Clinical trial results:
BI 655066 [risankizumab] versus placebo in a multicenter randomized double-blind study in participants with moderate to severe chronic plaque psoriasis evaluating the efficacy and safety with randomized withdrawal and re-treatment.

Summary

EudraCT number	2014-005102-38
Trial protocol	DE BE CZ
Global end of trial date	26 July 2018

Results information

Result version number	v1
This version publication date	01 August 2019
First version publication date	01 August 2019

Trial information

Trial identification

Sponsor protocol code	1311.4

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02672852
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Boehringer Ingelheim
Sponsor organisation address	Binger Strasse 173, Ingelheim am Rhein, Germany, Ingelheim am Rhein
Public contact	QRPE Processes and Systems Coordination, Clinical Trial Information Disclosure, Boehringer Ingelheim, +1 8002430127, clintriage.rdg@boehringer-ingelheim.com
Scientific contact	QRPE Processes and Systems Coordination, Clinical Trial Information Disclosure, Boehringer Ingelheim, +1 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	26 July 2018
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 August 2017
Global end of trial reached?	Yes
Global end of trial date	26 July 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objectives of this study were to assess the efficacy and safety of risankizumab compared with placebo in participants with moderate to severe chronic plaque psoriasis, the maintenance of response following drug withdrawal after Week 28 through Week 104, and the response after re-treatment in participants who experienced relapse after drug withdrawal and were re-treated with risankizumab.
In addition, this study was designed to assess the pharmacokinetics (PK) of risankizumab, emergence of anti-drug antibodies, and the effect of anti-drug antibodies on efficacy and safety.

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	29 February 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	Australia: 32
Country: Number of subjects enrolled	Belgium: 1
Country: Number of subjects enrolled	Canada: 117
Country: Number of subjects enrolled	Czech Republic: 15
Country: Number of subjects enrolled	France: 12
Country: Number of subjects enrolled	Germany: 27
Country: Number of subjects enrolled	Japan: 15
Country: Number of subjects enrolled	Korea, Republic of: 56
Country: Number of subjects enrolled	United States: 288
Worldwide total number of subjects	563
EEA total number of subjects	55

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)	493
From 65 to 84 years	70
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Part A1: double-blind (DB) risankizumab or placebo (Weeks 0,4). Part A2 (Week 16) DB placebo to DB risankizumab; rizankizumab continued rizankizumab. Part B (Week 28) risankizumab responders rerandomized to DB risankizumab/placebo; rizankizumab nonresponders continued risankizumab. Week 32: rerandomized relapsed switch adalimumab.

Period 1

Period 1 title	Part A1
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Blinding implementation details:

This was double-blind part of the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo (Part A1)

Arm description:

Participants randomized at Baseline to receive double-blind (DB) placebo by subcutaneous injection at Weeks 0 and 4 (Part A1).

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

Dosage and administration details:

Participants randomized at Baseline to receive double-blind (DB) placebo by subcutaneous injection at Weeks 0 and 4 (Part A1).

Arm title	Risankizumab (Part A1)

Arm description:

Participants randomized at Baseline to receive double-blind (DB) risankizumab 150 mg by subcutaneous injection at Weeks 0 and 4 (Part A1).

Arm type	Experimental
Investigational medicinal product name	Risankizumab
Investigational medicinal product code	
Other name	BI 655066
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants randomized at Baseline to receive double-blind (DB) risankizumab 150 mg by subcutaneous injection at Weeks 0 and 4 (Part A1).

Number of subjects in period 1[1]	Placebo (Part A1)	Risankizumab (Part A1)
Started	100	407
Completed	97	403
Not completed	3	4
Consent withdrawn by subject	1	1
Adverse event, non-fatal	-	1
Disease worsening	1	-
Lost to follow-up	1	2

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 patients who were randomised after successfully completing the screening period and received at least one dose of the trial medication.

Period 2

Period 2 title	Part A2
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Blinding implementation details:

This was double-blind part of the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo/Risankizumab Part A2/Part B

Arm description:

Participants randomized at Baseline to receive double-blind (DB) placebo then received DB risankizumab 150 mg by subcutaneous injection at Weeks 16 (Part A2) and at Week 28 and every 12 weeks up to 88 weeks (Part B).

Arm type	Placebo
Investigational medicinal product name	Risankizumab
Investigational medicinal product code	
Other name	BI 655066
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants randomized at Baseline to receive double-blind (DB) placebo then received DB risankizumab 150 mg by subcutaneous injection at Weeks 16 (Part A2) and at Week 28 and every 12 weeks up to 88 weeks (Part B).

Arm title	Risankizumab/Risankizumab Part A2

Arm description:

Participants randomized at Baseline to receive double-blind (DB) risankizumab then received DB risankizumab 150 mg by subcutaneous injection at Weeks 16 (Part A2).

Arm type	Experimental
Investigational medicinal product name	Risankizumab
Investigational medicinal product code	
Other name	BI 655066
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants randomized at Baseline to receive double-blind (DB) risankizumab then received DB risankizumab 150 mg by subcutaneous injection at Weeks 16 (Part A2).

Number of subjects in period 2[2]	Placebo/Risankizumab Part A2/Part B	Risankizumab/Risankizumab Part A2
Started	93	403
Completed	83	399
Not completed	10	4
Consent withdrawn by subject	1	-
Adverse event, non-fatal	3	-
Not entered in Part B	-	4
Not specified	3	-
Disease worsening	1	-
Lost to follow-up	2	-

Notes:

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

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

Period 3

Period 3 title	Part B
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator, Monitor, Carer, Data analyst, Assessor

Blinding implementation details:

This was double-blind part of the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Risankizumab/Placebo (Part B; Rerandomized Responders)

Arm description:

Participants who received risankizumab in Part A and were responders (sPGA 0 or 1) at Week 28, and rerandomized to receive placebo by subcutaneous injection at Week 28 and every 12 weeks up to Week 88 (Part B).

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

Dosage and administration details:

Participants who received risankizumab in Part A and were responders (sPGA 0 or 1) at Week 28, and rerandomized to receive placebo by subcutaneous injection at Week 28 and every 12 weeks up to Week 88 (Part B).

Arm title	Risankizumab/Risankizumab (Part B; Rerandomized Responders)

Arm description:

Participants who received risankizumab in Part A and were responders (sPGA 0 or 1) at Week 28, and rerandomized to receive Risankizumab 150 mg by subcutaneous injection at Week 28 and every 12 weeks up to Week 88 (Part B).

Arm type	Experimental
Investigational medicinal product name	Risankizumab
Investigational medicinal product code	
Other name	BI 655066
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants who received risankizumab in Part A and were responders (sPGA 0 or 1) at Week 28, and rerandomized to receive Risankizumab 150 mg by subcutaneous injection at Week 28 and every 12 weeks up to Week 88 (Part B).

Arm title	Risankizumab/Risankizumab Part B (Nonresponders)

Arm description:

Participants who received risankizumab in Part A and were nonresponders (sPGA ≥2) at Week 28 received risankizumab 150 mg by subcutaneous injection at Week 28 and every 12 weeks up to Week 88 (Part B).

Arm type	Experimental
Investigational medicinal product name	Risankizumab
Investigational medicinal product code	
Other name	BI 655066
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Participants who received risankizumab in Part A and were nonresponders (sPGA ≥2) at Week 28 received risankizumab 150 mg by subcutaneous injection at Week 28 and every 12 weeks up to Week 88 (Part B).

Number of subjects in period 3[3]	Risankizumab/Placebo (Part B; Rerandomized Responders)	Risankizumab/Risankizumab (Part B; Rerandomized Responders)	Risankizumab/Risankizumab Part B (Nonresponders)
Started	225	111	63
Completed	209	100	51
Not completed	16	11	12
Consent withdrawn by subject	5	-	7
Not specified	4	1	2
Other adverse event	3	5	1
Worsening pre-existing condition	-	1	-
Disease worsening	1	-	1

Lost to follow-up	3	4	1

Notes:

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

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

Baseline characteristics

Reporting groups	
Reporting group title	Placebo (Part A1)
Reporting group description:	
Participants randomized at Baseline to receive double-blind (DB) placebo by subcutaneous injection at Weeks 0 and 4 (Part A1).	
Reporting group title	Risankizumab (Part A1)
Reporting group description:	
Participants randomized at Baseline to receive double-blind (DB) risankizumab 150 mg by subcutaneous injection at Weeks 0 and 4 (Part A1).	

Reporting group values	Placebo (Part A1)	Risankizumab (Part A1)	Total
Number of subjects	100	407	507
Age categorical			
Units: Subjects			
Age Continuous			
Intent to Treat (ITT) Population in Part A1 (ITT_A1): All participants who were randomized at Baseline			
Units: years			
arithmetic mean	47.9	49.6	
standard deviation	± 13.78	± 13.17	-
Sex: Female, Male			
ITT_A1			
Units: Subjects			
Female	27	124	151
Male	73	283	356
Ethnicity (NIH/OMB)			
ITT_A1			
Units: Subjects			
Hispanic or Latino	11	45	56
Not Hispanic or Latino	89	362	451
Unknown or Not Reported	0	0	0
Race (NIH/OMB)			
ITT_A1			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	15	64	79
Native Hawaiian or Other Pacific Islander	1	3	4
Black or African American	2	18	20
White	82	320	402
More than one race	0	2	2
Unknown or Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	Placebo (Part A1)
Reporting group description:	
Participants randomized at Baseline to receive double-blind (DB) placebo by subcutaneous injection at Weeks 0 and 4 (Part A1).	
Reporting group title	Risankizumab (Part A1)
Reporting group description:	
Participants randomized at Baseline to receive double-blind (DB) risankizumab 150 mg by subcutaneous injection at Weeks 0 and 4 (Part A1).	
Reporting group title	Placebo/Risankizumab Part A2/Part B
Reporting group description:	
Participants randomized at Baseline to receive double-blind (DB) placebo then received DB risankizumab 150 mg by subcutaneous injection at Weeks 16 (Part A2) and at Week 28 and every 12 weeks up to 88 weeks (Part B).	
Reporting group title	Risankizumab/Risankizumab Part A2
Reporting group description:	
Participants randomized at Baseline to receive double-blind (DB) risankizumab then received DB risankizumab 150 mg by subcutaneous injection at Weeks 16 (Part A2).	
Reporting group title	Risankizumab/Placebo (Part B; Rerandomized Responders)
Reporting group description:	
Participants who received risankizumab in Part A and were responders (sPGA 0 or 1) at Week 28, and rerandomized to receive placebo by subcutaneous injection at Week 28 and every 12 weeks up to Week 88 (Part B).	
Reporting group title	Risankizumab/Risankizumab (Part B; Rerandomized Responders)
Reporting group description:	
Participants who received risankizumab in Part A and were responders (sPGA 0 or 1) at Week 28, and rerandomized to receive Risankizumab 150 mg by subcutaneous injection at Week 28 and every 12 weeks up to Week 88 (Part B).	
Reporting group title	Risankizumab/Risankizumab Part B (Nonresponders)
Reporting group description:	
Participants who received risankizumab in Part A and were nonresponders (sPGA ≥2) at Week 28 received risankizumab 150 mg by subcutaneous injection at Week 28 and every 12 weeks up to Week 88 (Part B).	

Primary: Percentage of Participants Achieving 90% Improvement Psoriasis Area and Severity Index (PASI) score (PASI90) from baseline to week 16

End point title	Percentage of Participants Achieving 90% Improvement Psoriasis Area and Severity Index (PASI) score (PASI90) from baseline to 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. Non-responder imputation (NRI) was used for missing data. Intent to treat (ITT) Population in Part A1(ITT_A1): all participants who were randomized at Baseline.	
End point type	Primary
End point timeframe:	
Baseline, Week 16	

End point values	Placebo (Part A1)	Risankizumab (Part A1)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	100[1]	407[2]		
Units: Percentage of participants				
number (not applicable)	2.0	73.2		

Notes:

[1] - ITT_A1

[2] - ITT_A1

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Across strata, P value was calculated from the Cochran-Mantel-Haenszel (CMH) test adjusted for strata. Within each stratum, P value was calculated based on the chi-square test (or Fisher's exact test if ≥25% of the cells had expected cell count <5).

Comparison groups	Placebo (Part A1) v Risankizumab (Part A1)
Number of subjects included in analysis	507
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	70.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	65.7
upper limit	76

Primary: Percentage of Participants Achieving static Physician Global Assessment (sPGA) score of clear or almost clear at week 16

End point title	Percentage of Participants Achieving static Physician Global Assessment (sPGA) score of clear or almost clear at week 16

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. NRI was used for missing data.

End point type	Primary

End point timeframe:

Week 16

End point values	Placebo (Part A1)	Risankizumab (Part A1)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	100[3]	407[4]		
Units: Percentage of participants				
number (not applicable)	7.0	83.5		

Notes:

[3] - ITT_A1

[4] - ITT_A1

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Across strata, P value was calculated from the CMH test adjusted for strata. Within each stratum, P value was calculated based on the chi-square test (or Fisher's exact test if ≥25% of the cells had expected cell count <5).

Comparison groups	Placebo (Part A1) v Risankizumab (Part A1)
Number of subjects included in analysis	507
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	76.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	70.4
upper limit	82.5

Primary: Percentage of Participants Achieving sPGA score of clear or almost clear at week 52

End point title	Percentage of Participants Achieving sPGA score of clear or almost clear at week 52

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. NRI was used for missing data. ITT Population in Part B for re-randomized participants (ITT_B_R): All participants who were randomized to Arm 1 at Baseline and re randomized at Week 28.

End point type	Primary

End point timeframe:

Week 52

End point values	Risankizumab/ Placebo (Part B; Rerandomized Responders)	Risankizumab/ Risankizumab (Part B; Rerandomized Responders)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	225[5]	111[6]		
Units: Percentage of participants				
number (not applicable)	61.3	87.4		

Notes:

[5] - ITT_B_R

[6] - ITT_B_R

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Across strata, P value was calculated from the CMH test adjusted for strata. Within each stratum, P value was calculated based on the chi-square test (or Fisher's exact test if ≥25% of the cells had expected cell count <5).

Comparison groups	Risankizumab/Placebo (Part B; Rerandomized Responders) v Risankizumab/Risankizumab (Part B; Rerandomized Responders)
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	25.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.3
upper limit	34.6

Secondary: Percentage of Participants Achieving 75% Improvement in PASI score (PASI75) at week 16

End point title	Percentage of Participants Achieving 75% Improvement in PASI score (PASI75) 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. PASI75 is defined as at least a 75% 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. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (Part A1)	Risankizumab (Part A1)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	100[7]	407[8]		
Units: Percentage of participants				
number (not applicable)	8.0	88.7		

Notes:

[7] - ITT_A1

[8] - ITT_A1

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Across strata, P value was calculated from the CMH test adjusted for strata. Within each stratum, P value was calculated based on the chi-square test (or Fisher's exact test if ≥25% of the cells had expected cell count <5).

Comparison groups	Placebo (Part A1) v Risankizumab (Part A1)
Number of subjects included in analysis	507
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	80.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	74.5
upper limit	86.6

Secondary: Percentage of Participants Achieving 100% improvement in PASI score (PASI100) at week 16

End point title	Percentage of Participants Achieving 100% improvement in PASI score (PASI100) 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. PASI100 is defined as a 100% 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. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (Part A1)	Risankizumab (Part A1)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	100[9]	407[10]		
Units: Percentage of participants				
number (not applicable)	1.0	47.2		

Notes:

[9] - ITT_A1

[10] - ITT_A1

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Across strata, P value was calculated from the CMH test adjusted for strata. Within each stratum, P value was calculated based on the chi-square test (or Fisher's exact test if ≥25% of the cells had expected cell count <5).

Comparison groups	Placebo (Part A1) v Risankizumab (Part A1)
Number of subjects included in analysis	507
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	45.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	40.3
upper limit	50.8

Secondary: Percentage of Participants Achieving an sPGA score of clear at Week 16

End point title	Percentage of Participants Achieving an sPGA score of clear at Week 16

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. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (Part A1)	Risankizumab (Part A1)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	100[11]	407[12]		
Units: Percentage of participants				
number (not applicable)	1.0	46.4		

Notes:

[11] - ITT_A1

[12] - ITT_A1

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Across strata, P value was calculated from the CMH test adjusted for strata. Within each stratum, P value was calculated based on the chi-square test (or Fisher's exact test if ≥25% of the cells had expected cell count <5).

Comparison groups	Placebo (Part A1) v Risankizumab (Part A1)
Number of subjects included in analysis	507
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	44.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	39.5
upper limit	50

Secondary: Percentage of Participants Achieving a Dermatology Life Quality Index (DLQI) score of 0 or 1 at Week 16

End point title	Percentage of Participants Achieving a Dermatology Life Quality Index (DLQI) score of 0 or 1 at Week 16

End point description:

The DLQI is a 10-question questionnaire that asks the participant to evaluate the degree that psoriasis has affected their quality of life in the last week and includes 6 domains (symptoms and feelings, daily activities, leisure, work and school, personal relationships, and treatment). Responses to each domain are not relevant (0), not at all (0), a little (1), a lot (2), and very much (3). The DLQI is calculated by summing the scores of the questions and ranges from 1 to 30, where 0-1 = no effect on patient's life, 2-5 = small effect, 6-10 = moderate effect, 11-20 = very large effect, and 21-30 = extremely large effect on patient's life. The higher the score, the more the quality of life is impaired. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 16

End point values	Placebo (Part A1)	Risankizumab (Part A1)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	100[13]	407[14]		
Units: Percentage of participants				
number (not applicable)	3.0	65.4		

Notes:

[13] - ITT_A1

[14] - ITT_A1

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Across strata, P value was calculated from the CMH test adjusted for strata. Within each stratum, P value was calculated based on the chi-square test (or Fisher's exact test if ≥25% of the cells had expected cell count <5).

Comparison groups	Placebo (Part A1) v Risankizumab (Part A1)
Number of subjects included in analysis	507
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	62.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	56.4
upper limit	67.9

Secondary: Percentage of Participants Achieving an sPGA score of clear or almost clear at Week 104

End point title	Percentage of Participants Achieving an sPGA score of clear or almost clear at Week 104

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. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 104

End point values	Risankizumab/ Placebo (Part B; Rerandomized Responders)	Risankizumab/ Risankizumab (Part B; Rerandomized Responders)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	225[15]	111[16]		
Units: Percentage of participants				
number (not applicable)	7.1	81.1		

Notes:

[15] - ITT_B_R

[16] - ITT_B_R

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Across strata, P value was calculated from the CMH test adjusted for strata. Within each stratum, P value was calculated based on the chi-square test (or Fisher's exact test if ≥25% of the cells had expected cell count <5).

Comparison groups	Risankizumab/Placebo (Part B; Rerandomized Responders) v Risankizumab/Risankizumab (Part B; Rerandomized Responders)
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	73.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	66
upper limit	81.9

Secondary: Percentage of Participants Achieving 75% improvement in PASI Score (PASI75) at Week 52

End point title	Percentage of Participants Achieving 75% improvement in PASI Score (PASI75) at Week 52

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. The percent reduction in score is calculated as (PASI score at Baseline - score at follow-up visit) / PASI score at Baseline * 100. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 52

End point values	Risankizumab/ Placebo (Part B; Rerandomized Responders)	Risankizumab/ Risankizumab (Part B; Rerandomized Responders)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	225[17]	111[18]		
Units: Percentage of participants				
number (not applicable)	71.6	92.8		

Notes:

[17] - ITT_B_R

[18] - ITT_B_R

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Across strata, P value was calculated from the CMH test adjusted for strata. Within each stratum, P value was calculated based on the chi-square test (or Fisher's exact test if ≥25% of the cells had expected cell count <5).

Comparison groups	Risankizumab/Placebo (Part B; Rerandomized Responders) v Risankizumab/Risankizumab (Part B; Rerandomized Responders)
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	21.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	13.7
upper limit	28.7

Secondary: Percentage of Participants Achieving 90% Improvement in PASI Score (PASI90) at Week 52

End point title	Percentage of Participants Achieving 90% Improvement in PASI Score (PASI90) at Week 52

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. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 52

End point values	Risankizumab/ Placebo (Part B; Rerandomized Responders)	Risankizumab/ Risankizumab (Part B; Rerandomized Responders)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	225[19]	111[20]		
Units: Percentage of participants				
number (not applicable)	52.4	85.6		

Notes:

[19] - ITT_B_R

[20] - ITT_B_R

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Across strata, P value was calculated from the CMH test adjusted for strata. Within each stratum, P value was calculated based on the chi-square test (or Fisher's exact test if ≥25% of the cells had expected cell count <5).

Comparison groups	Risankizumab/Placebo (Part B; Rerandomized Responders) v Risankizumab/Risankizumab (Part B; Rerandomized Responders)
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	33.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	24
upper limit	42.2

Secondary: Percentage of Participants Achieving 100% Improvement in PASI Score (PASI100) at Week 52

End point title	Percentage of Participants Achieving 100% Improvement in PASI Score (PASI100) at Week 52

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. The percent reduction in score is calculated as (PASI score at Baseline - score at follow-up visit) / PASI score at

Baseline * 100. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 52

End point values	Risankizumab/ Placebo (Part B; Rerandomized Responders)	Risankizumab/ Risankizumab (Part B; Rerandomized Responders)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	225[21]	111[22]		
Units: Percentage of participants				
number (not applicable)	30.2	64.0		

Notes:

[21] - ITT_B_R

[22] - ITT_B_R

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Across strata, P value was calculated from the CMH test adjusted for strata. Within each stratum, P value was calculated based on the chi-square test (or Fisher's exact test if ≥25% of the cells had expected cell count <5).

Comparison groups	Risankizumab/Placebo (Part B; Rerandomized Responders) v Risankizumab/Risankizumab (Part B; Rerandomized Responders)
Number of subjects included in analysis	336
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	33.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.2
upper limit	44.2

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 103 weeks).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	Placebo (Part A1)

Reporting group description:

Participants randomized at Baseline to receive double-blind (DB) placebo by subcutaneous injection at Weeks 0 and 4 (Part A1).

Reporting group title	Risankizumab (Part A1)

Reporting group description:

Participants randomized at Baseline to receive double-blind (DB) risankizumab 150 mg by subcutaneous injection at Weeks 0 and 4 (Part A1).

Reporting group title	Risankizumab/Risankizumab (Part B; Rerandomized Responders)

Reporting group description:

Participants who received risankizumab in Part A and were responders (sPGA 0 or 1) at Week 28, and rerandomized to receive Risankizumab 150 mg by subcutaneous injection at Week 28 and every 12 weeks up to Week 88 (Part B).

Reporting group title	Risankizumab/Placebo (Part B; Rerandomized Responders)

Reporting group description:

Participants who received risankizumab in Part A and were responders (sPGA 0 or 1) at Week 28, and rerandomized to receive placebo by subcutaneous injection at Week 28 and every 12 weeks up to Week 88 (Part B).

Reporting group title	Any Risankizumab

Reporting group description:

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

Serious adverse events	Placebo (Part A1)	Risankizumab (Part A1)	Risankizumab/Risankizumab (Part B; Rerandomized Responders)
Total subjects affected by serious adverse events			
subjects affected / exposed	8 / 100 (8.00%)	8 / 407 (1.97%)	13 / 111 (11.71%)
number of deaths (all causes)	0	0	2
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-cell lymphoma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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

Basal cell carcinoma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Breast cancer			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast cancer stage I			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Gastric cancer			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cancer metastatic			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal adenocarcinoma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Malignant melanoma in situ			
subjects affected / exposed	0 / 100 (0.00%)	1 / 407 (0.25%)	0 / 111 (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
Metastases to lymph nodes			

subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal carcinoma			
subjects affected / exposed	0 / 100 (0.00%)	1 / 407 (0.25%)	0 / 111 (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
Prostate cancer			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Squamous cell carcinoma of skin			
subjects affected / exposed	0 / 100 (0.00%)	1 / 407 (0.25%)	0 / 111 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 407 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Alcohol detoxification			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Reproductive system and breast disorders			
Benign prostatic hyperplasia			

subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cervical dysplasia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Menometrorrhagia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Menorrhagia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Chylothorax			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Pneumothorax			
subjects affected / exposed	0 / 100 (0.00%)	1 / 407 (0.25%)	0 / 111 (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
Pulmonary embolism			
subjects affected / exposed	0 / 100 (0.00%)	1 / 407 (0.25%)	0 / 111 (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
Psychiatric disorders			

Alcoholism			
subjects affected / exposed	1 / 100 (1.00%)	0 / 407 (0.00%)	0 / 111 (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
Anxiety			
subjects affected / exposed	1 / 100 (1.00%)	0 / 407 (0.00%)	0 / 111 (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
Delirium tremens			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Insomnia			
subjects affected / exposed	1 / 100 (1.00%)	0 / 407 (0.00%)	0 / 111 (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
Somatic symptom disorder			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Suicidal ideation			
subjects affected / exposed	1 / 100 (1.00%)	0 / 407 (0.00%)	0 / 111 (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
Injury, poisoning and procedural complications			
Burns second degree			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Fall			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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

Femur fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Hand fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Incisional hernia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ligament sprain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Muscle strain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Open globe injury			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thoracic vertebral fracture			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Congenital, familial and genetic disorders			
Benign familial pemphigus			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Huntington's disease			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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 myocardial infarction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina unstable			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Aortic valve disease mixed			
subjects affected / exposed	0 / 100 (0.00%)	1 / 407 (0.25%)	0 / 111 (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
Atrial fibrillation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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 arrest			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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 artery disease			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Intracardiac thrombus			

subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ventricular arrhythmia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Basal ganglia infarction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Carotid artery occlusion			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Cerebral infarction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	1 / 100 (1.00%)	0 / 407 (0.00%)	0 / 111 (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
Dementia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis autoimmune			

subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Epilepsy			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Hemiplegia			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Ischaemic stroke			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Seizure			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Tension headache			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Transient ischaemic attack			
subjects affected / exposed	1 / 100 (1.00%)	0 / 407 (0.00%)	0 / 111 (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
Blood and lymphatic system disorders			
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Diabetic retinopathy			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Retinal detachment			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Alcoholic pancreatitis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 407 (0.00%)	0 / 111 (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
Haemorrhoids			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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 hernia			
subjects affected / exposed	1 / 100 (1.00%)	0 / 407 (0.00%)	0 / 111 (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

Intestinal obstruction			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis acute			
subjects affected / exposed	0 / 100 (0.00%)	1 / 407 (0.25%)	0 / 111 (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
Hepatic cirrhosis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver injury			
subjects affected / exposed	1 / 100 (1.00%)	0 / 407 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Skin ulcer			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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			
Arthralgia			

subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Arthropathy			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Bursitis			
subjects affected / exposed	0 / 100 (0.00%)	1 / 407 (0.25%)	0 / 111 (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
Gouty tophus			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Jaw cyst			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Osteoarthritis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Psoriatic arthropathy			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Rotator cuff syndrome			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal abscess			

subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess neck			
subjects affected / exposed	0 / 100 (0.00%)	1 / 407 (0.25%)	0 / 111 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Appendicitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Bronchitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Cellulitis			
subjects affected / exposed	1 / 100 (1.00%)	0 / 407 (0.00%)	0 / 111 (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
Diverticulitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Meningitis bacterial			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nasopharyngitis			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			

subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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
Viral infection			
subjects affected / exposed	0 / 100 (0.00%)	0 / 407 (0.00%)	0 / 111 (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			
Dehydration			
subjects affected / exposed	0 / 100 (0.00%)	1 / 407 (0.25%)	0 / 111 (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
Hypokalaemia			
subjects affected / exposed	0 / 100 (0.00%)	1 / 407 (0.25%)	0 / 111 (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

Serious adverse events	Risankizumab/Placebo (Part B; Rerandomized Responders)	Any Risankizumab	
Total subjects affected by serious adverse events			
subjects affected / exposed	17 / 225 (7.56%)	55 / 500 (11.00%)	
number of deaths (all causes)	0	4	
number of deaths resulting from adverse events	0	0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
B-cell lymphoma			
subjects affected / exposed	1 / 225 (0.44%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			

subjects affected / exposed	1 / 225 (0.44%)	3 / 500 (0.60%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Breast cancer stage I			
subjects affected / exposed	1 / 225 (0.44%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric cancer			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cancer metastatic			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Intestinal adenocarcinoma			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Invasive ductal breast carcinoma			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Malignant melanoma in situ			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metastases to lymph nodes			

subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal carcinoma			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			
subjects affected / exposed	2 / 225 (0.89%)	2 / 500 (0.40%)	
occurrences causally related to treatment / all	0 / 2	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Squamous cell carcinoma of skin			
subjects affected / exposed	1 / 225 (0.44%)	2 / 500 (0.40%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 225 (0.00%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Alcohol detoxification			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
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			
Death			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			

subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cervical dysplasia			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Menometrorrhagia			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Menorrhagia			
subjects affected / exposed	1 / 225 (0.44%)	0 / 500 (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			
Acute respiratory failure			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chylothorax			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			

Alcoholism			
subjects affected / exposed	0 / 225 (0.00%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anxiety			
subjects affected / exposed	0 / 225 (0.00%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium tremens			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Insomnia			
subjects affected / exposed	0 / 225 (0.00%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somatic symptom disorder			
subjects affected / exposed	1 / 225 (0.44%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Suicidal ideation			
subjects affected / exposed	1 / 225 (0.44%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Burns second degree			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	1 / 225 (0.44%)	2 / 500 (0.40%)	
occurrences causally related to treatment / all	0 / 1	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

Femur fracture			
subjects affected / exposed	1 / 225 (0.44%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hand fracture			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Incisional hernia			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ligament sprain			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscle strain			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Open globe injury			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thoracic vertebral fracture			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Congenital, familial and genetic disorders			
Benign familial pemphigus			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Huntington's disease			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 225 (0.00%)	2 / 500 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina unstable			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aortic valve disease mixed			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Coronary artery disease			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracardiac thrombus			

subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ventricular arrhythmia			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Basal ganglia infarction			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Carotid artery occlusion			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral infarction			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	1 / 225 (0.44%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dementia			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis autoimmune			

subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hemiplegia			
subjects affected / exposed	0 / 225 (0.00%)	2 / 500 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tension headache			
subjects affected / exposed	1 / 225 (0.44%)	0 / 500 (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	0 / 225 (0.00%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Disseminated intravascular coagulation			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ear and labyrinth disorders			

Vertigo			
subjects affected / exposed	1 / 225 (0.44%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Amaurosis fugax			
subjects affected / exposed	1 / 225 (0.44%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diabetic retinopathy			
subjects affected / exposed	1 / 225 (0.44%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retinal detachment			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alcoholic pancreatitis			
subjects affected / exposed	0 / 225 (0.00%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Inguinal hernia			
subjects affected / exposed	0 / 225 (0.00%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Intestinal obstruction			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	0 / 225 (0.00%)	2 / 500 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver injury			
subjects affected / exposed	0 / 225 (0.00%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Skin ulcer			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
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			
Arthralgia			

subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arthropathy			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bursitis			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gouty tophus			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaw cyst			
subjects affected / exposed	1 / 225 (0.44%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteoarthritis			
subjects affected / exposed	0 / 225 (0.00%)	2 / 500 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psoriatic arthropathy			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rotator cuff syndrome			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Abdominal abscess			

subjects affected / exposed	1 / 225 (0.44%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abscess neck			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 225 (0.00%)	2 / 500 (0.40%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	1 / 225 (0.44%)	0 / 500 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis bacterial			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nasopharyngitis			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital cellulitis			

subjects affected / exposed	1 / 225 (0.44%)	0 / 500 (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	0 / 225 (0.00%)	2 / 500 (0.40%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Viral infection			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 225 (0.00%)	1 / 500 (0.20%)	
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 (Part A1)	Risankizumab (Part A1)	Risankizumab/Risankizumab (Part B; Rerandomized Responders)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	17 / 100 (17.00%)	52 / 407 (12.78%)	52 / 111 (46.85%)
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 100 (0.00%)	14 / 407 (3.44%)	8 / 111 (7.21%)
occurrences (all)	0	15	15
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	5 / 100 (5.00%)	2 / 407 (0.49%)	0 / 111 (0.00%)
occurrences (all)	6	2	0

Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 100 (2.00%)	7 / 407 (1.72%)	10 / 111 (9.01%)
occurrences (all)	2	7	10
Back pain			
subjects affected / exposed	0 / 100 (0.00%)	2 / 407 (0.49%)	4 / 111 (3.60%)
occurrences (all)	0	2	7
Infections and infestations			
Influenza			
subjects affected / exposed	1 / 100 (1.00%)	3 / 407 (0.74%)	7 / 111 (6.31%)
occurrences (all)	1	3	8
Nasopharyngitis			
subjects affected / exposed	6 / 100 (6.00%)	21 / 407 (5.16%)	23 / 111 (20.72%)
occurrences (all)	6	21	36
Upper respiratory tract infection			
subjects affected / exposed	5 / 100 (5.00%)	6 / 407 (1.47%)	16 / 111 (14.41%)
occurrences (all)	5	6	19

Non-serious adverse events	Risankizumab/Placebo (Part B; Rerandomized Responders)	Any Risankizumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	92 / 225 (40.89%)	242 / 500 (48.40%)	
Nervous system disorders			
Headache			
subjects affected / exposed	7 / 225 (3.11%)	34 / 500 (6.80%)	
occurrences (all)	9	47	
Skin and subcutaneous tissue disorders			
Psoriasis			
subjects affected / exposed	8 / 225 (3.56%)	4 / 500 (0.80%)	
occurrences (all)	8	4	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	13 / 225 (5.78%)	35 / 500 (7.00%)	
occurrences (all)	16	37	
Back pain			
subjects affected / exposed	12 / 225 (5.33%)	28 / 500 (5.60%)	
occurrences (all)	13	31	

Infections and infestations			
Influenza			
subjects affected / exposed	8 / 225 (3.56%)	22 / 500 (4.40%)	
occurrences (all)	10	24	
Nasopharyngitis			
subjects affected / exposed	45 / 225 (20.00%)	116 / 500 (23.20%)	
occurrences (all)	53	170	
Upper respiratory tract infection			
subjects affected / exposed	23 / 225 (10.22%)	77 / 500 (15.40%)	
occurrences (all)	29	97	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
11 March 2016	Added Infection Testing (Tuberculosis (TB)) to Screening. Several footnotes added. Vital Status information updated. Justification provide for Section 2.3. Section 3.1.2 and 3.1.3 clarified. Section 3.3.4.1, 5.1.3, 7.5 and 4.1.4 updated. Added tofacitinib (Xeljanz®), apremilast (Otezla®) and removed efalizumab (Raptiva®)in Table 4.2.2.1:1. Added a paragraph for TB testing in Section 6.2. Maximum of 2 visits a patient may need for screening was deleted. Updated Section 6.2.3, Follow-up Period and Trial Completion. Separated out re-randomized hypothesis from hypotheses tested on all randomized patients. Definition of analysis sets clarified. Wording "IPV's would be provided in trial statistical analysis plan (TSAP) and added verbiage about IPVs and PPS sensitivity analyses" and data monitoring committee (DMC) information deleted. Added "The hypothesis tests as described in Section 7.2 will be repeated on the PPS or RRSPPS populations, as appropriate". Order of Psoriatic arthritis (PsA) assessments changed at Visit 2. Investigator Brochure document ID was changed. References added. Added risankizumab after BI 655066.
28 July 2016	Footnotes were revised. Abbreviation added and corrected. Figure 3.1:1 was replaced with new trial design. Summary and Overall trial design and plan were updated. Section 3.3.4.2 updated. Section 4.1.2 re-written according to new study design to be consistent with section 3.1. 650666 changed to 655066 in section 4.1.3. Section 4.1.4 Drug assignment and administration of doses for each patient updated. Section 4.1.5.1 Blinding and 7.6 Randomisation re-written according to new study design to be consistent with section 3.1, clarifying the criteria for receiving open label. Deleted reference to Section 3.3.3, and corrected to 3.3.2. Text added in section 5.1.3 Further endpoints. Section 5.3.2 Vital Signs updated to specify timing of vitals relative to injection times and also timing of monitoring hypersensitivity with respect to injection times. Added absolute count to differential, activated to aPTT, calculated to LDL, creatinineand Albumin/creatinine ratio to urinalysis. Deleted "MB" from Troponin reflex and creatinine" from urinalysis stix in Table 5.3.3:1 laboratory tests. Added paragraph to note that efficacy questionnaires are direct data capture on an electronic device. Wording revised due to implementation of continuing blinded treatment. Further instructions given for staying in the trial or terminating from the trial when a patient ends treatment early updated. Added "and who have not discontinued drug prematurely" to definition of trial completion. Section 7.1, Section 7.3 Planned Analyses, 7.3.3 Further endpoint analyses, 7.3.3 Further endpoint analyses and 7.5 Handling of Missing Data updated. In Table 7.7.1 changed PBO to "placebo". Wording from "scored" to "scores" corrected. Response categories for Dermatology life quality index (DLQI) updated. Blind break for week 28 responders was updated.
11 October 2016	The compound name was revised to add "ABBV-066" to BI 655066 (risankizumab). Changed sponsor from Boehringer Ingelheim (BI) to AbbVie in the USA and BI for non-USA participating countries. Updated text to "AbbVie/Boehringer Ingelheim reserves the right to discontinue the trial overall or at a particular trial site at any time for the following reasons". Changed DNA banking sample storage from Boehringer Ingelheim to "AbbVie or a third party delegate (e.g. Boehringer Ingelheim Pharma GmbH & Co. KG; Birkendorfer Str. 65, 88397 Biberach, Germany)". Changed text to specify that AbbVie summary tables and listings will be produced and analyses based on AbbVie standards.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported