Clinical trial results:
A Randomized, Double-Blind, Placebo-Controlled, Proof-of-Concept Dose-Ranging Study of BI 655066/ABBV-066/Risankizumab in Patients with Active Psoriatic Arthritis

Summary

EudraCT number	2015-003625-34
Trial protocol	FI ES NL DE BE CZ FR
Global end of trial date	24 August 2017

Results information

Result version number	v2 (current)
This version publication date	23 September 2018
First version publication date	04 August 2018
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	1311.5

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02719171
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Boehringer Ingelheim
Sponsor organisation address	Binger Strasse 173, Ingelheim am Rhein, Germany, 55216
Public contact	QRPE Processes and Systems Coordination, Clinical Trial Information Disclosure, Boehringer Ingelheim, 001 8002430127, clintriage.rdg@boehringer-ingelheim.com
Scientific contact	QRPE Processes and Systems Coordination, Clinical Trial Information Disclosure, Boehringer Ingelheim, 001 8002430127, clintriage.rdg@boehringer-ingelheim.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	13 October 2017
Is this the analysis of the primary completion data?	Yes
Primary completion date	15 May 2017
Global end of trial reached?	Yes
Global end of trial date	24 August 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective was to provide proof-of-concept and dose-ranging for the efficacy of risankizumab as a treatment for psoriatic arthritis.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	13 April 2016
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 11
Country: Number of subjects enrolled	Belgium: 6
Country: Number of subjects enrolled	Czech Republic: 21
Country: Number of subjects enrolled	Finland: 22
Country: Number of subjects enrolled	France: 6
Country: Number of subjects enrolled	Germany: 25
Country: Number of subjects enrolled	Japan: 17
Country: Number of subjects enrolled	Poland: 44
Country: Number of subjects enrolled	Spain: 13
Country: Number of subjects enrolled	Taiwan: 8
Country: Number of subjects enrolled	United States: 66
Worldwide total number of subjects	239
EEA total number of subjects	137

Notes:

Subjects enrolled per age group

In utero	0

Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	205
From 65 to 84 years	34
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This Phase 2, multi-national, randomized, parallel-design, multiple-dose, placebo controlled, double-blind study compared risankizumab with placebo in patients with active psoriatic arthritis. Patients were randomized at a 2:2:2:1:2 ratio, stratified based on prior tumor necrosis factor inhibitor (TNFi) use and concurrent methotrexate (MTX) use

Pre-assignment

Screening details:

This study included a 6-week screening period. All subjects were screened for eligibility to participate in the trial. Subjects attended a specialist sites which ensured that they met all strictly implemented inclusion/exclusion criteria. Subjects were not to be entered to trial treatment if any one of the specific entry criteria was violated.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Data analyst

Blinding implementation details:

A Randomized, Double-Blind, Placebo-Controlled, Proof-of-Concept Dose-Ranging Study

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Participants randomized to receive double-blind (DB) placebo for risankizumab by subcutaneous (SC) injection every 4 weeks for 16 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo for Risankizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received placebo for risankizumab by subcutaneous (SC) injection every 4 weeks for 16 weeks.

Arm title	Risankizumab 150 mg Every 4 Weeks

Arm description:

Participants randomized to receive double-blind (DB) risankizumab 150 milligram (mg) by subcutaneous (SC) injection every 4 weeks for 16 weeks.

Arm type	Experimental
Investigational medicinal product name	Risankizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received risankizumab 150 mg by subcutaneous (SC) injection every 4 weeks for 16 weeks.

Arm title	Risankizumab 150 mg Weeks 0, 4, and 16

Arm description:

Participants randomized to receive double-blind (DB) risankizumab 150 mg by subcutaneous (SC) injection at Weeks 0, 4, and 16.

Arm type	Experimental
Investigational medicinal product name	Risankizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received risankizumab 150 mg by subcutaneous (SC) injection at Weeks 0, 4, and 16.

Arm title	Risankizumab 150 mg Weeks 0 and 12

Arm description:

Participants randomized to receive double-blind (DB) risankizumab 150 mg by subcutaneous (SC) injection at Weeks 0 and 12.

Arm type	Experimental
Investigational medicinal product name	Risankizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received risankizumab 150 mg by subcutaneous (SC) injection at Weeks 0 and 12.

Arm title	Risankizumab 75 mg Week 0

Arm description:

Participants randomized to receive double-blind (DB) risankizumab 75 mg by subcutaneous (SC) injection at Week 0.

Arm type	Experimental
Investigational medicinal product name	Risankizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received risankizumab 75 mg by subcutaneous (SC) injection at Weeks 0.

Number of subjects in period 1[1]	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16
Started	42	42	42
Completed	41	38	39
Not completed	1	4	3
Adverse event, non-fatal	1	2	-
Subject Withdrawal	-	2	2
Not Specified	-	-	-
Lost to follow-up	-	-	1

Number of subjects in period 1	Risankizumab 150 mg Weeks 0 and 12	Risankizumab 75 mg Week 0

[1]		
Started	39	20
Completed	37	18
Not completed	2	2
Adverse event, non-fatal	-	2
Subject Withdrawal	1	-
Not Specified	1	-
Lost to follow-up	-	-

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: Baseline characteristics are based on the patients who were randomized after successfully completing the screening period and received at least one of the trial medication.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Participants randomized to receive double-blind (DB) placebo for risankizumab by subcutaneous (SC) injection every 4 weeks for 16 weeks.	
Reporting group title	Risankizumab 150 mg Every 4 Weeks
Reporting group description:	
Participants randomized to receive double-blind (DB) risankizumab 150 milligram (mg) by subcutaneous (SC) injection every 4 weeks for 16 weeks.	
Reporting group title	Risankizumab 150 mg Weeks 0, 4, and 16
Reporting group description:	
Participants randomized to receive double-blind (DB) risankizumab 150 mg by subcutaneous (SC) injection at Weeks 0, 4, and 16.	
Reporting group title	Risankizumab 150 mg Weeks 0 and 12
Reporting group description:	
Participants randomized to receive double-blind (DB) risankizumab 150 mg by subcutaneous (SC) injection at Weeks 0 and 12.	
Reporting group title	Risankizumab 75 mg Week 0
Reporting group description:	
Participants randomized to receive double-blind (DB) risankizumab 75 mg by subcutaneous (SC) injection at Week 0.	

Reporting group values	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16
Number of subjects	42	42	42
Age categorical			
Full Analysis Set (FAS): All randomized participants who received at least one dose of study drug.			
Units: Subjects			
Age Continuous			
Full Analysis Set (FAS): All randomized participants who received at least one dose of study drug. Age at the time of signing informed consent form is presented.			
Units: years			
arithmetic mean	49.0	51.8	50.1
standard deviation	± 11.16	± 14.56	± 12.33
Sex: Female, Male			
Full Analysis Set (FAS): All randomized participants who received at least one dose of study drug. Participants are categorized as Male or Female.			
Units: Subjects			
Female	18	21	14
Male	24	21	28
Race			
Full Analysis Set (FAS): All randomized participants who received at least one dose of study drug. Participants are categorized as per race.			
Units: Subjects			
White|	36	35	37
Black or African American|	0	0	0
Asian|	5	6	3
American Indian or Alaska Native|	1	0	0

Missing|	0	1	2
Ethnicity			
(Full Analysis Set (FAS): All randomized participants who received at least one dose of study drug. Participants are categorized as per ethnicity			
Units: Subjects			
Hispanic or Latino	2	0	1
Not Hispanic or Latino	40	41	39
Missing	0	1	2

Reporting group values	Risankizumab 150 mg Weeks 0 and 12	Risankizumab 75 mg Week 0	Total
Number of subjects	39	20	185
Age categorical			
Full Analysis Set (FAS): All randomized participants who received at least one dose of study drug.			
Units: Subjects			

Age Continuous			
Full Analysis Set (FAS): All randomized participants who received at least one dose of study drug. Age at the time of signing informed consent form is presented.			
Units: years			
arithmetic mean	51.6	53.8	
standard deviation	± 11.87	± 10.98	-
Sex: Female, Male			
Full Analysis Set (FAS): All randomized participants who received at least one dose of study drug. Participants are categorized as Male or Female.			
Units: Subjects			
Female	17	10	80
Male	22	10	105
Race			
Full Analysis Set (FAS): All randomized participants who received at least one dose of study drug. Participants are categorized as per race.			
Units: Subjects			
White|	34	15	157
Black or African American|	0	0	0
Asian|	4	4	22
American Indian or Alaska Native|	0	0	1
Missing|	1	1	5
Ethnicity			
(Full Analysis Set (FAS): All randomized participants who received at least one dose of study drug. Participants are categorized as per ethnicity			
Units: Subjects			
Hispanic or Latino	0	0	3
Not Hispanic or Latino	38	19	177
Missing	1	1	5

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Participants randomized to receive double-blind (DB) placebo for risankizumab by subcutaneous (SC) injection every 4 weeks for 16 weeks.	
Reporting group title	Risankizumab 150 mg Every 4 Weeks
Reporting group description:	
Participants randomized to receive double-blind (DB) risankizumab 150 milligram (mg) by subcutaneous (SC) injection every 4 weeks for 16 weeks.	
Reporting group title	Risankizumab 150 mg Weeks 0, 4, and 16
Reporting group description:	
Participants randomized to receive double-blind (DB) risankizumab 150 mg by subcutaneous (SC) injection at Weeks 0, 4, and 16.	
Reporting group title	Risankizumab 150 mg Weeks 0 and 12
Reporting group description:	
Participants randomized to receive double-blind (DB) risankizumab 150 mg by subcutaneous (SC) injection at Weeks 0 and 12.	
Reporting group title	Risankizumab 75 mg Week 0
Reporting group description:	
Participants randomized to receive double-blind (DB) risankizumab 75 mg by subcutaneous (SC) injection at Week 0.	
Subject analysis set title	Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants randomized to receive double-blind (DB) risankizumab 150 mg by subcutaneous (SC) injection every 4 weeks for 16 weeks AND participants randomized to receive DB risankizumab 150 mg by SC injection at Weeks 0, 4, and 16.	
Subject analysis set title	Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants randomized to receive double-blind (DB) risankizumab 150 mg by subcutaneous (SC) injection at Weeks 0, 4, and 16 AND participants randomized to receive double-blind (DB) risankizumab 150 mg by subcutaneous (SC) injection at Weeks 0 and 12.	

Primary: Percentage of Participants Achieving American College of Rheumatology 20% (ACR20) Response at Week 16

End point title	Percentage of Participants Achieving American College of Rheumatology 20% (ACR20) Response at Week 16
End point description:	
Response defined by ACR20 criteria (improvement from baseline) at Week 16: ≥ 20% improvement in tender joint count; ≥ 20% improvement in swollen joint count; and ≥ 20% improvement in at least 3 of the 5 following parameters: ◦Patient assessment of pain ◦Patient global assessment of disease activity ◦Investigator's global assessment of disease activity ◦Health Assessment Questionnaire Disability Index (HAQ-DI) ◦Acute phase reactant value (C-reactive protein). Nonresponder imputation (NRI) was used for missing data. Full Analysis Set (FAS): All randomized participants who received at least one dose of study drug.	
End point type	Primary
End point timeframe:	
Week 16	

End point values	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0 and 12
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42[1]	42[2]	42[3]	39[4]
Units: Percentage of participants				
number (confidence interval 90%)	35.7 (23.5 to 49.5)	57.1 (43.3 to 70.2)	61.9 (48.0 to 74.4)	59.0 (44.6 to 72.3)

Notes:

[1] - FAS

[2] - FAS

[3] - FAS

[4] - FAS

End point values	Risankizumab 75 mg Week 0	Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	20[5]	84[6]	81[7]	
Units: Percentage of participants				
number (confidence interval 90%)	65.0 (44.2 to 82.3)	59.5 (50.0 to 68.6)	60.5 (50.8 to 69.6)	

Notes:

[5] - FAS

[6] - FAS

[7] - FAS

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

The 90% confidence interval (CI) for the difference in response rates between the groups and the 2-sided p-value are calculated using the Cochran Mantel-Haenszel method, stratified by prior tumor necrosis factor inhibitor (TNFi) use and concurrent methotrexate use.

Comparison groups	Placebo v Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.007
Method	Cochran-Mantel-Haenszel
Parameter estimate	Mean difference (final values)
Point estimate	24
Confidence interval	
level	90 %
sides	2-sided
lower limit	9.3
upper limit	38.7

Secondary: Percentage of Participants Achieving American College of Rheumatology 50% (ACR50) Response at Week 16

End point title	Percentage of Participants Achieving American College of Rheumatology 50% (ACR50) Response at Week 16

End point description:

Response defined by ACR50 criteria (improvement from baseline) at Week 16: ≥ 50% improvement in tender joint count; ≥ 50% improvement in swollen joint count; and ≥ 50% improvement in at least 3 of the 5 following parameters: ◦Patient assessment of pain ◦Patient global assessment of disease activity ◦Investigator's global assessment of disease activity ◦HAQ-DI ◦Acute phase reactant value (C-reactive protein). NRI was used for missing data. Full Analysis Set (FAS): All randomized participants who received at least one dose of study drug.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0 and 12
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42[8]	42[9]	42[10]	39[11]
Units: Percentage of participants				
number (confidence interval 90%)	11.9 (4.8 to 23.4)	23.8 (13.5 to 37.0)	23.8 (13.5 to 37.0)	38.5 (25.4 to 52.9)

Notes:

[8] - FAS

[9] - FAS

[10] - FAS

[11] - FAS

End point values	Risankizumab 75 mg Week 0	Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	20[12]	84[13]	81[14]	
Units: Percentage of participants				
number (confidence interval 90%)	25.0 (10.4 to 45.6)	23.8 (16.4 to 32.7)	30.9 (22.5 to 40.4)	

Notes:

[12] - FAS

[13] - FAS

[14] - FAS

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

The 90% CI for the difference in response rates between the groups and the 2-sided p-value are calculated using the Cochran Mantel-Haenszel method, stratified by prior TNFi use and concurrent methotrexate use.

Comparison groups	Placebo v Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.074
Method	Cochran-Mantel-Haenszel
Parameter estimate	Mean difference (final values)
Point estimate	12
Confidence interval	
level	90 %
sides	2-sided
lower limit	1
upper limit	23

Secondary: Percentage of Participants Achieving American College of Rheumatology 70% (ACR70) Response at Week 16

End point title	Percentage of Participants Achieving American College of Rheumatology 70% (ACR70) Response at Week 16

End point description:

Response defined by ACR70 criteria (improvement from baseline) at Week 16: ≥ 70% improvement in tender joint count; ≥ 70% improvement in swollen joint count; and ≥ 70% improvement in at least 3 of the 5 following parameters: ◦Patient assessment of pain ◦Patient global assessment of disease activity ◦Investigator's global assessment of disease activity ◦HAQ-DI ◦Acute phase reactant value (C-reactive protein). NRI was used for missing data. Full Analysis Set (FAS): All randomized participants who received at least one dose of study drug.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0 and 12
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42[15]	42[16]	42[17]	39[18]
Units: Percentage of participants				
number (confidence interval 90%)	0.0 (0.0 to 6.9)	14.3 (6.4 to 26.3)	7.1 (2.0 to 17.4)	25.6 (14.6 to 39.6)

Notes:

[15] - FAS

[16] - FAS

[17] - FAS

[18] - FAS

End point values	Risankizumab 75 mg Week 0	Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	20[19]	84[20]	81[21]	

Units: Percentage of participants				
number (confidence interval 90%)	15.0 (4.2 to 34.4)	10.7 (5.7 to 18.0)	16.0 (9.8 to 24.3)	

Notes:

[19] - FAS

[20] - FAS

[21] - FAS

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

The 90% CI for the difference in response rates between the groups and the 2-sided p-value are calculated using the Cochran Mantel-Haenszel method, stratified by prior TNFi use and concurrent methotrexate use.

Comparison groups	Placebo v Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16
Number of subjects included in analysis	126
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.006
Method	Cochran-Mantel-Haenszel
Parameter estimate	Mean difference (final values)
Point estimate	10.3
Confidence interval	
level	90 %
sides	2-sided
lower limit	4.1
upper limit	16.4

Secondary: Tender Joint Count (TJC68): Change from Baseline to Week 16

End point title	Tender Joint Count (TJC68): Change from Baseline to Week 16

End point description:

Sixty-eight joints were assessed and classified as either tender (1) or not tender (0). A negative change represents a decrease in the number of tender joints. Participants in the FAS with available data at Baseline and Week 16.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0 and 12
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42[22]	40[23]	41[24]	38[25]
Units: Tender joints				
least squares mean (confidence interval 90%)	-7.9 (-10.6 to -5.2)	-7.8 (-10.6 to -5.1)	-9.6 (-12.4 to -6.9)	-10.4 (-13.2 to -7.5)

Notes:

[22] - Participants in the FAS with available data at Baseline and Week 16.

[23] - Participants in the FAS with available data at Baseline and Week 16.

[24] - Participants in the FAS with available data at Baseline and Week 16.

[25] - Participants in the FAS with available data at Baseline and Week 16.

End point values	Risankizumab 75 mg Week 0	Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	18[26]	81[27]	79[28]	
Units: Tender joints				
least squares mean (confidence interval 90%)	-10.8 (-14.9 to -6.8)	-8.6 (-10.5 to -6.6)	-9.9 (-11.8 to -8.0)	

Notes:

[26] - Participants in the FAS with available data at Baseline and Week 16.

[27] - Participants in the FAS with available data at Baseline and Week 16.

[28] - Participants in the FAS with available data at Baseline and Week 16.

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16
Number of subjects included in analysis	123
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.69
Method	mixed model repeated measures model
Parameter estimate	Mean difference (final values)
Point estimate	-0.8
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4
upper limit	2.5

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12

Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.26
Method	mixed model repeated measures model
Parameter estimate	Mean difference (final values)
Point estimate	-2.1
Confidence interval	
level	90 %
sides	2-sided
lower limit	-5.3
upper limit	1

Secondary: Swollen Joint Count (SJC): Change from Baseline to Week 16

End point title	Swollen Joint Count (SJC): Change from Baseline to Week 16

End point description:

Sixty-six joints were assessed and classified as either swollen (1) or not swollen (0). A negative change represents a decrease in the number of swollen joints. Participants in the FAS with available data at Baseline and Week 16.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0 and 12
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42[29]	40[30]	41[31]	38[32]
Units: Swollen joints				
least squares mean (confidence interval 90%)	-7.1 (-8.5 to -5.7)	-6.8 (-8.3 to -5.4)	-7.8 (-9.3 to -6.4)	-8.3 (-9.7 to -6.8)

Notes:

[29] - Participants in the FAS with available data at Baseline and Week 16.

[30] - Participants in the FAS with available data at Baseline and Week 16.

[31] - Participants in the FAS with available data at Baseline and Week 16.

[32] - Participants in the FAS with available data at Baseline and Week 16.

End point values	Risankizumab 75 mg Week 0	Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	18[33]	81[34]	79[35]	
Units: Swollen joints				
least squares mean (confidence interval 90%)	-7.8 (-9.9 to -5.7)	-7.3 (-8.5 to -6.2)	-8.3 (-9.4 to -7.2)	

Notes:

[33] - Participants in the FAS with available data at Baseline and Week 16.

[34] - Participants in the FAS with available data at Baseline and Week 16.

[35] - Participants in the FAS with available data at Baseline and Week 16.

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16
Number of subjects included in analysis	123
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.791
Method	Cochran-Mantel-Haenszel
Parameter estimate	Mean difference (final values)
Point estimate	-0.3
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.1
upper limit	1.5

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.32
Method	mixed model repeated measures model
Parameter estimate	Mean difference (final values)
Point estimate	-1.1
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.8
upper limit	0.7

Secondary: Health Assessment Questionnaire Disability Index (HAQ-DI) Score: Change from Baseline to Week 16

End point title	Health Assessment Questionnaire Disability Index (HAQ-DI) Score: Change from Baseline to Week 16

End point description:

The HAQ-DI is a patient-reported questionnaire specific for rheumatoid arthritis that consists of 20 questions referring to 8 domains: dressing/grooming, arising, eating, walking, hygiene, reach, grip, and daily activities. Participants assessed their ability to do each task over the past week using the following response categories: without any difficulty (0); with some difficulty (1); with much difficulty (2); and unable to do (3). Scores on each task were summed and averaged to provide an overall score ranging from 0 to 3, where 0 represents no disability and 3 very severe, high-dependency disability. HAQ remission indicating normal physical function is defined by HAQ-DI score of < 0.5. Negative change from Baseline indicates improvement. Participants in the FAS with available data at Baseline and Week 16.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0 and 12
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42[36]	39[37]	40[38]	38[39]
Units: Units on a scale				
least squares mean (confidence interval 90%)	-0.089 (-0.204 to 0.026)	-0.182 (-0.299 to -0.065)	-0.163 (-0.280 to -0.047)	-0.245 (-0.365 to -0.126)

Notes:

[36] - Participants in the FAS with available data at Baseline and Week 16.

[37] - Participants in the FAS with available data at Baseline and Week 16.

[38] - Participants in the FAS with available data at Baseline and Week 16.

[39] - Participants in the FAS with available data at Baseline and Week 16.

End point values	Risankizumab 75 mg Week 0	Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	18[40]	79[41]	78[42]	
Units: Units on a scale				
least squares mean (confidence interval 90%)	-0.147 (-0.317 to 0.023)	-0.184 (-0.270 to -0.099)	-0.206 (-0.291 to -0.120)	

Notes:

[40] - Participants in the FAS with available data at Baseline and Week 16.

[41] - Participants in the FAS with available data at Baseline and Week 16.

[42] - Participants in the FAS with available data at Baseline and Week 16.

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16

Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.341
Method	mixed model repeated measures model
Parameter estimate	mixed model repeated measures model
Point estimate	-0.082
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.225
upper limit	0.06

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.181
Method	mixed model repeated measures model
Parameter estimate	Mean difference (final values)
Point estimate	-0.114
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.254
upper limit	0.027

Secondary: Short Form-36 Health Status Survey (SF-36) Physical Component: Change from Baseline to Week 16

End point title	Short Form-36 Health Status Survey (SF-36) Physical Component: Change from Baseline to Week 16

End point description:

The SF-36 determined participant's 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. Participants in the FAS with available data at Baseline and Week 16.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0 and 12
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42[43]	37[44]	41[45]	39[46]
Units: Units on a scale				
least squares mean (confidence interval 90%)	1.93 (0.17 to 3.70)	3.87 (2.03 to 5.71)	3.50 (1.72 to 5.27)	3.10 (1.27 to 4.93)

Notes:

[43] - Participants in the FAS with available data at Baseline and Week 16.

[44] - Participants in the FAS with available data at Baseline and Week 16.

[45] - Participants in the FAS with available data at Baseline and Week 16.

[46] - Participants in the FAS with available data at Baseline and Week 16.

End point values	Risankizumab 75 mg Week 0	Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	19[47]	78[48]	80[49]	
Units: Units on a scale				
least squares mean (confidence interval 90%)	7.42 (4.81 to 10.03)	3.80 (2.52 to 5.08)	3.32 (2.03 to 4.62)	

Notes:

[47] - Participants in the FAS with available data at Baseline and Week 16.

[48] - Participants in the FAS with available data at Baseline and Week 16.

[49] - Participants in the FAS with available data at Baseline and Week 16.

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.174
Method	mixed model repeated measures model
Parameter estimate	Mean difference (final values)
Point estimate	1.7
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.36
upper limit	3.77

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12
Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.284
Method	mixed model repeated measures model
Parameter estimate	Mean difference (final values)
Point estimate	1.35
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.73
upper limit	3.44

Secondary: Short Form-36 Health Status Survey (SF-36) Mental Component: Change from Baseline to Week 16

End point title	Short Form-36 Health Status Survey (SF-36) Mental Component: Change from Baseline to Week 16

End point description:

The SF-36 determined participant's 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 5-8 comprise the mental component of the SF-36. Scores on each item were summed and averaged (range = 0-100); a positive change from Baseline indicates improvement. Participants in the FAS with available data at Baseline and Week 16.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0 and 12
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	42[50]	37[51]	41[52]	39[53]
Units: Units on a scale				
least squares mean (confidence interval 90%)	0.48 (-1.74 to 2.69)	-0.36 (-2.68 to 1.96)	2.26 (0.03 to 4.49)	2.84 (0.54 to 5.14)

Notes:

[50] - Participants in the FAS with available data at Baseline and Week 16.

[51] - Participants in the FAS with available data at Baseline and Week 16.

[52] - Participants in the FAS with available data at Baseline and Week 16.

[53] - Participants in the FAS with available data at Baseline and Week 16.

End point values	Risankizumab 75 mg Week 0	Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	19[54]	78[55]	80[56]	
Units: Units on a scale				
least squares mean (confidence interval 90%)	-1.08 (-4.35 to 2.19)	1.31 (-0.38 to 3.00)	2.29 (0.59 to 3.99)	

Notes:

[54] - Participants in the FAS with available data at Baseline and Week 16.

[55] - Participants in the FAS with available data at Baseline and Week 16.

[56] - Participants in the FAS with available data at Baseline and Week 16.

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.718
Method	mixed model repeated measures model
Parameter estimate	Mean difference (final values)
Point estimate	0.59
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.12
upper limit	3.3

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12

Number of subjects included in analysis	122
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.204
Method	mixed model repeated measures model
Parameter estimate	Mean difference (final values)
Point estimate	2.06
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.61
upper limit	4.74

Secondary: Dactylitis Count: Change from Baseline to Week 16 in Participants with Dactylitis at Baseline

End point title	Dactylitis Count: Change from Baseline to Week 16 in Participants with Dactylitis at Baseline

End point description:

The number of fingers and toes with dactylitis (ranging from 0 to 20). A negative change represents a decrease in the number of fingers and toes affected by dactylitis. Participants in the FAS with available data at Baseline and Week 16.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0 and 12
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9[57]	11[58]	11[59]	10[60]
Units: Fingers and toes with dactylitis				
least squares mean (confidence interval 90%)	-2.6 (-3.9 to -1.4)	-1.1 (-2.2 to 0.1)	-1.9 (-3.0 to -0.8)	-2.9 (-4.1 to -1.7)

Notes:

[57] - Participants in the FAS with available data at Baseline and Week 16.

[58] - Participants in the FAS with available data at Baseline and Week 16.

[59] - Participants in the FAS with available data at Baseline and Week 16.

[60] - Participants in the FAS with available data at Baseline and Week 16.

End point values	Risankizumab 75 mg Week 0	Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	5[61]	22[62]	21[63]	
Units: Fingers and toes with dactylitis				
least squares mean (confidence interval 90%)	-3.5 (-5.2 to -1.8)	-1.5 (-2.4 to -0.6)	-2.4 (-3.0 to -1.9)	

Notes:

[61] - Participants in the FAS with available data at Baseline and Week 16.

[62] - Participants in the FAS with available data at Baseline and Week 16.

[63] - Participants in the FAS with available data at Baseline and Week 16.

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16
Number of subjects included in analysis	31
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.243
Method	mixed model repeated measures model
Parameter estimate	Mean difference (final values)
Point estimate	1.2
Confidence interval	
level	90 %
sides	2-sided
lower limit	-0.5
upper limit	2.8

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12
Number of subjects included in analysis	30
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.906
Method	mixed model repeated measures model
Parameter estimate	Mean difference (final values)
Point estimate	0.1
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1
upper limit	1.1

Secondary: Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index: Change from Baseline to Week 16 in Participants with Enthesitis at Baseline

End point title	Spondyloarthritis Research Consortium of Canada (SPARCC) Enthesitis Index: Change from Baseline to Week 16 in Participants with Enthesitis at Baseline

End point description:

Assessment of enthesitis was performed in the following 16 domains: left and right (L/R) medial epicondyle; L/R lateral epicondyle; L/R supraspinatus insertion into the greater tuberosity of humerus; L/R greater trochanter; L/R quadriceps insertion into superior border of patella; L/R patellar ligament insertion into inferior pole of patella or tibial tubercle; L/R Achilles tendon insertion into calcaneum; L/R plantar fascia insertion into calcaneum. Tenderness at each site was classified as either absent (0) or present (1) to yield total SPARCC scores ranging from 0 (0 sites with tenderness) to 16 (16 sites with tenderness). A negative change from Baseline indicates improvement. Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0 and 12
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	27[64]	27[65]	24[66]	25[67]
Units: Fingers and toes with dactylitis				
least squares mean (confidence interval 90%)	-1.1 (-2.1 to -0.2)	-1.4 (-2.3 to -0.5)	-2.4 (-3.3 to -1.4)	-1.8 (-2.7 to -0.8)

Notes:

[64] - Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.

[65] - Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.

[66] - Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.

[67] - Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.

End point values	Risankizumab 75 mg Week 0	Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	11[68]	51[69]	49[70]	
Units: Fingers and toes with dactylitis				
least squares mean (confidence interval 90%)	-3.7 (-5.1 to -2.3)	-1.7 (-2.4 to -1.0)	-2.1 (-2.7 to -1.4)	

Notes:

[68] - Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.

[69] - Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.

[70] - Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16
Number of subjects included in analysis	78
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.325
Method	mixed model repeated measures model
Parameter estimate	Mean difference (final values)
Point estimate	-0.7
Confidence interval	
level	90 %
sides	2-sided
lower limit	-1.8
upper limit	0.5

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.16
Method	mixed model repeated measures model
Parameter estimate	Mean difference (final values)
Point estimate	-0.9
Confidence interval	
level	90 %
sides	2-sided
lower limit	-2.1
upper limit	0.2

Secondary: Modified Nail Psoriasis Severity Index (mNAPSI): Change from Baseline to Week 16

End point title	Modified Nail Psoriasis Severity Index (mNAPSI): Change from Baseline to Week 16

End point description:

mNAPSI grades each fingernail for onycholysis (separation of the nail plate from the nail bed) and oil-drop (salmon patch) dyschromia (reddish-brown discoloration under the nail plate) on a scale of 0 (none present) to 3 (>30% of the nail); pitting (small, sharply defined depressions in the nail surface) on a scale of 0 (0 pits present) to 3 (>50 pits present); nail plate crumbling on a scale of 0 (no crumbling) to

3 (>50% of nail has crumbling); and presence (1) or absence (0) of leukonychia (white spots), splinter hemorrhages, nail bed hyperkeratosis, and red spots in the lunula. mNAPSI is calculated as the sum of all the components for all of the participants fingernails, for a maximal score of 130. A negative change from Baseline indicate improvement. Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0 and 12
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	28[71]	19[72]	23[73]	25[74]
Units: Fingers and toes with dactylitis				
least squares mean (confidence interval 90%)	-5.2 (-7.4 to -3.0)	-6.7 (-9.4 to -4.1)	-5.8 (-8.2 to -3.4)	-10.7 (-13.1 to -8.3)

Notes:

[71] - Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.
[72] - Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.
[73] - Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.
[74] - Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.

End point values	Risankizumab 75 mg Week 0	Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	9[75]	42[76]	48[77]	
Units: Fingers and toes with dactylitis				
least squares mean (confidence interval 90%)	-6.8 (-10.6 to -3.0)	-5.5 (-7.3 to -3.8)	-8.1 (-9.9 to -6.3)	

Notes:

[75] - Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.
[76] - Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.
[77] - Participants in the FAS with enthesitis at Baseline and with available data at Baseline and Week 16.

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.453
Method	mixed model repeated measures model
Parameter estimate	Mean difference (final values)
Point estimate	-1.2
Confidence interval	
level	90 %
sides	2-sided
lower limit	-4
upper limit	1.5

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

The 2-sided p-value is calculated using a mixed model repeated measures model with categorical fixed effects of treatment, stratification factors, week, and treatment-by-week interaction and the continuous fixed baseline measurement, with subject as a random effect.

Comparison groups	Placebo v Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12
Number of subjects included in analysis	76
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.111
Method	mixed model repeated measures model
Parameter estimate	Mean difference (final values)
Point estimate	-2.8
Confidence interval	
level	90 %
sides	2-sided
lower limit	-5.7
upper limit	0.1

Secondary: Percentage of Participants Achieving 90% Improvement in Psoriasis Area and Severity Index (PASI) Score (PASI90) at Week 16

End point title	Percentage of Participants Achieving 90% Improvement in Psoriasis Area and Severity Index (PASI) Score (PASI90) at Week 16

End point description:

PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The severity of each sign was assessed using a 5-point scale, where 0=no symptoms, 1=slight, 2=moderate, 3=marked, 4=very marked. The PASI score ranges from 0 to 72, where 0 indicates no psoriasis and 72 indicates very severe psoriasis. PASI90 is defined as at least a 90% reduction in PASI score compared with the Baseline PASI score. The percent reduction in score is calculated as (PASI score at Baseline - score at follow-up visit) / PASI score at Baseline * 100. The percentage of participants achieving PASI 90 at Week 16 are provided. NRI was used for missing data. Full Analysis Set (FAS): All randomized participants who received at least one dose of study drug.

End point type	Secondary

End point timeframe:
Week 16

End point values	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0 and 12
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	21[78]	12[79]	18[80]	23[81]
Units: Percentage of participants				
number (confidence interval 90%)	9.5 (1.7 to 27.1)	58.3 (31.5 to 81.9)	66.7 (44.6 to 84.4)	52.2 (33.5 to 70.4)

Notes:
[78] - FAS, only patients with BSA >/= 3% psoriatic plaque involvment at baseline were included
[79] - FAS, only patients with BSA >/= 3% psoriatic plaque involvment at baseline were included
[80] - FAS, only patients with BSA >/= 3% psoriatic plaque involvment at baseline were included
[81] - FAS, only patients with BSA >/= 3% psoriatic plaque involvment at baseline were included

End point values	Risankizumab 75 mg Week 0	Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16	Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12	
Subject group type	Reporting group	Subject analysis set	Subject analysis set	
Number of subjects analysed	9[82]	30[83]	41[84]	
Units: Percentage of participants				
number (confidence interval 90%)	55.6 (25.1 to 83.1)	63.3 (46.7 to 77.9)	58.5 (44.5 to 71.6)	

Notes:
[82] - FAS, only patients with BSA >/= 3% psoriatic plaque involvment at baseline were included
[83] - FAS, only patients with BSA >/= 3% psoriatic plaque involvment at baseline were included
[84] - FAS, only patients with BSA >/= 3% psoriatic plaque involvment at baseline were included

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:
The 90% CI for the difference in response rates between the groups and the 2-sided p-value are calculated using the Cochran Mantel-Haenszel method, stratified by prior TNFi use and concurrent methotrexate use.

Comparison groups	Placebo v Risankizumab 150 mg Every 4 Weeks; 150 mg Weeks 0, 4, and 16
Number of subjects included in analysis	51
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Mean difference (final values)
Point estimate	53.5
Confidence interval	
level	90 %
sides	2-sided
lower limit	35.9
upper limit	71.1

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: The 90% CI for the difference in response rates between the groups and the 2-sided p-value are calculated using the Cochran Mantel-Haenszel method, stratified by prior TNFi use and concurrent methotrexate use.	
Comparison groups	Placebo v Risankizumab 150 mg Weeks 0, 4, and 16; 150 mg Weeks 0 and 12
Number of subjects included in analysis	62
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Mean difference (final values)
Point estimate	48.8
Confidence interval	
level	90 %
sides	2-sided
lower limit	33.1
upper limit	64.5

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events (TEAEs) and serious adverse events (TESAEs) were collected from first dose of study drug until 15 weeks after the last dose of study drug (up to 31 weeks).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	20.0

Reporting groups

Reporting group title	Placebo

Reporting group description:

Participants randomized to receive double-blind (DB) placebo for risankizumab by subcutaneous (SC) injection every 4 weeks for 16 weeks.

Reporting group title	Risankizumab 150 mg Every 4 Weeks

Reporting group description:

Participants randomized to receive double-blind (DB) risankizumab 150 milligram (mg) by subcutaneous (SC) injection every 4 weeks for 16 weeks.

Reporting group title	Risankizumab 150 mg Weeks 0, 4, and 16

Reporting group description:

Participants randomized to receive double-blind (DB) risankizumab 150 mg by subcutaneous (SC) injection at Weeks 0, 4, and 16.

Reporting group title	Risankizumab 150 mg Weeks 0 and 12

Reporting group description:

Participants randomized to receive double-blind (DB) risankizumab 150 mg by subcutaneous (SC) injection at Weeks 0 and 12.

Reporting group title	Risankizumab 75 mg Week 0

Reporting group description:

Participants randomized to receive double-blind (DB) risankizumab 75 mg by subcutaneous (SC) injection at Week 0.

Serious adverse events	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 42 (4.76%)	3 / 42 (7.14%)	0 / 42 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Alanine aminot			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (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
Aspartate amin			

subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (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 bilirubi			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (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
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ovarian cancer			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (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			
Acute myocardi			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (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 failur			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (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
Coronary arter			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (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			
Nasal septal o			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 42 (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			
Cerebrovascula			

subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 42 (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
Immune system disorders			
Anaphylactic r			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 42 (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
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (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
Inguinal herni			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 42 (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
Renal and urinary disorders			
Acute kidney i			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Intervertebral			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	0 / 42 (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
Musculoskeleta			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 42 (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
Rotator cuff s			

subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (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			
Gastroenteriti			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (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
Influenza			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (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 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (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			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	0 / 42 (0.00%)	0 / 42 (0.00%)	0 / 42 (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	Risankizumab 150 mg Weeks 0 and 12	Risankizumab 75 mg Week 0	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 39 (5.13%)	3 / 20 (15.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from	0	0	

adverse events			
Investigations			
Alanine aminot			
subjects affected / exposed	1 / 39 (2.56%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate amin			
subjects affected / exposed	1 / 39 (2.56%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubi			
subjects affected / exposed	1 / 39 (2.56%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Ovarian cancer			
subjects affected / exposed	0 / 39 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardi			
subjects affected / exposed	0 / 39 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failur			
subjects affected / exposed	0 / 39 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary arter			
subjects affected / exposed	0 / 39 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Nasal septal o			

subjects affected / exposed	0 / 39 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Cerebrovascula			
subjects affected / exposed	0 / 39 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Anaphylactic r			
subjects affected / exposed	0 / 39 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 39 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal herni			
subjects affected / exposed	0 / 39 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney i			
subjects affected / exposed	0 / 39 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Intervertebral			
subjects affected / exposed	0 / 39 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeleta			

subjects affected / exposed	0 / 39 (0.00%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff s			
subjects affected / exposed	1 / 39 (2.56%)	0 / 20 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Gastroenteriti			
subjects affected / exposed	0 / 39 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 39 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 39 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract			
subjects affected / exposed	0 / 39 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	0 / 39 (0.00%)	1 / 20 (5.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	Risankizumab 150 mg Every 4 Weeks	Risankizumab 150 mg Weeks 0, 4, and 16
Total subjects affected by non-serious adverse events			
subjects affected / exposed	25 / 42 (59.52%)	16 / 42 (38.10%)	13 / 42 (30.95%)
Investigations			
Alanine aminot			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 42 (7.14%)	0 / 42 (0.00%)	1 / 42 (2.38%)
occurrences (all)	3	0	1
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 42 (7.14%)	3 / 42 (7.14%)	1 / 42 (2.38%)
occurrences (all)	3	3	2
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 42 (0.00%)	3 / 42 (7.14%)	1 / 42 (2.38%)
occurrences (all)	0	3	1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	1 / 42 (2.38%)
occurrences (all)	1	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	2 / 42 (4.76%)	3 / 42 (7.14%)	1 / 42 (2.38%)
occurrences (all)	2	3	1
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	3 / 42 (7.14%)	1 / 42 (2.38%)	0 / 42 (0.00%)
occurrences (all)	3	1	0
Musculoskeletal and connective tissue disorders			

Pain in extrem			
subjects affected / exposed	3 / 42 (7.14%)	0 / 42 (0.00%)	0 / 42 (0.00%)
occurrences (all)	3	0	0
Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 42 (7.14%)	1 / 42 (2.38%)	1 / 42 (2.38%)
occurrences (all)	3	1	1
Influenza			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	1 / 42 (2.38%)
occurrences (all)	0	1	1
Pharyngitis			
subjects affected / exposed	1 / 42 (2.38%)	0 / 42 (0.00%)	0 / 42 (0.00%)
occurrences (all)	1	0	0
Sinusitis			
subjects affected / exposed	0 / 42 (0.00%)	1 / 42 (2.38%)	2 / 42 (4.76%)
occurrences (all)	0	1	2
Upper respirat			
subjects affected / exposed	5 / 42 (11.90%)	2 / 42 (4.76%)	3 / 42 (7.14%)
occurrences (all)	6	2	6
Viral upper re			
subjects affected / exposed	2 / 42 (4.76%)	7 / 42 (16.67%)	5 / 42 (11.90%)
occurrences (all)	2	12	6

Non-serious adverse events	Risankizumab 150 mg Weeks 0 and 12	Risankizumab 75 mg Week 0	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 39 (48.72%)	8 / 20 (40.00%)	
Investigations			
Alanine aminot			
subjects affected / exposed	2 / 39 (5.13%)	1 / 20 (5.00%)	
occurrences (all)	2	2	
Vascular disorders			
Hypertension			
subjects affected / exposed	1 / 39 (2.56%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Nervous system disorders			
Headache			

subjects affected / exposed	3 / 39 (7.69%)	1 / 20 (5.00%)	
occurrences (all)	4	1	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	1 / 39 (2.56%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	2 / 39 (5.13%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 39 (2.56%)	0 / 20 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	0 / 39 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Pain in extrem			
subjects affected / exposed	0 / 39 (0.00%)	0 / 20 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 39 (2.56%)	1 / 20 (5.00%)	
occurrences (all)	1	1	
Influenza			
subjects affected / exposed	2 / 39 (5.13%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Pharyngitis			
subjects affected / exposed	2 / 39 (5.13%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Sinusitis			
subjects affected / exposed	2 / 39 (5.13%)	0 / 20 (0.00%)	
occurrences (all)	2	0	
Upper respirat			

subjects affected / exposed	2 / 39 (5.13%)	1 / 20 (5.00%)	
occurrences (all)	2	1	
Viral upper re			
subjects affected / exposed	9 / 39 (23.08%)	4 / 20 (20.00%)	
occurrences (all)	11	6	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
12 October 2016	Major changes from the original protocol to amendment 1 included the notification to sites of a change in sponsor of the study in the United States (from BI to AbbVie), and informed sites of an open label extension study for subjects completing required participation in this study. The open label extension study is sponsored by AbbVie as part of the collaboration between BI and AbbVie in the development of risankizumab. Amendment 1 also revised the study visit schedule and other protocol sections to clarify eligibility and study requirements for those subjects enrolling into the open label extension study. Amendment 1 was not considered to have an impact on the integrity or interpretation of the data.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported