Clinical trial results:
An international, multicentre, open label, interventional phase IV clinical study to investigate the efficacy and safety of tildrakizumab 100 mg in patients with moderate-to-severe chronic plaque psoriasis and its impact on their quality of life

Summary

EudraCT number	2019-002804-42
Trial protocol	ES IT
Global end of trial date	25 October 2021

Results information

Result version number	v1 (current)
This version publication date	15 December 2022
First version publication date	15 December 2022

Trial information

Trial identification

Sponsor protocol code	M-14745-42

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04229836
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Almirall S. A.
Sponsor organisation address	Ronda General Mitre, 151, Barcelona, Spain, 08022
Public contact	Internat. Clinical Trial Manager, Almirall SA, +34 93 291 30 00, gco@almirall.com
Scientific contact	Internat. Clinical Trial Manager, Almirall SA, +34 93 291 30 00, gco@almirall.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	25 October 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	25 October 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to assess the efficacy of tildrakizumab 100 milligram (mg) and impact of tildrakizumab on Health-Related Quality of Life (HRQoL) (assessed by Dermatology Life Quality Index [DLQI] score) in subjects with moderate-to-severe chronic plaque psoriasis at Week 24.

Protection of trial subjects:

The study was conducted in compliance with the protocol, regulatory requirements, good clinical practice (GCP) and the ethical principles of the latest revision of the Declaration of Helsinki as adopted by the World Medical Association.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	17 December 2019
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	Spain: 87
Country: Number of subjects enrolled	Italy: 90
Worldwide total number of subjects	177
EEA total number of subjects	177

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)	167
From 65 to 84 years	10
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted at 40 centers in Italy and Spain from 17 December 2019 to 25 October 2021.

Pre-assignment

Screening details:

A total of 198 subjects were screened, of which 21 were screen failures and 177 subjects were enrolled and treated in the study.

Period 1

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

Arms

Arm title	Tildrakizumab

Arm description:

Subjects received subcutaneous (SC) injection of tildrakizumab 100 mg at Week 0 (Day 1), Week 4, and Week 16.

Arm type	Experimental
Investigational medicinal product name	Tildrakizumab
Investigational medicinal product code	
Other name	Ilumetri®
Pharmaceutical forms	Solution for infusion in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Subject received tildrakizumab 100 mg SC injection at Week 0, (Day 1), Week 4, and Week 16.

Number of subjects in period 1	Tildrakizumab
Started	177
Completed	171
Not completed	6
Adverse event, non-fatal	2
Technical Problem	1
Lost to follow-up	1
Lack of efficacy	1
Protocol deviation	1

Baseline characteristics

Reporting groups	
Reporting group title	Tildrakizumab
Reporting group description:	
Subjects received subcutaneous (SC) injection of tildrakizumab 100 mg at Week 0 (Day 1), Week 4, and Week 16.	

Reporting group values	Tildrakizumab	Total	
Number of subjects	177	177	
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	44.62		
standard deviation	± 12.429	-	
Gender categorical Units: Subjects			
Female	54	54	
Male	123	123	
Ethnicity Units: Subjects			
Hispanic or Latino	4	4	
Not Hispanic or Latino	172	172	
Not reported	0	0	
Unknown	1	1	
Race Units: Subjects			
American Indian or Alaska Native	1	1	
Asian	1	1	
Black or African American	0	0	
Native Hawaiian or other Pacific Islander	0	0	
White	175	175	
Other	0	0	

End points

End points reporting groups

Reporting group title	Tildrakizumab

Reporting group description:

Subjects received subcutaneous (SC) injection of tildrakizumab 100 mg at Week 0 (Day 1), Week 4, and Week 16.

Primary: Absolute Psoriasis Area and Severity Index (PASI) Score at Week 24

End point title	Absolute Psoriasis Area and Severity Index (PASI) Score at Week 24[1]

End point description:

PASI was a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness) and scaling on a scale range from 0 (no symptoms) to 4 (very marked), together with the percentage (%) of the area affected, rated on a scale from 0 (0%) to 6 (90-100%). PASI scoring was performed at four body areas, the head, arms, trunk, and legs. The PASI score ranged from 0 (no psoriasis) to 72 (the most severe disease). Intent-to-treat (ITT) population included all subjects who received at least one dose of the study medication and had atleast one baseline efficacy/Health-Related Quality of Life (HRQoL) scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint.

End point type	Primary

End point timeframe:

At Week 24

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The system does not allow for statistical analysis for studies with a single treatment arm. Only descriptive statistics were planned for this single arm study.

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	173			
Units: score on a scale				
arithmetic mean (standard deviation)	1.04 (± 1.712)			

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in the Absolute PASI Score at Week 24

End point title	Change From Baseline in the Absolute PASI Score at Week 24[2]

End point description:

PASI was a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness)and scaling on a scale ranged from 0 (no symptoms) to 4 (very marked), together with the percentage of the area affected, rated on a scale from 0 (0%) to 6 (90-100%). PASI scoring was performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranged from 0 (no psoriasis) to 72 (the most severe disease). Change from baseline were calculated by subtracting post-dose value and baseline value. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint.

End point type	Primary

End point timeframe:

Baseline (Day 1), Week 24

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The system does not allow for statistical analysis for studies with a single treatment arm. Only descriptive statistics were planned for this single arm study.

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	173			
Units: score on a scale				
arithmetic mean (standard deviation)	-15.07 (± 8.458)			

Statistical analyses

No statistical analyses for this end point

Primary: Absolute Dermatology Life Quality Index (DLQI) Score at Week 24

End point title	Absolute Dermatology Life Quality Index (DLQI) Score at Week 24[3]

End point description:

DLQI questionnaire was used to evaluate the impact on subject's quality of life due to psoriasis. It was composed of ten items related to symptoms, feelings, daily activities, leisure, working or studying activities, personal relationships and opinions about dermatological treatment. Each item was scored from 0 (not affected at all) to 3 (very much affected). The DLQI score was the sum of the 10 individual question scores and ranges from 0 to 30, with lower scores indicating better quality of life. Response categories included "Not at all," "A little," "A lot," and "Very much," with corresponding scores of 0, 1, 2, and 3 respectively. Higher score indicated impaired quality of life. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint.

End point type	Primary

End point timeframe:

At Week 24

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The system does not allow for statistical analysis for studies with a single treatment arm. Only descriptive statistics were planned for this single arm study.

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	159			
Units: score on a scale				
arithmetic mean (standard deviation)	1.97 (± 3.602)			

Statistical analyses

No statistical analyses for this end point

Primary: Change From Baseline in the Absolute DLQI Score at Week 24

End point title	Change From Baseline in the Absolute DLQI Score at Week

End point description:

DLQI questionnaire was used to evaluate the impact on subject’s quality of life due to psoriasis. It was composed of ten items related to symptoms, feelings, daily activities, leisure, working or studying activities, personal relationships and opinions about dermatological treatment. Each item was scored from 0 (not affected at all) to 3 (very much affected). The DLQI score was the sum of the 10 individual question scores and ranges from 0 to 30, with lower scores indicating better quality of life. Response categories included "Not at all," "A little," "A lot," and "Very much," with corresponding scores of 0, 1, 2, and 3 respectively. Higher score indicated impaired quality of life. A negative change from baseline indicated improvement in quality of life. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint.

End point type	Primary

End point timeframe:

Baseline (Day 1), Week 24

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The system does not allow for statistical analysis for studies with a single treatment arm. Only descriptive statistics were planned for this single arm study.

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	153			
Units: score on a scale				
arithmetic mean (standard deviation)	-12.05 (± 7.693)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved Absolute DLQI Scores Between 0-1 at Week 24

End point title	Percentage of Subjects who Achieved Absolute DLQI Scores Between 0-1 at Week 24

End point description:

DLQI questionnaire was used to evaluate the impact on subject’s quality of life due to psoriasis. DLQI contains of 10 questions that involves 6 sections: symptoms and feelings, daily activities, leisure, work and school, personal relationships and treatment. Questions 1 and 2 assess symptoms and feelings; 3 and 4, daily activities; 5 and 6, leisure; 7, work and school; 8 and 9, personal relationships and 10, treatment. Each question was evaluated on a 4-point Likert scale (0=not at all / not relevant; 1=a little; 2=a lot; 3=very much affected); where higher scores indicated more impact on quality of life. Scores from all 10 questions added up to give DLQI total score range from 0 (not at all) to 30 (very much). Higher scores indicated more impact on quality of life of subjects. Percentage of subjects who achieved absolute DLQI scores between 0-1 at Week 24 was reported. ITT population was used. 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint.

End point type	Secondary

End point timeframe:

At Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	159			
Units: Percentage of subjects				
number (not applicable)	70.4			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved Absolute Dermatology Quality of Life Index Relevant (DLQI-R) Scores Between 0-1 at Week 24

End point title	Percentage of Subjects who Achieved Absolute Dermatology Quality of Life Index Relevant (DLQI-R) Scores Between 0-1 at Week 24

End point description:

DLQI-R was a scoring modification for the DLQI to better evaluate not relevant responses on the DLQI that could lead to underestimation of the impact on quality of life. The DLQI-R scoring modification involved multiplying the original DLQI score by a conversion factor that increased with the number of not relevant responses. Each question was evaluated on a 4-point Likert scale (0=not at all / not relevant; 1=a little; 2=a lot; 3=very much affected); where higher scores indicated more impact on quality of life. Percentage of subjects who achieved absolute DLQI-R Scores between 0-1 at Week 24 was reported. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint.

End point type	Secondary

End point timeframe:

At Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	159			
Units: percentage of subjects				
number (not applicable)	59.1			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Dermatology Life Quality Index (DLQI) Scores at Week 4, Week 16 and Week 24

End point title	Absolute Dermatology Life Quality Index (DLQI) Scores at Week 4, Week 16 and Week 24

End point description:

DLQI questionnaire was used to evaluate the impact on subject’s quality of life due to psoriasis. DLQI contains of 10 questions that involves 6 sections: symptoms and feelings, daily activities, leisure, work and school, personal relationships and treatment. Questions 1 and 2 assess symptoms and feelings; 3

and 4, daily activities; 5 and 6, leisure; 7, work and school; 8 and 9, personal relationships and 10, treatment. Each question was evaluated on a 4-point Likert scale (0=not at all / not relevant; 1=a little; 2=a lot; 3=very much affected); where higher scores indicated more impact on quality of life. Scores from all 10 questions added up to give DLQI total score range from 0 (not at all) to 30 (very much). Higher scores indicated more impact on quality of life of subjects. ITT population was used. Here 'Number of subjects analysed' signifies subjects who were evaluable for endpoint and 'n' signifies number of subjects with available data at specified time points.

End point type	Secondary

End point timeframe:

At Week 4, Week 16, and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	173			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (n=173)	8.57 (± 6.192)			
Week 16 (n=168)	3.08 (± 4.143)			
Week 24 (n=159)	1.97 (± 3.602)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Absolute DLQI Scores at Week 4, Week 16 and Week 24

End point title	Change from Baseline in the Absolute DLQI Scores at Week 4, Week 16 and Week 24

End point description:

DLQI questionnaire was used to evaluate impact on subject’s quality of life due to psoriasis. DLQI contains of 10 questions that involves 6 sections: symptoms and feelings, daily activities, leisure, work and school, personal relationships and treatment. Questions 1 and 2 assess symptoms and feelings; 3 and 4, daily activities; 5 and 6, leisure; 7, work and school; 8 and 9, personal relationships and 10, treatment. Each question was evaluated on a 4-point Likert scale (0=not at all / not relevant; 1=a little; 2=a lot; 3=very much affected); where higher scores indicated more impact on quality of life. Scores from all 10 questions added up to give DLQI total score range from 0 (not at all) to 30 (very much). Higher scores indicated more impact on quality of life of subjects. A negative change from baseline indicated improvement in quality of life. ITT population. 'Number of subjects analysed'=subjects evaluable for the endpoint; 'n'=subjects with available data at specified timepoint.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	165			
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n=165)	-5.29 (± 5.385)			
Change at Week 16 (n=160)	-10.83 (± 7.174)			
Change at Week 24 (n=153)	-12.05 (± 7.693)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute DLQI-R Scores at Week 4, Week 16 and Week 24

End point title	Absolute DLQI-R Scores at Week 4, Week 16 and Week 24

End point description:

DLQI-R was a scoring modification for the DLQI to better evaluate not relevant responses on the DLQI that could lead to underestimation of the impact on quality of life. The DLQI-R scoring modification involved multiplying the original DLQI score by a conversion factor that increased with the number of not relevant responses. Each question was evaluated on a 4-point Likert scale (0=not at all / not relevant; 1=a little; 2=a lot; 3=very much affected); where higher scores indicated more impact on quality of life. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint and 'n' signifies number of subjects with available data at specified time-points.

End point type	Secondary

End point timeframe:

At Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	173			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (n=173)	9.03 (± 6.372)			
Week 16 (n=168)	3.21 (± 4.268)			
Week 24 (n=159)	2.25 (± 3.990)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Absolute DLQI-R Scores at Week 4, Week 16 and Week 24

End point title	Change from Baseline in the Absolute DLQI-R Scores at Week 4, Week 16 and Week 24

End point description:

DLQI-R was a scoring modification for the DLQI to better evaluate not relevant responses on the DLQI that could lead to underestimation of the impact on quality of life. The DLQI-R scoring modification involved multiplying the original DLQI score by a conversion factor that increased with the number of not relevant responses. Each question was evaluated on a 4-point Likert scale (0=not at all / not relevant; 1=a little; 2=a lot; 3=very much affected); where higher scores indicated more impact on quality of life. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint and 'n' signifies number of subjects with available data at specified time-points.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	165			
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n=165)	-5.61 (± 5.574)			
Change at Week 16 (n=160)	-11.51 (± 7.326)			
Change at Week 24 (n=153)	-12.59 (± 8.004)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved Absolute PASI Score of Less than or equal to (<=) 5, <=3, and <=1

End point title	Percentage of Subjects who Achieved Absolute PASI Score of Less than or equal to (<=) 5, <=3, and <=1

End point description:

PASI was a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness)and scaling on a scale ranged from 0 (no symptoms) to 4 (very marked), together with the percentage of the area affected, rated on a scale from 0 (0%) to 6 (90-100%). PASI scoring was performed at four body areas, the head, arms, trunk, and legs. The PASI score ranged from 0 (no psoriasis) to 72 (the most severe disease). ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint and 'n' signifies number of subjects with available data at specified time-points.

End point type	Secondary

End point timeframe:

At Baseline (Day 1), Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	177			
Units: percentage of subjects				
number (not applicable)				
Baseline: PASI scores of <=5 (n=177)	1.7			
Week 4: PASI scores of <=5 (n=173)	27.7			
Week 16: PASI scores of <=5 (n=172)	90.1			
Week 24: PASI scores of <=5 (n=173)	96.0			
Baseline: PASI scores of <=3 (n=177)	1.1			
Week 4: PASI scores of <=3 (n=173)	11.0			
Week 16: PASI scores of <=3 (n=172)	80.8			
Week 24: PASI scores of <=3 (n=173)	88.4			
Baseline: PASI scores of <=1 (n=177)	0.0			
Week 4: PASI scores of <=1 (n=173)	1.7			
Week 16: PASI scores of <=1 (n=172)	47.1			
Week 24: PASI scores of <=1 (n=173)	66.5			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute PASI Scores at Week 4, Week 16 and Week 24

End point title	Absolute PASI Scores at Week 4, Week 16 and Week 24

End point description:

PASI was a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness)and scaling on a scale range from 0 (no symptoms) to 4 (very marked), together with the percentage of the area affected, rated on a scale from 0 (0%) to 6 (90-100%). PASI scoring was performed at four body areas, the head, arms, trunk, and legs. The PASI score ranged from 0 (no psoriasis) to 72 (the most severe disease). ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint and 'n' signifies number of subjects with available data at specified time-points.

End point type	Secondary

End point timeframe:

At Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	173			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (n=173)	8.63 (± 5.697)			
Week 16 (n=172)	1.99 (± 2.628)			
Week 24 (n=173)	1.04 (± 1.712)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Absolute PASI Scores at Week 4, Week 16 and Week 24

End point title	Change from Baseline in the Absolute PASI Scores at Week 4, Week 16 and Week 24

End point description:

PASI was a combination of the intensity of psoriasis, assessed by the erythema (reddening), induration (plaque thickness)and scaling on a scale ranged from 0 (no symptoms) to 4 (very marked), together with the percentage of the area affected, rated on a scale from 0 (0%) to 6 (90-100%). PASI scoring was performed at four body areas, the head, arms, trunk, and legs. The PASI score ranged from 0 (no psoriasis) to 72 (the most severe disease). Change from baseline were calculated by subtracting post-dose value and baseline value. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint and 'n' signifies number of subjects with available data at specified time-points.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	173			
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n=173)	-7.66 (± 6.996)			
Change at Week 16 (n=172)	-14.19 (± 8.515)			
Change at Week 24 (n=173)	-15.07 (± 8.458)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Physician Global Assessment (PGA) Scores at Week 4, Week 16 and Week 24

End point title	Absolute Physician Global Assessment (PGA) Scores at Week 4, Week 16 and Week 24

End point description:

The PGA used to assess the overall severity of the psoriasis lesions at the time of evaluation. The assessment of severity of disease was based on a 6-point scale (Clear [0], minimal [1], mild [2], moderate [3], severe [4], more severe [5]) ranging from 0-5. Higher score indicated more severe disease. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint and 'n' signifies number of subjects with available data at specified time-points.

End point type	Secondary

End point timeframe:

At Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	173			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (n=173)	1.92 (± 0.810)			
Week 16 (n=171)	0.78 (± 0.664)			
Week 24 (n=173)	0.55 (± 0.726)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Absolute PGA Scores at Week 4, Week 16 and Week 24

End point title	Change from Baseline in the Absolute PGA Scores at Week 4, Week 16 and Week 24

End point description:

The PGA used to assess the overall severity of the psoriasis lesions at the time of evaluation. The assessment of severity of disease was based on a 6-point scale (Clear [0], minimal [1], mild [2], moderate [3], severe [4], more severe [5]) ranging from 0-5. Higher score indicated more severe disease. Change from baseline were calculated by subtracting post-dose value and baseline value. A negative change from baseline indicated improvement. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint and 'n' signifies number of subjects with available data at specified time-points.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	173			
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n=173)	-0.94 (± 0.919)			
Change at Week 16 (n=171)	-2.08 (± 1.054)			
Change at Week 24 (n=173)	-2.31 (± 1.076)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved PGA Score of 0 or 1 with At Least a 2-Grade Reduction from Baseline

End point title	Percentage of Subjects who Achieved PGA Score of 0 or 1 with At Least a 2-Grade Reduction from Baseline

End point description:

The PGA used to assess the overall severity of the psoriasis lesions at the time of evaluation. The assessment of severity of disease was based on a 6-point scale (Clear [0], minimal [1], mild [2], moderate [3], severe [4], more severe [5]) ranging from 0-5. Higher score indicated more severe disease. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint and 'n' signifies number of subjects with available data at specified time-points.

End point type	Secondary

End point timeframe:

At Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	173			
Units: Percentage of subjects				
number (not applicable)				
Week 4 (n=173)	18.5			
Week 16 (n=171)	68.4			
Week 24 (n=173)	78.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Body Surface Area (BSA) Scores at Week 4, Week 16 and Week 24

End point title	Absolute Body Surface Area (BSA) Scores at Week 4, Week 16 and Week 24

End point description:

BSA was used to measure the total area of the body affected by psoriasis. BSA was calculated using the subject's palm using the 1% rule, 1 palm was equivalent to 1% with estimates of the number of palms it takes to cover the affected psoriasis area. Maximum number of palms were 10 palms for head and neck (10%), 20 palms for upper extremities (20%), 30 palms for trunk, including axilla and groin (30%), 40 palms for lower extremities, including buttocks (40%). ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint and 'n' signifies number of subjects with available data at specified time-points.

End point type	Secondary

End point timeframe:

At Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	173			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (n=173)	15.02 (± 11.262)			
Week 16 (n=171)	3.92 (± 5.675)			
Week 24 (n=173)	1.83 (± 3.385)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Absolute BSA Scores at Week 4, Week 16 and Week 24

End point title	Change from Baseline in the Absolute BSA Scores at Week 4, Week 16 and Week 24

End point description:

BSA was used to measure the total area of the body affected by psoriasis. BSA was calculated using the

subject's palm using the 1% rule, 1 palm was equivalent to 1% with estimates of the number of palms it takes to cover the affected psoriasis area. Maximum number of palms were 10 palms for head and neck (10%), 20 palms for upper extremities (20%), 30 palms for trunk, including axilla and groin (30%), 40 palms for lower extremities, including buttocks (40%). A negative change from baseline indicated improvement.
ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' are the subjects who were evaluable for the endpoint and 'n' are the subjects who were evaluable for the endpoint for given time points.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	173			
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n=173)	-6.76 (± 9.398)			
Change at Week 16 (n=171)	-17.88 (± 13.854)			
Change at Week 24 (n=173)	-19.92 (± 13.948)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Pruritus Numerical Rating Scale (NRS) Scores at Week 4, Week 16 and Week 24

End point title	Absolute Pruritus Numerical Rating Scale (NRS) Scores at Week 4, Week 16 and Week 24

End point description:

Pruritus NRS was an 11-point scale used by subjects to rate their worst itch severity over the past 24 hours with 0 indicating "No itch" and 10 indicating "Worst itch imaginable". ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint and 'n' signifies number of subjects with available data at specified time-points.

End point type	Secondary

End point timeframe:

At Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	172			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (n=172)	5.42 (± 2.566)			
Week 16 (n=168)	1.98 (± 2.236)			
Week 24 (n=162)	1.69 (± 2.279)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Absolute Pruritus NRS Scores at Week 4, Week 16 and Week 24

End point title	Change from Baseline in the Absolute Pruritus NRS Scores at Week 4, Week 16 and Week 24

End point description:

Pruritus NRS was an 11-point scale used by subjects to rate their worst itch severity over the past 24 hours with 0 indicating "No itch" and 10 indicating "Worst itch imaginable". Change from baseline were calculated by subtracting post-dose value and baseline value. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint and 'n' signifies number of subjects with available data at specified time-points.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	170			
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n=170)	-1.94 (± 2.417)			
Change at Week 16 (n=166)	-5.38 (± 2.929)			
Change at Week 16 (n=161)	-5.66 (± 3.076)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Pain-Numerical Rating Scale (NRS) Scores at Week 4, Week 16

and Week 24

End point title	Absolute Pain-Numerical Rating Scale (NRS) Scores at Week 4, Week 16 and Week 24

End point description:

The pain-NRS was an 11-point ordinal scale which assessed pain, from 0 (no pain) to 10 (worst imaginable pain). Higher scores depicted worst pain. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint and 'n' signifies number of subjects with available data at specified time-points.

End point type	Secondary

End point timeframe:

At Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	171			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (n=171)	3.36 (± 2.730)			
Week 16 (n=168)	1.35 (± 2.105)			
Week 24 (n=159)	1.13 (± 2.125)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Absolute Pain-Numerical Rating Scale (NRS) Scores at Week 4, Week 16 and Week 24

End point title	Change from Baseline in the Absolute Pain-Numerical Rating Scale (NRS) Scores at Week 4, Week 16 and Week 24

End point description:

The pain-NRS was an 11-point ordinal scale which assessed pain, from 0 (no pain) to 10 (worst imaginable pain). Higher scores depicted worst pain. Change from baseline were calculated by subtracting post-dose value and baseline value. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint and 'n' signifies number of subjects with available data at specified time-points.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	169			
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n=169)	-1.18 (± 2.326)			
Change at Week 16 (n=166)	-3.28 (± 3.453)			
Change at Week 24 (n=158)	-3.52 (± 3.434)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Scaling-Numerical Rating Scale (NRS) Scores at Week 4, Week 16 and Week 24

End point title	Absolute Scaling-Numerical Rating Scale (NRS) Scores at Week 4, Week 16 and Week 24

End point description:

The scaling-NRS was an 11-point ordinal scale which assessed scaling, from 0 (no pain) to 10 (worst imaginable pain). Higher scores depicted worst pain. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint and 'n' signifies number of subjects with available data at specified time-points.

End point type	Secondary

End point timeframe:

At Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	171			
Units: score on a scale				
arithmetic mean (standard deviation)				
Week 4 (n=171)	5.45 (± 2.467)			
Week 16 (n=168)	1.96 (± 2.256)			
Week 24 (n=160)	1.78 (± 2.482)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Absolute Scaling-Numerical Rating Scale (NRS) Scores at Week 4, Week 16 and Week 24

End point title	Change from Baseline in the Absolute Scaling-Numerical Rating Scale (NRS) Scores at Week 4, Week 16 and Week 24

End point description:

The scaling-NRS was an 11-point ordinal scale which assessed scaling, from 0 (no pain) to 10 (worst imaginable pain). Higher scores depicted worst pain. Change from baseline were calculated by subtracting post-dose value and baseline value. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint and 'n' signifies number of subjects with available data at specified time-points.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 4, Week 16 and Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	168			
Units: score on a scale				
arithmetic mean (standard deviation)				
Change at Week 4 (n=168)	-1.91 (± 2.621)			
Change at Week 16 (n=165)	-5.47 (± 3.015)			
Change at Week 24 (n=158)	-5.72 (± 3.095)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Skindex-16 Questionnaire Total Score at Week 24

End point title	Absolute Skindex-16 Questionnaire Total Score at Week 24

End point description:

Skindex was used to measure dermatology-specific health-related quality of life (HRQoL). The 16-item Skindex questionnaire was divided into three domains: questions related to the subject's symptoms (1–4), emotions (5 –11), and functioning (12–16). Each question asked the subject to quantify how much a specific aspect of their skin condition bothered them in the week prior to administration of the Skindex-16. The questions were answered on a scale from 0 (never bothered) to 6 (always bothered) with a total possible score ranging from 0 (best HRQoL) to 96 (worst HRQoL). ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint.

End point type	Secondary

End point timeframe:

At Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	153			
Units: score on a scale				
arithmetic mean (standard deviation)	14.91 (± 21.840)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Absolute Skindex-16 Questionnaire Total Score at Week 24

End point title	Change from Baseline in the Absolute Skindex-16 Questionnaire Total Score at Week 24

End point description:

Skindex was used to measure dermatology-specific HRQoL. The 16-item Skindex questionnaire was divided into three domains: questions related to the subject's symptoms (1– 4), emotions (5 –11), and functioning (12–16). Each question asked the subject to quantify how much a specific aspect of their skin condition bothered them in the week prior to administration of the Skindex-16. The questions were answered on a scale from 0 (never bothered) to 6 (always bothered) with a total possible score ranging from 0 (best HRQoL) to 96 (worst HRQoL). Change from baseline was calculated by subtracting post-dose value and baseline value. Negative change from baseline at Week 24 indicated an improvement in the subject's condition compared to the baseline. ITT population was assessed. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	149			
Units: score on a scale				
arithmetic mean (standard deviation)	-53.31 (± 29.861)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Medical Outcome Study (MOS) Sleep Scores at Week 24

End point title	Absolute Medical Outcome Study (MOS) Sleep Scores at Week

	24

End point description:

The MOS-Sleep included 12 items which assessed sleep disturbance, sleep adequacy, somnolence, quantity of sleep, snoring, and awakening short of breath or with a headache. Each sleep symptom or problem was presented on a 5-point categorical scale ranging from 'all of the time' to 'none of the time.' It includes 12 questions with the first question assessing how long it takes the subject to fall asleep. The second question asked how many hours each night the subject slept. The remaining 10 questions had a range of 6 responses from 1="all of the time" to 6="none of the time". MOS Sleep scale ranged from 0 to 100, with the exception of sleep quantity. Higher scores represented worse outcomes. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed'=subjects who were evaluable for the endpoint and 'n'=number of subjects with available data for specified categories.

End point type	Secondary

End point timeframe:

At Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	155			
Units: score on a scale				
arithmetic mean (standard deviation)				
Sleep Disturbance (n=155)	29.22 (± 20.870)			
Sleep Quantity (n=153)	6.80 (± 1.060)			
Sleep Adequacy (n=154)	60.88 (± 23.859)			
Shortness of breath/headache (n=154)	15.58 (± 20.428)			
Snoring (n=155)	39.35 (± 31.846)			
Somnolence (n=155)	27.53 (± 18.326)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Absolute Medical Outcome Study (MOS) Sleep Scores at Week 24

End point title	Change from Baseline in the Absolute Medical Outcome Study (MOS) Sleep Scores at Week 24

End point description:

The MOS-Sleep included 12 items which assessed sleep disturbance, sleep adequacy, somnolence, quantity of sleep, snoring, and awakening short of breath or with a headache. Each sleep symptom or problem was presented on a 5-point categorical scale ranging from 'all of the time' to 'none of the time.' It includes 12 questions with the first question assessing how long it takes the subject to fall asleep. The second question asked how many hours each night the subject slept. The remaining 10 questions had a range of 6 responses from 1="all of the time" to 6="none of the time". MOS Sleep scale ranged from 0 to 100, with the exception of sleep quantity. Higher scores represented worse outcomes. ITT population included all subjects who received at least one dose of the study medication and had at least one baseline efficacy/HRQoL scores. Here 'Number of subjects analysed'=subjects who were evaluable for the endpoint and 'n'=number of subjects with available data for specified categories.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	153			
Units: score on a scale				
arithmetic mean (standard deviation)				
Sleep Disturbance (n=153)	-14.03 (± 23.272)			
Sleep Quantity (n=148)	0.27 (± 1.171)			
Sleep Adequacy (n=152)	8.47 (± 28.649)			
Shortness of breath/headache (n=152)	-2.47 (± 25.534)			
Snoring (n=153)	-5.23 (± 31.759)			
Somnolence (n=153)	-6.43 (± 21.850)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Work Productivity and Activity Impairment (WPAI) Score at Week 24

End point title	Absolute Work Productivity and Activity Impairment (WPAI) Score at Week 24

End point description:

The WPAI questionnaire was used to measure impairments in both paid work and unpaid work. The WPAI questionnaire consists of 6 questions that were used to assess: 1-employment status (yes/no), 2-work time missed due to Psoriasis (hours), 3-work time missed due to other reasons (hours), 4-actual work time (hours), 5-impact of Psoriasis on work productivity while at work (0-10 point scale), and 6-the impact of Psoriasis on activities outside of work (0-10 point scale) for the 7 days prior to questionnaire completion. Four scores were derived from the questions: percent absenteeism(work time missed), percent presenteeism (impairment at work), percent work productivity loss (overall work impairment due to absenteeism and presenteeism), and percent activity impairment (activities performed outside of work). Higher scores indicated a higher level of impairment. ITT population was used. 'Number of subjects analysed'=subjects evaluable for endpoint, 'n'=subjects assessed for given categories.

End point type	Secondary

End point timeframe:

At Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	141			
Units: score on a scale				
arithmetic mean (standard deviation)				
Percent work time missed due to problem (n=85)	3.11 (± 15.621)			
Percent impairment, working due to problem (n=102)	5.78 (± 14.921)			
overall work impairment due to problem (n=85)	8.07 (± 19.721)			
Activity impairment due to problem (n=141)	8.30 (± 16.211)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Absolute Work Productivity and Activity Impairment (WPAI) Score at Week 24

End point title	Change from Baseline in the Absolute Work Productivity and Activity Impairment (WPAI) Score at Week 24

End point description:

The WPAI questionnaire was used to measure impairments in both paid work and unpaid work. The WPAI questionnaire consists of 6 questions that were used to assess: 1-employment status (yes/no), 2-work time missed due to Psoriasis (hours), 3-work time missed due to other reasons (hours), 4-actual work time (hours), 5-impact of Psoriasis on work productivity while at work (0-10 point scale), and 6-the impact of Psoriasis on activities outside of work (0-10 point scale) for the 7 days prior to questionnaire completion. Four scores were derived from the questions: percent absenteeism(work time missed), percent presenteeism (impairment at work), percent work productivity loss (overall work impairment due to absenteeism and presenteeism), and percent activity impairment (activities performed outside of work). Higher scores indicated a higher level of impairment. ITT population was used. 'Number of subjects analysed'=subjects evaluable for endpoint, 'n'=subjects assessed for given categories.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	122			
Units: score on a scale				
arithmetic mean (standard deviation)				
Percent work time missed due to problem (n=70)	-6.83 (± 22.175)			
Percent impairment, working due to problem (n=89)	-26.97 (± 28.099)			
overall work impairment due to problem (n=70)	-28.18 (± 27.303)			
Activity impairment due to problem (n=122)	-36.39 (± 34.690)			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Treatment Satisfaction Questionnaire for Medication (TSQM) Score at Week 24

End point title	Absolute Treatment Satisfaction Questionnaire for Medication (TSQM) Score at Week 24

End point description:

TSQM was a 14-item self-reported generic instrument designed to measure subject satisfaction with medication treatment. The 4 scales of TSQM included Effectiveness subscale, Side Effects subscale (items 4-8), Convenience subscale (items 9-11), Global Satisfaction subscale (items 12-14). Last subscale was regarded both in concept and in research as a superordinate, second-order global factor encompassing other 3 more specific domains of medication experiences. Responses were obtained on 5-point or a 7-point Likert scale (range, 1 extremely dissatisfied to 7 extremely satisfied) for all but 1 item that has a yes-no response option. Subscale scores were transformed into scores ranging from 0-100, higher scores represented higher satisfaction on that domain. Regarding Side Effects subscale, when subject answered no'' to experiencing side effects (item 4), this subscale is scored as 100. ITT population. 'Number of subjects analysed'=subjects evaluable; n=subjects assessed for categories.

End point type	Secondary

End point timeframe:

At Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	155			
Units: score on a scale				
arithmetic mean (standard deviation)				
Effectiveness (n=155)	77.63 (± 23.269)			
Side-Effect (n=154)	96.79 (± 12.460)			
Convenience (n=155)	79.55 (± 16.168)			
Global Satisfaction (n=154)	80.47 (± 18.515)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects who Achieved a Score Greater Than or Equal to (>=) 1 in the Absolute Patient Benefit Index (PBI) Score at Week 24.

End point title	Percentage of Subjects who Achieved a Score Greater Than or

	Equal to (>=) 1 in the Absolute Patient Benefit Index (PBI) Score at Week 24.

End point description:

PBI was a questionnaire of 23 items on subject-relevant therapy needs and benefits. First part of the instrument, subject Needs Questionnaire (PNQ), was filled in by the subject before therapy. Five-step Likert scale (0 =not important at all to 4=very important) recorded the individual relevance of the different items to the participant. The second part, PBQ, was filled in by subjects during or after therapy. It comprised of the same items as the PNQ, but in contrast, subjects evaluated the extent to which the treatment needs have been fulfilled by therapy (scaled from 0=treatment did not help at all to 4=treatment helped a lot). In addition, the Likert scale contained the option does not apply to me in the PNQ and the option did not apply to me in the PBQ. This questionnaire score ranged from 0 =no benefit to 4=maximal benefit. A PBI value of >=1 is considered as relevant benefit. ITT population was assessed. 'Number of subjects analysed' signifies subjects evaluable for endpoint.

End point type	Secondary

End point timeframe:

At Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	150			
Units: percentage of subjects				
number (not applicable)	98.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Treatment-emergent Adverse Events (TEAEs)

End point title	Number of Subjects with Treatment-emergent Adverse Events (TEAEs)

End point description:

An Adverse Event (AE) were considered as TEAE if it was not present prior to the first dose of the study drug or was present prior to the first dose of study drug, but increased in severity during the treatment period. Safety analyses set included all subjects who were included and had at least one dose of the study medication.

End point type	Secondary

End point timeframe:

Baseline (Day 1) up to Week 28

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	177			
Units: subjects	52			

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute High-sensitivity C-Reactive Protein (hs-CRP) Level at Week 24

End point title	Absolute High-sensitivity C-Reactive Protein (hs-CRP) Level at Week 24

End point description:

The hs-CRP was assessed as safety serum biochemistry parameters were reported. Safety analyses set included all subjects who were included and had at least one dose of the study medication. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint.

End point type	Secondary

End point timeframe:

At Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	158			
Units: milligram per decilitre (mg/dL)				
arithmetic mean (standard deviation)	0.32 (± 0.444)			

Statistical analyses

No statistical analyses for this end point

Secondary: Change from Baseline in the Absolute High-sensitivity C-Reactive Protein (hs-CRP) Level at Week 24

End point title	Change from Baseline in the Absolute High-sensitivity C-Reactive Protein (hs-CRP) Level at Week 24

End point description:

The hs-CRP were assessed as safety serum biochemistry parameters. Change from baseline were calculated by subtracting post-dose value and baseline value. Safety analyses set included all subjects who were included and had at least one dose of the study medication. Here 'Number of subjects analysed' signifies subjects who were evaluable for the endpoint.

End point type	Secondary

End point timeframe:

Baseline (Day 1), Week 24

End point values	Tildrakizumab			
Subject group type	Reporting group			
Number of subjects analysed	158			
Units: mg/dL				
arithmetic mean (standard deviation)	-0.03 (± 0.424)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Baseline (Day 1) up to Week 28	
Assessment type	Non-systematic
Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0
Reporting groups	
Reporting group title	Tildrakizumab
Reporting group description: Subjects received SC injection of tildrakizumab 100 mg at Week 0 (Day 1), Week 4, and Week 16.	

Serious adverse events	Tildrakizumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 177 (0.56%)		
number of deaths (all causes)	1		
number of deaths resulting from adverse events	0		
Infections and infestations			
Coronavirus infection			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Tildrakizumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	52 / 177 (29.38%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Keratoacanthoma			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Skin papilloma			

alternative assessment type: Systematic subjects affected / exposed occurrences (all)	1 / 177 (0.56%) 1		
Vascular disorders Hypertension alternative assessment type: Systematic subjects affected / exposed occurrences (all)	1 / 177 (0.56%) 2		
Surgical and medical procedures Tooth extraction alternative assessment type: Systematic subjects affected / exposed occurrences (all)	1 / 177 (0.56%) 1		
General disorders and administration site conditions Asthenia alternative assessment type: Systematic subjects affected / exposed occurrences (all)	2 / 177 (1.13%) 2		
Injection sitehypersensitivity alternative assessment type: Systematic subjects affected / exposed occurrences (all)	1 / 177 (0.56%) 1		
Malaise alternative assessment type: Systematic subjects affected / exposed occurrences (all)	1 / 177 (0.56%) 1		
Oedema peripheral alternative assessment type: Systematic subjects affected / exposed occurrences (all)	1 / 177 (0.56%) 1		
Immune system disorders Drug hypersensitivity alternative assessment type: Systematic subjects affected / exposed occurrences (all)	1 / 177 (0.56%) 1		

Hypersensitivity			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Seasonal allergy			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Reproductive system and breast disorders			
Breast pain			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Postmenopausal haemorrhage			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Oropharyngeal discomfort			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Oropharyngeal pain			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Productive cough			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		

Cough			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Psychiatric disorders			
Affect lability			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Anxiety			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Apathy			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Depression			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Depressive symptom			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Insomnia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Investigations			
Alanine aminotransferase increased			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			

Adverse eventfollowingimmunisation			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Fall			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Thermal burn			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Nervous system disorders			
Dizziness			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 177 (1.13%)		
occurrences (all)	3		
Headache			
alternative assessment type: Systematic			
subjects affected / exposed	11 / 177 (6.21%)		
occurrences (all)	14		
Migraine			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 177 (1.13%)		
occurrences (all)	3		
Blood and lymphatic system disorders			
Macrocytosis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Neutropenia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Eye disorders			

Lacrimation increased			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Gastrointestinal disorders			
Abdominal pain			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Diarrhoea			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Dyspepsia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Faeces soft			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Nausea			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 177 (1.13%)		
occurrences (all)	2		
Toothache			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Vomiting			
alternative assessment type: Systematic			
subjects affected / exposed	2 / 177 (1.13%)		
occurrences (all)	3		
Skin and subcutaneous tissue disorders			

Angioedema			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	2		
Dermal cyst			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	2		
Erythrodermic psoriasis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Pruritus			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 177 (1.69%)		
occurrences (all)	3		
Psoriasis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Renal and urinary disorders			
Leukocyturia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Back pain			
alternative assessment type: Systematic			
subjects affected / exposed	4 / 177 (2.26%)		
occurrences (all)	5		
Myalgia			

alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Polymyalgia rheumatica			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Rotator cuff syndrome			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Infections and infestations			
Corona virus infection			
alternative assessment type: Systematic			
subjects affected / exposed	3 / 177 (1.69%)		
occurrences (all)	3		
Gastroenteritis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Herpes zoster			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Lice infestation			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Nasopharyngitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Tinea pedis			
alternative assessment type: Systematic			

subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Tonsillitis			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Upper respiratory tractinfection			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	2		
Metabolism and nutrition disorders			
Decreased appetite			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Hypercholesterolaemia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		
Hypertriglyceridaemia			
alternative assessment type: Systematic			
subjects affected / exposed	1 / 177 (0.56%)		
occurrences (all)	1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported