risk difference = (risankizumab - placebo).

Comparison groups	Period 1 Risankizumab 1200mg IV v Period 1 Placebo IV

Number of subjects included in analysis	514
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	-10.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.2
upper limit	-5.2

Secondary: Percentage of Participants Without Draining Fistulas at Week 12 in Participants With Draining Fistulas at Baseline

End point title	Percentage of Participants Without Draining Fistulas at Week 12 in Participants With Draining Fistulas at Baseline

End point description:

Participants without draining fistulas at Week 12 in participants who had draining fistulas at baseline.

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	9	18	24	
Units: percentage of participants				
number (not applicable)	22.2	27.8	29.2	

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Risk difference = (risankizumab - placebo).

Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV

Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	5.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.6
upper limit	39.7

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Risankizumab 1200mg IV v Period 1 Placebo IV
Number of subjects included in analysis	33
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 1
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	6.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.7
upper limit	39.6

Secondary: Percentage of Participants With Crohn's Disease Activity Index (CDAI) Clinical Response at Week 4

End point title	Percentage of Participants With Crohn's Disease Activity Index (CDAI) Clinical Response at Week 4

End point description:

Crohn's Disease Activity Index (CDAI) is used to assess the symptoms of participants with Crohn's Disease. Higher CDAI scores indicate more severe disease. Clinical response is defined as reduction of CDAI ≥ 100 points from baseline.

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 4

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	336	339	
Units: percentage of participants				
number (not applicable)	25.2	40.8	37.2	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Risk difference = (risankizumab - placebo)	
Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV
Number of subjects included in analysis	511
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	15.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.2
upper limit	23.7

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Risk difference = (risankizumab - placebo)	
Comparison groups	Period 1 Risankizumab 1200mg IV v Period 1 Placebo IV
Number of subjects included in analysis	514
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	11.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.1
upper limit	19.2

Secondary: Percentage of Participants With Enhanced Clinical Response at Week 4

End point title	Percentage of Participants With Enhanced Clinical Response at Week 4

End point description:

Enhanced clinical response was defined as ≥ 60% decrease in average daily Stool Frequency and/or ≥ 35% decrease in average daily Abdominal Pain score and both not worse than baseline, and/or clinical remission.

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 4

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	336	339	
Units: percentage of participants				
number (not applicable)	31	46	43.4	

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Risk difference = (risankizumab - placebo)

Comparison groups	Period 1 Risankizumab 600mg IV v Period 1 Placebo IV
Number of subjects included in analysis	511
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	14.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.2
upper limit	23.5

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Risk difference = (risankizumab - placebo)

Comparison groups	Period 1 Risankizumab 1200mg IV v Period 1 Placebo IV

Number of subjects included in analysis	514
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.007
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	11.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.2
upper limit	20.3

Secondary: Change from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) total score at Week 12

End point title	Change from baseline in Inflammatory Bowel Disease Questionnaire (IBDQ) total score at Week 12

End point description:

The IBDQ is a 32-item (ranges 1 – 7) self-report questionnaire for patients with IBD to evaluate the patient reported outcomes across 4 dimensions: 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). The IBDQ total Score ranges from 32 to 224 with a higher score indicating better outcome.

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	134	302	310	
Units: units on a scale				
least squares mean (standard error)	23.6 (± 2.72)	44.3 (± 1.87)	43 (± 1.85)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Mean difference = (risankizumab - placebo).

Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV

Number of subjects included in analysis	436
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed-Effect Model Repeat Measurement
Parameter estimate	LS Mean
Point estimate	20.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	14.3
upper limit	27.1

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Mean difference = (risankizumab - placebo).	
Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 1200mg IV
Number of subjects included in analysis	444
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed-Effect Model Repeat Measurement
Parameter estimate	LS Mean
Point estimate	19.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.1
upper limit	25.8

Secondary: Change from baseline in Work Productivity and Impairment Questionnaire – Crohn's disease (WPAI-CD) Overall Work Impairment at Week 12

End point title	Change from baseline in Work Productivity and Impairment Questionnaire – Crohn's disease (WPAI-CD) Overall Work Impairment at Week 12

End point description:

WPAI: CD is a questionnaire used to evaluate lost productivity due to CD ; scores are presented as percentages (multiplying the scores by 100), with 0% representing no impact on productivity and 100% representing complete impact on productivity. Total work productivity impairment takes into account both hours missed due to CD symptoms and the patient's assessment of the degree to which CD affected their productivity while working (overall work impairment [OWI]). WPAI outcomes are expressed as impairment percentages, with higher numbers indicating greater impairment and less productivity.

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	65	156	162	
Units: units on a scale				
least squares mean (standard error)	-8.344 (± 3.5640)	-17.930 (± 2.3446)	-20.485 (± 2.3112)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV
Number of subjects included in analysis	221
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.024
Method	Mixed-Effect Model Repeat Measurement
Parameter estimate	LS Mean
Point estimate	-9.586
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.89
upper limit	-1.282

Statistical analysis title	Statistical Analysis 2
Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 1200mg IV
Number of subjects included in analysis	227
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.004
Method	Mixed-Effect Model Repeat Measurement
Parameter estimate	LS Mean
Point estimate	-12.141
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.39
upper limit	-3.892

Secondary: Change from baseline in Short Form-36 (SF-36) Physical Component Summary (PCS) score at Week 12

End point title	Change from baseline in Short Form-36 (SF-36) Physical Component Summary (PCS) score at Week 12

End point description:

The Short Form-36 Health Survey determined participants' overall quality of life by assessing 1) limitations in physical functioning due to health problems; 2) limitations in usual role because of physical health problems; 3) bodily pain; 4) general health perceptions; 5) vitality; 6) limitations in social functioning because of physical or emotional problems; 7) limitations in usual role due to emotional problems; and 8) general mental health. Items 1-4 comprise the physical component of the SF-36. Scores on each item were summed and averaged (range = 0-100); a positive change from Baseline indicates improvement.

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 12

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	134	302	309	
Units: units on a scale				
least squares mean (standard error)	5.482 (± 0.5985)	8.394 (± 0.4107)	8.756 (± 0.4071)	

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV
Number of subjects included in analysis	436
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed-Effect Model Repeat Measurement
Parameter estimate	LS Mean
Point estimate	2.913
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.512
upper limit	4.313

Statistical analysis title	Statistical Analysis 2
Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 1200mg IV

Number of subjects included in analysis	443
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Mixed-Effect Model Repeat Measurement
Parameter estimate	LS Mean
Point estimate	3.275
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.877
upper limit	4.672

Secondary: Percentage of Participants With Clinical Remission at Week 4

End point title	Percentage of Participants With Clinical Remission at Week 4

End point description:

Clinical remission is defined as using the average daily Stool Frequency (SF) ≤ 2.8 and not worse than Baseline AND average daily Abdominal Pain (AP) score ≤ 1 and not worse than Baseline.

Intent to Treat 1A Population: all randomized subjects who received at least one dose of study drug during the 12-Week Induction Period, and had baseline eligible SES-CD of ≥ 6 (≥ 4 for isolated ileal disease) excluding the narrowing component.

End point type	Secondary

End point timeframe:

Week 4

End point values	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV	Period 1 Risankizumab 1200mg IV	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	175	336	339	
Units: percentage of participants				
number (not applicable)	9.1	21.0	21.2	

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Risk difference = (risankizumab - placebo).

Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 600mg IV

Number of subjects included in analysis	511
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	11.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.4
upper limit	17.5

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Risk difference = (risankizumab - placebo).	
Comparison groups	Period 1 Placebo IV v Period 1 Risankizumab 1200mg IV
Number of subjects included in analysis	514
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted risk difference
Point estimate	11.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	5.7
upper limit	17.8

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From first dose of study drug until 140 days following last dose of study drug.	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	23.1

Reporting groups	
Reporting group title	Period 1 Risankizumab 1200mg IV
Reporting group description:	
Participants randomized to receive risankizumab 1200mg by intravenous infusion at Baseline, Weeks 4 and 8.	
Reporting group title	Period 1 Placebo IV
Reporting group description:	
Participants randomized to receive Placebo intravenous by intravenous infusion at Baseline, Weeks 4 and 8.	
Reporting group title	Period 1 Risankizumab 600mg IV
Reporting group description:	
Participants randomized to receive risankizumab 600mg by intravenous infusion at Baseline, Weeks 4 and 8.	
Reporting group title	Period 1 Risankizumab total
Reporting group description: -	
Reporting group title	Period 2 Risankizumab 360mg SC
Reporting group description:	
Participants randomized to receive risankizumab 360mg by subcutaneous injection at Weeks 12 and 20.	
Reporting group title	Period 2 Risankizumab 180mg SC
Reporting group description:	
Participants randomized to receive risankizumab 180mg by subcutaneous injection at Weeks 12 and 20.	
Reporting group title	Period 2 Risankizumab 1200mg IV
Reporting group description:	
Participants received risankizumab 1200mg by intravenous infusion at Weeks 12, 16, and 20.	
Reporting group title	Period 2 Risankizumab total
Reporting group description: -	
Reporting group title	Period 2 Placebo/Risankizumab 1200mg IV
Reporting group description:	
Participants who received placebo in Induction Period 1 received 1200 mg risankizumab by intravenous infusion at Weeks 12, 16, and 20.	

Serious adverse events	Period 1 Risankizumab 1200mg IV	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV
Total subjects affected by serious adverse events			
subjects affected / exposed	14 / 372 (3.76%)	28 / 186 (15.05%)	27 / 373 (7.24%)
number of deaths (all causes)	0	2	0
number of deaths resulting from adverse events	0	2	0

Vascular disorders			
DEEP VEIN THROMBOSIS			
subjects affected / exposed	1 / 372 (0.27%)	0 / 186 (0.00%)	0 / 373 (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
HYPERTENSION			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
ABORTION INDUCED			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYSTEMIC INFLAMMATORY RESPONSE SYNDROME			
subjects affected / exposed	1 / 372 (0.27%)	0 / 186 (0.00%)	0 / 373 (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
Immune system disorders			
FOOD ALLERGY			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ASTHMA			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			

subjects affected / exposed	1 / 372 (0.27%)	0 / 186 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
MENTAL DISORDER			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSESSIVE-COMPULSIVE DISORDER			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
BODY TEMPERATURE INCREASED			
subjects affected / exposed	1 / 372 (0.27%)	0 / 186 (0.00%)	0 / 373 (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
HAEMOGLOBIN DECREASED			
subjects affected / exposed	1 / 372 (0.27%)	0 / 186 (0.00%)	0 / 373 (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
WEIGHT DECREASED			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOREARM FRACTURE			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Cardiac disorders			
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 372 (0.27%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
RETINAL DISORDER			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL HERNIA			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 372 (0.00%)	2 / 186 (1.08%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS			

subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROHN'S DISEASE			
subjects affected / exposed	2 / 372 (0.54%)	15 / 186 (8.06%)	5 / 373 (1.34%)
occurrences causally related to treatment / all	1 / 2	2 / 16	0 / 7
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL INFLAMMATION			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL NECROSIS			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
ILEAL PERFORATION			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
ILEAL STENOSIS			
subjects affected / exposed	1 / 372 (0.27%)	0 / 186 (0.00%)	0 / 373 (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
ILEUS			

subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	2 / 373 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL ISCHAEMIA			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 372 (0.00%)	2 / 186 (1.08%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL STENOSIS			
subjects affected / exposed	0 / 372 (0.00%)	2 / 186 (1.08%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
LARGE INTESTINE PERFORATION			
subjects affected / exposed	1 / 372 (0.27%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATITIS ACUTE			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	1 / 372 (0.27%)	1 / 186 (0.54%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	1 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			

subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TERMINAL ILEITIS			
subjects affected / exposed	1 / 372 (0.27%)	0 / 186 (0.00%)	0 / 373 (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
VOMITING			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
BILE DUCT STONE			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS ACUTE			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FUNCTION ABNORMAL			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIVER DISORDER			
subjects affected / exposed	1 / 372 (0.27%)	0 / 186 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			

RASH			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
CALCULUS URINARY			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDRONEPHROSIS			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEPHROLITHIASIS			
subjects affected / exposed	1 / 372 (0.27%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETEROLITHIASIS			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	2 / 373 (0.54%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ANKYLOSING SPONDYLITIS			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRALGIA			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FIBROMYALGIA			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

FISTULA			
subjects affected / exposed	1 / 372 (0.27%)	0 / 186 (0.00%)	0 / 373 (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
SPONDYLITIS			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
ABDOMINAL WALL ABSCESS			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABSCESS INTESTINAL			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAL ABSCESS			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APPENDICITIS			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS NOROVIRUS			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEPTOSPIROSIS			

subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	1 / 373 (0.27%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS			
subjects affected / exposed	0 / 372 (0.00%)	0 / 186 (0.00%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	1 / 372 (0.27%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
PULMONARY SEPSIS			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TONSILLITIS			
subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 372 (0.27%)	0 / 186 (0.00%)	0 / 373 (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
VULVAL CELLULITIS			

subjects affected / exposed	0 / 372 (0.00%)	1 / 186 (0.54%)	0 / 373 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Period 1 Risankizumab total	Period 2 Risankizumab 360mg SC	Period 2 Risankizumab 180mg SC
Total subjects affected by serious adverse events			
subjects affected / exposed	41 / 745 (5.50%)	3 / 68 (4.41%)	3 / 67 (4.48%)
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 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
HYPERTENSION			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
Surgical and medical procedures			
ABORTION INDUCED			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
ASTHENIA			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYSTEMIC INFLAMMATORY RESPONSE SYNDROME			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
Immune system disorders			
FOOD ALLERGY			

subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ASTHMA			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
MENTAL DISORDER			
subjects affected / exposed	0 / 745 (0.00%)	1 / 68 (1.47%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSESSIVE-COMPULSIVE DISORDER			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
BODY TEMPERATURE INCREASED			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
HAEMOGLOBIN DECREASED			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
WEIGHT DECREASED			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
FOREARM FRACTURE			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
RETINAL DISORDER			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
ABDOMINAL HERNIA			

subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROHN'S DISEASE			
subjects affected / exposed	7 / 745 (0.94%)	0 / 68 (0.00%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	1 / 9	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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 HAEMORRHAGE			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL INFLAMMATION			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL NECROSIS			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ILEAL PERFORATION			

subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ILEAL STENOSIS			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
ILEUS			
subjects affected / exposed	2 / 745 (0.27%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL ISCHAEMIA			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL OBSTRUCTION			
subjects affected / exposed	1 / 745 (0.13%)	1 / 68 (1.47%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL STENOSIS			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINE PERFORATION			
subjects affected / exposed	2 / 745 (0.27%)	1 / 68 (1.47%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
PANCREATITIS ACUTE			

subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	2 / 745 (0.27%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TERMINAL ILEITIS			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
VOMITING			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
BILE DUCT STONE			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
CHOLANGITIS			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
CHOLECYSTITIS ACUTE			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FUNCTION ABNORMAL			

subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
LIVER DISORDER			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
Renal and urinary disorders			
CALCULUS URINARY			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	1 / 67 (1.49%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDRONEPHROSIS			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
NEPHROLITHIASIS			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETEROLITHIASIS			
subjects affected / exposed	2 / 745 (0.27%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ANKYLOSING SPONDYLITIS			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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

ARTHRALGIA			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
FIBROMYALGIA			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
FISTULA			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
SPONDYLITIS			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
ABDOMINAL WALL ABSCESS			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABSCESS INTESTINAL			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAL ABSCESS			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APPENDICITIS			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
GASTROENTERITIS			

subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS NOROVIRUS			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEPTOSPIROSIS			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
PERITONITIS			
subjects affected / exposed	0 / 745 (0.00%)	1 / 68 (1.47%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY SEPSIS			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TONSILLITIS			

subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	1 / 745 (0.13%)	0 / 68 (0.00%)	0 / 67 (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
VULVAL CELLULITIS			
subjects affected / exposed	0 / 745 (0.00%)	0 / 68 (0.00%)	0 / 67 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Period 2 Risankizumab 1200mg IV	Period 2 Risankizumab total	Period 2 Placebo/Risankizumab 1200mg IV
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 67 (5.97%)	14 / 278 (5.04%)	4 / 76 (5.26%)
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	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYPERTENSION			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
ABORTION INDUCED			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
ASTHENIA			

subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYSTEMIC INFLAMMATORY RESPONSE SYNDROME			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			
FOOD ALLERGY			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
ASTHMA			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY EMBOLISM			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
MENTAL DISORDER			
subjects affected / exposed	0 / 67 (0.00%)	1 / 278 (0.36%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
OBSESSIVE-COMPULSIVE DISORDER			
subjects affected / exposed	1 / 67 (1.49%)	1 / 278 (0.36%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
BODY TEMPERATURE INCREASED			

subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HAEMOGLOBIN DECREASED			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
WEIGHT DECREASED			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
FALL			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FOREARM FRACTURE			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
VENTRICULAR TACHYCARDIA			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
DIZZINESS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SYNCOPE			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
RETINAL DISORDER			
subjects affected / exposed	0 / 67 (0.00%)	1 / 278 (0.36%)	1 / 76 (1.32%)
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 HERNIA			
subjects affected / exposed	1 / 67 (1.49%)	1 / 278 (0.36%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COLITIS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CROHN'S DISEASE			
subjects affected / exposed	0 / 67 (0.00%)	1 / 278 (0.36%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
DIARRHOEA			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL HAEMORRHAGE			

subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL INFLAMMATION			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROINTESTINAL NECROSIS			
subjects affected / exposed	1 / 67 (1.49%)	1 / 278 (0.36%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ILEAL PERFORATION			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ILEAL STENOSIS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ILEUS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL ISCHAEMIA			
subjects affected / exposed	1 / 67 (1.49%)	1 / 278 (0.36%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL OBSTRUCTION			
subjects affected / exposed	0 / 67 (0.00%)	3 / 278 (1.08%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
INTESTINAL STENOSIS			

subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LARGE INTESTINE PERFORATION			
subjects affected / exposed	0 / 67 (0.00%)	1 / 278 (0.36%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NAUSEA			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PANCREATITIS ACUTE			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	1 / 67 (1.49%)	1 / 278 (0.36%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SUBILEUS			
subjects affected / exposed	0 / 67 (0.00%)	1 / 278 (0.36%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TERMINAL ILEITIS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VOMITING			
subjects affected / exposed	1 / 67 (1.49%)	1 / 278 (0.36%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
BILE DUCT STONE			

subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLANGITIS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
CHOLECYSTITIS ACUTE			
subjects affected / exposed	1 / 67 (1.49%)	1 / 278 (0.36%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HEPATIC FUNCTION ABNORMAL			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LIVER DISORDER			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
RASH			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
CALCULUS URINARY			
subjects affected / exposed	0 / 67 (0.00%)	1 / 278 (0.36%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
HYDRONEPHROSIS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
NEPHROLITHIASIS			

subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URETEROLITHIASIS			
subjects affected / exposed	1 / 67 (1.49%)	1 / 278 (0.36%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
ANKYLOSING SPONDYLITIS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ARTHRALGIA			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FIBROMYALGIA			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
FISTULA			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
SPONDYLITIS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
ABDOMINAL WALL ABSCESS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

ABSCESS INTESTINAL			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
ANAL ABSCESS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
APPENDICITIS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
GASTROENTERITIS NOROVIRUS			
subjects affected / exposed	0 / 67 (0.00%)	1 / 278 (0.36%)	1 / 76 (1.32%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LEPTOSPIROSIS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
LOWER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PERITONITIS			
subjects affected / exposed	0 / 67 (0.00%)	1 / 278 (0.36%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PNEUMONIA			

subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PULMONARY SEPSIS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
PYELONEPHRITIS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
TONSILLITIS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
VULVAL CELLULITIS			
subjects affected / exposed	0 / 67 (0.00%)	0 / 278 (0.00%)	0 / 76 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

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

Non-serious adverse events	Period 1 Risankizumab 1200mg IV	Period 1 Placebo IV	Period 1 Risankizumab 600mg IV
Total subjects affected by non-serious adverse events			
subjects affected / exposed	58 / 372 (15.59%)	35 / 186 (18.82%)	67 / 373 (17.96%)
Nervous system disorders			
HEADACHE			
subjects affected / exposed	20 / 372 (5.38%)	8 / 186 (4.30%)	24 / 373 (6.43%)
occurrences (all)	27	8	25

Blood and lymphatic system disorders ANAEMIA subjects affected / exposed occurrences (all)	9 / 372 (2.42%) 9	5 / 186 (2.69%) 5	11 / 373 (2.95%) 11
Gastrointestinal disorders CROHN'S DISEASE subjects affected / exposed occurrences (all) NAUSEA subjects affected / exposed occurrences (all)	4 / 372 (1.08%) 4 13 / 372 (3.49%) 13	10 / 186 (5.38%) 10 10 / 186 (5.38%) 10	5 / 373 (1.34%) 5 16 / 373 (4.29%) 17
Infections and infestations NASOPHARYNGITIS subjects affected / exposed occurrences (all)	22 / 372 (5.91%) 24	5 / 186 (2.69%) 5	22 / 373 (5.90%) 24

Non-serious adverse events	Period 1 Risankizumab total	Period 2 Risankizumab 360mg SC	Period 2 Risankizumab 180mg SC
Total subjects affected by non-serious adverse events subjects affected / exposed	125 / 745 (16.78%)	7 / 68 (10.29%)	4 / 67 (5.97%)
Nervous system disorders HEADACHE subjects affected / exposed occurrences (all)	44 / 745 (5.91%) 52	3 / 68 (4.41%) 3	1 / 67 (1.49%) 2
Blood and lymphatic system disorders ANAEMIA subjects affected / exposed occurrences (all)	20 / 745 (2.68%) 20	2 / 68 (2.94%) 2	0 / 67 (0.00%) 0
Gastrointestinal disorders CROHN'S DISEASE subjects affected / exposed occurrences (all) NAUSEA subjects affected / exposed occurrences (all)	9 / 745 (1.21%) 9 29 / 745 (3.89%) 30	1 / 68 (1.47%) 1 0 / 68 (0.00%) 0	2 / 67 (2.99%) 2 1 / 67 (1.49%) 1
Infections and infestations NASOPHARYNGITIS subjects affected / exposed occurrences (all)	44 / 745 (5.91%) 48	1 / 68 (1.47%) 1	1 / 67 (1.49%) 1

Non-serious adverse events	Period 2 Risankizumab 1200mg IV	Period 2 Risankizumab total	Period 2 Placebo/Risankizumab 1200mg IV
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 67 (5.97%)	27 / 278 (9.71%)	12 / 76 (15.79%)
Nervous system disorders			
HEADACHE			
subjects affected / exposed	2 / 67 (2.99%)	11 / 278 (3.96%)	5 / 76 (6.58%)
occurrences (all)	3	13	5
Blood and lymphatic system disorders			
ANAEMIA			
subjects affected / exposed	1 / 67 (1.49%)	7 / 278 (2.52%)	4 / 76 (5.26%)
occurrences (all)	1	7	4
Gastrointestinal disorders			
CROHN'S DISEASE			
subjects affected / exposed	0 / 67 (0.00%)	3 / 278 (1.08%)	0 / 76 (0.00%)
occurrences (all)	0	3	0
NAUSEA			
subjects affected / exposed	0 / 67 (0.00%)	4 / 278 (1.44%)	3 / 76 (3.95%)
occurrences (all)	0	4	3
Infections and infestations			
NASOPHARYNGITIS			
subjects affected / exposed	1 / 67 (1.49%)	5 / 278 (1.80%)	2 / 76 (2.63%)
occurrences (all)	1	5	2

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 July 2017	Major changes included: Added CDAI criteria to the inclusion criteria. Updated instructions on which hematocrit (Hct) value to use in calculating the CDAI for inclusion. Added "psychological or psychiatric cause" to Exclusion Criterion 29. Updated information on discontinuation of individual subjects for subjects who were not responders at Week 12. Updated contraception recommendations and criteria. Clarification of the blind-breaking process. Updated latent tuberculosis (TB) requirements. Updated pregnancy reporting timing. Added assent information for subjects less than 18 years old.
29 September 2017	Major changes included: Added an anaphylaxis adjudication committee. Revised to allow for local regulations for the difference in minimum age for adults. Updated of Inclusion Criterion 6 for immunomodulators (IMM) use. Updated of Exclusion Criterion 18 for CD related complications. Updated of prohibited medications. Added international normalized ratio (INR) and anaphylaxis testing. Added details for additional hepatitis testing and anaphylaxis testing. Added endoscopic remission to ranked secondary endpoints and Patient Global Impression of Severity (PGIS) and Patient Global Impression of Change (PGIC) to non ranked secondary endpoints. Added clinical and endoscopic remission over time as endpoints. Updated criteria for discontinuation of individual subjects. Revised to align with Common Toxicity Criteria for Adverse Events (CTCAE) grading criteria for adverse events (AEs). Revised to allow for additional types of anaphylactic reactions and to provide Investigators with guidance on reporting of events. Updated for alignment with template requirements and for consistency across the risankizumab programs. Clarifications of sample size calculation. Updated to reflect the most recent subject diary entries and addition of patient-reported outcome (PRO) for collection. Updated in the schedule of activities to reflect changes made in the body of the protocol. Addition of information on the sample collection schedule. Revised to align with regulatory agency feedback.

09 July 2018	Major changes included: Extension of the AE collection period duration, final follow-up call, and period for prohibition of vaccines. Modified benefits and risks to align with the IB. Added blood collection for tryptase following a suspected drug administration hypersensitivity reaction. Added "worsening" CD to common AEs associated with underlying disease. Added "intramuscular" as possible route of administration for prohibited anti-infectives. Exclusion of subjects who receive exclusive enteral nutrition to treat CD. Clarification and explanation of inclusion requirements for oral locally acting steroids, IV or oral systemic steroids. Added height measurement for pediatric subjects. Prohibition of local, routine testing for fecal calprotectin and high-sensitivity C-reactive protein. Modified contraception language. Removed stool sample collection for fecal-calprotectin (FCP) at screening. Clarified repeat screening tests and the qualifications for a screening period extension.
22 February 2019	Major changes included: Documentation of the DMC opinion to continue the trial and enroll 16-17 year olds. Added language to allow single repeat testing of transient exclusionary laboratory values during the screening period. Clarified the types of prohibited corticosteroids. Modified permit enrollment of not more than 20% subjects with prior exposure, including intolerance or inadequate response, to ustekinumab Specification that enrollment of subjects with Baseline SES-CD of ≥ 3 to < 6 for ileocolonic or colonic disease or Baseline SES-CD of 3 for isolated ileal disease would be no more than 10% of the total population. Added stratification factor of Baseline SES-CD. Updated definitions of endoscopic remission and endoscopic response. Revised to allow a commercially available assay to determine approved biologic washout. Clarified that TB prophylaxis is permissible. Revised the order and addition of ranked secondary endpoints, update of ranked secondary endpoints to non ranked secondary endpoints, and addition of non-ranked secondary endpoint. Updated statistical assumptions for sample size determination. Added details of multiplicity adjustment and subgroup analysis for Bio-IR and non Bio-IR population. Updated of the missing imputation methodology to remove last observation carried forward (LOCF).
19 December 2019	Major changes included: Specified total N of 855 for the primary intent-to-treat (ITT) population used for efficacy analysis, that the number of subjects with lower SES-CD will be no more than 85, and that data collected from subjects with the lower SES-CD will be analyzed as an exploratory efficacy analysis. Specified that Hct from the preceding visit may be used to calculate the CDAI if there are technical issues. Revised the definition of endoscopic remission. Revised the term "endoscopic healing" to "ulcer-free endoscopy". Updated of secondary endpoint ranking and combining and adding new ranked secondary endpoints. Clarified timing of DBL Removed the missing imputation method OC from the sensitivity analysis of the continuous efficacy variables. Added missing data handling methods. Clarified the way continuous laboratory and vital signs would be summarized. Removed Fisher's exact test for risankizumab treatment group differences versus placebo for AEs.

28 July 2020	Major changes included: Revised language throughout due to the Coronavirus disease – 2019 (COVID-19) pandemic, including benefit and risk, criteria to exclude subjects with active COVID-19, addition of COVID-19 AE data collection process, modification of study visits/protocol-specified procedures impacted by changes in local regulations, protocol deviations, missing data, data monitoring, and COVID-19 testing. Added language regarding site responsibility. Clarified HIV results language.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported