Clinical trial results:
A Phase II, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Lebrikizumab in Patients With Persistent Moderate to Severe Atopic Dermatitis That is Inadequately Controlled by Topical Corticosteroids

Summary

EudraCT number	2014-000049-56
Trial protocol	DE CZ ES FI NL PL
Global end of trial date	18 April 2016

Results information

Result version number	v1 (current)
This version publication date	04 May 2017
First version publication date	04 May 2017

Trial information

Trial identification

Sponsor protocol code	GS29250

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02340234
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	Roche Trial Information Hotline, F. Hoffmann-La Roche AG, +41 61 6878333, global.trial_information@roche.com
Scientific contact	Roche Trial Information Hotline, F. Hoffmann-La Roche AG, +41 61 6878333, global.trial_information@roche.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	29 June 2016
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	18 April 2016
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study was to evaluate the safety and efficacy of lebrikizumab used as adjunctive therapy with topical corticosteroids (TCS), compared with TCS in participants with persistent moderate to severe atopic dermatitis (AD).

Protection of trial subjects:

The study was conducted in accordance with the principles of the "Declaration of Helsinki" and Good Clinical Practice (GCP) according to the regulations and procedures described in the protocol. Approval from the Ethics Committee (EC)/Institutional Review Board (IRB) was obtained before study start. Roche also obtained approval from the relevant Competent Authority prior to starting the study. No modifications were made to the protocol after receipt of the EC/IRB approval.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	18 May 2015
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	Korea, Republic of: 18
Country: Number of subjects enrolled	Taiwan: 14
Country: Number of subjects enrolled	Czech Republic: 15
Country: Number of subjects enrolled	Finland: 11
Country: Number of subjects enrolled	France: 18
Country: Number of subjects enrolled	Germany: 6
Country: Number of subjects enrolled	United Kingdom: 10
Country: Number of subjects enrolled	Netherlands: 8
Country: Number of subjects enrolled	Poland: 17
Country: Number of subjects enrolled	Spain: 20
Country: Number of subjects enrolled	Switzerland: 6
Country: Number of subjects enrolled	Australia: 20
Country: Number of subjects enrolled	Canada: 15
Country: Number of subjects enrolled	United States: 34
Worldwide total number of subjects	212
EEA total number of subjects	105

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)	209
From 65 to 84 years	3
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 294 participants were screened, 212 participants were randomized, and 209 received at least one dose of study drug.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Lebrikizumab 250 mg Single Dose + TCS

Arm description:

Participants received a single dose of lebrikizumab 250 milligrams (mg) subcutaneous (SC) injection on Day 1 followed by placebo on Week 4 and Week 8. Participants continued to apply TCS cream (triamcenolone acetonide 0.1 percent [%] or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.

Arm type	Experimental
Investigational medicinal product name	Lebrikizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Lebrikizumab administered as SC injection as per the schedule specified in the respective arms.

Investigational medicinal product name	Triamcinolone acetonide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

Triamcinolone acetonide 0.1% cream was applied twice daily to active skin lesions.

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

Dosage and administration details:

Placebo matched to lebrikizumab

Investigational medicinal product name	Hydrocortisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

Hydrocortisone 2.5% cream was applied twice daily to active skin lesions.

Arm title	Lebrikizumab 125 mg Single Dose + TCS

Arm description:

Participants received a single dose of lebrikizumab 125 mg SC injection on Day 1 followed by placebo on Week 4 and Week 8. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.

Arm type	Experimental
Investigational medicinal product name	Lebrikizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Lebrikizumab administered as SC injection as per the schedule specified in the respective arms.

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

Dosage and administration details:

Placebo matched to lebrikizumab

Investigational medicinal product name	Triamcinolone acetonide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

Triamcinolone acetonide 0.1% cream was applied twice daily to active skin lesions.

Investigational medicinal product name	Hydrocortisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

Hydrocortisone 2.5% cream was applied twice daily to active skin lesions.

Arm title	Lebrikizumab 125 mg Q4W + TCS

Arm description:

Participants received lebrikizumab 125 mg SC injection every 4 weeks (Q4W) for a total of 3 doses. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.

Arm type	Experimental
Investigational medicinal product name	Lebrikizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection in pre-filled syringe
Routes of administration	Subcutaneous use

Dosage and administration details:

Lebrikizumab administered as SC injection as per the schedule specified in the respective arms.

Investigational medicinal product name	Hydrocortisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

Hydrocortisone 2.5% cream was applied twice daily to active skin lesions.

Investigational medicinal product name	Triamcinolone acetonide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

Triamcinolone acetonide 0.1% cream was applied twice daily to active skin lesions.

Arm title	Placebo Q4W + TCS Cream

Arm description:

Participants received placebo Q4W for a total of 3 doses. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.

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

Dosage and administration details:

Placebo matched to lebrikizumab

Investigational medicinal product name	Hydrocortisone
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

Hydrocortisone 2.5% cream was applied twice daily to active skin lesions.

Investigational medicinal product name	Triamcinolone acetonide
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Cream
Routes of administration	Cutaneous use

Dosage and administration details:

Triamcinolone acetonide 0.1% cream was applied twice daily to active skin lesions.

Number of subjects in period 1	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS
Started	53	53	52
Treated	53	52	51
Completed	53	49	48
Not completed	0	4	4

Consent withdrawn by subject	-	2	1
Other unspecified	-	1	1
Adverse Event	-	-	1
Lost to follow-up	-	1	-
Lack of efficacy	-	-	1

Number of subjects in period 1	Placebo Q4W + TCS Cream
Started	54
Treated	53
Completed	47
Not completed	7
Consent withdrawn by subject	3
Other unspecified	-
Adverse Event	1
Lost to follow-up	3
Lack of efficacy	-

Baseline characteristics

Reporting groups	
Reporting group title	Lebrikizumab 250 mg Single Dose + TCS
Reporting group description:	
Participants received a single dose of lebrikizumab 250 milligrams (mg) subcutaneous (SC) injection on Day 1 followed by placebo on Week 4 and Week 8. Participants continued to apply TCS cream (triamcenolone acetonide 0.1 percent [%] or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.	
Reporting group title	Lebrikizumab 125 mg Single Dose + TCS
Reporting group description:	
Participants received a single dose of lebrikizumab 125 mg SC injection on Day 1 followed by placebo on Week 4 and Week 8. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.	
Reporting group title	Lebrikizumab 125 mg Q4W + TCS
Reporting group description:	
Participants received lebrikizumab 125 mg SC injection every 4 weeks (Q4W) for a total of 3 doses. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.	
Reporting group title	Placebo Q4W + TCS Cream
Reporting group description:	
Participants received placebo Q4W for a total of 3 doses. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.	

Reporting group values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS
Number of subjects	53	53	52
Age Categorical Units: Subjects			
Age Continuous Units: years arithmetic mean standard deviation	 34.4 ± 12.3	 34.9 ± 12.6	 36.8 ± 12.2
Gender Categorical Units: Subjects			
Female Male	22 31	18 35	16 36

Reporting group values	Placebo Q4W + TCS Cream	Total	
Number of subjects	54	212	
Age Categorical Units: Subjects			
Age Continuous Units: years arithmetic mean standard deviation	 38.8 ± 13.1	 -	

Gender Categorical Units: Subjects			
Female	18	74	
Male	36	138	

End points

End points reporting groups

Reporting group title	Lebrikizumab 250 mg Single Dose + TCS

Reporting group description:

Participants received a single dose of lebrikizumab 250 milligrams (mg) subcutaneous (SC) injection on Day 1 followed by placebo on Week 4 and Week 8. Participants continued to apply TCS cream (triamcenolone acetonide 0.1 percent [%] or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.

Reporting group title	Lebrikizumab 125 mg Single Dose + TCS

Reporting group description:

Participants received a single dose of lebrikizumab 125 mg SC injection on Day 1 followed by placebo on Week 4 and Week 8. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.

Reporting group title	Lebrikizumab 125 mg Q4W + TCS

Reporting group description:

Participants received lebrikizumab 125 mg SC injection every 4 weeks (Q4W) for a total of 3 doses. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.

Reporting group title	Placebo Q4W + TCS Cream

Reporting group description:

Participants received placebo Q4W for a total of 3 doses. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.

Subject analysis set title	Lebrikizumab 250 mg Single Dose + TCS
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received a single dose of lebrikizumab 250 mg SC injection on Day 1 followed by placebo on Week 4 and Week 8. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.

Subject analysis set title	Lebrikizumab 125 mg Single Dose + TCS
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received a single dose of lebrikizumab 125 mg SC injection on Day 1 followed by placebo on Week 4 and Week 8. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.

Subject analysis set title	Lebrikizumab 125 mg Q4W + TCS
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received lebrikizumab 125 mg SC injection every 4 weeks (Q4W) for a total of 3 doses. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.

Subject analysis set title	Placebo Q4W + TCS Cream
Subject analysis set type	Safety analysis

Subject analysis set description:

Participants received placebo Q4W for a total of 3 doses. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.

Primary: Percentage of Participants Who Achieved a 50 Percent (%) Reduction From Baseline in EASI Score (EASI-50) at Week 12

End point title	Percentage of Participants Who Achieved a 50 Percent (%) Reduction From Baseline in EASI Score (EASI-50) at Week 12

End point description:

The EASI score was used to measure the severity and extent of AD and measures erythema, induration-papulation, excoriation and lichenification on a scale of 0 (none) to 3 (severe) on 4 anatomic regions of

the body: head and neck, trunk, upper limbs, and lower limbs. Degree of involvement on each of the 4 anatomic regions is scored on a scale of 0 (no eruption) to 6 (greater than [>] 90 %-100% eruption). The total score is the sum of the four body-region scores, maximum=72, minimum=0, with higher scores reflecting greater disease severity. The total qualitative score is multiplied by the degree of involvement for each anatomic region and then multiplied by a constant and summed to yield the EASI score. mITT population.

End point type	Primary
End point timeframe:	
Baseline, Week 12	

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	52	51	53
Units: percentage of participants				
number (confidence interval 95%)	69.8 (57.45 to 82.17)	69.2 (56.69 to 81.78)	82.4 (71.89 to 92.82)	62.3 (49.21 to 75.31)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Cochran-Mantel-Haenszel (CMH) chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% confidence interval (CI) was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4361
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	7.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.43
upper limit	25.52

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4792
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	6.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.13
upper limit	25.07

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0261
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	20.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	3.36
upper limit	36.81

Secondary: Percent Change From Baseline in EASI Score at Week 12

End point title	Percent Change From Baseline in EASI Score at Week 12

End point description:

The EASI score was used to measure the severity and extent of AD and measures erythema, induration-papulation, excoriation and lichenification on a scale of 0 (none) to 3 (severe) on 4 anatomic regions of the body: head and neck, trunk, upper limbs, and lower limbs. Degree of involvement on each of the 4 anatomic regions is scored on a scale of 0 (no eruption) to 6 (> 90%-100% eruption). The total score is the sum of the four body-region scores, maximum=72, minimum=0, with higher scores reflecting greater disease severity. The total qualitative score is multiplied by the degree of involvement for each anatomic region and then multiplied by a constant and summed to yield the EASI score. mITT population. Here, number of subjects analysed (N)=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	50	49	50
Units: percent change				
least squares mean (standard error)	-57.7 (± 5.263)	-58.46 (± 5.364)	-70.5 (± 5.452)	-53.14 (± 5.382)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and standard error of mean (SE) was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5458
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-4.56
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.41
upper limit	10.3
Variability estimate	Standard error of the mean
Dispersion value	7.533

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4844
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-5.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.29
upper limit	9.65
Variability estimate	Standard error of the mean
Dispersion value	7.594

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0247
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-17.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-32.48
upper limit	-2.23
Variability estimate	Standard error of the mean
Dispersion value	7.671

Secondary: Absolute Change From Baseline in EASI Score at Week 12

End point title	Absolute Change From Baseline in EASI Score at Week 12

End point description:

The EASI score was used to measure the severity and extent of AD and measures erythema, induration-papulation, excoriation and lichenification on a scale of 0 (none) to 3 (severe) on 4 anatomic regions of the body: head and neck, trunk, upper limbs, and lower limbs. Degree of involvement on each of the 4 anatomic regions is scored on a scale of 0 (no eruption) to 6 (> 90%-100% eruption). The total score is the sum of the four body-region scores, maximum=72, minimum=0, with higher scores reflecting greater disease severity. The total qualitative score is multiplied by the degree of involvement for each anatomic region and then multiplied by a constant and summed to yield the EASI score. mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	50	49	50
Units: units on scale				
least squares mean (standard error)	-15.63 (± 1.343)	-14.68 (± 1.367)	-17.73 (± 1.39)	-12.67 (± 1.372)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1256
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-2.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.75
upper limit	0.83
Variability estimate	Standard error of the mean
Dispersion value	1.922

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3022
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-5.82
upper limit	1.81
Variability estimate	Standard error of the mean
Dispersion value	1.936

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0105
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-5.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.91
upper limit	-1.2
Variability estimate	Standard error of the mean
Dispersion value	1.956

Secondary: Percentage of Participants Who Achieved a 75% Reduction From Baseline in EASI Score (EASI-75) at Week 12

End point title	Percentage of Participants Who Achieved a 75% Reduction From Baseline in EASI Score (EASI-75) at Week 12

End point description:

The EASI score was used to measure the severity and extent of AD and measures erythema, induration-papulation, excoriation and lichenification on a scale of 0 (none) to 3 (severe) on 4 anatomic regions of the body: head and neck, trunk, upper limbs, and lower limbs. Degree of involvement on each of the 4 anatomic regions is scored on a scale of 0 (no eruption) to 6 (> 90%-100% eruption). The total score is the sum of the four body-region scores, maximum=72, minimum=0, with higher scores reflecting greater disease severity. The total qualitative score is multiplied by the degree of involvement for each anatomic region and then multiplied by a constant and summed to yield the EASI score. mITT population.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	52	51	53
Units: percentage of participants				
number (confidence interval 95%)	49.1 (35.6 to 62.52)	38.5 (25.24 to 51.68)	54.9 (41.25 to 68.56)	34 (21.21 to 46.71)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

CMH chi-square test was stratified by geographic region. 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.123
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	15.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.44
upper limit	33.63

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

CMH chi-square test was stratified by geographic region. 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6627
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	4.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.87
upper limit	22.87

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

CMH chi-square test was stratified by geographic region. 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.036
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	20.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.26
upper limit	39.62

Secondary: Percentage of Participants Who Achieved an Investigator's Global Assessment (IGA) Score of 0 or 1 at Week 12

End point title	Percentage of Participants Who Achieved an Investigator's Global Assessment (IGA) Score of 0 or 1 at Week 12

End point description:

The IGA score is an assessment of the participant's disease state at the time of examination and does not attempt a comparison with any of the participant's previous disease states. The IGA utilizes a 6-point scale ranging from 0 to 5 where 0 = clear (no inflammatory signs of AD), 1 = almost clear (just perceptible erythema and papulation induration), 2 = mild (mild erythema and papulation induration; no oozing or crusting), 3 = moderate (moderate erythema and papulation induration; oozing and crusting may be present), 4 = severe (severe erythema and papulation induration; oozing and crusting is present) and 5 = very severe AD. mITT population.

End point type	Secondary

End point timeframe:

Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	52	51	53
Units: percentage of participants				
number (confidence interval 95%)	28.3 (16.17 to 40.43)	21.2 (10.05 to 32.25)	33.3 (20.4 to 46.27)	18.9 (8.33 to 29.4)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.263
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	9.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.63
upper limit	25.5

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7745
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	2.29

Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.02
upper limit	17.59

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0976
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	14.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.22
upper limit	31.15

Secondary: Percentage of Participants With a Greater Than or Equal to (>/=) 2 Point Reduction From Baseline in IGA at Week 12

End point title	Percentage of Participants With a Greater Than or Equal to (>/=) 2 Point Reduction From Baseline in IGA at Week 12

End point description:

The IGA score is an assessment of the participant's disease state at the time of examination and does not attempt a comparison with any of the participant's previous disease states. The IGA utilizes a 6-point scale ranging from 0 to 5 where 0 = clear (no inflammatory signs of AD), 1 = almost clear (just perceptible erythema and papulation induration), 2 = mild (mild erythema and papulation induration; no oozing or crusting), 3 = moderate (moderate erythema and papulation induration; oozing and crusting may be present), 4 = severe (severe erythema and papulation induration; oozing and crusting is present) and 5 = very severe AD. mITT population.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	52	51	53
Units: percentage of participants				
number (confidence interval 95%)	35.8 (22.94 to 48.76)	23.1 (11.63 to 34.53)	37.3 (23.99 to 50.52)	24.5 (12.94 to 36.11)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2154
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	11.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.02
upper limit	28.67

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8603
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-1.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.74
upper limit	14.84

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1673
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	12.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.89
upper limit	30.34

Secondary: Absolute Change From Baseline in IGA at Week 12

End point title	Absolute Change From Baseline in IGA at Week 12

End point description:

The IGA score is an assessment of the participant's disease state at the time of examination and does not attempt a comparison with any of the participant's previous disease states. The IGA utilizes a 6-point scale ranging from 0 to 5 where 0 = clear (no inflammatory signs of AD), 1 = almost clear (just perceptible erythema and papulation induration), 2 = mild (mild erythema and papulation induration; no oozing or crusting), 3 = moderate (moderate erythema and papulation induration; oozing and crusting may be present), 4 = severe (severe erythema and papulation induration; oozing and crusting is present) and 5 = very severe AD. mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	50	49	50
Units: units on scale				
least squares mean (standard error)	-1.13 (± 0.125)	-1.04 (± 0.128)	-1.33 (± 0.13)	-0.92 (± 0.128)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2281
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.57
upper limit	0.14
Variability estimate	Standard error of the mean
Dispersion value	0.179

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5038
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.48
upper limit	0.24
Variability estimate	Standard error of the mean
Dispersion value	0.181

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was

included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0258
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.77
upper limit	-0.05
Variability estimate	Standard error of the mean
Dispersion value	0.182

Secondary: Percentage of Participants Who Achieved an Investigator Global Signs Assessment (IGSA) Score of 0 or 1 at Week 12

End point title	Percentage of Participants Who Achieved an Investigator Global Signs Assessment (IGSA) Score of 0 or 1 at Week 12

End point description:

The IGSA score is an assessment of AD signs. Investigator assesses signs in 2 steps: Step 1: Lesional assessment: Investigator chooses the lesional grade that best describes the participant's involved skin, on average. Step 2: Consider Upgrade or Downgrade: based on skin lesion extent and location. Upgrade refers to the disease extends over the majority (>50% of a region) of one or more body regions, or is prominently affecting high visibility/functionally-important areas (face and hands). Downgrade refers to the disease localized to only one or two small areas (less than 1-2 palms) that are not highly visible or functionally important. A region is defined by i) arms combined, ii) legs combined, iii) trunk, and iv) head and neck, for a total of four regions. The IGSA utilizes a 5-point scale ranging from 0 (clear) to 5 (severe disease) where 0 = clear (no inflammatory signs of AD), 1 = almost clear, 2 = mild, 3 = moderate, 4 = severe AD. mITT population.

End point type	Secondary

End point timeframe:

Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	52	51	53
Units: percentage of participants				
number (confidence interval 95%)	30.2 (17.83 to 42.55)	19.2 (8.52 to 29.94)	29.4 (16.91 to 41.92)	22.6 (11.37 to 33.91)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3945
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	7.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.18
upper limit	24.27

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.647
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-3.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.96
upper limit	12.14

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4395
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	6.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.06
upper limit	23.6

Secondary: Percentage of Participants With a >/=2 Point Reduction From Baseline in IGSA at Week 12

End point title	Percentage of Participants With a >/=2 Point Reduction From Baseline in IGSA at Week 12

End point description:

The IGSA score is an assessment of AD signs. Investigator assesses signs in 2 steps: Step 1: Lesional assessment: Investigator chooses the lesional grade that best describes the participant's involved skin, on average. Step 2: Consider Upgrade or Downgrade: based on skin lesion extent and location. Upgrade refers to the disease extends over the majority (>50% of a region) of one or more body regions, or is prominently affecting high visibility/functionally-important areas (face and hands). Downgrade refers to the disease localized to only one or two small areas (less than 1-2 palms) that are not highly visible or functionally important. A region is defined by i) arms combined, ii) legs combined, iii) trunk, and iv) head and neck, for a total of four regions. The IGSA utilizes a 5-point scale ranging from 0 (clear) to 5 (severe disease) where 0 = clear (no inflammatory signs of AD), 1 = almost clear, 2 = mild, 3 = moderate, 4 = severe AD. mITT population.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	52	51	53
Units: percentage of participants				
number (confidence interval 95%)	43.4 (30.05 to 56.74)	26.9 (14.87 to 38.98)	41.2 (27.67 to 54.68)	26.4 (14.55 to 38.28)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS

	Cream
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0729
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	16.98
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.88
upper limit	34.84

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1186
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	14.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.22
upper limit	32.74

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9636
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	0.51

Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.41
upper limit	17.43

Secondary: Absolute Change From Baseline in IGSA at Week 12

End point title	Absolute Change From Baseline in IGSA at Week 12

End point description:

IGSA score is an assessment of AD signs. Investigator assesses signs in 2 steps: Step 1:Lesional assessment:Investigator chooses lesional grade that best describes participant's involved skin, on average. Step 2: Consider Upgrade or Downgrade:based on skin lesion extent and location. Upgrade refers to disease extends over majority (>50% of a region) of one or more body regions, or is prominently affecting high visibility/functionally-important areas (face and hands). Downgrade refers to disease localized to only one or two small areas (less than 1-2 palms) that are not highly visible or functionally important. A region is defined by i) arms combined, ii) legs combined, iii) trunk, and iv) head and neck, for a total of four regions. IGSA utilizes a 5-point scale ranging from 0 (clear) to 5 (severe disease) where 0=clear(no inflammatory signs of AD), 1=almost clear, 2=mild, 3=moderate, 4=severe AD. mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	50	49	50
Units: units on scale				
least squares mean (standard error)	-1.27 (± 0.136)	-1.14 (± 0.139)	-1.4 (± 0.141)	-1.02 (± 0.14)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2027
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.25

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.63
upper limit	0.14
Variability estimate	Standard error of the mean
Dispersion value	0.195

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5316
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.51
upper limit	0.26
Variability estimate	Standard error of the mean
Dispersion value	0.197

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0568
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.38

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.77
upper limit	0.01
Variability estimate	Standard error of the mean
Dispersion value	0.199

Secondary: Percent Change From Baseline in Severity Scoring of Atopic Dermatitis (SCORAD) Index Score at Week 12

End point title	Percent Change From Baseline in Severity Scoring of Atopic Dermatitis (SCORAD) Index Score at Week 12

End point description:

The SCORAD index scale combines 1) intensity of six lesion characteristics (erythema, edema/papulation, oozing/crusts, excoriations, lichenification, dryness) as assessed by the physician on a scale of 0 (absent) to 3 (severe) across four regions (head, trunk, upper and lower extremities); and 2) subjective symptoms of pruritus and sleep disturbance as reported by the participant on a visual analog scale (VAS) from 0 to 10 (increasing severity); along with 3) Physician assessment of affected areas (extent) in each region is made as percentage of body surface (head [10%], upper extremities [20%], trunk [30%], and lower extremities [40%]). The final SCORAD index score, ranging from 0 (absent disease) to 103 (severe disease), is calculated according to the weighted formula: (0.2 x area) + (3.5 x [sum of intensity score for each of the 6 items]) + participant's subjective score. mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	50	49	50
Units: percent change				
least squares mean (standard error)	-42.63 (± 4.069)	-38.72 (± 4.143)	-53.45 (± 4.218)	-35.41 (± 4.159)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2161
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-7.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.69
upper limit	4.25
Variability estimate	Standard error of the mean
Dispersion value	5.818

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5734
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-3.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.89
upper limit	8.27
Variability estimate	Standard error of the mean
Dispersion value	5.873

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0026
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-18.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.72
upper limit	-6.36
Variability estimate	Standard error of the mean
Dispersion value	5.923

Secondary: Absolute Change From Baseline in SCORAD Index Score at Week 12

End point title	Absolute Change From Baseline in SCORAD Index Score at Week 12

End point description:

The SCORAD index scale combines 1) intensity of six lesion characteristics (erythema, edema/papulation, oozing/crusts, excoriations, lichenification, dryness) as assessed by the physician on a scale of 0 (absent) to 3 (severe) across four regions (head, trunk, upper and lower extremities); and 2) subjective symptoms of pruritus and sleep disturbance as reported by the participant on a VAS from 0 to 10 (increasing severity); along with 3) Physician assessment of affected areas (extent) in each region is made as percentage of body surface (head [10%], upper extremities [20%], trunk [30%], and lower extremities [40%]). The final SCORAD index score, ranging from 0 (absent disease) to 103 (severe disease), is calculated according to the weighted formula: (0.2 x area) + (3.5 x [sum of intensity score for each of the 6 items]) + participant's subjective score. mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	50	49	50
Units: units on scale				
least squares mean (standard error)	-26.17 (± 2.354)	-22.98 (± 2.395)	-31.84 (± 2.438)	-20.6 (± 2.404)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was

included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0989
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-5.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.21
upper limit	1.06
Variability estimate	Standard error of the mean
Dispersion value	3.364

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4841
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-2.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.07
upper limit	4.31
Variability estimate	Standard error of the mean
Dispersion value	3.395

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0012
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-11.24
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.99
upper limit	-4.49
Variability estimate	Standard error of the mean
Dispersion value	3.423

Secondary: Percentage of Participants With a 50% or 75% Reduction From Baseline in SCORAD Index Score (SCORAD-50/SCORAD-75) at Week 12

End point title	Percentage of Participants With a 50% or 75% Reduction From Baseline in SCORAD Index Score (SCORAD-50/SCORAD-75) at Week 12

End point description:

The SCORAD index scale combines 1) intensity of six lesion characteristics (erythema, edema/papulation, oozing/crusts, excoriations, lichenification, dryness) as assessed by the physician on a scale of 0 (absent) to 3 (severe) across four regions (head, trunk, upper and lower extremities); and 2) subjective symptoms of pruritus and sleep disturbance as reported by the participant on a VAS from 0 to 10 (increasing severity); along with 3) Physician assessment of affected areas (extent) in each region is made as percentage of body surface (head [10%], upper extremities [20%], trunk [30%], and lower extremities [40%]). The final SCORAD index score, ranging from 0 (absent disease) to 103 (severe disease), is calculated according to the weighted formula: (0.2 x area) + (3.5 x [sum of intensity score for each of the 6 items]) + participant's subjective score. mITT population.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	52	51	53
Units: percentage of participants				
number (confidence interval 95%)				
SCORAD-50	47.2 (33.73 to 60.61)	34.6 (21.68 to 47.55)	51 (37.26 to 64.7)	26.4 (14.55 to 38.28)
SCORAD-75	11.3 (2.79 to 19.85)	13.5 (4.18 to 22.74)	21.6 (10.28 to 32.86)	13.2 (4.09 to 22.32)

Statistical analyses

Statistical analysis title	Statistical Analysis 1: SCORAD-50

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0297
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	20.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	2.82
upper limit	38.69

Statistical analysis title	Statistical Analysis 2: SCORAD-50

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3817
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	8.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.35
upper limit	25.75

Statistical analysis title	Statistical Analysis 3: SCORAD-50

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0117
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	24.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	6.42
upper limit	42.71

Statistical analysis title	Statistical Analysis 4: SCORAD-75
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	106
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7636
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-1.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.37
upper limit	10.6

Statistical analysis title	Statistical Analysis 5: SCORAD-75
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	105
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9764
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	0.25

Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.75
upper limit	13.26

Statistical analysis title	Statistical Analysis 6: SCORAD-75

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	104
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2663
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	8.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.15
upper limit	22.87

Secondary: Percentage of Participants Who Achieved EASI-50 (50% Reduction From Baseline in EASI Score) at Week 12 and Maintained EASI-50 at Week 16

End point title	Percentage of Participants Who Achieved EASI-50 (50% Reduction From Baseline in EASI Score) at Week 12 and Maintained EASI-50 at Week 16

End point description:

The EASI score was used to measure the severity and extent of AD and measures erythema, induration-papulation, excoriation and lichenification on a scale of 0 (none) to 3 (severe) on 4 anatomic regions of the body: head and neck, trunk, upper limbs, and lower limbs. Degree of involvement on each of the 4 anatomic regions is scored on a scale of 0 (no eruption) to 6 (> 90%-100% eruption). The total score is the sum of the four body-region scores, maximum=72, minimum=0, with higher scores reflecting greater disease severity. The total qualitative score is multiplied by the degree of involvement for each anatomic region and then multiplied by a constant and summed to yield the EASI score. mITT population. Here, N=participants who achieved EASI-50 at Week 12.

End point type	Secondary

End point timeframe:

Baseline, Weeks 12, 16

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	36	42	33
Units: percentage of participants				
number (confidence interval 95%)	94.6 (87.31 to 100)	80.6 (67.63 to 93.48)	95.2 (88.8 to 100)	81.8 (68.66 to 94.98)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0991
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	12.78
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.27
upper limit	27.82

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9529
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-1.26
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.7
upper limit	17.18

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0676
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	13.42
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.23
upper limit	28.07

Secondary: Percentage of Participants Who Achieved EASI-50 (50% Reduction From Baseline in EASI Score) at Week 12 and Maintained EASI-50 at Both Weeks 16 and 20

End point title	Percentage of Participants Who Achieved EASI-50 (50% Reduction From Baseline in EASI Score) at Week 12 and Maintained EASI-50 at Both Weeks 16 and 20

End point description:

The EASI score was used to measure the severity and extent of AD and measures erythema, induration-papulation, excoriation and lichenification on a scale of 0 (none) to 3 (severe) on 4 anatomic regions of the body: head and neck, trunk, upper limbs, and lower limbs. Degree of involvement on each of the 4 anatomic regions is scored on a scale of 0 (no eruption) to 6 (> 90%-100% eruption). The total score is the sum of the four body-region scores, maximum=72, minimum=0, with higher scores reflecting greater disease severity. The total qualitative score is multiplied by the degree of involvement for each anatomic region and then multiplied by a constant and summed to yield the EASI score. mITT population. Here, N=participants who achieved EASI-50 at Week 12.

End point type	Secondary

End point timeframe:

Baseline, Weeks 12, 16, 20

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	36	42	33
Units: percentage of participants				
number (confidence interval 95%)	78.4 (65.11 to 91.64)	80.6 (67.63 to 93.48)	90.5 (81.6 to 99.35)	72.7 (57.53 to 87.92)

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5771
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	5.65
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.5
upper limit	25.82

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3913
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	7.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.1
upper limit	27.78

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	75
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0477
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	17.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.15
upper limit	35.35

Secondary: Percentage of Participants Who Achieved IGA Score of 0 or 1 at Week 12 and Maintained IGA Score of 0 or 1 at Week 16

End point title	Percentage of Participants Who Achieved IGA Score of 0 or 1 at Week 12 and Maintained IGA Score of 0 or 1 at Week 16

End point description:

The IGA score is an assessment of AD severity. It is an assessment of the participant's disease state at the time of examination and does not attempt a comparison with any of the participant's previous disease states. The IGA utilizes a 6-point scale ranging from 0 (clear) to 5 (very severe disease) where 0 = clear (no inflammatory signs of AD), 1 = almost clear (just perceptible erythema and papulation induration), 2 = mild (mild erythema and papulation induration; no oozing or crusting), 3 = moderate (moderate erythema and papulation induration; oozing and crusting may be present), 4 = severe (severe erythema and papulation induration; oozing and crusting is present) and 5 = very severe AD. mITT population. Here, N=participants who achieved IGA score of 0 or 1 at Week 12.

End point type	Secondary

End point timeframe:

Weeks 12, 16

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	11	17	10
Units: percentage of participants				
number (confidence interval 95%)	60 (35.21 to 84.79)	72.7 (46.41 to 99.05)	82.4 (64.23 to 100)	80 (55.21 to 100)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.254
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-20
Confidence interval	
level	95 %
sides	2-sided
lower limit	-55.1
upper limit	15.06

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8809
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-7.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-43.4
upper limit	28.88

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6744
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	2.35
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.4
upper limit	33.06

Secondary: Percentage of Participants Who Achieved IGA Score of 0 or 1 at Week 12 and Maintained IGA Score of 0 or 1 at Both Weeks 16 and 20

End point title	Percentage of Participants Who Achieved IGA Score of 0 or 1 at Week 12 and Maintained IGA Score of 0 or 1 at Both Weeks 16 and 20

End point description:

The IGA score is an assessment of AD severity. It is an assessment of the participant's disease state at the time of examination and does not attempt a comparison with any of the participant's previous disease states. The IGA utilizes a 6-point scale ranging from 0 (clear) to 5 (very severe disease) where 0 = clear (no inflammatory signs of AD), 1 = almost clear (just perceptible erythema and papulation induration), 2 = mild (mild erythema and papulation induration; no oozing or crusting), 3 = moderate (moderate erythema and papulation induration; oozing and crusting may be present), 4 = severe (severe erythema and papulation induration; oozing and crusting is present) and 5 = very severe AD. mITT population. Here, N=participants who achieved IGA score of 0 or 1 at Week 12.

End point type	Secondary

End point timeframe:

Weeks 12, 16, 20

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	11	17	10
Units: percentage of participants				
number (confidence interval 95%)	60 (35.21 to 84.79)	54.5 (25.12 to 83.97)	70.6 (48.93 to 92.25)	60 (29.64 to 90.36)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	25
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9409
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-39.2
upper limit	39.2

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	21
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9712
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-5.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-47.7
upper limit	36.83

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.582
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	10.59

Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.7
upper limit	47.89

Secondary: Percentage of Participants Who Achieved IGSA Score of 0 or 1 at Week 12 and Maintained IGSA Score of 0 or 1 at Week 16

End point title	Percentage of Participants Who Achieved IGSA Score of 0 or 1 at Week 12 and Maintained IGSA Score of 0 or 1 at Week 16

End point description:

IGSA score is an assessment of AD signs. Investigator assesses signs in 2 steps: Step 1: Lesional assessment: Investigator chooses lesional grade that best describes participant's involved skin, on average. Step 2: Consider Upgrade or Downgrade: based on skin lesion extent and location. Upgrade refers to disease extends over majority (>50% of a region) of one or more body regions, or is prominently affecting high visibility/functionally-important areas (face and hands). Downgrade refers to disease localized to only one or two small areas (less than 1-2 palms) that are not highly visible or functionally important. A region is defined by i) arms combined, ii) legs combined, iii) trunk, and iv) head and neck, for a total of four regions. IGSA utilizes a 5-point scale ranging from 0 (clear) to 5 (severe disease) where 0=clear (no inflammatory signs of AD), 1=almost clear, 2=mild, 3=moderate, 4=severe AD. mITT population. Here, N=participants who achieved IGSA score of 0 or 1 at Week 12.

End point type	Secondary

End point timeframe:

Weeks 12, 16

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	10	15	12
Units: percentage of participants				
number (confidence interval 95%)	62.5 (38.78 to 86.22)	80 (55.21 to 100)	73.3 (50.95 to 95.71)	83.3 (62.25 to 100)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1708
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-20.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	-52.6
upper limit	10.91

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8752
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-3.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.9
upper limit	29.21

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9458
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-10

Confidence interval	
level	95 %
sides	2-sided
lower limit	-40.7
upper limit	20.75

Secondary: Percentage of Participants Who Achieved IGSA Score of 0 or 1 at Week 12 and Maintained IGSA Score of 0 or 1 at Both Weeks 16 and 20

End point title	Percentage of Participants Who Achieved IGSA Score of 0 or 1 at Week 12 and Maintained IGSA Score of 0 or 1 at Both Weeks 16 and 20

End point description:

IGSA score is an assessment of AD signs. Investigator assesses signs in 2 steps: Step 1: Lesional assessment: Investigator chooses lesional grade that best describes participant's involved skin, on average. Step 2: Consider Upgrade or Downgrade: based on skin lesion extent and location. Upgrade refers to disease extends over majority (>50% of a region) of one or more body regions, or is prominently affecting high visibility/functionally-important areas (face and hands). Downgrade refers to disease localized to only one or two small areas (less than 1-2 palms) that are not highly visible or functionally important. A region is defined by i) arms combined, ii) legs combined, iii) trunk, and iv) head and neck, for a total of four regions. IGSA utilizes a 5-point scale ranging from 0 (clear) to 5 (severe disease) where 0=clear (no inflammatory signs of AD), 1=almost clear, 2=mild, 3=moderate, 4=severe AD. mITT population. Here, N=participants who achieved IGSA score of 0 or 1 at Week 12.

End point type	Secondary

End point timeframe:

Weeks 12, 16, 20

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	16	10	15	12
Units: percentage of participants				
number (confidence interval 95%)	56.3 (31.94 to 80.56)	60 (29.64 to 90.36)	60 (35.21 to 84.79)	50 (21.71 to 78.29)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	28
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9439
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	6.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31
upper limit	43.55

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	22
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6297
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	10
Confidence interval	
level	95 %
sides	2-sided
lower limit	-31.5
upper limit	51.5

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	27
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5347
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	10

Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.6
upper limit	47.62

Secondary: Percentage of Participants Who Achieved SCORAD-50 (50% Reduction From Baseline in SCORAD Index Score) at Week 12 and Maintained SCORAD-50 at Week 16

End point title	Percentage of Participants Who Achieved SCORAD-50 (50% Reduction From Baseline in SCORAD Index Score) at Week 12 and Maintained SCORAD-50 at Week 16

End point description:

The SCORAD index scale combines 1) intensity of six lesion characteristics (erythema, edema/papulation, oozing/crusts, excoriations, lichenification, dryness) as assessed by the physician on a scale of 0 (absent) to 3 (severe) across four regions (head, trunk, upper and lower extremities); and 2) subjective symptoms of pruritus and sleep disturbance as reported by the participant on a VAS from 0 to 10 (increasing severity); along with 3) Physician assessment of affected areas (extent) in each region is made as percentage of body surface (head [10%], upper extremities [20%], trunk [30%], and lower extremities [40%]). The final SCORAD index score, ranging from 0 (absent disease) to 103 (severe disease), is calculated according to the weighted formula: (0.2 x area) + (3.5 x [sum of intensity score for each of the 6 items]) + participant's subjective score. mITT population. Here, N=participants who achieved SCORAD-50 at Week 12.

End point type	Secondary

End point timeframe:

Baseline, Weeks 12, 16

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	18	26	14
Units: percentage of participants				
number (confidence interval 95%)	72 (54.4 to 89.6)	72.2 (51.53 to 92.91)	76.9 (60.73 to 93.12)	85.7 (67.38 to 100)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4875
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-13.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-39.1
upper limit	11.7

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3375
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-13.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-41.1
upper limit	14.15

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1334
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-8.79

Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.3
upper limit	15.67

Secondary: Percentage of Participants Who Achieved SCORAD-50 (50% Reduction From Baseline in SCORAD Index Score) at Week 12 and Maintained SCORAD-50 at Both Weeks 16 and 20

End point title	Percentage of Participants Who Achieved SCORAD-50 (50% Reduction From Baseline in SCORAD Index Score) at Week 12 and Maintained SCORAD-50 at Both Weeks 16 and 20

End point description:

The SCORAD index scale combines 1) intensity of six lesion characteristics (erythema, edema/papulation, oozing/crusts, excoriations, lichenification, dryness) as assessed by the physician on a scale of 0 (absent) to 3 (severe) across four regions (head, trunk, upper and lower extremities); and 2) subjective symptoms of pruritus and sleep disturbance as reported by the participant on a VAS from 0 to 10 (increasing severity); along with 3) Physician assessment of affected areas (extent) in each region is made as percentage of body surface (head [10%], upper extremities [20%], trunk [30%], and lower extremities [40%]). The final SCORAD index score, ranging from 0 (absent disease) to 103 (severe disease), is calculated according to the weighted formula: (0.2 x area) + (3.5 x [sum of intensity score for each of the 6 items]) + participant's subjective score. mITT population. Here, N=participants who achieved SCORAD-50 at Week 12.

End point type	Secondary

End point timeframe:

Baseline, Weeks 12, 16, 20

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	25	18	26	14
Units: percentage of participants				
number (confidence interval 95%)	64 (45.18 to 82.82)	61.1 (38.59 to 83.63)	50 (30.78 to 69.22)	78.6 (57.08 to 100)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	39
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4852
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-14.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-43.1
upper limit	13.99

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	32
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3375
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-17.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	-48.6
upper limit	13.67

Statistical analysis title	Statistical Analysis 3
Statistical analysis description:	
CMH chi-square test was stratified by geographic region (US/Canada versus Europe versus others). 95% CI was based on normal approximation for binomial proportion.	
Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1334
Method	Cochran-Mantel-Haenszel
Parameter estimate	Response Rate Difference
Point estimate	-28.6

Confidence interval	
level	95 %
sides	2-sided
lower limit	-57.4
upper limit	0.26

Secondary: Percent Change From Baseline in Total % Body Surface Area (BSA) Affected With AD at Week 12

End point title	Percent Change From Baseline in Total % Body Surface Area (BSA) Affected With AD at Week 12

End point description:

Affected BSA was assessed for each of the following four body regions: head and neck, upper limbs, trunk, and lower limbs. Affected BSA was assessed on a 7-point ordinal scale, where 0=no eruption, 1=<10%, 2=>10%-29%, 3=>30%-49%, 4=>50%-69%, 5=>70%-89%, and 6=>90%-100%. mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	50	49	50
Units: percent change				
least squares mean (standard error)	-38.6 (± 8.069)	-45.2 (± 8.206)	-57.68 (± 8.35)	-47.42 (± 8.242)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4453
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	8.83

Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.93
upper limit	31.58
Variability estimate	Standard error of the mean
Dispersion value	11.541

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8487
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	2.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.7
upper limit	25.14
Variability estimate	Standard error of the mean
Dispersion value	11.625

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3835
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-10.25

Confidence interval	
level	95 %
sides	2-sided
lower limit	-33.39
upper limit	12.89
Variability estimate	Standard error of the mean
Dispersion value	11.736

Secondary: Absolute Change From Baseline in Pruritus as Measured by the Pruritus Visual Analog Scale (VAS) at Week 12

End point title	Absolute Change From Baseline in Pruritus as Measured by the Pruritus Visual Analog Scale (VAS) at Week 12

End point description:

Pruritus VAS score was measured as a part of SCORAD. Subjective symptoms of pruritus were reported by the participant on a VAS. VAS is an eleven point scale ranging from 0 (no pruritus) to 10 centimeters (cm) (most severe pruritus). mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	50	49	50
Units: cm				
least squares mean (standard error)	-2.03 (± 0.325)	-2.06 (± 0.331)	-2.53 (± 0.336)	-1.83 (± 0.332)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6591
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.21

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.12
upper limit	0.71
Variability estimate	Standard error of the mean
Dispersion value	0.464

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6223
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.16
upper limit	0.69
Variability estimate	Standard error of the mean
Dispersion value	0.469

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1391
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.63
upper limit	0.23
Variability estimate	Standard error of the mean
Dispersion value	0.472

Secondary: Percent Change From Baseline in Pruritus as Measured by the Pruritus VAS at Week 12

End point title	Percent Change From Baseline in Pruritus as Measured by the Pruritus VAS at Week 12

End point description:

Pruritus VAS score was measured as a part of SCORAD. Subjective symptoms of pruritus were reported by the participant on a VAS. VAS is an eleven point scale ranging from 0 (no pruritus) to 10 centimeters (cm) (most severe pruritus). mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	50	49	50
Units: percent change				
least squares mean (standard error)	-32.82 (± 5.953)	-34.92 (± 6.143)	-40.71 (± 6.188)	-27.54 (± 6.124)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	103
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5374
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-5.28

Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.12
upper limit	11.56
Variability estimate	Standard error of the mean
Dispersion value	8.54

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	100
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.396
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-7.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.5
upper limit	9.73
Variability estimate	Standard error of the mean
Dispersion value	8.679

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	99
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.132
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-13.17

Confidence interval	
level	95 %
sides	2-sided
lower limit	-30.34
upper limit	4
Variability estimate	Standard error of the mean
Dispersion value	8.706

Secondary: Absolute Change From Baseline in Pruritus as Measured by the 5-D Itch Scale at Week 12

End point title	Absolute Change From Baseline in Pruritus as Measured by the 5-D Itch Scale at Week 12

End point description:

The 5-D itch scale is a 5-item, validated questionnaire used to evaluate change in itch over time. The 5-D itch scale refers to the previous 2 weeks and the questions are organized into 5 domains: duration, degree, direction, disability, and distribution. The total 5-D itch score is calculated by summing each of the separately scored 5 domains. Total score ranges between 5 (no pruritus) and 25 (most severe pruritus). Higher scores mean greater impairment of the participant's health-related QoL. mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	45	49
Units: units on scale				
least squares mean (standard error)	-3.24 (± 0.557)	-2.26 (± 0.57)	-3.74 (± 0.581)	-2.55 (± 0.57)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3842
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.27
upper limit	0.88
Variability estimate	Standard error of the mean
Dispersion value	0.798

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7226
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.31
upper limit	1.88
Variability estimate	Standard error of the mean
Dispersion value	0.809

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1446
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-1.19

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.79
upper limit	0.41
Variability estimate	Standard error of the mean
Dispersion value	0.813

Secondary: Percent Change From Baseline in Pruritus as Measured by the 5-D Itch Scale at Week 12

End point title	Percent Change From Baseline in Pruritus as Measured by the 5-D Itch Scale at Week 12

End point description:

The 5-D itch scale is a 5-item, validated questionnaire used to evaluate change in itch over time. The 5-D itch scale refers to the previous 2 weeks and the questions are organized into 5 domains: duration, degree, direction, disability, and distribution. The total 5-D itch score is calculated by summing each of the separately scored 5 domains. Total score ranges between 5 (no pruritus) and 25 (most severe pruritus). Higher scores mean greater impairment of the participant's health-related QoL. mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	45	49
Units: percent change				
least squares mean (standard error)	-15.23 (± 3.71)	-10.57 (± 3.798)	-20.51 (± 3.877)	-13.05 (± 3.799)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6816
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-2.18

Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.66
upper limit	8.3
Variability estimate	Standard error of the mean
Dispersion value	5.313

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6464
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	2.47
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.15
upper limit	13.09
Variability estimate	Standard error of the mean
Dispersion value	5.385

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1697
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-7.47

Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.15
upper limit	3.22
Variability estimate	Standard error of the mean
Dispersion value	5.419

Secondary: Total Amount of TCS Used From Baseline to Week 12

End point title	Total Amount of TCS Used From Baseline to Week 12

End point description:

Total amount of TCS (Triamcinolone acetonide 0.1% cream or hydrocortisone 2.5% cream) used in grams from baseline to Week 12 was reported. mITT population. Here, n=participants who used triamcinolone acetonide 0.1% cream or hydrocortisone 2.5% cream at specified time-point per arm, respectively.

End point type	Secondary

End point timeframe:

From Baseline to Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	52	51	53
Units: grams				
arithmetic mean (standard deviation)				
Triamcinolone acetonide 0.1% (n=33, 32, 42, 29)	608.7 (± 740)	510.2 (± 478.5)	669.4 (± 975)	699.9 (± 687.5)
Hydrocortisone 2.5% (n=27, 32, 32, 32)	28.2 (± 26.2)	36.2 (± 68.2)	29.3 (± 32.2)	38.9 (± 66.6)

Statistical analyses

No statistical analyses for this end point

Secondary: Total Amount of TCS Used From Week 12 to End of Study or Early Termination

End point title	Total Amount of TCS Used From Week 12 to End of Study or Early Termination

End point description:

Total amount of TCS (Triamcinolone acetonide 0.1% cream or hydrocortisone 2.5% cream) in grams used from Week 12 to the end of study or early termination was reported. mITT population. Here, n=participants who used triamcinolone acetonide 0.1% cream or hydrocortisone 2.5% cream at specified time-point per arm, respectively.

End point type	Secondary

End point timeframe:

From Week 12 to end of study or early termination (up to 20 weeks)

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	52	51	53
Units: grams				
arithmetic mean (standard deviation)				
Triamcinolone acetonide 0.1% (n=36, 40, 43, 36)	459.4 (± 630.1)	379.4 (± 443.5)	279.4 (± 243.2)	415.1 (± 414.4)
Hydrocortisone 2.5% (n=32, 36, 34, 34)	15 (± 16.5)	15 (± 25)	19.4 (± 22.4)	16 (± 19.9)

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Experienced AD Disease Flares From Baseline to Week 12

End point title	Percentage of Participants Who Experienced AD Disease Flares From Baseline to Week 12

End point description:

Disease flare was defined as a measurable increase in extent or severity of lesions over a period of at least 3 days, under continued treatment and corresponding with a clinically significant increase in disease severity (as assessed by the treating physician and/or by the participant) necessitating an escalation in therapy, as defined by the protocol or initiated separately by the participant or a treating physician outside of the protocol. mITT population.

End point type	Secondary

End point timeframe:

From Baseline to Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	53	52	51	53
Units: percentage of participants				
number (not applicable)	5.7	0	2	5.7

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change From Baseline in AD Symptoms at Week 12, as Assessed by the Atopic Dermatitis Symptom Diary (ADSD)

End point title	Absolute Change From Baseline in AD Symptoms at Week 12, as Assessed by the Atopic Dermatitis Symptom Diary (ADSD)

End point description:

The 8-item ADSD was used to assess participants' AD symptoms; specifically, itchiness, skin pain, bleeding, skin sensitivity, skin irritation, skin flakiness, skin dryness, and weeping or oozing of clear fluid from the skin. The diary items were assessed on an 11-point numeric rating scale ranging from 0 (no symptom) to 10 (symptom as bad as one can imagine) and a Yes/No wake question. The diary had a recall specification of 24 hours. Scores of individual items were added to yield a total ADSD score (0-80), where higher scores mean worst symptom. mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	33	32	37
Units: units on scale				
least squares mean (standard error)	-11.3 (± 1.963)	-10.32 (± 1.815)	-11.82 (± 1.837)	-9.49 (± 1.96)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5143
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-1.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.31
upper limit	3.68
Variability estimate	Standard error of the mean
Dispersion value	2.776

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7552
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.83
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.12
upper limit	4.45
Variability estimate	Standard error of the mean
Dispersion value	2.671

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3878
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-2.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.66
upper limit	2.99
Variability estimate	Standard error of the mean
Dispersion value	2.691

Secondary: Percent Change From Baseline in AD Symptoms at Week 12, as Assessed by the ADSD

End point title	Percent Change From Baseline in AD Symptoms at Week 12, as Assessed by the ADSD

End point description:

The 8-item ADSD was used to assess participants' AD symptoms; specifically, itchiness, skin pain,

bleeding, skin sensitivity, skin irritation, skin flakiness, skin dryness, and weeping or oozing of clear fluid from the skin. The diary items were assessed on an 11-point numeric rating scale ranging from 0 (no symptom) to 10 (symptom as bad as one can imagine) and a Yes/No wake question. The diary had a recall specification of 24 hours. Scores of individual items were added to yield a total ADSD score (0-80), where higher scores mean worst symptom. mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	33	33	32	37
Units: percent change				
least squares mean (standard error)	-14.23 (± 12.981)	-18.21 (± 12.011)	-40.31 (± 12.224)	-32.91 (± 12.897)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3096
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	18.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.56
upper limit	54.92
Variability estimate	Standard error of the mean
Dispersion value	18.315

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4058
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	14.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.18
upper limit	49.58
Variability estimate	Standard error of the mean
Dispersion value	17.626

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	69
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6782
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-7.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-42.59
upper limit	27.8
Variability estimate	Standard error of the mean
Dispersion value	17.791

Secondary: Absolute Change From Baseline in AD-Specific Health-Related Quality of Life (QoL) at Week 12, as Assessed by the Atopic Dermatitis Impact Questionnaire (ADIQ)

End point title	Absolute Change From Baseline in AD-Specific Health-Related Quality of Life (QoL) at Week 12, as Assessed by the Atopic Dermatitis Impact Questionnaire (ADIQ)

End point description:

The ADIQ is a 17-item questionnaire used to assess the participants' AD-specific health-related QoL. The questionnaire assesses AD's impact on emotions, energy, activities of daily living, and social activities. The ADIQ had a recall specification of 7 days. The questions were assessed on a 5-point likert scale: 0

(not at all), 1 (a little), 2 (somewhat), 3 (quite a bit), and 4 (extreme). Scores of individual items were added to yield a total ADIQ score (0-68), where higher scores mean greater impairment of the participant's health-related QoL. mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	45	49
Units: units on scale				
least squares mean (standard error)	-10.92 (± 1.551)	-9.28 (± 1.58)	-12.75 (± 1.607)	-6.24 (± 1.578)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0357
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-4.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-9.05
upper limit	-0.32
Variability estimate	Standard error of the mean
Dispersion value	2.214

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1751
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-3.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.45
upper limit	1.37
Variability estimate	Standard error of the mean
Dispersion value	2.234

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0043
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-6.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.95
upper limit	-2.07
Variability estimate	Standard error of the mean
Dispersion value	2.251

Secondary: Percent Change From Baseline in AD-Specific Health-Related QoL at Week 12, as Assessed by the ADIQ

End point title	Percent Change From Baseline in AD-Specific Health-Related QoL at Week 12, as Assessed by the ADIQ

End point description:

The ADIQ is a 17-item questionnaire used to assess the participants' AD-specific health-related QoL. The questionnaire assesses AD's impact on emotions, energy, activities of daily living, and social activities. The ADIQ had a recall specification of 7 days. The questions were assessed on a 5-point likert scale: 0 (not at all), 1 (a little), 2 (somewhat), 3 (quite a bit), and 4 (extreme). Scores of individual items were added to yield a total ADIQ score (0-68), where higher scores mean greater impairment of the participant's health-related QoL. mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	45	49
Units: percent change				
least squares mean (standard error)	-30.79 (± 8.989)	-33.2 (± 9.153)	-54.29 (± 9.173)	-29.49 (± 9.133)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9193
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-1.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.59
upper limit	23.99
Variability estimate	Standard error of the mean
Dispersion value	12.818

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7742
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-3.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	-29.23
upper limit	21.8
Variability estimate	Standard error of the mean
Dispersion value	12.934

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0568
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-24.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-50.33
upper limit	0.72
Variability estimate	Standard error of the mean
Dispersion value	12.94

Secondary: Absolute Change From Baseline in Health-Related QoL at Week 12, as Measured by the Dermatology Life Quality Index (DLQI)

End point title	Absolute Change From Baseline in Health-Related QoL at Week 12, as Measured by the Dermatology Life Quality Index (DLQI)

End point description:

The DLQI is a 10-item, validated questionnaire used routinely in clinical practice to evaluate the impact of dermatologic diseases on participants' lives. The DLQI refers to the previous 7 days and questions are categorized into six domains: symptoms and feelings (2 items), daily activities (2 items), leisure (2 items), work and school (1 item), personal relationships (2 items), and treatment (1 item). The questions were assessed on a 4-point likert scale: 0 (not at all), 1 (a little), 2 (a lot), and 3 (very much). Scores of individual items were added to yield a total DLQI score (0-30), where higher scores mean greater impairment of the participant’s health-related QoL. mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	45	49
Units: units on scale				
least squares mean (standard error)	-5.64 (± 0.653)	-5.45 (± 0.665)	-5.15 (± 0.678)	-4.52 (± 0.666)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2313
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.96
upper limit	0.72
Variability estimate	Standard error of the mean
Dispersion value	0.933

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3229
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.93
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.79
upper limit	0.93
Variability estimate	Standard error of the mean
Dispersion value	0.943

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5045
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.63
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.51
upper limit	1.24
Variability estimate	Standard error of the mean
Dispersion value	0.949

Secondary: Percent Change From Baseline in Health-Related QoL at Week 12, as Measured by the DLQI

End point title	Percent Change From Baseline in Health-Related QoL at Week 12, as Measured by the DLQI

End point description:

The DLQI is a 10-item, validated questionnaire used routinely in clinical practice to evaluate the impact of dermatologic diseases on participants' lives. The DLQI refers to the previous 7 days and questions are categorized into six domains: symptoms and feelings (2 items), daily activities (2 items), leisure (2 items), work and school (1 item), personal relationships (2 items), and treatment (1 item). The questions were assessed on a 4-point likert scale: 0 (not at all), 1 (a little), 2 (a lot), and 3 (very much). Scores of individual items were added to yield a total DLQI score (0-30), where higher scores mean greater impairment of the participant’s health-related QoL. mITT population. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Baseline, Week 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	52	49	45	49
Units: percent change				
least squares mean (standard error)	-40.67 (± 6.691)	-34.33 (± 6.929)	-43.12 (± 7.017)	-33.57 (± 6.928)

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with exchangeable covariance structure.

Comparison groups	Lebrikizumab 250 mg Single Dose + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	101
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4621
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-7.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.04
upper limit	11.85
Variability estimate	Standard error of the mean
Dispersion value	9.637

Statistical analysis title	Statistical Analysis 2

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Single Dose + TCS v Placebo Q4W + TCS Cream

Number of subjects included in analysis	98
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9383
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-0.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-20.04
upper limit	18.52
Variability estimate	Standard error of the mean
Dispersion value	9.809

Statistical analysis title	Statistical Analysis 3

Statistical analysis description:

Adjusted mean and SE was calculated using linear mixed effects model including fixed effects of baseline value, treatment arm, visit, treatment by visit interaction, and geographic region; participant was included in the model as random effects with unstructured covariance structure.

Comparison groups	Lebrikizumab 125 mg Q4W + TCS v Placebo Q4W + TCS Cream
Number of subjects included in analysis	94
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.333
Method	Mixed models analysis
Parameter estimate	Adjusted Mean Difference
Point estimate	-9.55
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.91
upper limit	9.82
Variability estimate	Standard error of the mean
Dispersion value	9.85

Secondary: Number of Participants With Anti-Therapeutic Antibodies (ATA) to Lebrikizumab

End point title	Number of Participants With Anti-Therapeutic Antibodies (ATA) to Lebrikizumab

End point description:

Safety evaluable (SE) population was defined as participants who received at least one dose of the study treatment. Participants were analysed as per actual treatment received. Here, N=participants evaluable for this outcome. n=participants evaluable for specified category, per arm, respectively.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1), post-baseline (pre-dose on Days 29, 85,141, study discontinuation visit [up to Day 141])

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	52	53	50	53
Units: participants				
Baseline (n=51, 53, 50, 53)	4	1	5	2
Post-baseline (n=52,53,50,52)	8	19	11	2

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Participants With ATA to Phospholipase B-Like 2 (PLBL2) Protein

End point title	Number of Participants With ATA to Phospholipase B-Like 2 (PLBL2) Protein

End point description:

Treatment-induced PLBL2 = a participant with negative or missing baseline PLBL2 result and at least one positive post-baseline PLBL2 result. Treatment-enhanced PLBL2 = a participant with positive PLBL2 result at baseline who had one or more post-baseline titer results that were at least 0.60 t.u. greater than the baseline titer result. SE population. Participants were analysed as per actual treatment received. Here, N=participants evaluable for this outcome. n=participants evaluable for specified category, per arm, respectively.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1), post-baseline (pre-dose on Days 29, 85,141, study discontinuation visit [up to Day 141])

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	51	52	50	53
Units: participants				
Baseline (n=51, 52, 50, 53)	1	0	2	1
Post-baseline:Treatment-induced (n=51, 48, 49, 50)	1	1	2	0
Post-baseline:Treatment-enhanced(n=51, 48, 49, 50)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Disease Rebound

End point title	Percentage of Participants With Disease Rebound

End point description:

Disease rebound was defined as a significant worsening of disease severity after cessation of therapy to a severity level that is greater than prior to commencing therapy. SE population.

End point type	Secondary

End point timeframe:

From Week 12 up to 20 weeks

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	Placebo Q4W + TCS Cream
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	52	54	50	53
Units: percentage of participants				
number (not applicable)	0	0	0	1.9

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Serum Concentration (Cmax) of Lebrikizumab

End point title	Maximum Observed Serum Concentration (Cmax) of Lebrikizumab

End point description:

SE population, only participants who received lebrikizumab were to be analysed for this outcome. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

After first dose of lebrikizumab at Week 1

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	51	54	50	
Units: micrograms per milliliter (mcg/mL)				
arithmetic mean (standard deviation)	35.6 (± 10.8)	17 (± 5.22)	16.1 (± 5.19)	

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Reach Cmax (Tmax) of Lebrikizumab

End point title	Time to Reach Cmax (Tmax) of Lebrikizumab

End point description:

SE population, only participants who received lebrikizumab were to be analysed for this outcome. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

After first dose of lebrikizumab at Week 1

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	51	54	50	
Units: days				
median (full range (min-max))	6.97 (4.88 to 14.9)	6.98 (4.92 to 14.6)	6.96 (1.98 to 10.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Minimum Serum Concentration (Cmin) of Lebrikizumab

End point title	Minimum Serum Concentration (Cmin) of Lebrikizumab

End point description:

SE population, only participants who received lebrikizumab were to be analysed for this outcome. Here, N=participants analysed for this outcome. n=participants analysed at specified time-point.

End point type	Secondary

End point timeframe:

Pre-dose (Hour 0) at Weeks 4, 8, 12

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	52	53	50	
Units: mcg/mL				
arithmetic mean (standard deviation)				
Week 4 (n=51, 53, 50)	21.4 (± 6.87)	10.2 (± 3)	9.15 (± 2.99)	
Week 8 (n=52, 50, 46)	9.53 (± 3.53)	4.59 (± 2.12)	13.6 (± 5.34)	
Week 12 (n=50, 49, 46)	3.77 (± 2.01)	2.28 (± 1.72)	14.4 (± 5.69)	

Statistical analyses

No statistical analyses for this end point

Secondary: Elimination Half-Life (t1/2) of Lebrikizumab

End point title	Elimination Half-Life (t1/2) of Lebrikizumab

End point description:

SE population, only participants who received lebrikizumab were to be analysed for this outcome. Here, N=participants analysed for this outcome.

End point type	Secondary

End point timeframe:

Pre-dose (Hour 0) on Days 1, 8, 29, 43, 57, 85, 113, 141, study discontinuation visit (up to Day 141)

End point values	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS	
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	
Number of subjects analysed	52	52	48	
Units: days				
arithmetic mean (standard deviation)	22.2 (± 6.18)	18.5 (± 5.06)	20.9 (± 4.17)	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
From Screening up to Week 20	
Adverse event reporting additional description:	
SE population	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups	
Reporting group title	Lebrikizumab 250 mg Single Dose + TCS
Reporting group description:	
Participants received a single dose of lebrikizumab 250 milligrams (mg) subcutaneous (SC) injection on Day 1 followed by placebo on Week 4 and Week 8. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.	
Reporting group title	Lebrikizumab 125 mg Single Dose + TCS
Reporting group description:	
Participants received a single dose of lebrikizumab 125 mg SC injection on Day 1 followed by placebo on Week 4 and Week 8. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.	
Reporting group title	Lebrikizumab 125 mg Q4W + TCS
Reporting group description:	
Participants received lebrikizumab 125 mg SC injection every 4 weeks (Q4W) for a total of 3 doses. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.	
Reporting group title	Placebo Q4W + TCS Cream
Reporting group description:	
Participants received placebo Q4W for a total of 3 doses. Participants continued to apply TCS cream (triamcenolone acetonide 0.1% or hydrocortisone 2.5% cream) twice daily to active skin lesions throughout the 12-week treatment period.	

Serious adverse events	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 52 (0.00%)	3 / 54 (5.56%)	2 / 50 (4.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 52 (0.00%)	1 / 54 (1.85%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoaesthesia			

subjects affected / exposed	0 / 52 (0.00%)	1 / 54 (1.85%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple sclerosis			
subjects affected / exposed	0 / 52 (0.00%)	1 / 54 (1.85%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sensory loss			
subjects affected / exposed	0 / 52 (0.00%)	1 / 54 (1.85%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Cyst			
subjects affected / exposed	0 / 52 (0.00%)	1 / 54 (1.85%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 52 (0.00%)	1 / 54 (1.85%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Inguinal hernia			
subjects affected / exposed	0 / 52 (0.00%)	1 / 54 (1.85%)	0 / 50 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Rebound atopic dermatitis			
subjects affected / exposed	0 / 52 (0.00%)	0 / 54 (0.00%)	0 / 50 (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
Renal and urinary disorders			
Nephrolothiasis			

subjects affected / exposed	0 / 52 (0.00%)	0 / 54 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Myopathy			
subjects affected / exposed	0 / 52 (0.00%)	0 / 54 (0.00%)	1 / 50 (2.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Postoperative abcess			
subjects affected / exposed	0 / 52 (0.00%)	0 / 54 (0.00%)	0 / 50 (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

Serious adverse events	Placebo Q4W + TCS Cream		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 53 (3.77%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypoaesthesia			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Multiple sclerosis			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Sensory loss			

subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Cyst			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Diplopia			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Inguinal hernia			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Rebound atopic dermatitis			
subjects affected / exposed	1 / 53 (1.89%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Nephrolothiasis			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Myopathy			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			

Postoperative abcess			
subjects affected / exposed	1 / 53 (1.89%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Lebrikizumab 250 mg Single Dose + TCS	Lebrikizumab 125 mg Single Dose + TCS	Lebrikizumab 125 mg Q4W + TCS
Total subjects affected by non-serious adverse events			
subjects affected / exposed	22 / 52 (42.31%)	23 / 54 (42.59%)	16 / 50 (32.00%)
Nervous system disorders			
Headache			
subjects affected / exposed	4 / 52 (7.69%)	2 / 54 (3.70%)	4 / 50 (8.00%)
occurrences (all)	8	3	4
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	2 / 52 (3.85%)	4 / 54 (7.41%)	2 / 50 (4.00%)
occurrences (all)	2	4	3
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	3 / 52 (5.77%)	3 / 54 (5.56%)	1 / 50 (2.00%)
occurrences (all)	4	3	1
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	4 / 52 (7.69%)	0 / 54 (0.00%)	0 / 50 (0.00%)
occurrences (all)	4	0	0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	3 / 52 (5.77%)	0 / 54 (0.00%)	1 / 50 (2.00%)
occurrences (all)	3	0	1
Pruritus			
subjects affected / exposed	2 / 52 (3.85%)	4 / 54 (7.41%)	3 / 50 (6.00%)
occurrences (all)	2	4	3
Infections and infestations			
Conjunctivitis			

subjects affected / exposed	0 / 52 (0.00%)	3 / 54 (5.56%)	0 / 50 (0.00%)
occurrences (all)	0	3	0
Nasopharyngitis			
subjects affected / exposed	8 / 52 (15.38%)	10 / 54 (18.52%)	5 / 50 (10.00%)
occurrences (all)	10	13	8
Postoperative wound infection			
subjects affected / exposed	1 / 52 (1.92%)	0 / 54 (0.00%)	0 / 50 (0.00%)
occurrences (all)	1	0	0
Rhinitis			
subjects affected / exposed	3 / 52 (5.77%)	0 / 54 (0.00%)	1 / 50 (2.00%)
occurrences (all)	3	0	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 52 (1.92%)	7 / 54 (12.96%)	2 / 50 (4.00%)
occurrences (all)	1	7	4

Non-serious adverse events	Placebo Q4W + TCS Cream		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	19 / 53 (35.85%)		
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 53 (3.77%)		
occurrences (all)	2		
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 53 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Dermatitis atopic			

subjects affected / exposed	3 / 53 (5.66%)		
occurrences (all)	3		
Pruritus			
subjects affected / exposed	1 / 53 (1.89%)		
occurrences (all)	2		
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	2 / 53 (3.77%)		
occurrences (all)	2		
Nasopharyngitis			
subjects affected / exposed	8 / 53 (15.09%)		
occurrences (all)	9		
Postoperative wound infection			
subjects affected / exposed	3 / 53 (5.66%)		
occurrences (all)	4		
Rhinitis			
subjects affected / exposed	1 / 53 (1.89%)		
occurrences (all)	1		
Upper respiratory tract infection			
subjects affected / exposed	5 / 53 (9.43%)		
occurrences (all)	6		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 January 2015	- Antiviral medication to treat herpes zoster was deleted from the list of therapies permitted during the study. - Herpes zoster infection was added as a reason requiring study treatment discontinuation.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported