Clinical trial results:
A Multicenter, Randomized, Open Label, Efficacy Assessor-Blinded Study of Risankizumab Compared to Secukinumab for the Treatment of Adult Subjects With Moderate to Severe Plaque Psoriasis Who Are Candidates for Systemic Therapy

Summary

EudraCT number	2017-004932-12
Trial protocol	DE GB NL ES FR IT
Global end of trial date	07 July 2020

Results information

Result version number	v1 (current)
This version publication date	07 July 2021
First version publication date	07 July 2021

Trial information

Trial identification

Sponsor protocol code	M16-766

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03478787
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AbbVie
Sponsor organisation address	AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6 4UB
Public contact	Global Medical Services, AbbVie, 001 8006339110, abbvieclinicaltrials@abbvie.com
Scientific contact	Global Medical Services, AbbVie, 001 8006339110, abbvieclinicaltrials@abbvie.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final

Date of interim/final analysis	07 July 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	07 July 2020
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study is to evaluate the efficacy and safety of risankizumab compared with secukinumab for the
treatment of adult subjects with moderate to severe plaque psoriasis who are candidates for systemic therapy.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	08 May 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 45
Country: Number of subjects enrolled	United States: 171
Country: Number of subjects enrolled	France: 34
Country: Number of subjects enrolled	Germany: 3
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	Netherlands: 1
Country: Number of subjects enrolled	Poland: 30
Country: Number of subjects enrolled	Spain: 32
Country: Number of subjects enrolled	United Kingdom: 9
Worldwide total number of subjects	327
EEA total number of subjects	102

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)	290
From 65 to 84 years	35
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

A total of 327 participants were randomized from 53 sites across 9 countries including Canada, France, Germany, Italy, The Netherlands, Poland, Spain, the United Kingdom, and the United States.

Pre-assignment

Screening details:

Eligible participants were randomized to receive risankizumab or secukinumab in a 1:1 ratio. The randomization was stratified by weight (≤ 100 kg vs. > 100 kg) and prior systemic biologic for psoriasis (0 vs. ≥ 1).

Period 1

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

Blinding implementation details:

This is an open-label study; however, the efficacy assessor remained blinded to each subject's treatment, clinical laboratory results, and all subject safety data during the course of the study.

Arms

Are arms mutually exclusive?	Yes
Arm title	Secukinumab

Arm description:

Participants randomized to secukinumab received 2 injections of active secukinumab (300 mg total dosage) subcutaneously (SC) at Weeks 0, 1, 2, 3, and 4, and then every 4 weeks (q4w) thereafter until the last dose at Week 48.

Arm type	Active comparator
Investigational medicinal product name	secukinumab
Investigational medicinal product code	
Other name	Cosentyx
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Study site staff administered comparator subcutaneously (secukinumab 300 mg [2 × 150 mg pre-filled syringe]).

Arm title	Risankizumab

Arm description:

Participants randomized to risankizumab received 2 injections of active risankizumab (150 mg total dosage) SC at Weeks 0 and 4, and then every 12 weeks (q12w) thereafter until the last dose at Week 40 (Week 64 for participants in France).

Arm type	Experimental
Investigational medicinal product name	Risankizumab
Investigational medicinal product code	ABBV-066
Other name	BI 655066, SKYRIZI
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Study site staff will administer study drug subcutaneously (risankizumab 150 mg [2 × 75 mg pre-filled syringe]).

Number of subjects in period 1	Secukinumab	Risankizumab
Started	163	164
Completed	134	151
Not completed	29	13
Protocol deviation	3	-
Other, not specified	3	-
Adverse event	5	1
Lack of efficacy	7	1
Consent withdrawn by subject	2	6
Lost to follow-up	9	5

Baseline characteristics

Reporting groups	
Reporting group title	Secukinumab
Reporting group description:	
Participants randomized to secukinumab received 2 injections of active secukinumab (300 mg total dosage) subcutaneously (SC) at Weeks 0, 1, 2, 3, and 4, and then every 4 weeks (q4w) thereafter until the last dose at Week 48.	
Reporting group title	Risankizumab
Reporting group description:	
Participants randomized to risankizumab received 2 injections of active risankizumab (150 mg total dosage) SC at Weeks 0 and 4, and then every 12 weeks (q12w) thereafter until the last dose at Week 40 (Week 64 for participants in France).	

Reporting group values	Secukinumab	Risankizumab	Total
Number of subjects	163	164	327
Age categorical Units: Subjects			
< 40 years	60	50	110
40 to < 65 years	81	99	180
>/= 65 years	22	15	37
Gender categorical Units: Subjects			
Female	62	52	114
Male	101	112	213
Ethnicity Units: Subjects			
Hispanic or Latino	34	37	71
Not Hispanic or Latino	129	127	256
Race Units: Subjects			
American Indian or Alaska Native	0	1	1
Asian	11	6	17
Native Hawaiian or Other Pacific Islander	2	0	2
Black or African American	6	6	12
White	144	151	295

End points

End points reporting groups

Reporting group title	Secukinumab
Reporting group description:	
Participants randomized to secukinumab received 2 injections of active secukinumab (300 mg total dosage) subcutaneously (SC) at Weeks 0, 1, 2, 3, and 4, and then every 4 weeks (q4w) thereafter until the last dose at Week 48.	
Reporting group title	Risankizumab
Reporting group description:	
Participants randomized to risankizumab received 2 injections of active risankizumab (150 mg total dosage) SC at Weeks 0 and 4, and then every 12 weeks (q12w) thereafter until the last dose at Week 40 (Week 64 for participants in France).	

Primary: Percentage of Participants With a 90% Reduction From Baseline Psoriasis Area and Severity Index (PASI 90) at Week 16

End point title	Percentage of Participants With a 90% Reduction From Baseline Psoriasis Area and Severity Index (PASI 90) at Week 16
End point description:	
The 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 PASI score ranges from 0 to 72, where 0 indicates no psoriasis and 72 indicates very severe psoriasis. PASI 90 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) analysis set: all participants who were randomized at Baseline. Non-responder imputation (NRI) was used for missing data.	
End point type	Primary
End point timeframe:	
Week 16	

End point values	Secukinumab	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	163	164		
Units: percentage of participants				
number (not applicable)	65.6	73.8		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Across the strata, 96.25% confidence interval (CI) for adjusted difference was calculated according to the Cochran-Mantel-Haenszel test for the comparison of 2 treatment groups.	
Comparison groups	Secukinumab v Risankizumab
Number of subjects included in analysis	327

Analysis specification	Pre-specified
Analysis type	non-inferiority[1]
Parameter estimate	Adjusted percentage difference
Point estimate	8.2
Confidence interval	
level	Other: 96.25 %
sides	2-sided
lower limit	-2.2
upper limit	18.6

Notes:

[1] - Non-inferiority is met if the lower bound of the 96.25% CI of adjusted treatment difference is above –12%.

Primary: Percentage of Participants With a PASI 90 at Week 52

End point title	Percentage of Participants With a PASI 90 at Week 52

End point description:

The 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 PASI score ranges from 0 to 72, where 0 indicates no psoriasis and 72 indicates very severe psoriasis. PASI 90 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.

ITT analysis set: all participants who were randomized at Baseline. NRI was used for missing data.

End point type	Primary

End point timeframe:

Week 52

End point values	Secukinumab	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	163	164		
Units: percentage of participants				
number (not applicable)	57.1	86.6		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Across the strata, 95% CI for adjusted difference was calculated according to the Cochran-Mantel-Haenszel test for the comparison of 2 treatment groups.

Comparison groups	Secukinumab v Risankizumab
Number of subjects included in analysis	327
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [2]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	29.8
Confidence interval	

level	95 %
sides	2-sided
lower limit	20.8
upper limit	38.8

Notes:

[2] - Across the strata, p-value was calculated from the from the Cochran-Mantel-Haenszel test adjusted for strata.

Secondary: Percentage of Participants With a 100% Reduction From Baseline Psoriasis Area and Severity Index (PASI 100) at Week 52

End point title	Percentage of Participants With a 100% Reduction From Baseline Psoriasis Area and Severity Index (PASI 100) 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 PASI score ranges from 0 to 72, where 0 indicates no psoriasis and 72 indicates very severe psoriasis. PASI 100 is defined as 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.

ITT analysis set: all participants who were randomized at Baseline. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 52

End point values	Secukinumab	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	163	164		
Units: percentage of participants				
number (not applicable)	39.9	65.9		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Across the strata, 95% CI for adjusted difference was calculated according to the Cochran-Mantel-Haenszel test for the comparison of 2 treatment groups.

Comparison groups	Secukinumab v Risankizumab
Number of subjects included in analysis	327
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [3]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	26.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	15.9

upper limit	36.5

Notes:

[3] - Across the strata, p-value was calculated from the from the Cochran-Mantel-Haenszel test adjusted for strata.

Secondary: Percentage of Participants Achieving Static Physician Global Assessment (sPGA) of Clear or Almost Clear at Week 52

End point title	Percentage of Participants Achieving Static Physician Global Assessment (sPGA) 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, induration, and scaling of psoriatic lesions 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.

ITT analysis set: all participants who were randomized at Baseline. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 52

End point values	Secukinumab	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	163	164		
Units: percentage of participants				
number (not applicable)	58.3	87.8		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Across the strata, 95% CI for adjusted difference was calculated according to the Cochran-Mantel-Haenszel test for the comparison of 2 treatment groups.

Comparison groups	Secukinumab v Risankizumab
Number of subjects included in analysis	327
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [4]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	29.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	20.9
upper limit	38.8

Notes:

[4] - Across the strata, p-value was calculated from the from the Cochran-Mantel-Haenszel test adjusted for strata.

Secondary: Percentage of Participants With a 75% Reduction From Baseline Psoriasis Area and Severity Index (PASI 75) at Week 52

End point title	Percentage of Participants With a 75% Reduction From Baseline Psoriasis Area and Severity Index (PASI 75) at Week 52

End point description:

The 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 PASI score ranges from 0 to 72, where 0 indicates no psoriasis and 72 indicates very severe psoriasis. PASI 75 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.

ITT analysis set: all participants who were randomized at Baseline. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 52

End point values	Secukinumab	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	163	164		
Units: percentage of participants				
number (not applicable)	69.9	89.6		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Across the strata, 95% CI for adjusted difference was calculated according to the Cochran-Mantel-Haenszel test for the comparison of 2 treatment groups.

Comparison groups	Risankizumab v Secukinumab
Number of subjects included in analysis	327
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.001 [5]
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	20
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.7
upper limit	28.3

Notes:

[5] - Across the strata, p-value was calculated from the from the Cochran-Mantel-Haenszel test adjusted for strata.

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events are reported from first dose of study drug through 20 weeks after last dose of study drug (up to Week 68 for the Secukinumab arm, and up to Week 84 for the Risankizumab arm).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups

Reporting group title	Secukinumab

Reporting group description:

Participants randomized to secukinumab received 2 injections of active secukinumab (300 mg total dosage) subcutaneously (SC) at Weeks 0, 1, 2, 3, and 4, and then every 4 weeks (q4w) thereafter until the last dose at Week 48 and received at least one dose of study drug.

Reporting group title	Risankizumab

Reporting group description:

Participants randomized to risankizumab received 2 injections of active risankizumab (150 mg total dosage) SC at Weeks 0 and 4, and then every 12 weeks (q12w) thereafter until the last dose at Week 40 (Week 64 for participants in France) and received at least one dose of study drug.

Serious adverse events	Secukinumab	Risankizumab	
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 163 (3.68%)	9 / 164 (5.49%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Vascular disorders			
ARTERIOSCLEROSIS			
subjects affected / exposed	1 / 163 (0.61%)	0 / 164 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
HISTIOCYTIC NECROTISING LYMPHADENITIS			
subjects affected / exposed	0 / 163 (0.00%)	1 / 164 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
MENTAL STATUS CHANGES			
subjects affected / exposed	0 / 163 (0.00%)	1 / 164 (0.61%)	

occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUICIDAL IDEATION			
subjects affected / exposed	0 / 163 (0.00%)	1 / 164 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
SUICIDE ATTEMPT			
subjects affected / exposed	0 / 163 (0.00%)	1 / 164 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
OVARIAN CYST			
subjects affected / exposed	0 / 163 (0.00%)	1 / 164 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
OVERDOSE			
subjects affected / exposed	1 / 163 (0.61%)	0 / 164 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
ACUTE MYOCARDIAL INFARCTION			
subjects affected / exposed	0 / 163 (0.00%)	1 / 164 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
ARRHYTHMIA SUPRAVENTRICULAR			
subjects affected / exposed	0 / 163 (0.00%)	1 / 164 (0.61%)	
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 / 163 (0.00%)	1 / 164 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Respiratory, thoracic and mediastinal disorders			
ACUTE RESPIRATORY FAILURE			
subjects affected / exposed	1 / 163 (0.61%)	0 / 164 (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			
TOXIC ENCEPHALOPATHY			
subjects affected / exposed	1 / 163 (0.61%)	0 / 164 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
COLITIS ULCERATIVE			
subjects affected / exposed	1 / 163 (0.61%)	0 / 164 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
DIVERTICULUM INTESTINAL HAEMORRHAGIC			
subjects affected / exposed	1 / 163 (0.61%)	0 / 164 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
SMALL INTESTINAL OBSTRUCTION			
subjects affected / exposed	1 / 163 (0.61%)	0 / 164 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
CHOLELITHIASIS			
subjects affected / exposed	1 / 163 (0.61%)	0 / 164 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
NEPHROLITHIASIS			
subjects affected / exposed	0 / 163 (0.00%)	1 / 164 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			

RASH PRURITIC			
subjects affected / exposed	1 / 163 (0.61%)	0 / 164 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
BASEDOW'S DISEASE			
subjects affected / exposed	0 / 163 (0.00%)	1 / 164 (0.61%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
URINARY TRACT INFECTION			
subjects affected / exposed	0 / 163 (0.00%)	2 / 164 (1.22%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Secukinumab	Risankizumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	71 / 163 (43.56%)	66 / 164 (40.24%)	
Vascular disorders			
HYPERTENSION			
subjects affected / exposed	5 / 163 (3.07%)	9 / 164 (5.49%)	
occurrences (all)	5	10	
Nervous system disorders			
HEADACHE			
subjects affected / exposed	15 / 163 (9.20%)	9 / 164 (5.49%)	
occurrences (all)	27	20	
Gastrointestinal disorders			
DIARRHOEA			
subjects affected / exposed	9 / 163 (5.52%)	9 / 164 (5.49%)	
occurrences (all)	12	11	
Musculoskeletal and connective tissue disorders			
ARTHRALGIA			
subjects affected / exposed	10 / 163 (6.13%)	9 / 164 (5.49%)	
occurrences (all)	13	12	

Infections and infestations			
BRONCHITIS			
subjects affected / exposed	11 / 163 (6.75%)	3 / 164 (1.83%)	
occurrences (all)	11	3	
NASOPHARYNGITIS			
subjects affected / exposed	27 / 163 (16.56%)	35 / 164 (21.34%)	
occurrences (all)	38	48	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	14 / 163 (8.59%)	21 / 164 (12.80%)	
occurrences (all)	20	25	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 August 2019	Of the 327 subjects in the global study, 16 subjects in France who were randomized to risankizumab had 2 additional dosing visits at Week 52 and Week 64 under Amendment 1.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported