Clinical trial results:
An open-label, randomized, Phase IV study, to assess the efficacy and safety of tildrakizumab in patients with moderate to severe chronic plaque psoriasis who are non-responders to dimethyl fumarate therapy

Summary

EudraCT number	2019-000817-35
Trial protocol	GB DE NL
Global end of trial date	16 February 2022

Results information

Result version number	v1 (current)
This version publication date	09 March 2023
First version publication date	09 March 2023

Trial information

Trial identification

Sponsor protocol code	M-14745-41

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04263610
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	ALMIRALL, S.A.
Sponsor organisation address	General Mitre, 151, Barcelona, Spain, 08022
Public contact	International Clinical Trial Manager, ALMIRALL, S.A., +34 933128992, valentina.cappello@almirall.com
Scientific contact	International Clinical Trial Manager, ALMIRALL, S.A., +34 933128992, valentina.cappello@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	16 February 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	16 February 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to assess the efficacy of tildrakizumab treatment (as assessed by PASI 75) in moderate-to-severe plaque psoriasis patients who are non-responders to dimethyl fumarate (DMF).

Protection of trial subjects:

This trial was conducted in accordance with the recommendations guiding physicians in biomedical research involving human patients adopted by the 18th World Medical Assembly of Helsinki (1964), as amended in Fortaleza, Brazil (2013), as well as in compliance with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Good Clinical Practice (GCP) guidelines, and local laws of the countries in which the study centres were located.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	01 July 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	Germany: 183
Country: Number of subjects enrolled	United Kingdom: 6
Worldwide total number of subjects	189
EEA total number of subjects	183

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)	179
From 65 to 84 years	10

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Total 189 subjects were randomized in Part 1 out of which 143 completed Part 1 and total 140 subjects were included in Part 2 out of which 129 completed Part 2.

Period 1

Period 1 title	Part 1
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	Dimethyl fumarate standard scheme

Arm description:

Participants received DMF standard scheme from baseline to Week 16.

Arm type	Experimental
Investigational medicinal product name	Dimethyl fumarate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gastro-resistant tablet
Routes of administration	Oral use

Dosage and administration details:

Participants will receive DMF gastro-resistant tablet orally from baseline to Week 16, at a dose of 30 milligrams (mg) once daily, twice daily, thrice daily in Week 1, Week 2, Week 3 respectively, 120 mg only once in Week 4. Participants will increase DMF dose by 120 mg tablet per week for the subsequent 5 weeks. Participants achieving Psoriasis area and severity Index (PASI) 50-75 (partial responder) or 75 (responder) will continue the DMF treatment until Week 40. The maximum daily dose taken by a participant will be 720 mg.

Arm title	Simplified DMF treatment scheme

Arm description:

Participants achieving a PASI 75 response (responders) and participants failing to achieve a PASI 75 response but having achieved a PASI 50 response (partial responders) at Week 16 continued with DMF treatment until Week 40. Participants failing to achieve a PASI 50 response (non-responders) at Week 16 were treated with Tildrakizumab until Week 40.

Arm type	Experimental
Investigational medicinal product name	Dimethyl fumarate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gastro-resistant tablet
Routes of administration	Oral use

Dosage and administration details:

Participants will receive DMF gastro-resistant tablet orally at a dose of 60, 120, 180, 240, 360 mg daily in Week 1, Week 2, Week 3, Week 4, Week 5 respectively, and 480 mg daily from Week 6 to Week 8. If a PASI is greater than or equal to (>=) 30% at Week 8, no dose increase will be done and if PASI is less than (<) 30% at Week 8, participants will receive 600 mg daily in Week 9 and 720 mg from the Week 10 onwards.

Number of subjects in period 1	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme
Started	143	46
Completed	110	33
Not completed	33	13
Consent withdrawn by subject	7	4
Other	-	1
Adverse event	13	3
Investigator decision	2	-
Withdrawal due to low leukocytes or lymphocytes	1	1
Lost to follow-up	7	1
Non compliance with study drug	1	2
Lack of efficacy	2	1

Period 2

Period 2 title	Part 2
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	DMF treatment

Arm description:

Participants achieving a Psoriasis Area and Severity Index (PASI) 75 response (responders) and participants failing to achieve a PASI 75 response but having achieved a PASI 50 response (partial responders) at Week 16 continued with DMF treatment until Week 40.

Arm type	Experimental
Investigational medicinal product name	Dimethyl fumarate
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Gastro-resistant tablet
Routes of administration	Oral use

Dosage and administration details:

Participants will receive DMF gastro-resistant tablet orally from baseline to Week 16, at a dose of 30 milligrams (mg) once daily, twice daily, thrice daily in Week 1, Week 2, Week 3 respectively, 120 mg only once in Week 4. Participants will increase DMF dose by 120 mg tablet per week for the subsequent 5 weeks. Participants achieving Psoriasis area and severity Index (PASI) 50-75 (partial responder) or 75 (responder) will continue the DMF treatment until Week 40. The maximum daily dose taken by a participant will be 720 mg.

Arm title	Tildrakizumab treatment

Arm description:

Participants who achieve PASI less than (<) 50 (non-responders) at Week 16 received Tildrakizumab subcutaneous injection at a dose of either 100 or 200 mg [(as per the Summary of Product Characteristics (SmPC)] at Weeks 16, 20 and 32 up to Week 40.

Arm type	Experimental

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

Dosage and administration details:

Participants who achieve PASI less than (<) 50 (non-responders) at Week 16 will receive Tildrakizumab subcutaneous injection at a dose of either 100 or 200 mg [(as per the Summary of Product Characteristics (SmPC)] at Weeks 16, 20 and 32 up to Week 40.

Number of subjects in period 2[1]	DMF treatment	Tildrakizumab treatment
Started	37	103
Completed	27	102
Not completed	10	1
Consent withdrawn by subject	1	1
Other	1	-
Adverse event	5	-
Withdrawal due to low leukocytes or lymphocytes	1	-
Lost to follow-up	2	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Three subjects who completed Part 1 of the study did not start Part 2

Baseline characteristics

Reporting groups	
Reporting group title	Dimethyl fumarate standard scheme
Reporting group description:	
Participants received DMF standard scheme from baseline to Week 16.	
Reporting group title	Simplified DMF treatment scheme
Reporting group description:	
Participants achieving a PASI 75 response (responders) and participants failing to achieve a PASI 75 response but having achieved a PASI 50 response (partial responders) at Week 16 continued with DMF treatment until Week 40. Participants failing to achieve a PASI 50 response (non-responders) at Week 16 were treated with Tildrakizumab until Week 40.	

Reporting group values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme	Total
Number of subjects	143	46	189
Age categorical			
Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous			
Units: years			
arithmetic mean	43.10	41.57	
standard deviation	± 14.01	± 12.20	-
Gender categorical			
Units: Subjects			
Female	51	21	72
Male	92	25	117

End points

End points reporting groups

Reporting group title	Dimethyl fumarate standard scheme
Reporting group description:	
Participants received DMF standard scheme from baseline to Week 16.	
Reporting group title	Simplified DMF treatment scheme
Reporting group description:	
Participants achieving a PASI 75 response (responders) and participants failing to achieve a PASI 75 response but having achieved a PASI 50 response (partial responders) at Week 16 continued with DMF treatment until Week 40. Participants failing to achieve a PASI 50 response (non-responders) at Week 16 were treated with Tildrakizumab until Week 40.	
Reporting group title	DMF treatment
Reporting group description:	
Participants achieving a Psoriasis Area and Severity Index (PASI) 75 response (responders) and participants failing to achieve a PASI 75 response but having achieved a PASI 50 response (partial responders) at Week 16 continued with DMF treatment until Week 40.	
Reporting group title	Tildrakizumab treatment
Reporting group description:	
Participants who achieve PASI less than (<) 50 (non-responders) at Week 16 received Tildrakizumab subcutaneous injection at a dose of either 100 or 200 mg [(as per the Summary of Product Characteristics (SmPC)] at Weeks 16, 20 and 32 up to Week 40.	

Primary: Part 2: Percentage of subjects who were non-responders to DMF at Week 16 that were treated with tildrakizumab and achieved a PASI 75 at Week 40

End point title	Part 2: Percentage of subjects who were non-responders to DMF at Week 16 that were treated with tildrakizumab and achieved a PASI 75 at Week 40[1]

End point description:

PASI is 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 is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 (no psoriasis) to 72 (the most severe disease). PASI 75 response, is defined as having an improvement (reduction) of greater than or equal to (>=) 75% in PASI score compared to the baseline score. The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication.

End point type	Primary

End point timeframe:

Up to Week 40

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: Only descriptive data was planned to be analysed for this endpoint.

End point values	Tildrakizumab treatment			
Subject group type	Reporting group			
Number of subjects analysed	101			
Units: percentage of subjects				
number (not applicable)	77.2			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Percentage of subjects achieving PASI 50, PASI 75 and PASI 90 responses at Week 8 and Week 16 Visits

End point title	Part 1: Percentage of subjects achieving PASI 50, PASI 75 and PASI 90 responses at Week 8 and Week 16 Visits

End point description:

PASI is 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 is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 (no psoriasis) to 72 (the most severe disease). PASI 50, 75, 90 response, is defined as having an improvement (reduction) of greater than or equal to (>=) 50%, 75%, 90% and 100% respectively in PASI score compared to the baseline score. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value.

End point type	Secondary

End point timeframe:

Week 8 and 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: percentage of subjects				
number (not applicable)				
PASI 50 at Week 8	20.3	21.6		
PASI 75 at Week 8	4.2	2.7		
PASI 90 at Week 8	0.0	2.7		
PASI 50 at Week 16	28.8	27.3		
PASI 75 at Week 16	12.6	15.2		
PASI 90 at Week 16	4.5	6.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Percentage of subjects achieving absolute PASI scores of ≤5, ≤3 and ≤1 at Week 8 and Week 16 Visits

End point title	Part 1: Percentage of subjects achieving absolute PASI scores of ≤5, ≤3 and ≤1 at Week 8 and Week 16 Visits

End point description:

PASI is 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 is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 (no psoriasis) to 72 (the most severe disease). Percentage of participants who achieved an absolute PASI score <= 5, 3 and 1 at Week 8 and Week 16 is reported. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value.

End point type	Secondary

End point timeframe:

Week 8 and 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: percentage of subjects				
number (not applicable)				
PASI ≤5 at Week 8	6.8	10.8		
PASI ≤3 at Week 8	2.5	2.7		
PASI ≤1 at Week 8	0.0	0.0		
PASI ≤5 at Week 16	25.2	18.2		
PASI ≤3 at Week 16	11.7	15.2		
PASI ≤1 at Week 16	4.5	6.1		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute PASI score at Week 8 and Week 16 Visits

End point title	Part 1: Absolute PASI score at Week 8 and Week 16 Visits

End point description:

PASI is 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 is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 (no psoriasis) to 72 (the most severe disease). The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value. Here, n is defined as number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Week 8 and 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n= 118, 37)	12.97 (± 8.31)	11.63 (± 5.77)		
Week 16 (n= 111, 33)	11.42 (± 8.22)	11.41 (± 7.03)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change from baseline in the absolute PASI score at Week 8 and Week 16 Visits

End point title	Part 1: Change from baseline in the absolute PASI score at Week 8 and Week 16 Visits

End point description:

PASI is 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 is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 (no psoriasis) to 72 (the most severe disease). Baseline value is defined as values collected at Week 1 of Part 1 of the study. Change from baseline is calculated by subtracting post-dose value baseline value. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Baseline, Week 8 and 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n= 118, 37)	-3.87 (± 5.79)	-5.52 (± 4.98)		
Week 16 (n= 111, 33)	-5.42 (± 5.76)	-5.82 (± 5.63)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change from Baseline in Absolute Body Surface Area (BSA) Score at Week 8 and Week 16 Visits

End point title	Part 1: Change from Baseline in Absolute Body Surface Area (BSA) Score at Week 8 and Week 16 Visits

End point description:

BSA is a numerical score used to measure the total area of the body affected by psoriasis. The palm method will be applied: the participant's palm, including the five digits is used as a reference (representing approximately 1% of the total body surface area) and is used to repeatedly cover the lesions on the body. The investigator totals the number of palms required and then estimates the percentage (%) in each of the four body regions: head (including scalp) and neck (10%); upper extremities (20%); trunk (30%); and lower extremities (40%). Baseline value is defined as values collected at Week 1 of Part 1 of the study. Change from baseline is calculated by subtracting post-dose value baseline value. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Baseline, Week 8 and 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n= 118, 37)	-2.68 (± 9.83)	-3.44 (± 6.05)		
Week 16 (n= 111, 33)	-4.43 (± 9.22)	-5.45 (± 8.05)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Body Surface Area (BSA) Score at Week 8 and Week 16 Visits

End point title	Part 1: Absolute Body Surface Area (BSA) Score at Week 8 and Week 16 Visits

End point description:

BSA is a numerical score used to measure the total area of the body affected by psoriasis. The palm method will be applied: the participant's palm, including the five digits is used as a reference (representing approximately 1% of the total body surface area) and is used to repeatedly cover the lesions on the body. The investigator totals the number of palms required and then estimates the percentage (%) in each of the four body regions: head (including scalp) and neck (10%); upper extremities (20%); trunk (30%); and lower extremities (40%). The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary
End point timeframe: Week 8 and 16	

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n= 118, 37)	18.09 (± 15.29)	17.36 (± 12.46)		
Week 16 (n= 111, 33)	16.58 (± 16.76)	16.39 (± 13.16)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Percentage of subjects achieving PGA scores of 0 or 1 at Week 8 and Week 16 Visits

End point title	Part 1: Percentage of subjects achieving PGA scores of 0 or 1 at Week 8 and Week 16 Visits

End point description:

The PGA score is used to assess the overall severity of the psoriasis lesions at the time of evaluation. Overall lesions will be graded for erythema, induration, and scale based on 6-point scale ranging from 0 (clear) to 5 (severe). The sum of 3 scales will be divided by 3 to obtain final PGA score. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary
End point timeframe: Week 8 and 16	

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: percentage of subjects				
number (not applicable)				
Week 8 (n= 118, 37)	5.9	8.1		
Week 16 (n= 111, 33)	14.4	24.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Percentage of subjects achieving Scalp Physician Global Assessment (scPGA) and Palmoplantar Physician's Global Assessment (PPPGA) Scores of 0 or 1 at Week 8 and Week 16 Visits

End point title	Part 1: Percentage of subjects achieving Scalp Physician Global Assessment (scPGA) and Palmoplantar Physician's Global Assessment (PPPGA) Scores of 0 or 1 at Week 8 and Week 16 Visits

End point description:

The scPGA score is used to assess the average severity of scalp psoriasis lesions. The scPGA is also 5-point scale ranging from 0 (clear) to 4 (severe), where higher score indicates severe scalp psoriasis lesions. Only in participants with scalp involvement, the scPGA assessment was performed. The PPPGA score is used to assess the average severity of severity of psoriasis lesions on hands and/or feet. The PPPGA is a 5-point scale ranging from 0 (clear) to 4 (severe), where higher score indicates severe psoriasis lesions on hands and/or feet. Only in participants with palmar or plantar involvement the PPPGA assessment was performed. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Week 8 and 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: percentage of subjects				
number (not applicable)				
PPPGA (0,1) at Week 8 (n= 109, 34)	81.7	76.5		
ScPGA (0,1) at Week 8 (n= 117, 36)	28.2	36.1		
PPPGA (0,1) at Week 16 (n= 101, 30)	84.2	76.7		
ScPGA (0,1) at Week 16 (n= 108, 32)	38.0	43.8		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute PGA scores at Week 8 and Week 16 Visits

End point title	Part 1: Absolute PGA scores at Week 8 and Week 16 Visits

End point description:

The PGA score is used to assess the overall severity of the psoriasis lesions at the time of evaluation. Overall lesions is graded for erythema, induration, and scale based on 6-point scale ranging from 0 (clear) to 5 (severe). The sum of 3 scales is divided by 3 to obtain final PGA score. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Week 8 and 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n= 118, 37)	2.72 (± 0.82)	2.54 (± 0.84)		
Week 16 (n= 111, 33)	2.44 (± 1.02)	2.45 (± 1.12)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute ScPGA and PPPGA scores at Week 8 and Week 16 Visits

End point title	Part 1: Absolute ScPGA and PPPGA scores at Week 8 and Week 16 Visits

End point description:

The scPGA score is used to assess the average severity of scalp psoriasis lesions. The scPGA is also 5-point scale ranging from 0 (clear) to 4 (severe), where higher score indicates severe scalp psoriasis lesions. Only in participants with scalp involvement, the scPGA assessment was performed. The PPPGA score is used to assess the average severity of psoriasis lesions on hands and/or feet. The PPPGA is a 5-point scale ranging from 0 (clear) to 4 (severe), where higher score indicates severe psoriasis lesions on hands and/or feet. Only in participants with palmar or plantar involvement the PPPGA assessment was performed. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Week 8 and 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: units on a scale				
arithmetic mean (standard deviation)				
ScPGA at Week 8 (n= 117, 36)	2.03 (± 1.20)	1.86 (± 1.38)		
PPPGA at Week 8 (n= 109, 34)	0.54 (± 1.03)	0.74 (± 1.40)		
ScPGA at Week 16 (n= 117, 36)	1.81 (± 1.26)	1.41 (± 1.34)		
PPPGA at Week 16 (n= 101, 30)	0.42 (± 0.89)	0.70 (± 1.26)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change from baseline in the absolute PGA scores at Week 8 and Week 16 Visits

End point title	Part 1: Change from baseline in the absolute PGA scores at Week 8 and Week 16 Visits

End point description:

The PGA score is used to assess the overall severity of the psoriasis lesions at the time of evaluation. Overall lesions was graded for erythema, induration, and scale based on 6-point scale ranging from 0 (clear) to 5 (severe). The sum of 3 scales was divided by 3 to obtain final PGA score. Baseline value is defined as values collected at Week 1 of Part 1 of the study. Change from baseline was calculated by subtracting post-dose value baseline value. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Baseline, Week 8 and 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n= 118, 37)	-0.49 (± 0.80)	-0.65 (± 0.59)		
Week 16 (n= 111, 33)	-0.77 (± 1.00)	-0.76 (± 0.87)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change from baseline in the absolute ScPGA and PPPGA scores at Week 8 and Week 16 Visits

End point title	Part 1: Change from baseline in the absolute ScPGA and PPPGA scores at Week 8 and Week 16 Visits

End point description:

The scPGA score is used to assess the average severity of scalp psoriasis lesions. The scPGA is also 5-point scale ranging from 0 (clear) to 4 (severe), where higher score indicates severe scalp psoriasis lesions. Only in participants with scalp involvement, the scPGA assessment was performed. The PPPGA score is used to assess the average severity of psoriasis lesions on hands and/or feet. The PPPGA is a 5-point scale ranging from 0 (clear) to 4 (severe), where higher score indicates severe psoriasis lesions on hands and/or feet. Only in participants with palmar or plantar involvement the PPPGA assessment was performed. Baseline value is defined as values collected at Week 1 of Part 1 of the study. Change from baseline was calculated by subtracting post-dose value baseline value. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value.

End point type	Secondary

End point timeframe:

Baseline, Week 8 and 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: units on a scale				
arithmetic mean (standard deviation)				
PPPGA at Week 8 (n= 102, 33)	-0.09 (± 0.86)	-0.03 (± 0.47)		
ScPGA at Week 8 (n= 115, 36)	-0.52 (± 0.98)	-0.50 (± 0.78)		
PPPGA at Week 16 (n= 96, 29)	-0.17 (± 0.90)	-0.03 (± 0.82)		
ScPGA at Week 16 (n= 107, 32)	-0.74 (± 1.23)	-1.09 (± 1.38)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Percentage of subjects achieving Dermatology Quality of Life Index (DLQI) scores of 0 or 1 at Week 8 and Week 16 Visits

End point title	Part 1: Percentage of subjects achieving Dermatology Quality of Life Index (DLQI) scores of 0 or 1 at Week 8 and Week 16 Visits

End point description:

DLQI is a questionnaire which is to evaluate the impact on participant's quality of life due to psoriasis. It is composed of ten items related to symptoms, feelings, daily activities, leisure, working or studying activities, personal relationships and opinions about dermatological treatment. Each item is scored from 0 (not affected at all) to 3 (very much affected). The DLQI score is the sum of the 10 individual question scores and ranges from 0 to 30, with lower scores indicating better quality of life. The higher the score, the more quality of life is impaired. The DLQI can also be expressed as a percentage of the maximum possible score of 30. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary
End point timeframe: Week 8 and 16	

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: percentage of subjects				
number (not applicable)				
Week 8	8.7	5.6		
Week 16	16.5	15.2		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute DLQI score at Week 8 and Week 16 Visits

End point title	Part 1: Absolute DLQI score at Week 8 and Week 16 Visits

End point description:

DLQI is a questionnaire which is to evaluate the impact on participant's quality of life due to psoriasis. It is composed of ten items related to symptoms, feelings, daily activities, leisure, working or studying activities, personal relationships and opinions about dermatological treatment. Each item is scored from 0 (not affected at all) to 3 (very much affected). The DLQI score is the sum of the 10 individual question scores and ranges from 0 to 30, with lower scores indicating better quality of life. The higher the score, the more quality of life is impaired. The DLQI can also be expressed as a percentage of the maximum possible score of 30. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary
End point timeframe: Week 8 and 16	

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n= 115, 36)	10.58 (± 7.23)	8.44 (± 5.47)		
Week 16 (n= 109, 33)	9.33 (± 7.65)	5.73 (± 4.35)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change from baseline in the absolute DLQI score at Week 8 and Week 16 Visits

End point title	Part 1: Change from baseline in the absolute DLQI score at Week 8 and Week 16 Visits

End point description:

DLQI is a questionnaire which is to evaluate the impact on participant's quality of life due to psoriasis. It is composed of ten items related to symptoms, feelings, daily activities, leisure, working or studying activities, personal relationships and opinions about dermatological treatment. Each item is scored from 0 (not affected at all) to 3 (very much affected). The DLQI score is the sum of the 10 individual question scores and ranges from 0 to 30, with lower scores indicating better quality of life. The higher the score, the more quality of life is impaired. The DLQI can also be expressed as a percentage of the maximum possible score of 30. Baseline value is defined as values collected at Week 1 of Part 1 of the study. Change from baseline is calculated by subtracting post-dose value baseline value. ITT population included and "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Baseline, Week 8 and 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n= 114, 35)	-2.07 (± 5.63)	-3.49 (± 4.92)		
Week 16 (n= 109, 32)	-3.32 (± 6.81)	-6.50 (± 6.87)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Skindex-16 score at Week 8 and Week 16 Visits

End point title	Part 1: Absolute Skindex-16 score at Week 8 and Week 16 Visits

End point description:

Skindex is the dermatological instruments to measure dermatology-specific Health-Related Quality of Life (HRQoL). The 16-item Skindex questionnaire is divided into three domains: questions related to the participant's symptoms (1-4), emotions (5-11), and functioning (12-16). Each question asks the

participant 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 are 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). Each item is then transformed to a linear scale from 0 to 100. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Week 8 and 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n= 116, 36)	51.93 (± 27.43)	45.01 (± 23.20)		
Week 16 (n= 109, 33)	45.26 (± 29.21)	37.19 (± 23.15)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change from baseline in the absolute Skindex-16 score at Week 8 and Week 16 Visits

End point title	Part 1: Change from baseline in the absolute Skindex-16 score at Week 8 and Week 16 Visits

End point description:

Skindex is the best dermatological instruments to measure dermatology-specific Health-Related Quality of Life (HRQoL). The 16-item Skindex questionnaire is divided into three domains: questions related to the participant's symptoms (1-4), emotions (5-11), and functioning (12-16). Each question asks the participant 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 are 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). Each item is then transformed to a linear scale from 0 to 100. Baseline value is defined as values collected at Week 1 of Part 1 of the study. Change from baseline is calculated by subtracting post-dose value baseline value. ITT population included and "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Baseline, Week 8 and 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n= 116, 36)	-8.69 (± 20.42)	-14.80 (± 18.73)		
Week 16 (n= 109, 33)	-14.77 (± 25.13)	-23.54 (± 28.22)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute pruritus-VAS score at Week 8 and Week 16 Visits

End point title	Part 1: Absolute pruritus-VAS score at Week 8 and Week 16 Visits

End point description:

The pruritus-VAS is used to assess the pruritus by ticking the scale, which describes pruritus the best. The pruritus-VAS is a single-item continuous scale comprised of a 10 centimeter (cm) [(100 millimeter (mm)] horizontal/vertical line anchored by two verbal descriptors, one for each symptom extreme. For pruritus intensity, the scale is anchored by "no pruritus" (score of 0) and "worst imaginable pruritus" (score of 100 mm). The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Week 8 and 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n= 117, 36)	5.06 (± 2.65)	4.69 (± 2.51)		
Week 16 (n= 110, 33)	4.63 (± 2.97)	3.91 (± 2.38)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change from baseline in the absolute pruritus-VAS score at Week 8 and Week 16 Visits

End point title	Part 1: Change from baseline in the absolute pruritus-VAS score at Week 8 and Week 16 Visits

End point description:

The pruritus-VAS is used to assess the pruritus by ticking the scale, which describes pruritus the best. The pruritus-VAS is a single-item continuous scale comprised of a 10 centimeter (cm) [(100 millimeter (mm)] horizontal/vertical line anchored by two verbal descriptors, one for each symptom extreme. For pruritus intensity, the scale is anchored by "no pruritus" (score of 0) and "worst imaginable pruritus" (score of 100 mm). Baseline value is defined as values collected at Week 1 of Part 1 of the study. Change from baseline is calculated by subtracting post-dose value baseline value. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Baseline, Week 8 and 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 8 (n= 117, 36)	-0.89 (± 2.81)	-0.31 (± 3.23)		
Week 16 (n= 110, 33)	-1.27 (± 3.22)	-1.33 (± 3.57)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Absolute Medical Outcomes Study Score (MOSS) at Week 16 Visit

End point title	Part 1: Absolute Medical Outcomes Study Score (MOSS) at Week 16 Visit

End point description:

The MOSS questionnaire consists of 12 items leading to 6 subscales or domains: sleep disturbance, sleep adequacy, daytime sleepiness, 'supposed or known' snoring, being awakened by shortness of breath or by a headache, and quantity of sleep. Subscales are standardized to yield scores from 0 to 100, with the exception of sleep quantity. Higher scores on the MOSS reflects more of the attribute indicated by the subscale name. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value.

End point type	Secondary

End point timeframe:

Week 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	110	33		
Units: units on a scale				
arithmetic mean (standard deviation)				
Disturbance	38.30 (± 21.45)	33.71 (± 15.78)		
Quantity	6.73 (± 1.27)	6.82 (± 0.98)		
Adequacy	56.59 (± 24.75)	57.58 (± 21.86)		
Shortness of breath/headache	22.05 (± 24.36)	18.18 (± 19.03)		
Snoring	43.64 (± 35.59)	38.64 (± 27.31)		
Somnolence	35.08 (± 22.30)	32.32 (± 16.50)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Change from baseline in the absolute MOSS score at Week 16 Visits

End point title	Part 1: Change from baseline in the absolute MOSS score at Week 16 Visits

End point description:

The MOSS questionnaire consists of 12 items leading to 6 subscales or domains: sleep disturbance, sleep adequacy, daytime sleepiness, 'supposed or known' snoring, being awakened by shortness of breath or by a headache, and quantity of sleep. Subscales are standardised to yield scores from 0 to 100, with the exception of sleep quantity. Higher scores on the MOSS reflects more of the attribute indicated by the subscale name. Baseline value is defined as values collected at Week 1 of Part 1 of the study. Change from baseline is calculated by subtracting post-dose value baseline value. The intention-to-treat (ITT) population for Part 1 was defined as all included patients who took at least one dose of the study medication in Part 1 of the study and had at least one efficacy baseline value.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Dimethyl fumarate standard scheme	Simplified DMF treatment scheme		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	46		
Units: units on a scale				
arithmetic mean (standard deviation)				
Disturbance	-4.09 (± 19.65)	-1.52 (± 15.15)		
Quantity	0.08 (± 1.20)	0.00 (± 0.79)		

Adequacy	1.82 (± 19.95)	-1.52 (± 25.15)		
Shortness of breath/headache	2.73 (± 19.56)	-4.55 (± 26.85)		
Snoring	-3.18 (± 26.69)	5.30 (± 21.43)		
Somnolence	2.42 (± 18.70)	3.79 (± 15.60)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of subjects achieving PASI 50, PASI 75 and PASI 90 responses

End point title	Part 2: Percentage of subjects achieving PASI 50, PASI 75 and PASI 90 responses

End point description:

PASI is 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 is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 (no psoriasis) to 72 (the most severe disease). PASI 50, 75, 90 response, is defined as having an improvement (reduction) of greater than or equal to (>=) 50%, 75%, and 90% respectively in PASI score compared to the baseline score. Here, 99999 indicates that there were no observes cases at specified timepoint for the group. The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Week 20/24; Week 32/36; Week 40; End of Study

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: percentage of subjects				
number (not applicable)				
PASI 50 at Week 20/24 (n=37,100)	97.3	58.0		
PASI 75 at Week 20/24 (n=37,100)	75.7	21.0		
PASI 90 at Week 20/24 (n=37,100)	29.7	8.0		
PASI 50 at Week 32/36 (n=30,103)	96.7	89.3		
PASI 75 at Week 32/36 (n=30,103)	73.3	70.9		
PASI 90 at Week 32/36 (n=30,103)	33.3	48.5		
PASI 50 at Week 40 (n=30,101)	100.0	95.0		
PASI 75 at Week 40 (n=30,101)	80.0	77.2		
PASI 90 at Week 40 (n=30,101)	33.3	54.5		
PASI 50 at EOS (n=5,0)	100.0	99999		
PASI 75 at EOS (n=5,0)	80.0	99999		
PASI 90 at EOS (n=5,0)	20.0	99999		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of subjects achieving absolute PASI scores of ≤5, ≤3 and ≤1

End point title	Part 2: Percentage of subjects achieving absolute PASI scores of ≤5, ≤3 and ≤1

End point description:

PASI is 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 is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 (no psoriasis) to 72 (the most severe disease). The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication.Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Week 20/24; Week 32/36; Week 40; End of Study

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: percentage of subjects				
number (not applicable)				
PASI ≤ 5 at Week 20/24 (n=37,100)	86.5	30.0		
PASI ≤ 3 at Week 20/24 (n=37,100)	64.9	14.0		
PASI ≤ 1 at Week 20/24 (n=37,100)	27.0	5.0		
PASI ≤ 5 at Week 32/36 (n=30,103)	83.3	75.7		
PASI ≤ 3 at Week 32/36 (n=30,103)	66.7	66.0		
PASI ≤ 1 at Week 32/36 (n=30,103)	26.7	36.9		
PASI ≤ 5 at Week 40 (n=30,101)	86.7	84.2		
PASI ≤ 3 at Week 40 (n=30,101)	73.3	68.3		
PASI ≤ 1 at Week 40 (n=30,101)	23.3	45.5		
PASI ≤ 5 at EOS (n=5,0)	100.0	99999		
PASI ≤ 3 at EOS (n=5,0)	60.0	99999		
PASI ≤ 1 at EOS (n=5,0)	0.0	99999		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute PASI score at each visit

End point title	Part 2: Absolute PASI score at each visit

End point description:

PASI is 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 is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 (no psoriasis) to 72 (the most severe disease). The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Week 20/24; Week 32/36; Week 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 20/24 (n= 37, 100)	2.81 (± 2.88)	8.67 (± 7.26)		
Week 32/36 (n= 30, 103)	2.41 (± 1.95)	3.56 (± 5.11)		
Week 40 (n= 30, 101)	2.41 (± 1.94)	2.77 (± 4.42)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change from baseline in the absolute PASI score at each visit

End point title	Part 2: Change from baseline in the absolute PASI score at each visit

End point description:

PASI is 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 is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 (no psoriasis) to 72 (the most severe disease). Baseline value is defined as values collected at Week 1 of Part 1 of the study. Change from baseline is calculated by subtracting post-dose value baseline value. The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Baseline; Week 20/24; Week 32/36; Week 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 20/24 (n= 37, 100)	-12.06 (± 5.41)	-9.38 (± 6.55)		
Week 32/36 (n= 30, 103)	-12.49 (± 5.36)	-14.31 (± 6.96)		
Week 40 (n= 30, 101)	-12.49 (± 4.96)	-14.91 (± 6.77)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percent change from baseline in the absolute PASI score at each visit

End point title	Part 2: Percent change from baseline in the absolute PASI score at each visit

End point description:

PASI is 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 is performed at four body areas, the head, arms, trunk, and legs. The total PASI score ranges from 0 (no psoriasis) to 72 (the most severe disease). Baseline value is defined as values collected at Week 1 of Part 1 of the study. Percent Change from Baseline=Change from baseline/baseline value*100. If baseline value was 0, percent change from baseline was not computed. The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Baseline; Week 20/24; Week 32/36; Week 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: percent change				
arithmetic mean (standard deviation)				
Week 20/24 (n= 37, 100)	-80.12 (± 18.61)	-52.20 (± 26.15)		
Week 32/36 (n= 30, 103)	-82.74 (± 14.00)	-81.41 (± 19.15)		
Week 40 (n= 30, 101)	-83.38 (± 12.53)	-85.66 (± 16.08)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Body Surface Area (BSA) Score at each visit

End point title	Part 2: Absolute Body Surface Area (BSA) Score at each visit

End point description:

BSA is a numerical score used to measure the total area of the body affected by psoriasis. The palm method will be applied: the participant's palm, including the five digits is used as a reference (representing approximately 1% of the total body surface area) and is used to repeatedly cover the lesions on the body. The investigator totals the number of palms required and then estimates the percentage (%) in each of the four body regions: head (including scalp) and neck (10%); upper extremities (20%); trunk (30%); and lower extremities (40%). The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Week 20/24; Week 32/36; Week 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 20/24 (n= 37, 100)	3.44 (± 3.37)	14.88 (± 12.66)		
Week 32/36 (n= 30, 103)	2.49 (± 2.99)	5.92 (± 7.67)		
Week 40 (n= 30, 101)	2.20 (± 2.35)	3.87 (± 6.12)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change from baseline in the absolute BSA score at each visit

End point title	Part 2: Change from baseline in the absolute BSA score at each visit

End point description:

BSA is a numerical score used to measure the total area of the body affected by psoriasis. The palm method will be applied: the participant's palm, including the five digits is used as a reference (representing approximately 1% of the total body surface area) and is used to repeatedly cover the lesions on the body. The investigator totals the number of palms required and then estimates the percentage (%) in each of the four body regions: head (including scalp) and neck (10%); upper extremities (20%); trunk (30%); and lower extremities (40%).The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Baseline; Week 20/24; Week 32/36; Week 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	100		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 20/24 (n=37,100)	-14.90 (± 12.43)	-7.82 (± 12.10)		
Week 32/36 (n=30,103)	-15.67 (± 11.48)	-16.45 (± 16.82)		
Week 40 (n=30,101)	-15.96 (± 11.80)	-18.23 (± 17.50)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of subjects achieving PGA scores of 0 or 1 at each visit

End point title	Part 2: Percentage of subjects achieving PGA scores of 0 or 1 at each visit

End point description:

The PGA score is used to assess the overall severity of the psoriasis lesions at the time of evaluation. Overall lesions is graded for erythema, induration, and scale based on 6-point scale ranging from 0 (clear) to 5 (severe). The sum of 3 scales is divided by 3 to obtain final PGA score.The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Baseline; Week 20/24; Week 32/36; Week 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: percentage of subjects				
number (not applicable)				
Week 20/24 (n=37,100)	56.8	34.0		
Week 32/36 (n=30,103)	50.0	70.9		
Week 40 (n=30,100)	50.0	78.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of subjects achieving ScPGA and PPPGA scores of 0 or 1 at each visit

End point title	Part 2: Percentage of subjects achieving ScPGA and PPPGA scores of 0 or 1 at each visit

End point description:

The scPGA score is used to assess the average severity of scalp psoriasis lesions. The scPGA is also 5-point scale ranging from 0 (clear) to 4 (severe), where higher score indicates severe scalp psoriasis lesions. Only in participants with scalp involvement, scPGA assessment was performed. The PPPGA score is used to assess the average severity of psoriasis lesions on hands and/or feet. The PPPGA is 5- point scale ranging from 0 (clear) to 4 (severe), where higher score indicates severe psoriasis lesions on hands and/or feet. Only in participants with palmar or plantar involvement the PPPGA assessment was performed. Baseline value is defined as values collected at Week 1 of Part 1 of study. Change from baseline is calculated by subtracting post-dose value baseline value. The ITT population for Part 2 was defined as all patients entering Part 2 of study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Baseline; Week 20/24; Week 32/36; Week 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: percentage of subjects				
number (not applicable)				
PPPGA (0,1) at Week 20/24 (n=31,97)	93.5	84.5		
ScPGA (0,1) at Week 20/24 (n=35,99)	74.3	47.5		
PPPGA (0,1) at Week 32/36 (n=25,101)	92.0	94.1		
ScPGA (0,1) at Week 32/36 (n=27,102)	70.4	72.5		
PPPGA (0,1) at Week 40 (n=27,99)	92.6	91.9		
ScPGA (0,1) at Week 40 (n=30,100)	63.3	79.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute PGA scores at each visit

End point title	Part 2: Absolute PGA scores at each visit

End point description:

The PGA score is used to assess the overall severity of the psoriasis lesions at the time of evaluation. Overall lesions is graded for erythema, induration, and scale based on 6-point scale ranging from 0 (clear) to 5 (severe). The sum of 3 scales is divided by 3 to obtain final PGA score. The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Week 20/24; Week 32/36; Week 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 20/24 (n= 37, 100)	1.35 (± 0.86)	1.91 (± 0.88)		
Week 32/36 (n= 30, 103)	1.40 (± 1.00)	1.22 (± 0.91)		
Week 40 (n= 30, 100)	1.57 (± 1.04)	0.93 (± 0.90)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percent change from baseline in the absolute PGA scores at each visit

End point title	Part 2: Percent change from baseline in the absolute PGA scores at each visit

End point description:

The PGA score is used to assess the overall severity of the psoriasis lesions at the time of evaluation. Overall lesions will be graded for erythema, induration, and scale based on 6-point scale ranging from 0 (clear) to 5 (severe). The sum of 3 scales will be divided by 3 to obtain final PGA score. Baseline value is defined as values collected at Week 1 of Part 1 of the study. Change from baseline is calculated by subtracting post-dose value baseline value. The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Baseline; Week 20/24; Week 32/36; Week 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: percent change				
arithmetic mean (standard deviation)				
Week 20/24 (n= 37, 100)	-55.86 (± 30.80)	-41.77 (± 22.80)		
Week 32/36 (n= 30, 103)	-55.83 (± 32.69)	-62.17 (± 26.07)		
Week 40 (n= 30, 100)	-50.28 (± 32.57)	-70.93 (± 26.99)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percent change from baseline in the absolute ScPGA and PPPGA

scores at each visit

End point title	Part 2: Percent change from baseline in the absolute ScPGA and PPPGA scores at each visit

End point description:

The scPGA score is used to assess average severity of scalp psoriasis lesions. scPGA is also 5- point scale ranging from 0 (clear) to 4 (severe), higher score indicate severe scalp psoriasis lesions. Only in participants with scalp involvement, the scPGA assessment was performed. PPPGA score is used to assess average severity of psoriasis lesions on hands and/or feet. PPPGA is a 5- point scale ranging from 0 (clear) to 4 (severe), higher score indicates severe psoriasis lesions on hands and/or feet. Only in participants with palmar or plantar involvement, PPPGA assessment was performed. Baseline value is defined as values collected at Week 1 of Part 1 of study. Percent Change from Baseline=Change from baseline/baseline value*100. If baseline value was 0, percent change from baseline was not computed. ITT population for Part 2 = all patients entering Part 2 of study who took at least one dose of assigned Part 2 study medication. Here, "n"= number of subjects analysed for each category.

End point type	Secondary

End point timeframe:

Baseline; Week 20/24; Week 32/36; Week 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: percent change				
arithmetic mean (standard deviation)				
PPPGA: Week 20/24 (n= 6, 25)	-77.78 (± 40.37)	-61.00 (± 39.80)		
PPPGA: Week 32/36 (n= 5, 27)	-86.67 (± 29.81)	-84.57 (± 29.12)		
PPPGA: Week 40 (n= 5, 27)	-80.00 (± 44.72)	-84.88 (± 27.45)		
ScPGA: Week 20/24 (n= 32, 85)	-69.01 (± 40.34)	-47.06 (± 32.22)		
ScPGA: Week 32/36 (n= 25, 87)	-70.67 (± 44.69)	-71.55 (± 33.61)		
ScPGA: Week 40 (n= 27, 86)	-63.89 (± 43.30)	-73.74 (± 30.48)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of subjects achieving Dermatology Quality of Life Index (DLQI) scores of 0 or 1 at Week 32 and Week 40 Visits

End point title	Part 2: Percentage of subjects achieving Dermatology Quality of Life Index (DLQI) scores of 0 or 1 at Week 32 and Week 40 Visits

End point description:

DLQI is a questionnaire which is to evaluate the impact on participant's quality of life due to psoriasis. It is composed of ten items related to symptoms, feelings, daily activities, leisure, working or studying activities, personal relationships and opinions about dermatological treatment. Each item is scored from 0 (not affected at all) to 3 (very much affected). The DLQI score is the sum of the 10 individual question scores and ranges from 0 to 30, with lower scores indicating better quality of life. The higher the score, the more quality of life is impaired. The DLQI can also be expressed as a percentage of the maximum

possible score of 30. The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Week 32 and 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: percentage of subjects				
number (not applicable)				
Week 32 (n=28,101)	50.0	45.5		
Week 40 (n=29,100)	51.7	56.0		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute DLQI score at Week 32 and Week 40 Visits

End point title	Part 2: Absolute DLQI score at Week 32 and Week 40 Visits

End point description:

DLQI is a questionnaire which is to evaluate the impact on participant's quality of life due to psoriasis. It is composed of ten items related to symptoms, feelings, daily activities, leisure, working or studying activities, personal relationships and opinions about dermatological treatment. Each item is scored from 0 (not affected at all) to 3 (very much affected). The DLQI score is the sum of the 10 individual question scores and ranges from 0 to 30, with lower scores indicating better quality of life. The higher the score, the more quality of life is impaired. The DLQI can also be expressed as a percentage of the maximum possible score of 30. The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Week 32, 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 32 (n= 28, 101)	3.50 (± 4.84)	3.75 (± 4.94)		
Week 40 (n= 29, 100)	3.41 (± 5.21)	3.36 (± 4.96)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percent change from baseline in the absolute DLQI score at Week 32 and Week 40 Visits

End point title	Part 2: Percent change from baseline in the absolute DLQI score at Week 32 and Week 40 Visits

End point description:

DLQI is a questionnaire which is to evaluate the impact on participant's quality of life due to psoriasis. It is composed of ten items related to symptoms, feelings, daily activities, leisure, working or studying activities, personal relationships and opinions about dermatological treatment. Each item is scored from 0 (not affected at all) to 3 (very much affected). The DLQI score is the sum of the 10 individual question scores and ranges from 0 to 30, with lower scores indicating better quality of life. The higher the score, the more quality of life is impaired. The DLQI can also be expressed as a percentage of the maximum possible score of 30. Percent Change from Baseline=Change from baseline/baseline value*100. If baseline value was 0, percent change from baseline was not computed. The ITT population for Part 2 was defined as all patients entering Part 2 of study who took at least one dose of assigned Part 2 study medication. Here, "n"=number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Baseline, Week 32 and 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: percent change				
arithmetic mean (standard deviation)				
Week 32 (n= 28, 99)	-68.47 (± 30.69)	-65.83 (± 46.56)		
Week 40 (n= 29, 98)	-65.82 (± 44.70)	-66.78 (± 48.67)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute Skindex-16 score at Week 32 and Week 40 Visits

End point title	Part 2: Absolute Skindex-16 score at Week 32 and Week 40 Visits

End point description:

Skindex is the dermatological instruments to measure dermatology-specific Health-Related Quality of Life (HRQoL). The 16-item Skindex questionnaire is divided into three domains: questions related to the participant's symptoms (1-4), emotions (5-11), and functioning (12-16). Each question asks the

participant 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 are 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). Each item is then transformed to a linear scale from 0 to 100. The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Week 32 and 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 32 (n= 28, 101)	17.86 (± 24.30)	20.24 (± 23.94)		
Week 40 (n= 29, 100)	19.40 (± 24.75)	18.97 (± 24.11)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percent change from baseline in the absolute Skindex-16 score at Week 32 and Week 40 Visits

End point title	Part 2: Percent change from baseline in the absolute Skindex-16 score at Week 32 and Week 40 Visits

End point description:

Skindex is dermatological instruments to measure dermatology-specific Health-Related Quality of Life (HRQoL). The 16-item Skindex questionnaire is divided into three domains: questions related to participant's symptoms (1-4), emotions (5-11), and functioning (12-16). Each question asks the participant to quantify how much a specific aspect of their skin condition bothered them in week prior to administration of the Skindex-16. The questions are 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). Each item is then transformed to linear scale from 0 to 100. Percent Change from Baseline=Change from baseline/baseline value*100. If baseline value was 0, percent change from baseline was not computed. The ITT population for Part 2 was defined as all patients entering Part 2 of study who took at least one dose of assigned Part 2 study medication. Here, "n"=number of subjects analysed for each category.

End point type	Secondary

End point timeframe:

Baseline, Week 32 and Week 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: percent change				
arithmetic mean (standard deviation)				
Week 32 (n= 27, 95)	-70.66 (± 33.90)	-53.59 (± 131.66)		
Week 40 (n= 28, 94)	-67.48 (± 34.06)	-54.01 (± 114.09)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute pruritus-VAS score at each visit

End point title	Part 2: Absolute pruritus-VAS score at each visit

End point description:

The pruritus-VAS is used to assess the pruritus by ticking the scale, which describes pruritus the best. The pruritus-VAS is a single-item continuous scale comprised of a 10 centimeter (cm) [(100 millimeter (mm)] horizontal/vertical line anchored by two verbal descriptors, one for each symptom extreme. For pruritus intensity, the scale is anchored by "no pruritus" (score of 0) and "worst imaginable pruritus" (score of 100 mm). Baseline value is defined as values collected at Week 1 of Part 1 of the study. Change from baseline is calculated by subtracting post-dose value baseline value. The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Week 20/24; Week 32/36; Week 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: units on a scale				
arithmetic mean (standard deviation)				
Week 20/24 (n= 35, 102)	1.77 (± 1.68)	3.73 (± 2.74)		
Week 32/36 (n= 28, 101)	1.82 (± 2.13)	2.46 (± 2.53)		
Week 40 (n= 29, 100)	1.97 (± 2.37)	2.13 (± 2.44)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percent change from baseline in the absolute pruritus-VAS score at each visit

End point title	Part 2: Percent change from baseline in the absolute pruritus-

	VAS score at each visit

End point description:

The pruritus-VAS is used to assess the pruritus by ticking the scale, which describes pruritus the best. The pruritus-VAS is a single-item continuous scale comprised of a 10 centimeter (cm) [(100 millimeter (mm)] horizontal/vertical line anchored by two verbal descriptors, one for each symptom extreme. For pruritus intensity, the scale is anchored by "no pruritus" (score of 0) and "worst imaginable pruritus" (score of 100 mm). Baseline value is defined as values collected at Week 1 of Part 1 of the study. Percent Change from Baseline=Change from baseline/baseline value*100. If baseline value was 0, percent change from baseline was not computed. The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Baseline; Week 20/24; Week 32/36; Week 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: percent change				
arithmetic mean (standard deviation)				
Week 20/24 (n= 33, 96)	-62.69 (± 34.953)	-14.25 (± 112.46)		
Week 32/36 (n= 27, 95)	-60.33 (± 44.02)	-37.56 (± 110.72)		
Week 40 (n= 28, 94)	-54.02 (± 58.39)	-44.50 (± 117.03)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Absolute MOSS score at Week 40 Visit

End point title	Part 2: Absolute MOSS score at Week 40 Visit

End point description:

The MOSS questionnaire consists of 12 items leading to 6 subscales or domains: sleep disturbance, sleep adequacy, daytime sleepiness, 'supposed or known' snoring, being awakened by shortness of breath or by a headache, and quantity of sleep. Subscales are standardized to yield scores from 0 to 100, with the exception of sleep quantity. Higher scores on the MOSS reflects more of the attribute indicated by the subscale name.The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication.

End point type	Secondary

End point timeframe:

Week 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	29	100		
Units: units on a scale				
arithmetic mean (standard deviation)				
Disturbance	29.53 (± 22.47)	34.56 (± 21.38)		
Quantity	6.97 (± 1.02)	6.87 (± 1.23)		
Adequacy	60.34 (± 24.34)	57.75 (± 23.82)		
Shortness of breath/headache	13.79 (± 17.15)	19.00 (± 22.51)		
Snoring	36.21 (± 33.80)	42.75 (± 31.04)		
Somnolence	28.45 (± 20.72)	31.67 (± 20.03)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percent change from baseline in the absolute MOSS score at Week 40 Visit

End point title	Part 2: Percent change from baseline in the absolute MOSS score at Week 40 Visit

End point description:

The MOSS questionnaire consists of 12 items leading to 6 subscales or domains: sleep disturbance, sleep adequacy, daytime sleepiness, 'supposed or known' snoring, being awakened by shortness of breath or by a headache, and quantity of sleep. Subscales are standardized to yield scores from 0 to 100, with the exception of sleep quantity. Higher scores on the MOSS reflects more of the attribute indicated by the subscale name. Percent Change from Baseline=Change from baseline/baseline value*100. If baseline value was 0, percent change from baseline was not computed. The ITT population for Part 2 was defined as all patients entering Part 2 of the study who took at least one dose of the assigned Part 2 study medication. Here, "n" signifies number of subjects analyzed for each category.

End point type	Secondary

End point timeframe:

Baseline and Week 40

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: percent change				
arithmetic mean (standard deviation)				
Disturbance (n=28,100)	-16.61 (± 50.12)	2.45 (± 85.52)		
Quantity (n=29,100)	3.61 (± 13.41)	4.85 (± 21.12)		
Adequacy (n=28,99)	20.41 (± 73.70)	20.86 (± 82.03)		
Shortness of breath/headache (n=11,54)	-18.18 (± 81.46)	-29.32 (± 60.65)		

Snoring (n=20,80) Somnolence (n=28,97)	8.75 (± 72.22) 2.71 (± 73.96)	-7.08 (± 56.41) 21.89 (± 136.39)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of Subjects with Treatment-Emergent Adverse Events (TEAEs)

End point title	Part 2: Number of Subjects with Treatment-Emergent Adverse Events (TEAEs)

End point description:

An Adverse event (AE) is defined as "any untoward medical occurrence in a clinical trial participant (regardless of the administration of the study drug and its causal relationship to it). An AE can therefore be any unfavourable and unintended medical occurrence during the participant's participation in the trial, including deterioration of a pre-existing medical condition, an abnormal clinically significant finding in a laboratory assessment, or an abnormal clinically significant finding in the physical examination or vital sign. Any AE occurring following the start of treatment or occurring before treatment but increasing in severity afterward will be counted as TEAE. The Safety Analyses Set (SAF) was defined as all subjects who were included and took at least one dose of the study medication.

End point type	Secondary

End point timeframe:

Up to Week 49

End point values	DMF treatment	Tildrakizumab treatment		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	37	103		
Units: subjects	24	41		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to Week 49	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups	
Reporting group title	Part 1: Standard DMF treatment scheme
Reporting group description:	
Participants received DMF standard scheme from baseline to Week 16.	
Reporting group title	Part 1: Simplified DMF treatment scheme
Reporting group description:	
Participants achieving a PASI 75 response (responders) and participants failing to achieve a PASI 75 response but having achieved a PASI 50 response (partial responders) at Week 16 continued with DMF treatment until Week 40. Participants failing to achieve a PASI 50 response (non-responders) at Week 16 were treated with Tildrakizumab until Week 40.	
Reporting group title	Part 2: DMF treatment
Reporting group description:	
Participants achieving a Psoriasis Area and Severity Index (PASI) 75 response (responders) and participants failing to achieve a PASI 75 response but having achieved a PASI 50 response (partial responders) at Week 16 continued with DMF treatment until Week 40.	
Reporting group title	Part 2: Tildrakizumab treatment
Reporting group description:	
Participants who achieve PASI less than (<) 50 (non-responders) at Week 16 received Tildrakizumab subcutaneous injection at a dose of either 100 or 200 mg [(as per the Summary of Product Characteristics (SmPC)] at Weeks 16, 20 and 32 up to Week 40.	

Serious adverse events	Part 1: Standard DMF treatment scheme	Part 1: Simplified DMF treatment scheme	Part 2: DMF treatment
Total subjects affected by serious adverse events			
subjects affected / exposed	5 / 143 (3.50%)	0 / 46 (0.00%)	0 / 37 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 143 (0.00%)	0 / 46 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Chest pain			

subjects affected / exposed	1 / 143 (0.70%)	0 / 46 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Gastric ulcer			
subjects affected / exposed	1 / 143 (0.70%)	0 / 46 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal hernia			
subjects affected / exposed	1 / 143 (0.70%)	0 / 46 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	1 / 143 (0.70%)	0 / 46 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 2: Tildrakizumab treatment		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 103 (0.97%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Chest pain			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			

Gastric ulcer			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Inguinal hernia			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Gastroenteritis			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Frequency threshold for reporting non-serious adverse events: 2 %

Non-serious adverse events	Part 1: Standard DMF treatment scheme	Part 1: Simplified DMF treatment scheme	Part 2: DMF treatment
Total subjects affected by non-serious adverse events			
subjects affected / exposed	123 / 143 (86.01%)	40 / 46 (86.96%)	24 / 37 (64.86%)
Vascular disorders			
Hot flush			
subjects affected / exposed	10 / 143 (6.99%)	2 / 46 (4.35%)	0 / 37 (0.00%)
occurrences (all)	10	3	0
Hypertension			
subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
Flushing			
subjects affected / exposed	40 / 143 (27.97%)	12 / 46 (26.09%)	2 / 37 (5.41%)
occurrences (all)	47	15	2
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	3 / 143 (2.10%)	2 / 46 (4.35%)	0 / 37 (0.00%)
occurrences (all)	3	2	0
Reproductive system and breast disorders			

Dysmenorrhoea			
subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Sleep disorder			
subjects affected / exposed	1 / 143 (0.70%)	0 / 46 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Investigations			
Transaminases increased			
subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Lymphocyte count decreased			
subjects affected / exposed	7 / 143 (4.90%)	3 / 46 (6.52%)	1 / 37 (2.70%)
occurrences (all)	7	3	1
Weight increased			
subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
CD8 lymphocytes decreased			
subjects affected / exposed	2 / 143 (1.40%)	0 / 46 (0.00%)	1 / 37 (2.70%)
occurrences (all)	2	0	1
CD4 lymphocytes decreased			
subjects affected / exposed	0 / 143 (0.00%)	0 / 46 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Blood creatine phosphokinase increased			
subjects affected / exposed	4 / 143 (2.80%)	0 / 46 (0.00%)	1 / 37 (2.70%)
occurrences (all)	4	0	1
Injury, poisoning and procedural complications			
Vaccination complication			
subjects affected / exposed	0 / 143 (0.00%)	2 / 46 (4.35%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Traumatic arthropathy			

subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Meniscus injury			
subjects affected / exposed	1 / 143 (0.70%)	0 / 46 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Nervous system disorders			
Migraine			
subjects affected / exposed	2 / 143 (1.40%)	2 / 46 (4.35%)	0 / 37 (0.00%)
occurrences (all)	2	2	0
Paraesthesia			
subjects affected / exposed	4 / 143 (2.80%)	2 / 46 (4.35%)	1 / 37 (2.70%)
occurrences (all)	5	2	1
Headache			
subjects affected / exposed	14 / 143 (9.79%)	6 / 46 (13.04%)	1 / 37 (2.70%)
occurrences (all)	15	7	2
Dizziness			
subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	1 / 143 (0.70%)	0 / 46 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Eosinophilia			
subjects affected / exposed	1 / 143 (0.70%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Lymphopenia			
subjects affected / exposed	17 / 143 (11.89%)	3 / 46 (6.52%)	8 / 37 (21.62%)
occurrences (all)	17	3	8
Gastrointestinal disorders			
Dry mouth			
subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Colitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 46 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Diarrhoea			

subjects affected / exposed	61 / 143 (42.66%)	12 / 46 (26.09%)	2 / 37 (5.41%)
occurrences (all)	64	14	2
Constipation			
subjects affected / exposed	4 / 143 (2.80%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	4	1	0
Abdominal pain upper			
subjects affected / exposed	34 / 143 (23.78%)	15 / 46 (32.61%)	0 / 37 (0.00%)
occurrences (all)	36	15	0
Abdominal pain			
subjects affected / exposed	25 / 143 (17.48%)	7 / 46 (15.22%)	1 / 37 (2.70%)
occurrences (all)	27	10	1
Toothache			
subjects affected / exposed	2 / 143 (1.40%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	2	1	0
GI pain			
subjects affected / exposed	4 / 143 (2.80%)	0 / 46 (0.00%)	0 / 37 (0.00%)
occurrences (all)	6	0	0
Vomiting			
subjects affected / exposed	5 / 143 (3.50%)	2 / 46 (4.35%)	0 / 37 (0.00%)
occurrences (all)	5	2	0
Nausea			
subjects affected / exposed	14 / 143 (9.79%)	4 / 46 (8.70%)	1 / 37 (2.70%)
occurrences (all)	15	4	1
Abdominal discomfort			
subjects affected / exposed	5 / 143 (3.50%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	7	1	0
Gastritis			
subjects affected / exposed	4 / 143 (2.80%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	5	1	0
GI disorder			
subjects affected / exposed	15 / 143 (10.49%)	6 / 46 (13.04%)	0 / 37 (0.00%)
occurrences (all)	16	6	0
Skin and subcutaneous tissue disorders			
Skin swelling			
subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	0	1	0

Seborrhoeic dermatitis			
subjects affected / exposed	1 / 143 (0.70%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Rash			
subjects affected / exposed	3 / 143 (2.10%)	0 / 46 (0.00%)	0 / 37 (0.00%)
occurrences (all)	3	0	0
Psoriasis			
subjects affected / exposed	7 / 143 (4.90%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	8	1	0
Pruritus			
subjects affected / exposed	9 / 143 (6.29%)	3 / 46 (6.52%)	0 / 37 (0.00%)
occurrences (all)	11	3	0
Renal and urinary disorders			
Ketonuria			
subjects affected / exposed	1 / 143 (0.70%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Glycosuria			
subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	1 / 143 (0.70%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	2	1	0
Musculoskeletal pain			
subjects affected / exposed	3 / 143 (2.10%)	0 / 46 (0.00%)	0 / 37 (0.00%)
occurrences (all)	4	0	0
Back pain			
subjects affected / exposed	1 / 143 (0.70%)	0 / 46 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Muscle tightness			
subjects affected / exposed	1 / 143 (0.70%)	0 / 46 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Arthralgia			
subjects affected / exposed	5 / 143 (3.50%)	0 / 46 (0.00%)	0 / 37 (0.00%)
occurrences (all)	5	0	0
Infections and infestations			

Herpes zoster			
subjects affected / exposed	1 / 143 (0.70%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Gastroenteritis			
subjects affected / exposed	2 / 143 (1.40%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	2	1	0
Diverticulitis			
subjects affected / exposed	0 / 143 (0.00%)	0 / 46 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Cystitis			
subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
Hordeolum			
subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Coronavirus infection			
subjects affected / exposed	4 / 143 (2.80%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	4	1	0
Tonsillitis			
subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Tinea versicolour			
subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Subcutaneous abscess			
subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Sinusitis bacterial			
subjects affected / exposed	0 / 143 (0.00%)	0 / 46 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Nasopharyngitis			
subjects affected / exposed	11 / 143 (7.69%)	3 / 46 (6.52%)	4 / 37 (10.81%)
occurrences (all)	11	3	4
Metabolism and nutrition disorders			
Hyperuricaemia			

subjects affected / exposed	1 / 143 (0.70%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 143 (0.00%)	1 / 46 (2.17%)	0 / 37 (0.00%)
occurrences (all)	0	1	0

Non-serious adverse events	Part 2: Tildrakizumab treatment		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	41 / 103 (39.81%)		
Vascular disorders			
Hot flush			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	2 / 103 (1.94%)		
occurrences (all)	2		
Flushing			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Sleep disorder			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Investigations			

Transaminases increased subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1		
Lymphocyte count decreased subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1		
Weight increased subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0		
CD8 lymphocytes decreased subjects affected / exposed occurrences (all)	2 / 103 (1.94%) 2		
CD4 lymphocytes decreased subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0		
Blood creatine phosphokinase increased subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1		
Injury, poisoning and procedural complications Vaccination complication subjects affected / exposed occurrences (all)	2 / 103 (1.94%) 2		
Traumatic arthropathy subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0		
Meniscus injury subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0		
Nervous system disorders Migraine subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1		
Paraesthesia subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0		
Headache			

subjects affected / exposed	6 / 103 (5.83%)		
occurrences (all)	6		
Dizziness			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Eosinophilia			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Lymphopenia			
subjects affected / exposed	3 / 103 (2.91%)		
occurrences (all)	3		
Gastrointestinal disorders			
Dry mouth			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Colitis			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Diarrhoea			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences (all)	1		
Constipation			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Abdominal pain upper			
subjects affected / exposed	2 / 103 (1.94%)		
occurrences (all)	2		
Abdominal pain			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Toothache			

subjects affected / exposed	1 / 103 (0.97%)		
occurrences (all)	1		
GI pain			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences (all)	1		
Nausea			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Abdominal discomfort			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Gastritis			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
GI disorder			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Skin swelling			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Seborrhoeic dermatitis			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences (all)	1		
Rash			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Psoriasis			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences (all)	1		
Pruritus			
subjects affected / exposed	2 / 103 (1.94%)		
occurrences (all)	2		

Renal and urinary disorders			
Ketonuria			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences (all)	1		
Glycosuria			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences (all)	1		
Musculoskeletal pain			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	2 / 103 (1.94%)		
occurrences (all)	2		
Muscle tightness			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Arthralgia			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences (all)	1		
Infections and infestations			
Herpes zoster			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences (all)	1		
Gastroenteritis			
subjects affected / exposed	1 / 103 (0.97%)		
occurrences (all)	1		
Diverticulitis			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		
Cystitis			
subjects affected / exposed	0 / 103 (0.00%)		
occurrences (all)	0		

Hordeolum subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0		
Coronavirus infection subjects affected / exposed occurrences (all)	5 / 103 (4.85%) 5		
Tonsillitis subjects affected / exposed occurrences (all)	1 / 103 (0.97%) 1		
Tinea versicolour subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0		
Subcutaneous abscess subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0		
Sinusitis bacterial subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0		
Nasopharyngitis subjects affected / exposed occurrences (all)	2 / 103 (1.94%) 2		
Metabolism and nutrition disorders Hyperuricaemia subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0		
Hypertriglyceridaemia subjects affected / exposed occurrences (all)	0 / 103 (0.00%) 0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
20 September 2019	Amendment 1: -Included laboratory parameters for haematology: differential count (absolute and relative) for CD4+ and CD8+ T lymphocytes as well as CD4/CD8 ratio. -Changed the withdrawal criterion about the violation of eligibility criteria to make this criterion the same for all centres. -Clarified the exclusion criterion about the excipient (criterion number 5). -Included the rational for simplified DMF scheme and the non-washout period between the DMF and tildrakizumab administration. -Clarified the wording of exclusion criteria number 13 and 14. -Eliminated albumin as a urinalysis parameter in the laboratory safety measurements. -Clarified information about the subsequent medication information to be collected after the last dose of the study drug. -Aligned the contraceptive methods advice in the protocol with those in tildrakizumab and DMF SmPCs. -To clarify the destruction of the remaining study medication; license from company in charge of the destruction was requested.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
31 March 2020	The screening and recruitment of new participants was paused due to the ongoing SARS-CoV-2 pandemic in Europe. The decision was based on commitment to protect the safety and health of study participants, site staff and their families and the challenges expressed by the investigators in regards to enrolling participants during the pandemic.	13 May 2020

Notes:

Limitations and caveats

None reported