Clinical trial results:
A Randomized, Controlled, Multicenter, Open Label Study with Blinded Assessment of the Efficacy of the Humanized Anti-IL-23p19 Risankizumab Compared to FUMADERM® in Subjects with Moderate to Severe Plaque Psoriasis Who are Naïve to and Candidates for Systemic Therapy

Summary

EudraCT number	2016-003718-28
Trial protocol	DE
Global end of trial date	06 July 2018

Results information

Result version number	v2 (current)
This version publication date	18 December 2019
First version publication date	13 July 2019
Version creation reason	• Correction of full data set number discrepancy

Trial information

Trial identification

Sponsor protocol code	M16-178

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03255382
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AbbVie Deutschland GmbH & Co. KG
Sponsor organisation address	AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6-4UB
Public contact	Global Medical Services, AbbVie , 001 800-633-9110,
Scientific contact	David Williams, MD, MPH, AbbVie, david.a.williams@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	06 July 2018
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 July 2018
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The objective of this study is to compare the efficacy and safety of subcutaneous (SC) risankizumab and oral FUMADERM® provided as study medication in subjects with moderate to severe plaque psoriasis who are naïve to and candidates for systemic therapy.

Protection of trial subjects:

Subject and/or parent 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	22 August 2017
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	Germany: 120
Worldwide total number of subjects	120
EEA total number of subjects	120

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)	113
From 65 to 84 years	7

85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Intent-to-treat (ITT) analysis set included all participants enrolled in the study (N = 120). Safety analysis set included all participants enrolled in the study and who received at least 1 dose of study drug (N = 117).

Pre-assignment

Screening details:

A total of 120 participants were enrolled and included in the ITT population; 3 randomized participants discontinued prior to receiving any study drug and were excluded from the safety population.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Fumaderm

Arm description:

Participants randomized to receive open-label Fumaderm 30 mg administered as a tablet orally once daily from Week 0 to Week 2, then up to 240 mg, 3 times daily from Week 3 to Week 24 if PASI90 is not achieved and if tolerability allows.

Arm type	Active comparator
Investigational medicinal product name	Fumaderm
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Fumaderm tablet administered orally

Arm title	Risankizumab

Arm description:

Participants randomized to receive open-label risankizumab 150 mg by subcutaneous injection at Weeks 0, 4, and 16.

Arm type	Experimental
Investigational medicinal product name	Risankizumab
Investigational medicinal product code	
Other name	ABBV-066, BI 655066
Pharmaceutical forms	Injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Risankizumab administered by subcutaneous (SC) injection

Number of subjects in period 1	Fumaderm	Risankizumab
Started	60	60
Completed	47	60
Not completed	13	0
Not specified	6	-
Adverse event	3	-
Withdrawal by Subject	2	-
Lost to follow-up	2	-

Baseline characteristics

Reporting groups	
Reporting group title	Fumaderm
Reporting group description:	
Participants randomized to receive open-label Fumaderm 30 mg administered as a tablet orally once daily from Week 0 to Week 2, then up to 240 mg, 3 times daily from Week 3 to Week 24 if PASI90 is not achieved and if tolerability allows.	
Reporting group title	Risankizumab
Reporting group description:	
Participants randomized to receive open-label risankizumab 150 mg by subcutaneous injection at Weeks 0, 4, and 16.	

Reporting group values	Fumaderm	Risankizumab	Total
Number of subjects	60	60	120
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	42.5	42.0	
standard deviation	± 12.71	± 13.75	-
Gender categorical			
Units: Subjects			
Female	22	27	49
Male	38	33	71
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	1	0	1
Not Hispanic or Latino	59	60	119
Unknown or Not Reported	0	0	0
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	0	1	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	60	59	119
More than one race	0	0	0
Unknown or Not Reported	0	0	0

End points

End points reporting groups

Reporting group title	Fumaderm
Reporting group description:	
Participants randomized to receive open-label Fumaderm 30 mg administered as a tablet orally once daily from Week 0 to Week 2, then up to 240 mg, 3 times daily from Week 3 to Week 24 if PASI90 is not achieved and if tolerability allows.	
Reporting group title	Risankizumab
Reporting group description:	
Participants randomized to receive open-label risankizumab 150 mg by subcutaneous injection at Weeks 0, 4, and 16.	

Primary: Percentage of Participants Achieving 90% Improvement in Psoriasis Area and Severity Index (PASI90) at Week 24

End point title	Percentage of Participants Achieving 90% Improvement in Psoriasis Area and Severity Index (PASI90) at Week 24
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 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.	
End point type	Primary
End point timeframe:	
Week 24	

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[1]	60[2]		
Units: Percentage of Participants				
number (not applicable)	10.0	83.3		

Notes:

[1] - Intent to Treat (ITT) analysis set: all participants who were randomized.

[2] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
P-value was calculated from the Cochran-Mantel-Haenszel (CMH) test adjusted for strata (prior phototherapy [yes/no]).	
Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	73.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	61.3
upper limit	85.3

Secondary: Percentage of Participants Achieving 50% Improvement in PASI Score (PASI50) at Week 4

End point title	Percentage of Participants Achieving 50% Improvement in PASI Score (PASI50) at Week 4

End point description:

PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The severity of each sign was assessed using a 5-point scale, where 0=no symptoms, 1=slight, 2=moderate, 3=marked, 4=very marked. The PASI score ranges from 0 to 72, where 0 indicates no psoriasis and 72 indicates very severe psoriasis. PASI50 is defined as at least a 50% reduction in PASI score compared with the Baseline PASI score. The percent reduction in score is calculated as (PASI score at Baseline - score at follow-up visit) I PASI score at Baseline * 100. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 4

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[3]	60[4]		
Units: Percentage of Participants				
number (not applicable)	6.7	53.3		

Notes:

[3] - ITT analysis set

[4] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Risankizumab v Fumaderm

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	46.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.8
upper limit	60.8

Secondary: Percentage of Participants Achieving 50% Improvement in PASI Score (PASI50) at Week 8

End point title	Percentage of Participants Achieving 50% Improvement in PASI Score (PASI50) at Week 8

End point description:

PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The severity of each sign was assessed using a 5-point scale, where 0=no symptoms, 1=slight, 2=moderate, 3=marked, 4=very marked. The PASI score ranges from 0 to 72, where 0 indicates no psoriasis and 72 indicates very severe psoriasis. PASI50 is defined as at least a 50% reduction in PASI score compared with the Baseline PASI score. 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 8

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[5]	60[6]		
Units: Percentage of Participants				
number (not applicable)	28.3	91.7		

Notes:

[5] - ITT analysis set

[6] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	63.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	50.2
upper limit	76.6

Secondary: Percentage of Participants Achieving 50% Improvement in PASI Score (PASI50) at Week 12

End point title	Percentage of Participants Achieving 50% Improvement in PASI Score (PASI50) at Week 12

End point description:

PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The severity of each sign was assessed using a 5-point scale, where 0=no symptoms, 1=slight, 2=moderate, 3=marked, 4=very marked. The PASI score ranges from 0 to 72, where 0 indicates no psoriasis and 72 indicates very severe psoriasis. PASI50 is defined as at least a 50% reduction in PASI score compared with the Baseline PASI score. 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 12

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[7]	60[8]		
Units: Percentage of Participants				
number (not applicable)	46.7	100		

Notes:

[7] - ITT analysis set

[8] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	53.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	40.4
upper limit	65.7

Secondary: Percentage of Participants Achieving 50% Improvement in PASI Score (PASI50) at Week 16

End point title	Percentage of Participants Achieving 50% Improvement in PASI Score (PASI50) 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. PAS150 is defined as at least a 50% 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) I PASI score at Baseline * 100. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[9]	60[10]		
Units: Percentage of Participants				
number (not applicable)	60.0	100		

Notes:

[9] - ITT analysis set

[10] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	39.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	27.3
upper limit	51.9

Secondary: Percentage of Participants Achieving 50% Improvement in PASI Score (PASI50) at Week 20

End point title	Percentage of Participants Achieving 50% Improvement in PASI Score (PASI50) at Week 20

End point description:

PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The severity of each sign was assessed using a 5-point scale, where 0=no symptoms, 1=slight, 2=moderate, 3=marked, 4=very marked. The PASI score ranges from 0 to 72, where 0 indicates no psoriasis and 72 indicates very severe psoriasis. PASI50 is defined as at least a 50% reduction in PASI score compared with the Baseline PASI score. 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 20

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[11]	60[12]		
Units: Percentage of Participants				
number (not applicable)	63.3	100		

Notes:

[11] - ITT analysis set

[12] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	36.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	24.1
upper limit	48.5

Secondary: Percentage of Participants Achieving 50% Improvement in PASI Score (PASI50) at Week 24

End point title	Percentage of Participants Achieving 50% Improvement in PASI Score (PASI50) at Week 24

End point description:

PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The severity of each sign was assessed using a 5-point scale, where 0=no symptoms, 1=slight, 2=moderate, 3=marked, 4=very marked. The PASI score ranges from 0 to 72, where 0 indicates no psoriasis and 72 indicates very severe psoriasis. PASI50 is defined as at least a 50% reduction in PASI score compared with the Baseline PASI score. 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 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[13]	60[14]		
Units: Percentage of Participants				
number (not applicable)	53.3	100		

Notes:

[13] - ITT analysis set

[14] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	46.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	33.7
upper limit	59

Secondary: Percentage of Participants Achieving 75% Improvement in PASI Score (PASI75) at Week 4

End point title	Percentage of Participants Achieving 75% Improvement in PASI Score (PASI75) at Week 4

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 4

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[15]	60[16]		
Units: Percentage of Participants				
number (not applicable)	3.3	13.3		

Notes:

[15] - ITT analysis set

[16] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.047
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	9.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	19.7

Secondary: Percentage of Participants Achieving 75% Improvement in PASI Score (PASI75) at Week 8

End point title	Percentage of Participants Achieving 75% Improvement in PASI Score (PASI75) at Week 8

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. PAS175 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) I PASI score at Baseline * 100. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 8

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[17]	60[18]		
Units: Percentage of Participants				
number (not applicable)	8.3	75.0		

Notes:

[17] - ITT analysis set

[18] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	66.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.8
upper limit	79.5

Secondary: Percentage of Participants Achieving 75% Improvement in PAST Score (PAS175) at Week 12

End point title	Percentage of Participants Achieving 75% Improvement in PAST Score (PAS175) at Week 12

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 PAST 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 12

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[19]	60[20]		
Units: Percentage of Participants				
number (not applicable)	20.0	86.7		

Notes:

[19] - ITT analysis set

[20] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	66.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.3
upper limit	79.9

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	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[21]	60[22]		
Units: Percentage of Participants				
number (not applicable)	26.7	93.3		

Notes:

[21] - ITT analysis set

[22] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	66.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.8
upper limit	79.5

Secondary: Percentage of Participants Achieving 75% Improvement in PASI Score (PASI75) at Week 20

End point title	Percentage of Participants Achieving 75% Improvement in PASI Score (PASI75) at Week 20

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 20

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[23]	60[24]		
Units: Percentage of Participants				
number (not applicable)	38.3	95.0		

Notes:

[23] - ITT analysis set

[24] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	56.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	43
upper limit	70

Secondary: Percentage of Participants Achieving 75% Improvement in PASI Score (PASI75) at Week 24

End point title	Percentage of Participants Achieving 75% Improvement in PASI Score (PASI75) at Week 24

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. PAS175 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 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[25]	60[26]		
Units: Percentage of Participants				
number (not applicable)	33.3	98.3		

Notes:

[25] - ITT analysis set

[26] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other[27]
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	64.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	52.5
upper limit	77.2

Notes:

[27] - P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Secondary: Percentage of Participants Achieving 90% Improvement in PASI Score (PASI90) at Week 4

End point title	Percentage of Participants Achieving 90% Improvement in PASI Score (PASI90) at Week 4

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 4

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[28]	60[29]		
Units: Percentage of Participants				
number (not applicable)	0	1.7		

Notes:

[28] - ITT analysis set

[29] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.392
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	5.4

Secondary: Percentage of Participants Achieving 90% Improvement in PASI Score (PASI90) at Week 8

End point title	Percentage of Participants Achieving 90% Improvement in PASI Score (PASI90) at Week 8

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 8

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[30]	60[31]		
Units: Percentage of Participants				
number (not applicable)	1.7	38.3		

Notes:

[30] - ITT analysis set

[31] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	36.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.8
upper limit	49.3

Secondary: Percentage of Participants Achieving 90% Improvement in PASI Score (PASI90) at Week 12

End point title	Percentage of Participants Achieving 90% Improvement in PASI Score (PASI90) at Week 12

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 12

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[32]	60[33]		
Units: Percentage of Participants				
number (not applicable)	5.0	61.7		

Notes:

[32] - ITT analysis set

[33] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	56.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	43.2
upper limit	70

Secondary: Percentage of Participants Achieving 90% Improvement in PASI Score (PASI90) at Week 16

End point title	Percentage of Participants Achieving 90% Improvement in PASI Score (PASI90) at Week 16

End point description:

PASI is a composite score based on the degree of effect on body surface area of psoriasis and the extension of erythema (reddening), induration (thickness), desquamation (scaling) of the lesions and area affected as observed on the day of examination. The severity of each sign was assessed using a 5-point scale, where 0=no symptoms, 1=slight, 2=moderate, 3=marked, 4=very marked. The PASI score ranges from 0 to 72, where 0 indicates no psoriasis and 72 indicates very severe psoriasis. PAS190 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 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[34]	60[35]		
Units: Percentage of Participants				
number (not applicable)	11.7	76.7		

Notes:

[34] - ITT analysis set

[35] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	64.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	51.5
upper limit	78.3

Secondary: Percentage of Participants Achieving 90% Improvement in PASI Score (PASI90) at Week 20

End point title	Percentage of Participants Achieving 90% Improvement in PASI Score (PASI90) at Week 20

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 20

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[36]	60[37]		
Units: Percentage of Participants				
number (not applicable)	16.7	83.3		

Notes:

[36] - ITT analysis set

[37] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	66.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.3
upper limit	79.8

Secondary: Percentage of Participants Achieving 100% Improvement in PASI (PASI100) at Week 4

End point title	Percentage of Participants Achieving 100% Improvement in PASI (PASI100) at Week 4

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 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) I PASI score at Baseline * 100. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 4

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[38]	60[39]		
Units: Percentage of Participants				
number (not applicable)	0	0		

Notes:

[38] - ITT analysis set

[39] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.991
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2
upper limit	2.1

Secondary: Percentage of Participants Achieving 100% Improvement in PASI (PASI100) at Week 8

End point title	Percentage of Participants Achieving 100% Improvement in PASI (PASI100) at Week 8

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 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 8

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[40]	60[41]		
Units: Percentage of Participants				
number (not applicable)	1.7	5.0		

Notes:

[40] - ITT analysis set

[41] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.323
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	3.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	9.8

Secondary: Percentage of Participants Achieving 100% Improvement in PASI (PASI100) at Week 12

End point title	Percentage of Participants Achieving 100% Improvement in PASI (PASI100) at Week 12

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 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 12

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[42]	60[43]		
Units: Percentage of Participants				
number (not applicable)	1.7	23.3		

Notes:

[42] - ITT analysis set

[43] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	21.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	10.4
upper limit	32.6

Secondary: Percentage of Participants Achieving 100% Improvement in PASI (PASI100) at Week 16

End point title	Percentage of Participants Achieving 100% Improvement in PASI (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 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	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[44]	60[45]		
Units: Percentage of Participants				
number (not applicable)	1.7	35.0		

Notes:

[44] - ITT analysis set

[45] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
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	20.7
upper limit	45.5

Secondary: Percentage of Participants Achieving 100% Improvement in PASI (PASI100) at Week 20

End point title	Percentage of Participants Achieving 100% Improvement in PASI (PASI100) at Week 20

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 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 20

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[46]	60[47]		
Units: Percentage of Participants				
number (not applicable)	6.7	48.3		

Notes:

[46] - ITT analysis set

[47] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	41.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	27.3
upper limit	55.3

Secondary: Percentage of Participants Achieving 100% Improvement in PASI (PASI100) at Week 24

End point title	Percentage of Participants Achieving 100% Improvement in PASI (PASI100) at Week 24

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 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 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[48]	60[49]		
Units: Percentage of Participants				
number (not applicable)	5.0	50.0		

Notes:

[48] - ITT analysis set

[49] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no])

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	44.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	30.9
upper limit	58.5

Secondary: The Psoriasis Area and Severity Index (PASI): Change From Baseline to Week 4

End point title	The Psoriasis Area and Severity Index (PASI): Change From Baseline to Week 4

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. Last observation carried forward (LOCF) imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 4

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58[50]	60[51]		
Units: units on a scale				
least squares mean (standard error)	-2.37 (± 0.669)	-9.56 (± 0.673)		

Notes:

[50] - ITT analysis set

[51] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and the treatment in this model.

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-7.19
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.82
upper limit	-5.56
Variability estimate	Standard error of the mean
Dispersion value	0.825

Secondary: PASI: Change From Baseline to Week 8

End point title	PASI: Change From Baseline to Week 8

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. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 8

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58[52]	60[53]		
Units: units on a scale				
least squares mean (standard error)	-5.61 (± 0.759)	-15.18 (± 0.763)		

Notes:

[52] - ITT analysis set

[53] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-9.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.43
upper limit	-7.72
Variability estimate	Standard error of the mean
Dispersion value	0.936

Secondary: PASI: Change From Baseline to Week 12

End point title	PASI: Change From Baseline to Week 12

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. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58[54]	60[55]		
Units: units on a scale				
least squares mean (standard error)	-7.69 (± 0.788)	-16.49 (± 0.793)		

Notes:

[54] - ITT analysis set

[55] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-8.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.72
upper limit	-6.87
Variability estimate	Standard error of the mean
Dispersion value	0.972

Secondary: PASI: Change From Baseline to Week 16

End point title	PASI: Change 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. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58[56]	60[57]		
Units: units on a scale				
least squares mean (standard error)	-9.11 (± 0.777)	-16.89 (± 0.782)		

Notes:

[56] - ITT analysis set

[57] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-7.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.68
upper limit	-5.88
Variability estimate	Standard error of the mean
Dispersion value	0.958

Secondary: PASI: Change From Baseline to Week 20

End point title	PASI: Change From Baseline to Week 20

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. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 20

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58[58]	60[59]		
Units: units on a scale				
least squares mean (standard error)	-9.46 (± 0.894)	-17.35 (± 0.899)		

Notes:

[58] - ITT analysis set

[59] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-7.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.07
upper limit	-5.71
Variability estimate	Standard error of the mean
Dispersion value	1.101

Secondary: PASI: Change From Baseline to Week 24

End point title	PASI: Change From Baseline to Week 24

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. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58[60]	60[61]		
Units: units on a scale				
least squares mean (standard error)	-9.31 (± 0.953)	-17.69 (± 0.959)		

Notes:

[60] - ITT analysis set

[61] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-8.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.71
upper limit	-6.06
Variability estimate	Standard error of the mean
Dispersion value	1.175

Secondary: Percentage of Participants Achieving Static Physician Global Assessment (sPGA) Score of Clear or Almost Clear at Week 4

End point title	Percentage of Participants Achieving Static Physician Global Assessment (sPGA) Score of Clear or Almost Clear at Week 4

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 4

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[62]	60[63]		
Units: Percentage of Participants				
number (not applicable)	3.3	33.3		

Notes:

[62] - ITT analysis set

[63] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	29.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	17.1
upper limit	42.4

Secondary: Percentage of Participants Achieving sPGA Score of Clear or Almost Clear at Week 8

End point title	Percentage of Participants Achieving sPGA Score of Clear or Almost Clear at Week 8

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 8

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[64]	60[65]		
Units: Percentage of Participants				
number (not applicable)	15.0	81.7		

Notes:

[64] - ITT analysis set

[65] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	66.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	53.4
upper limit	80

Secondary: Percentage of Participants Achieving sPGA Score of Clear or Almost Clear at Week 12

End point title	Percentage of Participants Achieving sPGA Score of Clear or Almost Clear at Week 12

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 12

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[66]	60[67]		
Units: Percentage of Participants				
number (not applicable)	33.3	90.0		

Notes:

[66] - ITT analysis set

[67] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	56.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.7
upper limit	70.8

Secondary: Percentage of Participants Achieving sPGA Score of Clear or Almost Clear at Week 16

End point title	Percentage of Participants Achieving 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	Secondary

End point timeframe:

Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[68]	60[69]		
Units: Percentage of Participants				
number (not applicable)	31.7	91.7		

Notes:

[68] - ITT analysis set

[69] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	59.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	46.3
upper limit	73.6

Secondary: Percentage of Participants Achieving sPGA Score of Clear or Almost Clear at Week 20

End point title	Percentage of Participants Achieving sPGA Score of Clear or Almost Clear at Week 20

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 20

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[70]	60[71]		
Units: Percentage of Participants				
number (not applicable)	48.3	93.3		

Notes:

[70] - ITT analysis set

[71] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	44.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	30.8
upper limit	59.1

Secondary: Percentage of Participants Achieving sPGA Score of Clear or Almost Clear at Week 24

End point title	Percentage of Participants Achieving sPGA Score of Clear or Almost Clear at Week 24

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 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58[72]	60[73]		
Units: Percentage of Participants				
number (not applicable)	38.3	93.3		

Notes:

[72] - ITT Analysis Set

[73] - ITT Analysis Set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	55
Confidence interval	
level	95 %
sides	2-sided
lower limit	41.2
upper limit	68.8

Secondary: Percentage of Participants Achieving sPGA Score of Clear at Week 4

End point title	Percentage of Participants Achieving sPGA Score of Clear at Week 4

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 4

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[74]	60[75]		
Units: Percentage of Participants				
number (not applicable)	0	1.7		

Notes:

[74] - ITT analysis set

[75] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Risankizumab v Fumaderm

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.392
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	1.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.1
upper limit	5.4

Secondary: Percentage of Participants Achieving sPGA Score of Clear at Week 8

End point title	Percentage of Participants Achieving sPGA Score of Clear at Week 8

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 8

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[76]	60[77]		
Units: Percentage of Participants				
number (not applicable)	1.7	10.0		

Notes:

[76] - ITT analysis set

[77] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.048
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	8.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1
upper limit	16.7

Secondary: Percentage of Participants Achieving sPGA Score of Clear at Week 12

End point title	Percentage of Participants Achieving sPGA Score of Clear at Week 12

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 12

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[78]	60[79]		
Units: Percentage of Participants				
number (not applicable)	3.3	21.7		

Notes:

[78] - ITT analysis set

[79] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	18.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.1
upper limit	29.5

Secondary: Percentage of Participants Achieving sPGA Score of Clear at Week 16

End point title	Percentage of Participants Achieving 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	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[80]	60[81]		
Units: Percentage of Participants				
number (not applicable)	3.3	36.7		

Notes:

[80] - ITT analysis set

[81] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	33
Confidence interval	
level	95 %
sides	2-sided
lower limit	20.2
upper limit	45.9

Secondary: Percentage of Participants Achieving sPGA Score of Clear at Week 20

End point title	Percentage of Participants Achieving sPGA Score of Clear at Week 20

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 20

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[82]	60[83]		
Units: Percentage of Participants				
number (not applicable)	6.7	48.3		

Notes:

[82] - ITT analysis set

[83] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	41.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	27.3
upper limit	55.3

Secondary: Percentage of Participants Achieving sPGA Score of Clear at Week 24

End point title	Percentage of Participants Achieving sPGA Score of Clear at Week 24

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 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[84]	60[85]		
Units: Percentage of Participants				
number (not applicable)	5.0	51.7		

Notes:

[84] - ITT analysis set

[85] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	46.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	32.6
upper limit	60.1

Secondary: Percentage of Participants With Psoriasis Symptoms Scale (PSS) Score of 0 at Week 16

End point title	Percentage of Participants With Psoriasis Symptoms Scale (PSS) Score of 0 at Week 16

End point description:

The PSS asks the participant to rate the severity of symptoms of psoriasis in the last 24 hours (pain, redness, itching, and burning) using a 5-point Likert -type scale ranging from 0 (none) to 4 (very severe). The PSS is calculated by summing the scores of the questions and ranges from 0 to 16, where the higher the score, the greater the severity of psoriasis symptoms. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[86]	60[87]		
Units: Percentage of Participants				
number (not applicable)	5.0	25.0		

Notes:

[86] - ITT analysis set

[87] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	19.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	7.6
upper limit	31.9

Secondary: Percentage of Participants With PSS Score of 0 at Week 24

End point title	Percentage of Participants With PSS Score of 0 at Week 24

End point description:

The PSS asks the participant to rate the severity of symptoms of psoriasis in the last 24 hours (pain, redness, itching, and burning) using a 5-point Likert -type scale ranging from 0 (none) to 4 (very severe). The PSS is calculated by summing the scores of the questions and ranges from 0 to 16, where the higher the score, the greater the severity of psoriasis symptoms. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[88]	60[89]		
Units: Percentage of Participants				
number (not applicable)	3.3	41.7		

Notes:

[88] - ITT analysis set

[89] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	38.3

Confidence interval	
level	95 %
sides	2-sided
lower limit	25
upper limit	51.5

Secondary: PSS Total Score: Change From Baseline to Week 16

End point title	PSS Total Score: Change From Baseline to Week 16

End point description:

The PSS asks the participant to rate the severity of symptoms of psoriasis in the last 24 hours (pain, redness, itching, and burning) using a 5-point Likert -type scale ranging from 0 (none) to 4 (very severe). The PSS is calculated by summing the scores of the questions and ranges from 0 to 16, where the higher the score, the greater the severity of psoriasis symptoms. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55[90]	59[91]		
Units: units on a scale				
least squares mean (standard error)	-5.5 (± 0.52)	-8.7 (± 0.51)		

Notes:

[90] - ITT analysis set

[91] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated by stratified van Elteren test.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	van Elteren test
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.5
upper limit	-2
Variability estimate	Standard error of the mean
Dispersion value	0.63

Secondary: PSS Total Score: Change From Baseline to Week 24

End point title	PSS Total Score: Change From Baseline to Week 24

End point description:

The PSS asks the participant to rate the severity of symptoms of psoriasis in the last 24 hours (pain, redness, itching, and burning) using a 5-point Likert -type scale ranging from 0 (none) to 4 (very severe). The PSS is calculated by summing the scores of the questions and ranges from 0 to 16, where the higher the score, the greater the severity of psoriasis symptoms. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55[92]	60[93]		
Units: units on a scale				
least squares mean (standard error)	-5.6 (± 0.49)	-9.5 (± 0.48)		

Notes:

[92] - ITT analysis set

[93] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated by stratified van Elteren test.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	van Elteren test
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.1
upper limit	-2.7
Variability estimate	Standard error of the mean
Dispersion value	0.59

Secondary: Summary of Patient Benefit Index (PBI) at Week 16

End point title	Summary of Patient Benefit Index (PBI) at Week 16

End point description:

The PBI is a patient-reported outcome instrument that assesses the benefit of psoriasis treatment.The PBI assessment consists of 2 steps: before treatment, every participant defines his/her treatment needs according to a standardized list (Patient Needs Questionnaire [PNQ]). After treatment, the participant rates the degree of benefits achieved (Patient Benefits Questionnaire [PBQ]). 25 items are rated on a 5-point scale with values from 0 (not at all) to 4 (very), allowing for "did not apply to me" (5) and missing. For each treatment goal the PNQ importance is derived by dividing the respective PNQ item by the sum of all PNQ items. The weighted sum of each PBQ item with its respective PNQ importance yields the PBI score. An increase in PBI indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54[94]	59[95]		
Units: units on a scale				
arithmetic mean (standard deviation)	1.970 (± 1.1971)	3.118 (± 0.8246)		

Notes:

[94] - ITT analysis set

[95] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	1.146
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.764
upper limit	1.528

Secondary: Summary of PBI at Week 24

End point title	Summary of PBI at Week 24

End point description:

The PBI is a patient-reported outcome instrument that assesses the benefit of psoriasis treatment. The PBI is a patient-reported outcome instrument that assesses the benefit of psoriasis treatment. The PBI

assessment consists of 2 steps: before treatment, every participant defines his/her treatment needs according to a standardized list (PNQ). After treatment, the participant rates the degree of benefits achieved (PBQ). 25 items are rated on a 5-point scale with values from 0 (not at all) to 4 (very), allowing for "did not apply to me" (5) and missing. For each treatment goal the PNQ importance is derived by dividing the respective PNQ item by the sum of all PNQ items. The weighted sum of each PBQ item with its respective PNQ importance yields the PBI score. An increase in PBI indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	54[96]	60[97]		
Units: units on a scale				
arithmetic mean (standard deviation)	1.997 (± 1.2710)	3.316 (± 0.7487)		

Notes:

[96] - ITT analysis set

[97] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	1.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.936
upper limit	1.704

Secondary: Clinical Severity of Nail Psoriasis (NAPPA-CLIN) Total Score: Change From Baseline to Week 16

End point title	Clinical Severity of Nail Psoriasis (NAPPA-CLIN) Total Score: Change From Baseline to Week 16

End point description:

The NAPPA-CLIN is an investigator assessment used to assess the severity of nail matrix psoriasis (leukonychia, red spots, dots, nail plate crumbling) and psoriasis of the nail bed (oil drop, splinter haemorrhage, subungual hyperkeratosis, onycholysis). NAPPA-CLIN has been developed from the Nail

Psoriasis Severity Index (NAPSI) score, a nail psoriasis-specific score, which in its original version comprises the assessment of matrix and nail bed involvement in every finger and toe by 2 criteria for each nail. The NAPPA-CLIN is a simplified version of the NAPSI which only assesses the least and the worst involved nail of both hands or both feet respectively. Thus, the NAPPA-CLIN scores for hands or feet range from 0 to 16. A higher score indicates a worse involvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56[98]	58[99]		
Units: units on a scale				
arithmetic mean (standard error)	-0.4 (± 0.51)	-2.7 (± 0.51)		

Notes:

[98] - ITT analysis set

[99] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.6
upper limit	-1.1
Variability estimate	Standard error of the mean
Dispersion value	0.63

Secondary: NAPPA-CLIN Total Score: Change From Baseline to Week 24

End point title	NAPPA-CLIN Total Score: Change From Baseline to Week 24

End point description:

The NAPPA-CLIN is an investigator assessment used to assess the severity of nail matrix psoriasis (leukonychia, red spots, dots, nail plate crumbling) and psoriasis of the nail bed (oil drop, splinter haemorrhage, subungual hyperkeratosis, onycholysis). NAPPA-CLIN has been developed from the NAPSI score, a nail psoriasis-specific score, which in its original version comprises the assessment of matrix

and nail bed involvement in every finger and toe by 2 criteria for each nail. The NAPPA-CLIN is a simplified version of the NAPSI which only assesses the least and the worst involved nail of both hands or both feet respectively. Thus, the NAPPA-CLIN scores for hands or feet range from 0 to 16. A higher score indicates a worse involvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56[100]	58[101]		
Units: units on a scale				
arithmetic mean (standard error)	-0.7 (± 0.53)	-3.7 (± 0.54)		

Notes:

[100] - ITT analysis set

[101] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.3
upper limit	-1.6
Variability estimate	Standard error of the mean
Dispersion value	0.66

Secondary: Palmoplantar Psoriasis Severity Index (PPASI): Change From Baseline to Week 16

End point title	Palmoplantar Psoriasis Severity Index (PPASI): Change From Baseline to Week 16

End point description:

The PPASI is an assessment by the investigator that provides a numeric scoring for psoriasis affecting the hands and feet with scores ranging from 0 to 72. It is a linear combination of percent of surface area of palms and soles that are affected and the severity of erythema, induration, and desquamation. The higher the score, the greater the severity of psoriasis symptoms. LOCF imputation was used for missing

data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56[102]	60[103]		
Units: units on a scale				
arithmetic mean (standard error)	-0.76 (± 0.251)	-1.04 (± 0.249)		

Notes:

[102] - ITT analysis set

[103] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.352
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.9
upper limit	0.32
Variability estimate	Standard error of the mean
Dispersion value	0.307

Secondary: PPASI: Change From Baseline to Week 24

End point title	PPASI: Change From Baseline to Week 24

End point description:

The PPASI is an assessment by the investigator that provides a numeric scoring for psoriasis affecting the hands and feet with scores ranging from 0 to 72. It is a linear combination of percent of surface area of palms and soles that are affected and the severity of erythema, induration, and desquamation. The higher the score, the greater the severity of psoriasis symptoms. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56[104]	60[105]		
Units: units on a scale				
arithmetic mean (standard error)	-0.87 (± 0.242)	-1.17 (± 0.240)		

Notes:

[104] - ITT analysis set

[105] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.315
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.88
upper limit	0.29
Variability estimate	Standard error of the mean
Dispersion value	0.296

Secondary: Body Surface Area (BSA) Affected by Psoriasis: Change From Baseline to Week 4

End point title	Body Surface Area (BSA) Affected by Psoriasis: Change From Baseline to Week 4

End point description:

BSA affected by psoriasis was measured by the physician selecting the participants right or left hand as the measuring device. For purposes of clinical estimation, the total surface of the palm plus 5 digits was to be assumed to be approximately equivalent to 1% BSA. Measurement of the total area of involvement by the physician was aided by imagining if scattered plaques were moved so that they were next to each other and then estimated the total area involved. A decrease in BSA affected by psoriasis indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 4

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58[106]	60[107]		
Units: percentage estimated body surface area				
least squares mean (standard error)	-0.3 (± 0.86)	-5.2 (± 0.86)		

Notes:

[106] - ITT Analysis Set

[107] - ITT Analysis Set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-4.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.9
upper limit	-2.7
Variability estimate	Standard error of the mean
Dispersion value	1.06

Secondary: BSA Affected by Psoriasis: Change From Baseline to Week 8

End point title	BSA Affected by Psoriasis: Change From Baseline to Week 8

End point description:

BSA affected by psoriasis was measured by the physician selecting the participant's right or left hand as the measuring device. For purposes of clinical estimation, the total surface of the palm plus 5 digits was to be assumed to be approximately equivalent to 1% BSA. Measurement of the total area of involvement by the physician was aided by imagining if scattered plaques were moved so that they were next to each other and then estimated the total area involved. A decrease in BSA affected by psoriasis indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 8

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58[108]	60[109]		
Units: percentage estimated body surface area				
least squares mean (standard error)	-3.5 (± 1.33)	-12.8 (± 1.33)		

Notes:

[108] - ITT Analysis Set

[109] - ITT Analysis Set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-9.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.6
upper limit	-6.1
Variability estimate	Standard error of the mean
Dispersion value	1.64

Secondary: BSA Affected by Psoriasis: Change From Baseline to Week 12

End point title	BSA Affected by Psoriasis: Change From Baseline to Week 12

End point description:

BSA affected by psoriasis was measured by the physician selecting the participant's right or left hand as the measuring device. For purposes of clinical estimation, the total surface of the palm plus 5 digits was to be assumed to be approximately equivalent to 1% BSA. Measurement of the total area of involvement by the physician was aided by imagining if scattered plaques were moved so that they were next to each other and then estimated the total area involved. A decrease in BSA affected by psoriasis indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58[110]	60[111]		
Units: percentage estimated body surface area				
least squares mean (standard error)	-6.0 (± 1.22)	-16.2 (± 1.23)		

Notes:

[110] - ITT Analysis Set

[111] - ITT Analysis Set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-10.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.2
upper limit	-7.2
Variability estimate	Standard error of the mean
Dispersion value	1.51

Secondary: BSA Affected by Psoriasis: Change From Baseline to Week 16

End point title	BSA Affected by Psoriasis: Change From Baseline to Week 16

End point description:

BSA affected by psoriasis was measured by the physician selecting the participants right or left hand as the measuring device. For purposes of clinical estimation, the total surface of the palm plus 5 digits was to be assumed to be approximately equivalent to 1% BSA. Measurement of the total area of involvement by the physician was aided by imagining if scattered plaques were moved so that they were next to each other and then estimated the total area involved. A decrease in BSA affected by psoriasis indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58[112]	60[113]		
Units: percentage estimated body surface area				
least squares mean (standard error)	-8.2 (± 1.22)	-18.0 (± 1.22)		

Notes:

[112] - ITT Analysis Set

[113] - ITT Analysis Set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-9.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.8
upper limit	-6.8
Variability estimate	Standard error of the mean
Dispersion value	1.51

Secondary: BSA Affected by Psoriasis: Change From Baseline to Week 20

End point title	BSA Affected by Psoriasis: Change From Baseline to Week 20

End point description:

BSA affected by psoriasis was measured by the physician selecting the participant's right or left hand as the measuring device. For purposes of clinical estimation, the total surface of the palm plus 5 digits was to be assumed to be approximately equivalent to 1% BSA. Measurement of the total area of involvement by the physician was aided by imagining if scattered plaques were moved so that they were next to each other and then estimated the total area involved. A decrease in BSA affected by psoriasis indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 20

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58[114]	60[115]		
Units: percentage estimated body surface area				
least squares mean (standard error)	-9.7 (± 1.13)	-19.3 (± 1.13)		

Notes:

[114] - ITT Analysis Set

[115] - ITT Analysis Set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-9.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.4
upper limit	-6.8
Variability estimate	Standard error of the mean
Dispersion value	1.39

Secondary: BSA Affected by Psoriasis: Change From Baseline to Week 24

End point title	BSA Affected by Psoriasis: Change From Baseline to Week 24

End point description:

BSA affected by psoriasis was measured by the physician selecting the participant's right or left hand as the measuring device. For purposes of clinical estimation, the total surface of the palm plus 5 digits was to be assumed to be approximately equivalent to 1% BSA. Measurement of the total area of involvement by the physician was aided by imagining if scattered plaques were moved so that they were next to each other and then estimated the total area involved. A decrease in BSA affected by psoriasis indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	58[116]	60[117]		
Units: percentage estimated body surface area				
least squares mean (standard error)	-9.8 (± 1.19)	-19.8 (± 1.19)		

Notes:

[116] - ITT Analysis Set

[117] - ITT Analysis Set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	118
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-10
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.9
upper limit	-7.1
Variability estimate	Standard error of the mean
Dispersion value	1.47

Secondary: Short Form Health Survey 36, Version 2 (SF-36 V2) Physical Component Summary (PCS) Score: Change From Baseline to Week 16

End point title	Short Form Health Survey 36, Version 2 (SF-36 V2) Physical Component Summary (PCS) Score: Change From Baseline to Week 16

End point description:

The SF-36 V2 Health determined participants' overall quality of life by assessing 1) limitations in physical functioning due to health problems; 2) limitations in usual role because of physical health problems; 3) bodily pain; 4) general health perceptions; 5) vitality; 6) limitations in social functioning because of physical or emotional problems; 7) limitations in usual role due to emotional problems; and 8) general mental health. Items 1-4 comprise the physical component of the SF-36. Scores on each item were summed and averaged (PCS Score; range = 0-100); a positive change from Baseline indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55[118]	59[119]		
Units: units on a scale				
least squares mean (standard error)	2.87 (± 1.153)	7.36 (± 1.135)		

Notes:

[118] - ITT analysis set

[119] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.002
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	4.49
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.74
upper limit	7.23
Variability estimate	Standard error of the mean
Dispersion value	1.385

Secondary: SF-36 V2 PCS Score: Change From Baseline to Week 24

End point title	SF-36 V2 PCS Score: Change From Baseline to Week 24

End point description:

The SF-36 V2 Health determined participants' overall quality of life by assessing 1) limitations in physical functioning due to health problems; 2) limitations in usual role because of physical health problems; 3) bodily pain; 4) general health perceptions; 5) vitality; 6) limitations in social functioning because of physical or emotional problems; 7) limitations in usual role due to emotional problems; and 8) general mental health. Items 1-4 comprise the physical component of the SF-36. Scores on each item were summed and averaged (PCS Score; range = 0-100); a positive change from Baseline indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55[120]	60[121]		
Units: units on a scale				
least squares mean (standard error)	3.68 (± 1.104)	8.31 (± 1.083)		

Notes:

[120] - ITT analysis set

[121] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	4.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.01
upper limit	7.25
Variability estimate	Standard error of the mean
Dispersion value	1.322

Secondary: SF-36 V2 Mental Component Summary (MCS) Score: Change From Baseline: to Week 16

End point title	SF-36 V2 Mental Component Summary (MCS) Score: Change From Baseline: to Week 16

End point description:

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

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55[122]	59[123]		
Units: units on a scale				
least squares mean (standard error)	4.20 (± 1.493)	10.86 (± 1.472)		

Notes:

[122] - ITT analysis set

[123] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using
ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	6.66
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.11
upper limit	10.2
Variability estimate	Standard error of the mean
Dispersion value	1.787

Secondary: SF-36 V2 MCS Score: Change From Baseline to Week 24

End point title	SF-36 V2 MCS Score: Change From Baseline to Week 24

End point description:

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

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55[124]	60[125]		
Units: units on a scale				
least squares mean (standard error)	3.56 (± 1.494)	11.41 (± 1.470)		

Notes:

[124] - ITT analysis set

[125] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	7.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	4.31
upper limit	11.38
Variability estimate	Standard error of the mean
Dispersion value	1.784

Secondary: Patient's Global Assessment (PtGA): Change From Baseline to Week 16

End point title	Patient's Global Assessment (PtGA): Change From Baseline to Week 16

End point description:

The PtGA is a patient-reported outcome instrument to assess the patient's assessment of disease severity. This self-reported measure is used to assess disease activity using a 4-point scale where a higher score indicates a higher level of disease activity. Disease activity is assessed from 0 ("complete disease control") to 3 ("uncontrolled disease"). LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56[126]	59[127]		
Units: units on a scale				
least squares mean (standard error)	-1.0 (± 0.11)	-1.9 (± 0.11)		

Notes:

[126] - ITT analysis set

[127] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.2
upper limit	-0.7
Variability estimate	Standard error of the mean
Dispersion value	0.13

Secondary: PtGA: Change From Baseline to Week 24

End point title	PtGA: Change From Baseline to Week 24

End point description:

The PtGA is a patient-reported outcome instrument to assess the patient's assessment of disease severity. This self-reported measure is used to assess disease activity using a 4-point scale where a higher score indicates a higher level of disease activity. Disease activity is assessed from 0 ("complete disease control") to 3 ("uncontrolled disease"). LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56[128]	60[129]		
Units: units on a scale				
least squares mean (standard error)	-1.0 (± 0.11)	-2.0 (± 0.11)		

Notes:

[128] - ITT analysis set

[129] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using
ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.3
upper limit	-0.8
Variability estimate	Standard error of the mean
Dispersion value	0.13

Secondary: Hospital Anxiety and Depression Scale (HADS) Total Score-Anxiety: Change From Baseline to Week 16

End point title	Hospital Anxiety and Depression Scale (HADS) Total Score-Anxiety: Change From Baseline to Week 16

End point description:

The HADS was a patient-reported questionnaire used to assess the level of anxiety and depression in the selling of a hospital medical outpatient clinic. The anxiety and depression subscales each have a range from 0-21, higher scores indicated higher levels of anxiety and depression, respectively. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55[130]	59[131]		
Units: units on a scale				
least squares mean (standard error)	-2.2 (± 0.48)	-4.3 (± 0.47)		

Notes:

[130] - ITT analysis set

[131] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.2
upper limit	-0.9
Variability estimate	Standard error of the mean
Dispersion value	0.57

Secondary: HADS Total Score-Anxiety: Change From Baseline to Week 24

End point title	HADS Total Score-Anxiety: Change From Baseline to Week 24

End point description:

The HADS was a patient-reported questionnaire used to assess the level of anxiety and depression in the setting of a hospital medical outpatient clinic. The anxiety and depression subscales each have a range from 0-21, higher scores indicated higher levels of anxiety and depression, respectively. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55[132]	60[133]		
Units: units on a scale				
least squares mean (standard error)	-1.8 (± 0.49)	-4.0 (± 0.48)		

Notes:
[132] - ITT analysis set
[133] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.	
Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5
upper limit	-1.1
Variability estimate	Standard error of the mean
Dispersion value	0.59

Secondary: HADS Total Score-Depression: Change From Baseline to Week 16

End point title	HADS Total Score-Depression: Change From Baseline to Week 16
End point description:	
The HADS was a patient-reported questionnaire used to assess the level of anxiety and depression in the setting of a hospital medical outpatient clinic. The anxiety and depression subscales each have a range from 0-21, higher scores indicated higher levels of anxiety and depression, respectively. LOCF imputation was used for missing data.	
End point type	Secondary
End point timeframe:	
Baseline, Week 16	

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55[134]	59[135]		
Units: units on a scale				
least squares mean (standard error)	-1.8 (± 0.50)	-4.9 (± 0.50)		

Notes:
[134] - ITT analysis set
[135] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.3
upper limit	-1.9
Variability estimate	Standard error of the mean
Dispersion value	0.61

Secondary: HADS Total Score-Depression: Change From Baseline to Week 24

End point title	HADS Total Score-Depression: Change From Baseline to Week 24

End point description:

The HADS was a patient-reported questionnaire used to assess the level of anxiety and depression in the setting of a hospital medical outpatient clinic. The anxiety and depression subscales each have a range from 0-21, higher scores indicated higher levels of anxiety and depression, respectively.. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55[136]	60[137]		
Units: units on a scale				
least squares mean (standard error)	-1.7 (± 0.54)	-4.8 (± 0.53)		

Notes:

[136] - ITT analysis set

[137] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.4
upper limit	-1.8
Variability estimate	Standard error of the mean
Dispersion value	0.65

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

End point title	Percentage of Participants Achieving 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. A 5-point change from baseline is considered a clinically important difference. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[138]	60[139]		
Units: Percentage of Participants				
number (not applicable)	10.0	48.3		

Notes:

[138] - ITT analysis set

[139] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	38.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	23.6
upper limit	53.1

Secondary: Percentage of Participants Achieving DLQI Score of 0 or 1 at Week 24

End point title	Percentage of Participants Achieving DLQI Score of 0 or 1 at Week 24

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. A 5-point change from baseline is considered a clinically important difference. NRI was used for missing data.

End point type	Secondary

End point timeframe:

Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	60[140]	60[141]		
Units: Percentage of Participants				
number (not applicable)	10.0	66.7		

Notes:

[140] - ITT analysis set

[141] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-value was calculated from the CMH test adjusted for strata (prior phototherapy [yes/no]).

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	Cochran-Mantel-Haenszel
Parameter estimate	Adjusted percentage difference
Point estimate	56.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	42.7
upper limit	70.9

Secondary: DLQI Total Score: Change From Baseline to Week 16

End point title	DLQI Total Score: Change From Baseline to 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. A 5-point change from baseline is considered a clinically important difference. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56[142]	59[143]		
Units: units on a scale				
least squares mean (standard error)	-9.7 (± 0.94)	-17.0 (± 0.94)		

Notes:

[142] - ITT analysis set

[143] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with prior phototherapy (yes/no), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-7.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.6
upper limit	-5.1
Variability estimate	Standard error of the mean
Dispersion value	1.15

Secondary: DLQI: Change From Baseline to Week 24

End point title	DLQI: Change From Baseline to Week 24

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. A 5-point change from baseline is considered a clinically important difference. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56[144]	60[145]		
Units: units on a scale				
least squares mean (standard error)	-11.2 (± 0.87)	-18.8 (± 0.87)		

Notes:

[144] - ITT analysis set

[145] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-7.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.7
upper limit	-5.5
Variability estimate	Standard error of the mean
Dispersion value	1.06

Secondary: Psoriasis Scalp Severity Index (PSSI): Change From Baseline at Week 16

End point title	Psoriasis Scalp Severity Index (PSSI): Change From Baseline at Week 16

End point description:

The physician assessed the severity of scalp psoriasis using the PSSI, which consists of an assessment of erythema, induration, and desquamation on a scale from 0 (none) to 4 (very severe) and the percentage of scalp involved on a scale from 0 (0% of scalp involved) to 6 (90-100% of scalp involved). The composite score is calculated as the sum of symptom scores multiplied by the score for the area of scalp involved. The PSSI ranges from 0 (best) to 72 (worst). A negative change from Baseline indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56[146]	60[147]		
Units: units on a scale				
least squares mean (standard error)	-14.6 (± 1.01)	-21.2 (± 1.01)		

Notes:

[146] - ITT analysis set

[147] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-6.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9
upper limit	-4.1
Variability estimate	Standard error of the mean
Dispersion value	1.23

Secondary: PSSI: Change From Baseline at Week 24

End point title	PSSI: Change From Baseline at Week 24

End point description:

The physician assessed the severity of scalp psoriasis using the PSSI, which consists of an assessment of erythema, induration, and desquamation on a scale from 0 (none) to 4 (very severe) and the percentage of scalp involved on a scale from 0 (0% of scalp involved) to 6 (90-100% of scalp involved). The composite score is calculated as the sum of symptom scores multiplied by the score for the area of scalp involved. The PSSI ranges from 0 (best) to 72 (worst). A negative change from Baseline indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56[148]	60[149]		
Units: units on a scale				
least squares mean (standard error)	-13.9 (± 1.25)	-22.0 (± 1.25)		

Notes:

[148] - ITT analysis set

[149] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	116
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-8.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.1
upper limit	-5
Variability estimate	Standard error of the mean
Dispersion value	1.53

Secondary: European Quality of Life 5 Dimensions (EQ-5D-5L) Total Score: Change From Baseline to Week 16

End point title	European Quality of Life 5 Dimensions (EQ-5D-5L) Total Score: Change From Baseline to Week 16

End point description:

The EQ-5D-5L is a standardized non-disease specific instrument for describing and valuing health-related quality of life. The EQ-5D-5L descriptive system comprises 5 dimensions of health (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) to describe the subject's current health state. Each dimension comprises 5 levels with corresponding numeric scores, where 1 indicates no problems, and 5 indicates extreme problems. A unique EQ-50-5L health state is defined by combining the numeric level scores for each of the 5 dimensions and the total score is normalized from -0.594 to 1.000, with higher scores representing a better health state. An increase in the EQ-5D-5L total score indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55[150]	58[151]		
Units: units on a scale				
least squares mean (standard error)	0.083 (± 0.0179)	0.171 (± 0.0176)		

Notes:

[150] - ITT analysis set

[151] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	0.087
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.045
upper limit	0.13
Variability estimate	Standard error of the mean
Dispersion value	0.0215

Secondary: EQ-5D-5L Total Score: Change From Baseline to Week 24

End point title	EQ-5D-5L Total Score: Change From Baseline to Week 24

End point description:

The EQ-5D-5L is a standardized non-disease specific instrument for describing and valuing health-related quality of life. The EQ-5D-5L descriptive system comprises 5 dimensions of health (mobility, self -care, usual activities, pain/discomfort, and anxiety/depression) to describe the subject's current health state. Each dimension comprises 5 levels with corresponding numeric scores, where 1 indicates no problems, and 5 indicates extreme problems. A unique EQ-5D-5L health state is defined by combining the numeric level scores for each of the 5 dimensions and the total score is normalized from -0.594 to 1.000, with higher scores representing a better health state. An increase in the EQ-5D-5L total score indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55[152]	60[153]		
Units: units on a scale				
least squares mean (standard error)	0.106 (± 0.0155)	0.165 (± 0.0152)		

Notes:

[152] - ITT analysis set

[153] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.002
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	0.059
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.022
upper limit	0.096
Variability estimate	Standard error of the mean
Dispersion value	0.0186

Secondary: EQ-5D-5L Visual Analog Scale (VAS): Change From Baseline to Week 16

End point title	EQ-5D-5L Visual Analog Scale (VAS): Change From Baseline to Week 16

End point description:

The EQ-5D-5L is a standardized non-disease specific instrument for describing and valuing health-related quality of life. The EQ-5D-5L VAS records the participant's self-rated health on a vertical visual analogue scale numbered from 100 (best health imagined) to 0 (worst health imagined). The VAS score from the scale is then entered as a number by the participant. This can be used as a quantitative measure of health outcome that reflects the participant's own judgement. An increase in the EQ-5D-5L VAS score indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55[154]	58[155]		
Units: units on a scale				
least squares mean (standard error)	11.0 (± 2.32)	26.0 (± 2.28)		

Notes:

[154] - ITT analysis set

[155] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	113
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	14.9
Confidence interval	
level	95 %
sides	2-sided
lower limit	9.4
upper limit	20.5
Variability estimate	Standard error of the mean
Dispersion value	2.8

Secondary: EQ-5D-5L VAS: Change From Baseline to Week 24

End point title	EQ-5D-5L VAS: Change From Baseline to Week 24

End point description:

The EQ-5D-5L is a standardized non-disease specific instrument for describing and valuing health-related quality of life. The EQ-5D-5L VAS records the participant's self-rated health on a vertical visual analogue scale numbered from 100 (best health imagined) to 0 (worst health imagined). The VAS score from the scale is then entered as a number by the participant. This can be used as a quantitative measure of health outcome that reflects the participant's own judgement. An increase in the EQ-5D-5L VAS score indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	55[156]	60[157]		
Units: units on a scale				
least squares mean (standard error)	11.6 (± 2.29)	28.4 (± 2.23)		

Notes:

[156] - ITT analysis set

[157] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and treatment in the model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	16.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	11.4
upper limit	22.2
Variability estimate	Standard error of the mean
Dispersion value	2.73

Secondary: Nail Psoriasis Severity Index (NAPSI): Change From Baseline to Week 16

End point title	Nail Psoriasis Severity Index (NAPSI): Change From Baseline to Week 16

End point description:

The NAPSI score is calculated by summing the scores of all the nails which for each nail are the sum of the nail matrix score and nail bed score. Each of these is scored as 0=none, 1=present in 1/4 nail, 2=present in 2/4 nail, 3=present in 3/4 nail, 4=present in 4/4 nail. Each nail has a matrix score (0-4) and a nail bed score (0-4). The total nail score is the sum of those 2 (nail matrix and nail bed) individual scores (0-8). The sum of the total score of all involved fingernails is then the total NAPSI score. The NAPSI score is calculated only if all questions in the case report form are completed. A negative change from Baseline indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56[158]	58[159]		
Units: units on a scale				
least squares mean (standard error)	-2.2 (± 2.13)	-13.6 (± 2.14)		

Notes:

[158] - ITT analysis set

[159] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and the treatment in this model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-11.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.6
upper limit	-6.2
Variability estimate	Standard error of the mean
Dispersion value	2.64

Secondary: NAPSI: Change From Baseline to Week 24

End point title	NAPSI: Change From Baseline to Week 24

End point description:

The NAPSI score is calculated by summing the scores of all the nails which for each nail are the sum of the nail matrix score and nail bed score. Each of these is scored as 0=none, 1=present in 1/4 nail, 2=present in 2/4 nail, 3=present in 3/4 nail, 4=present in 4/4 nail. Each nail has a matrix score (0-4) and a nail bed score (0-4). The total nail score is the sum of those 2 (nail matrix and nail bed) individual scores (0-8). The sum of the total score of all involved fingernails is then the total NAPSI score. The NAPSI score is calculated only if all questions in the case report form are completed. A negative change from Baseline indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	56[160]	58[161]		
Units: units on a scale				
least squares mean (standard error)	-4.4 (± 2.18)	-18.1 (± 2.19)		

Notes:

[160] - ITT analysis set

[161] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and the treatment in this model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-13.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.1
upper limit	-8.4
Variability estimate	Standard error of the mean
Dispersion value	2.7

Secondary: Participants With Baseline NAPSI >0: Change From Baseline to Week 16

End point title	Participants With Baseline NAPSI >0: Change From Baseline to Week 16

End point description:

The NAPSI score is calculated by summing the scores of all the nails which for each nail are the sum of the nail matrix score and nail bed score. Each of these is scored as 0=none, 1=present in 1/4 nail, 2=present in 2/4 nail, 3=present in 3/4 nail, 4=present in 4/4 nail. The NAPSI score is calculated only if all questions in the case report form are completed. A negative change from Baseline indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 16

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33[162]	42[163]		
Units: units on a scale				
least squares mean (standard error)	-4.2 (± 3.11)	-21.4 (± 2.86)		

Notes:

[162] - ITT analysis set

[163] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and the treatment in this model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-17.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.8
upper limit	-9.8
Variability estimate	Standard error of the mean
Dispersion value	3.75

Secondary: Participants With Baseline NAPSI >0: Change From Baseline to Week 24

End point title	Participants With Baseline NAPSI >0: Change From Baseline to Week 24

End point description:

The NAPSI score is calculated by summing the scores of all the nails which for each nail are the sum of the nail matrix score and nail bed score. Each of these is scored as 0=none, 1=present in 1/4 nail, 2=present in 2/4 nail, 3=present in 3/4 nail, 4=present in 4/4 nail. The NAPSI score is calculated only if all questions in the case report form are completed. A negative change from Baseline indicates improvement. LOCF imputation was used for missing data.

End point type	Secondary

End point timeframe:

Baseline, Week 24

End point values	Fumaderm	Risankizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	33[164]	42[165]		
Units: units on a scale				
least squares mean (standard error)	-6.0 (± 3.03)	-27.5 (± 2.79)		

Notes:

[164] - ITT analysis set

[165] - ITT analysis set

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

P-values were calculated using ANCOVA with strata (phototherapy [yes/no]), baseline value, and the treatment in this model.

Comparison groups	Fumaderm v Risankizumab
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	other
P-value	< 0.001
Method	ANCOVA
Parameter estimate	Least Squares Mean Difference
Point estimate	-21.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.8
upper limit	-14.2
Variability estimate	Standard error of the mean
Dispersion value	3.66

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 risankizumab (up to 31 weeks) or until 1 week after the last dose of Fumaderm (up to 25 weeks)

Adverse event reporting additional description:

Safety analysis set included all participants enrolled in the study and who received at least 1 dose of study drug (N = 117).

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	21.0

Reporting groups

Reporting group title	Fumaderm

Reporting group description:

Participants randomized to receive open-label Fumaderm Initial once daily from Week 0 to Week 2 and Fumaderm once daily from Week 3 to Week 24.

Reporting group title	Risankizumab

Reporting group description:

Participants randomized to receive open-label risankizumab 150 mg at Weeks 0, 4, and 16.

Serious adverse events	Fumaderm	Risankizumab	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 57 (3.51%)	1 / 60 (1.67%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events			
Respiratory, thoracic and mediastinal disorders			
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 57 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			

Influenza			
subjects affected / exposed	0 / 57 (0.00%)	1 / 60 (1.67%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Obesity			
subjects affected / exposed	1 / 57 (1.75%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Fumaderm	Risankizumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	54 / 57 (94.74%)	45 / 60 (75.00%)	
Vascular disorders			
Flushing			
subjects affected / exposed	23 / 57 (40.35%)	0 / 60 (0.00%)	
occurrences (all)	28	0	
Hypertension			
subjects affected / exposed	2 / 57 (3.51%)	4 / 60 (6.67%)	
occurrences (all)	2	4	
Nervous system disorders			
Dizziness			
subjects affected / exposed	4 / 57 (7.02%)	0 / 60 (0.00%)	
occurrences (all)	4	0	
Headache			
subjects affected / exposed	7 / 57 (12.28%)	5 / 60 (8.33%)	
occurrences (all)	15	6	
Migraine			
subjects affected / exposed	3 / 57 (5.26%)	0 / 60 (0.00%)	
occurrences (all)	3	0	
Blood and lymphatic system disorders			
Lymphopenia			
subjects affected / exposed	8 / 57 (14.04%)	0 / 60 (0.00%)	
occurrences (all)	9	0	
Gastrointestinal disorders			

Abdominal pain			
subjects affected / exposed	11 / 57 (19.30%)	0 / 60 (0.00%)	
occurrences (all)	13	0	
Abdominal pain upper			
subjects affected / exposed	26 / 57 (45.61%)	1 / 60 (1.67%)	
occurrences (all)	34	1	
Diarrhoea			
subjects affected / exposed	32 / 57 (56.14%)	4 / 60 (6.67%)	
occurrences (all)	57	4	
Nausea			
subjects affected / exposed	9 / 57 (15.79%)	0 / 60 (0.00%)	
occurrences (all)	12	0	
Toothache			
subjects affected / exposed	0 / 57 (0.00%)	3 / 60 (5.00%)	
occurrences (all)	0	4	
Respiratory, thoracic and mediastinal disorders			
Oropharyngeal pain			
subjects affected / exposed	2 / 57 (3.51%)	5 / 60 (8.33%)	
occurrences (all)	2	5	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	5 / 57 (8.77%)	2 / 60 (3.33%)	
occurrences (all)	8	2	
Skin burning sensation			
subjects affected / exposed	3 / 57 (5.26%)	0 / 60 (0.00%)	
occurrences (all)	3	0	
Urticaria			
subjects affected / exposed	4 / 57 (7.02%)	0 / 60 (0.00%)	
occurrences (all)	4	0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	3 / 57 (5.26%)	2 / 60 (3.33%)	
occurrences (all)	3	2	
Pain in extremity			
subjects affected / exposed	3 / 57 (5.26%)	2 / 60 (3.33%)	
occurrences (all)	3	2	

Infections and infestations			
Bronchitis			
subjects affected / exposed	3 / 57 (5.26%)	3 / 60 (5.00%)	
occurrences (all)	3	3	
Influenza			
subjects affected / exposed	3 / 57 (5.26%)	4 / 60 (6.67%)	
occurrences (all)	3	4	
Nasopharyngitis			
subjects affected / exposed	26 / 57 (45.61%)	35 / 60 (58.33%)	
occurrences (all)	32	47	
Rhinitis			
subjects affected / exposed	3 / 57 (5.26%)	3 / 60 (5.00%)	
occurrences (all)	4	4	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 March 2017	Revisions included changing the pharmacokinetic and anti-drug antibody sample collection from plasma to serum as the bioanalysis method utilizes serum instead of plasma. The study schematic was updated to reflect timing of dosing of FUMADERM® INITIAL and FUMADERM®.
05 July 2017	Revisions included updating the number of study sites from approximately 20 to approximately 25 sites, clarifying that the duration of treatment is 16 weeks for risankizumab vs 24 weeks for FUMADERM®. Changes made to Exclusion Criteria included changing language of complete blood count and microalbuminuria and specifying that the relevant values are from Screening. Exclusion Criterion 14 was modified to make the language closer to medical practice and closely control blood pressure to prevent the risk of renal insufficiency associated with FUMADERM®. Prior phototherapy was modified, as UV-therapy and balneotherapy are considered systemic therapy when associated with UV-sensitizing agents and are not considered systemic therapy when they are not associated with UV-sensitizing agents. A cap for stratum of participants with prior phototherapy resulted in changes regarding stratification of randomization and corresponding analyses. Blood pressure measurement technique was provided to improve screening of the participants who will request a consultation to explore elevated blood pressure values at the Screening visit. Study Procedures clarification was made that differential white blood cell count should be transferred as absolute (not relative) values for consistency within the protocol. A slow increase in FUMADERM® INITIAL or FUMADERM® dose or a return to FUMADERM® INITIAL after initiation of FUMADERM® clarification was added in order to increase the retention of participants randomized to FUMADERM®. For NAPPA-CLIN: specifying that use of artificial nails and/or nail polish should be avoided for participants with nail psoriasis to optimize nail assessment and to record the severity of nail psoriasis for all fingers and toes in the e-CRF instead of only the worst affected one and the least affected one. The Rheumatology Common Toxicity Criteria v.2.0 was removed as this is no longer used in the risankizumab program.

28 November 2017	Revisions included a change to Prohibited Therapy: moving the time point from which phototherapy (e.g., UVA, UVB, any other UV-therapy or balneotherapy) not-associated with systemic UV-sensitizing agents, topical treatment for psoriasis or any other skin condition (e.g., corticosteroids,c vitamin D analogues, vitamin A analogues, pimecrolimus, retinoids, salicylvaseline, salicylic acid, lactic acid, tacrolimus, tar, urea, andanthralin, α-hydroxy acid, fruit acids) are prohibited from 14 days prior to Screening to 14 days prior to Baseline. The half-life of those therapies is short and no interaction with study medication is to be expected if they are discontinued 14 weeks before 1st dose of study medication, i.e., 14 days before Baseline (Day 1, Week 0). FUMADERM® INITIAL and FUMADERM® Subject Diary: Clarified that the subject diary dispensed at every visit, starting at the Week 0/Baseline Visit rather than at the Screening Visit, and training will occur at the Week 0/Baseline Visit. Discontinuation of Subjects on FUMADERM®: Restriction of the discontinuation of the participants on FUMADERM® for rash/flush to those with severe rash/flush to be consistent with clinical practice where only severe persistent rash/flush leads to discontinuation of patients from FUMADERM®. FUMADERM® label does not request discontinuation of FUMADERM® treatment for all adverse events of rash/flush, but says: "... severe forms (of rash/flush) may lead to (FUMADERM®) treatment discontinuation." Treatments Administered: "Additional dosing instructions will be provided separately from this protocol" was removed as risankizumab administered by site personnel only, so no additional instructions on administering SC injection required. Prohibition of artificial nail and/or nail polish to all participants instead of participants with nail psoriasis only changed as analysis of efficacy on nail psoriasis planned on all participants regardless of concomitant nail psoriasis.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported