Clinical trial results:
An Open Label Extension Trial Assessing the Safety and Efficacy of BI 655066/ABBV-066/Risankizumab Administered Subcutaneously in Patients with Moderate to Severe Chronic Plaque Psoriasis

Summary

EudraCT number	2014-001687-36
Trial protocol	FI DE
Global end of trial date	04 September 2018

Results information

Result version number	v1 (current)
This version publication date	01 August 2019
First version publication date	01 August 2019

Trial information

Trial identification

Sponsor protocol code	1311.13 (M16-009)

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
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, 001 800 243 0127, clintriage.rdg@boehringer-ingelheim.com
Scientific contact	QRPE Processes and Systems Coordination Clinical Trial Information Disclosure, Boehringer Ingelheim, 001 800 243 0127, clintriage.rdg@boehringer-ingelheim.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	26 September 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	04 September 2018
Global end of trial reached?	Yes
Global end of trial date	04 September 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objective of Study M16-009 was to investigate the safety of risankizumab in participants with moderate to severe chronic plaque psoriasis who were receiving long-term treatment. Additional study objectives were to further investigate the long-term efficacy, tolerability, pharmacokinetics, pharmacodynamics, and immunogenicity of risankizumab.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	20 November 2014
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: 28
Country: Number of subjects enrolled	France: 9
Country: Number of subjects enrolled	Germany: 6
Country: Number of subjects enrolled	United States: 67
Worldwide total number of subjects	110
EEA total number of subjects	15

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)	98
From 65 to 84 years	12
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Participants who completed Study 1311.2 (lead-in study) and met eligibility criteria for this study were enrolled. At Week 12, those with ≥90% improvement in Psoriasis Area and Severity Index (PASI90) Score continued risankizumab 90 mg by subcutaneous (SC) injection; those with <PASI90 Score switched to risankizumab 180 mg by SC injection.

Period 1

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

Blinding implementation details:

This is a Phase 2, multicenter, open-label extension (OLE) study.

Arms

Arm title	Risankizumab 90 mg or 180 mg

Arm description:

Participants received open-label (OL) risankizumab 90 mg or 180 mg by subcutaneous (SC) injection at Week 12 and every 12 weeks for 4 years.

Arm type	Experimental
Investigational medicinal product name	Risankizumab 180 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received open-label (OL) risankizumab 180 mg by subcutaneous (SC) injection at Week 12 and every 12 weeks for 4 years.

Investigational medicinal product name	Risankizumab 90 mg
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants received open-label (OL) risankizumab 90 mg by subcutaneous (SC) injection at Week 12 and every 12 weeks for 4 years.

Number of subjects in period 1	Risankizumab 90 mg or 180 mg
Started	110
Completed	99
Not completed	11
Consent withdrawn by subject	6
Not Specified	1

Lost to follow-up	4

Baseline characteristics

Reporting groups	
Reporting group title	Risankizumab 90 mg or 180 mg
Reporting group description:	
Participants received open-label (OL) risankizumab 90 mg or 180 mg by subcutaneous (SC) injection at Week 12 and every 12 weeks for 4 years.	

Reporting group values	Risankizumab 90 mg or 180 mg	Total	
Number of subjects	110	110	
Age categorical			
Units: Subjects			
Age Continuous			
Intent to Treat (ITT) Population: All participants that received at least one dose of study drug in the study.			
Units: years			
arithmetic mean	49.0		
standard deviation	± 13.04	-	
Sex: Female, Male			
ITT			
Units: Subjects			
Female	44	44	
Male	66	66	
Ethnicity (NIH/OMB)			
ITT			
Units: Subjects			
Hispanic or Latino	18	18	
Not Hispanic or Latino	92	92	
Unknown or Not Reported	0	0	
Race (NIH/OMB)			
ITT			
Units: Subjects			
American Indian or Alaska Native	1	1	
Asian	3	3	
Native Hawaiian or Other Pacific Islander	2	2	
Black or African American	2	2	
White	101	101	
More than one race	1	1	
Unknown or Not Reported	0	0	

End points

End points reporting groups

Reporting group title	Risankizumab 90 mg or 180 mg

Reporting group description:

Participants received open-label (OL) risankizumab 90 mg or 180 mg by subcutaneous (SC) injection at Week 12 and every 12 weeks for 4 years.

Subject analysis set title	Risankizumab 90 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants entered the study receiving risankizumab 90 mg by subcutaneous (SC) injection and had ≥ PASI 90 at week 12 continued to receive risankizumab 90 mg at Week 12 and every 12 weeks for 4 years.

Subject analysis set title	Risankizumab 180 mg
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants entered the study receiving risankizumab 90 mg by subcutaneous (SC) injection and had < PASI 90 at week 12 switched to risankizumab 180 mg at Week 12 and every 12 weeks for 4 years.

Subject analysis set title	Risankizumab 18 mg/Risankizumab
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who received risankizumab 18 mg in the lead-in study received open-label (OL) risankizumab 90 mg or 180 mg by subcutaneous (SC) injection in this study at Week 12 and every 12 weeks for 4 years.

Subject analysis set title	Risankizumab 90 mg/Risankizumab
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who received risankizumab 90 mg in the lead-in study received open-label (OL) risankizumab 90 mg or 180 mg by subcutaneous (SC) injection in this study at Week 12 and every 12 weeks for 4 years.

Subject analysis set title	Risankizumab 180 mg/Risankizumab
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who received risankizumab 180 mg in the lead-in study received open-label (OL) risankizumab 90 mg or 180 mg by subcutaneous (SC) injection in this study at Week 12 and every 12 weeks for 4 years.

Subject analysis set title	Ustekinumab/Risankizumab
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants who received ustekinumab 45 mg or 90 mg in the lead-in study received open-label (OL) risankizumab 90 mg or 180 mg by subcutaneous (SC) injection in this study at Week 12 and every 12 weeks for 4 years.

Primary: Number of Participants With Treatment-Emergent Adverse Events (TEAEs)

End point title	Number of Participants With Treatment-Emergent Adverse Events (TEAEs)[1]

End point description:

An adverse event (AE) is any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. The investigator assessed the relationship of each event to the use of study drug as either probably related, possibly related, probably not related, not related. A serious AE (SAE) is an event that results in death, is life-threatening, requires or prolongs hospitalization, results in a congenital anomaly, persistent or significant disability/incapacity or is an important medical event that, based on medical judgment, may jeopardize the subject and may require medical or surgical intervention to prevent any of the outcomes listed above. TEAE/TESAEs are any events with an onset after the first dose of risankizumab in this study. See the AE section for details. Safety population is defined as all participants who received at least one dose of study drug in the study.

End point type	Primary

End point timeframe:

From the first dose of study drug until 12 weeks after the last dose of study drug (up to 4.5 years)

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was evaluated only descriptively. Thus, no statistical hypothesis were tested.

End point values	Risankizumab 90 mg	Risankizumab 180 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	87[2]	23[3]		
Units: participants	67	18		

Notes:

[2] - Safety population. Safety population is same as ITT

[3] - Safety population

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Drug-related TEAEs

End point title	Number of Participants with Drug-related TEAEs[4]

End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. The investigator assessed the relationship of each event to the use of study drug as either probably related, possibly related, probably not related or not related. A serious adverse event (SAE) is an event that results in death, is life-threatening, requires or prolongs hospitalization, results in a congenital anomaly, persistent or significant disability/incapacity or is an important medical event that, based on medical judgment, may jeopardize the subject and may require medical or surgical intervention to prevent any of the outcomes listed above. Treatment-emergent events (TEAEs/TESAEs) are defined as any event with an onset after the first dose of risankizumab in this study. See the AE section for details.

End point type	Primary

End point timeframe:

From the first dose of study drug until 12 weeks after the last dose of study drug (up to 4.5 years)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was evaluated only descriptively. Thus, no statistical hypothesis were tested.

End point values	Risankizumab 90 mg	Risankizumab 180 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	87[5]	23[6]		
Units: participants	12	3		

Notes:

[5] - Safety population

[6] - Safety population

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants with Treatment-Emergent Serious Adverse Events

(TESAEs)

End point title	Number of Participants with Treatment-Emergent Serious Adverse Events (TESAEs)[7]

End point description:

An adverse event (AE) is defined as any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. The investigator assessed the relationship of each event to the use of study drug as either probably related, possibly related, probably not related or not related. A serious adverse event (SAE) is an event that results in death, is life-threatening, requires or prolongs hospitalization, results in a congenital anomaly, persistent or significant disability/incapacity or is an important medical event that, based on medical judgment, may jeopardize the subject and may require medical or surgical intervention to prevent any of the outcomes listed above. Treatment-emergent events (TEAEs/TESAEs) are defined as any event with an onset after the first dose of risankizumab in this study. See the AE section for details.

End point type	Primary

End point timeframe:

From the first dose of study drug until 12 weeks after the last dose of study drug (up to 4.5 years)

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was evaluated only descriptively. Thus, no statistical hypothesis were tested.

End point values	Risankizumab 90 mg	Risankizumab 180 mg		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	87[8]	23[9]		
Units: participants	12	2		

Notes:

[8] - Safety population

[9] - Safety population

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Achieving 90% improvement in Psoriasis Area and Severity Index (PASI90) score at week 48 in the Extended dosing period

End point title	Percentage of Participants Achieving 90% improvement in Psoriasis Area and Severity Index (PASI90) score at week 48 in the Extended dosing period[10]

End point description:

Psoriasis Area and Severity Index (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. Baseline PASI for this study is defined as the baseline PASI in the lead-in study. The percent reduction in score is calculated as (PASI score at Baseline - score at follow-up visit) / PASI score at Baseline * 100.

End point type	Primary

End point timeframe:

Baseline, Week 48

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: This endpoint was evaluated only descriptively. Thus, no statistical hypothesis were tested.

End point values	Risankizumab 18 mg/Risankizumab	Risankizumab 90 mg/Risankizumab	Risankizumab 180 mg/Risankizumab	Ustekinumab/Risankizumab
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22[11]	27[12]	32[13]	27[14]
Units: percentage of participants				
number (confidence interval 95%)	72.7 (54.1 to 91.3)	77.8 (62.1 to 93.5)	71.9 (56.3 to 87.5)	74.1 (57.5 to 90.6)

Notes:

[11] - ITT

[12] - ITT

[13] - ITT

[14] - ITT

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants achieving Static Physician Global Assessment (sPGA) of clear or almost clear at Week 48 of Extended Dosing period

End point title	Percentage of Participants achieving Static Physician Global Assessment (sPGA) of clear or almost clear at Week 48 of Extended Dosing period

End point description:

The sPGA is an assessment by the investigator of the overall disease severity at the time of evaluation. Erythema (E), induration (I), and desquamation (D) are scored on a 5-point scale ranging from 0 (none) to 4 (severe). The sPGA ranges from 0 to 4, and is calculated as Clear (0) = 0 for all three; Almost clear (1) = mean >0, <1.5; Mild (2) = mean ≥1.5, <2.5; Moderate (3) = mean ≥2.5, <3.5; and Severe (4) = mean ≥3.5. Baseline is defined as the last non-missing value on or before the date of the first dose of study drug in the lead-in study.

End point type	Secondary

End point timeframe:

Week 48

End point values	Risankizumab 18 mg/Risankizumab	Risankizumab 90 mg/Risankizumab	Risankizumab 180 mg/Risankizumab	Ustekinumab/Risankizumab
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22[15]	27[16]	32[17]	27[18]
Units: percentage of participants				
number (confidence interval 95%)	63.6 (43.5 to 83.7)	70.4 (53.1 to 87.6)	68.8 (52.7 to 84.8)	66.7 (48.9 to 84.4)

Notes:

[15] - ITT

[16] - ITT

[17] - ITT

[18] - ITT

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving 50% Improvement in PASI (PASI50) Score at week 48 in the Extended dosing period

End point title	Percentage of Participants Achieving 50% Improvement in PASI (PASI50) Score at week 48 in the Extended dosing period

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. PASI50 is defined as at least a 50% reduction in PASI score compared with the Baseline PASI score. Baseline PASI for this study is defined as the baseline PASI in the lead-in study. The percent reduction in score is calculated as (PASI score at Baseline - score at follow-up visit) / PASI score at Baseline * 100.

End point type	Secondary

End point timeframe:

Baseline, Week 48

End point values	Risankizumab 18 mg/Risankizumab	Risankizumab 90 mg/Risankizumab	Risankizumab 180 mg/Risankizumab	Ustekinumab/Risankizumab
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22[19]	27[20]	32[21]	27[22]
Units: percentage of participants				
number (confidence interval 95%)	95.5 (86.8 to 100.0)	96.3 (89.2 to 100.0)	100.0 (100.0 to 100.0)	100.0 (100.0 to 100.0)

Notes:

[19] - ITT

[20] - ITT

[21] - ITT

[22] - ITT

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving 75% Improvement in PASI (PASI75) Score at week 48 in the Extended dosing period

End point title	Percentage of Participants Achieving 75% Improvement in PASI (PASI75) Score at week 48 in the Extended dosing period

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. PASI75 is defined as at least a 75% reduction in PASI score compared with the Baseline PASI score. Baseline PASI for this study is defined as the baseline PASI in the lead-in study. The percent reduction in score is calculated as (PASI score at Baseline - score at follow-up visit) / PASI score at Baseline * 100.

End point type	Secondary

End point timeframe:

Baseline, Week 48

End point values	Risankizumab 18 mg/Risankizumab	Risankizumab 90 mg/Risankizumab	Risankizumab 180 mg/Risankizumab	Ustekinumab/Risankizumab
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22[23]	27[24]	32[25]	27[26]
Units: percentage of participants				
number (confidence interval 95%)	86.4 (72.0 to 100.0)	92.6 (82.7 to 100.0)	90.6 (80.5 to 100.0)	96.3 (89.2 to 100.0)

Notes:

[23] - ITT

[24] - ITT

[25] - ITT

[26] - ITT

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving 100% Improvement in PASI (PASI100) Score at week 48 in the Extended dosing period

End point title	Percentage of Participants Achieving 100% Improvement in PASI (PASI100) Score at week 48 in the Extended dosing period

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. PASI100 is defined as a 100% reduction in PASI score compared with the Baseline PASI score. Baseline PASI for this study is defined as the baseline PASI in the lead-in study. The percent reduction in score is calculated as (PASI score at Baseline - score at follow-up visit) / PASI score at Baseline * 100.

End point type	Secondary

End point timeframe:

Baseline, Week 48

End point values	Risankizumab 18 mg/Risankizumab	Risankizumab 90 mg/Risankizumab	Risankizumab 180 mg/Risankizumab	Ustekinumab/Risankizumab
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22[27]	27[28]	32[29]	27[30]
Units: percentage of participants				
number (confidence interval 95%)	54.5 (33.7 to 75.4)	55.6 (36.8 to 74.3)	50.0 (32.7 to 67.3)	55.6 (36.8 to 74.3)

Notes:

[27] - ITT

[28] - ITT

[29] - ITT

[30] - ITT

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants achieving sPGA of clear at Week 48 of Extended Dosing period

End point title	Percentage of Participants achieving sPGA of clear at Week 48 of Extended Dosing period

End point description:

The sPGA is an assessment by the investigator of the overall disease severity at the time of evaluation. Erythema (E), induration (I), and desquamation (D) are scored on a 5-point scale ranging from 0 (none) to 4 (severe). The sPGA ranges from 0 to 4, and is calculated as Clear (0) = 0 for all three; Almost clear (1) = mean >0, <1.5; Mild (2) = mean ≥1.5, <2.5; Moderate (3) = mean ≥2.5, <3.5; and Severe (4) = mean ≥3.5. Baseline is defined as the last non-missing value on or before the date of the first dose of study drug in the lead-in study.

End point type	Secondary

End point timeframe:

Week 48

End point values	Risankizumab 18 mg/Risankizumab	Risankizumab 90 mg/Risankizumab	Risankizumab 180 mg/Risankizumab	Ustekinumab/Risankizumab
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	22[31]	27[32]	32[33]	27[34]
Units: percentage of participants				
number (confidence interval 95%)	54.5 (33.7 to 75.4)	63.0 (44.7 to 81.2)	56.3 (39.1 to 73.4)	55.6 (36.8 to 74.3)

Notes:

[31] - ITT

[32] - ITT

[33] - ITT

[34] - ITT

Statistical analyses

No statistical analyses for this end point

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 12 weeks after the last dose of study drug (up to 4.5 years).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	Risankizumab 90 mg

Reporting group description:

Participants entered the study receiving risankizumab 90 mg by subcutaneous (SC) injection and had ≥ PASI 90 at week 12 continued to receive risankizumab 90 mg at Week 12 and every 12 weeks for 4 years.

Reporting group title	Risankizumab 180 mg

Reporting group description:

Participants entered the study receiving risankizumab 90 mg by subcutaneous (SC) injection and had < PASI 90 at week 12 switched to risankizumab 180 mg at Week 12 and every 12 weeks for 4 years.

Serious adverse events	Risankizumab 90 mg	Risankizumab 180 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 87 (13.79%)	2 / 23 (8.70%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal cell carcinoma			
subjects affected / exposed	1 / 87 (1.15%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Papilloma			
subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural			

complications			
Fall			
subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower limb fracture			
subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Myocardial infarction			
subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Carpal tunnel syndrome			
subjects affected / exposed	0 / 87 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transient ischaemic attack			
subjects affected / exposed	2 / 87 (2.30%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulnar neuritis			
subjects affected / exposed	0 / 87 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Non-cardiac chest pain			

subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Glaucoma			
subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Macular degeneration			
subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 87 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Psychotic disorder			
subjects affected / exposed	0 / 87 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Goitre			
subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthritis			
subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intervertebral disc protrusion			

subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cystitis			
subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	0 / 87 (0.00%)	1 / 23 (4.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Hypoglycaemia			
subjects affected / exposed	1 / 87 (1.15%)	0 / 23 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Risankizumab 90 mg	Risankizumab 180 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	46 / 87 (52.87%)	15 / 23 (65.22%)	
Injury, poisoning and procedural complications			
Muscle strain			

subjects affected / exposed	2 / 87 (2.30%)	2 / 23 (8.70%)	
occurrences (all)	2	2	
Vascular disorders			
Hypertension			
subjects affected / exposed	6 / 87 (6.90%)	0 / 23 (0.00%)	
occurrences (all)	6	0	
Skin and subcutaneous tissue disorders			
Dermal cyst			
subjects affected / exposed	2 / 87 (2.30%)	2 / 23 (8.70%)	
occurrences (all)	2	2	
Dermatitis contact			
subjects affected / exposed	2 / 87 (2.30%)	3 / 23 (13.04%)	
occurrences (all)	2	3	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	9 / 87 (10.34%)	2 / 23 (8.70%)	
occurrences (all)	10	2	
Pain in extremity			
subjects affected / exposed	4 / 87 (4.60%)	2 / 23 (8.70%)	
occurrences (all)	4	2	
Infections and infestations			
Bronchitis			
subjects affected / exposed	5 / 87 (5.75%)	2 / 23 (8.70%)	
occurrences (all)	6	2	
Influenza			
subjects affected / exposed	7 / 87 (8.05%)	0 / 23 (0.00%)	
occurrences (all)	7	0	
Nasopharyngitis			
subjects affected / exposed	16 / 87 (18.39%)	3 / 23 (13.04%)	
occurrences (all)	33	8	
Sinusitis			
subjects affected / exposed	3 / 87 (3.45%)	3 / 23 (13.04%)	
occurrences (all)	5	3	
Upper respiratory tract infection			
subjects affected / exposed	11 / 87 (12.64%)	4 / 23 (17.39%)	
occurrences (all)	16	5	

Tooth abscess subjects affected / exposed occurrences (all)	6 / 87 (6.90%) 6	0 / 23 (0.00%) 0	
Urinary tract infection subjects affected / exposed occurrences (all)	8 / 87 (9.20%) 9	1 / 23 (4.35%) 1	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
26 September 2014	Modification of study duration and maximum administration of study drug from approximately 4 years to 1 calendar year; deletion of text describing possible dose adjustment, due to the removal of the risankizumab 180 mg dose; addition of further description of signs of hypersensitive reactions; addition of PASI 75 as a standard clinical endpoint; and removal of the erythrocyte sedimentation rate test.
15 October 2014	Administrative changes to clarify timing of visits, study procedures for drug administrations, withdrawals, and collection of vital signs and vital status follow-up, as well as the removal of the tolerability assessment since only 1 dose was being administered.
10 June 2015	Return to the original protocol wording allowing a maximum study duration of approximately 4 years and the potential for dose adjustment to risankizumab 180 mg as needed, based on availability of new toxicity data. In addition, a new visit schedule for an extended dosing period and a new residual effect period were implemented, as well as a change to the specification of visits for electrocardiograms (ECGs).
12 October 2016	The change in study sponsor from Boehringer-ingelheim (BI) to AbbVie and associated revisions resulting from this change.
30 January 2018	The decision to end the current study and transition subjects who had not previously prematurely discontinued to open-label treatment in Study M15-997, as well as changes to the serum pregnancy and tuberculosis (TB) screening requirements for the end of study (EOS) visit for Study M16-009.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported