Clinical trial results:
A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging Study Investigating the Efficacy, Safety, and Pharmacokinetic Profile of ANB020 Administered to Adult Subjects with Moderate-to-Severe Atopic Dermatitis

Summary

EudraCT number	2018-000331-27
Trial protocol	GB DE CZ PL
Global end of trial date	03 December 2019

Results information

Result version number	v1
This version publication date	26 March 2021
First version publication date	26 March 2021

Trial information

Trial identification

Sponsor protocol code	ANB020-005

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03533751
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AnaptysBio, Inc
Sponsor organisation address	10421 Pacific Center Court, Suite 200, San Diego, United States, CA 92121
Public contact	AnaptysBio Clinical Trials Information, AnaptysBio, Inc, +1 8583626387, clinicaltrialinfo@anaptysbio.com
Scientific contact	AnaptysBio Clinical Trials Information, AnaptysBio, Inc, +1 8583626387, clinicaltrialinfo@anaptysbio.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	03 December 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 December 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this study was to evaluate the effects of etokimab (ANB020) on skin lesions.

Protection of trial subjects:

This study was conducted in accordance with the protocol and with the following:
• Consensus ethical principles derived from international guidelines including the Declaration of Helsinki and Council for International Organizations of Medical Sciences International Ethical Guidelines;
• Applicable International Council for Harmonisation Good Clinical Practice Guidelines;
• Applicable laws and regulations.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	19 June 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Canada: 21
Country: Number of subjects enrolled	United States: 134
Country: Number of subjects enrolled	Germany: 19
Country: Number of subjects enrolled	Poland: 47
Country: Number of subjects enrolled	Czechia: 46
Country: Number of subjects enrolled	United Kingdom: 35
Worldwide total number of subjects	302
EEA total number of subjects	112

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)	279
From 65 to 84 years	23
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

This study was conducted in adults with moderate to severe atopic dermatitis (AD). Subjects were randomized on Day 1 to 1 of 5 treatment groups in a 1:1:1:1:1 ratio.

Pre-assignment

Screening details:

The study had a screening period of up to 4 weeks (Week -4 to 0) prior to administration of study drug on Day 1, treatment period of 16 weeks (Week 0 to 16), and safety follow-up period of 8 weeks (Week 16 to 24).

Period 1

Period 1 title	Randomization Through Start of Treatment
Is this the baseline period?	No
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Subjects randomized to receive matching placebo administered subcutaneously (SC) once every 4 weeks (Q4W) for up to 16 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Period is prior to the start of treatment; no study drug administered.

Arm title	Etokimab 20 mg Q4W

Arm description:

Subjects randomized to receive etokimab 20 milligrams (mg) administered SC Q4W for up to 16 weeks.

Arm type	Experimental
Investigational medicinal product name	Etokimab
Investigational medicinal product code	ANB020
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Period is prior to the start of treatment; no study drug administered.

Arm title	Etokimab 300 mg load + 150 mg Q8W

Arm description:

Subjects randomized to receive etokimab 150 mg administered SC once every 8 weeks (Q8W) following an initial 300 mg loading dose for up to 16 weeks.

Arm type	Experimental

Investigational medicinal product name	Etokimab
Investigational medicinal product code	ANB020
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Period is prior to the start of treatment; no study drug administered.

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Period is prior to the start of treatment; no study drug administered.

Arm title	Etokimab 300 mg load + 150 mg Q4W

Arm description:

Subjects randomized to receive etokimab 150 mg administered SC Q4W following an initial 300 mg loading dose for up to 16 weeks.

Arm type	Experimental
Investigational medicinal product name	Etokimab
Investigational medicinal product code	ANB020
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Period is prior to the start of treatment; no study drug administered.

Arm title	Etokimab 600 mg load + 300 mg Q4W

Arm description:

Subjects randomized to receive etokimab 300 mg administered SC Q4W following an initial 600 mg loading dose for up to 16 weeks.

Arm type	Experimental
Investigational medicinal product name	Etokimab
Investigational medicinal product code	ANB020
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Period is prior to the start of treatment; no study drug administered.

Number of subjects in period 1	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W
Started	60	61	61
Completed	60	61	59
Not completed	0	0	2
Consent withdrawn by subject	-	-	1
Lost to follow-up	-	-	1

Number of subjects in period 1	Etokimab 300 mg load + 150 mg Q4W	Etokimab 600 mg load + 300 mg Q4W

Started	60	60
Completed	60	60
Not completed	0	0
Consent withdrawn by subject	-	-
Lost to follow-up	-	-

Period 2

Period 2 title	Treatment Through End of Study
Is this the baseline period?	Yes[1]
Allocation method	Randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo

Arm description:

Matching placebo was administered SC Q4W for up to 16 weeks.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo was formulated as a sterile solution in single use glass vials containing 1.2 milliliters (mL) of solution.

Arm title	Etokimab 20 mg Q4W

Arm description:

Etokimab 20 mg was administered SC Q4W for up to 16 weeks.

Arm type	Experimental
Investigational medicinal product name	Etokimab
Investigational medicinal product code	ANB020
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Etokimab was formulated as a sterile solution in single use glass vials containing 1.2 mL of solution.

Arm title	Etokimab 300 mg load + 150 mg Q8W

Arm description:

Etokimab 150 mg was administered SC Q8W following an initial 300 mg loading dose for up to 16 weeks. At Weeks 4 and 12, the subjects received a placebo dose.

Arm type	Experimental

Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Placebo was formulated as a sterile solution in single use glass vials containing 1.2 mL of solution.

Investigational medicinal product name	Etokimab
Investigational medicinal product code	ANB020
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Etokimab was formulated as a sterile solution in single use glass vials containing 1.2 mL of solution.

Arm title	Etokimab 300 mg load + 150 mg Q4W

Arm description:

Etokimab 150 mg was administered SC Q4W following an initial 300 mg loading dose for up to 16 weeks.

Arm type	Experimental
Investigational medicinal product name	Etokimab
Investigational medicinal product code	ANB020
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Etokimab was formulated as a sterile solution in single use glass vials containing 1.2 mL of solution.

Arm title	Etokimab 600 mg load + 300 mg Q4W

Arm description:

Etokimab 300 mg was administered SC Q4W following an initial 600 mg loading dose for up to 16 weeks.

Arm type	Experimental
Investigational medicinal product name	Etokimab
Investigational medicinal product code	ANB020
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Etokimab was formulated as a sterile solution in single use glass vials containing 1.2 mL of solution.

Notes:

[1] - Period 1 is not the baseline period. It is expected that period 1 will be the baseline period.

Justification: Period 1 presents data for all subjects randomized until the start of treatment and Period 2, presents data for all subjects who received study drug. Baseline characteristics are based on subjects who were randomized and who received even a partial dose of study drug; Period 2 is therefore the baseline period.

Number of subjects in period 2[2]	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W
Started	60	61	59
Completed	41	36	39
Not completed	19	25	20
Consent withdrawn by subject	12	6	10

Physician decision	-	2	1
Adverse event, non-fatal	4	7	2
Other	-	2	-
Miscellaneous	-	-	1
Prohibited medication	-	1	-
Lost to follow-up	3	7	5
Sponsor decision	-	-	1

Number of subjects in period 2[2]	Etokimab 300 mg load + 150 mg Q4W	Etokimab 600 mg load + 300 mg Q4W
Started	60	60
Completed	40	37
Not completed	20	23
Consent withdrawn by subject	9	10
Physician decision	2	1
Adverse event, non-fatal	4	5
Other	-	-
Miscellaneous	-	3
Prohibited medication	-	1
Lost to follow-up	4	3
Sponsor decision	1	-

Notes:

[2] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.
Justification: Period 1 presents data for all subjects randomized until the start of treatment and Period 2, presents data for all subjects who received study drug. Baseline characteristics are based on subjects who were randomized and who received even a partial dose of study drug; Period 2 is therefore the baseline period.

Baseline characteristics

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Matching placebo was administered SC Q4W for up to 16 weeks.	
Reporting group title	Etokimab 20 mg Q4W
Reporting group description:	
Etokimab 20 mg was administered SC Q4W for up to 16 weeks.	
Reporting group title	Etokimab 300 mg load + 150 mg Q8W
Reporting group description:	
Etokimab 150 mg was administered SC Q8W following an initial 300 mg loading dose for up to 16 weeks. At Weeks 4 and 12, the subjects received a placebo dose.	
Reporting group title	Etokimab 300 mg load + 150 mg Q4W
Reporting group description:	
Etokimab 150 mg was administered SC Q4W following an initial 300 mg loading dose for up to 16 weeks.	
Reporting group title	Etokimab 600 mg load + 300 mg Q4W
Reporting group description:	
Etokimab 300 mg was administered SC Q4W following an initial 600 mg loading dose for up to 16 weeks.	

Reporting group values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W
Number of subjects	60	61	59
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	39.5	40.1	39.7
standard deviation	± 15.92	± 16.76	± 14.38
Gender categorical Units: Subjects			
Female	29	25	36
Male	31	36	23
Race Units: Subjects			
American Indian or Alaska Native	0	1	0
Asian	5	2	0
Black or African American	6	9	10

White	49	48	46
Other	0	1	3
Ethnicity Units: Subjects			
Hispanic or Latino	10	11	8
Not Hispanic or Latino	50	49	51
Not Reported	0	1	0
Unknown	0	0	0
Height Units: centimeter(s)			
arithmetic mean	169.3	169.8	167.7
standard deviation	± 9.40	± 10.35	± 9.14
Weight Units: kilogram(s)			
arithmetic mean	76.4	77.3	76.0
standard deviation	± 15.67	± 14.42	± 14.73
Body Mass Index Units: kilogram per meter squared			
arithmetic mean	26.6	26.7	26.9
standard deviation	± 4.73	± 4.00	± 4.53

Reporting group values	Etokimab 300 mg load + 150 mg Q4W	Etokimab 600 mg load + 300 mg Q4W	Total
Number of subjects	60	60	300
Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			0
Newborns (0-27 days)			0
Infants and toddlers (28 days-23 months)			0
Children (2-11 years)			0
Adolescents (12-17 years)			0
Adults (18-64 years)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	38.9	37.1	
standard deviation	± 14.61	± 14.78	-
Gender categorical Units: Subjects			
Female	24	32	146
Male	36	28	154
Race Units: Subjects			
American Indian or Alaska Native	0	2	3
Asian	0	6	13
Black or African American	4	6	35
White	55	45	243
Other	1	1	6
Ethnicity			

Units: Subjects			
Hispanic or Latino	8	7	44
Not Hispanic or Latino	50	53	253
Not Reported	1	0	2
Unknown	1	0	1
Height			
Units: centimeter(s)			
arithmetic mean	173.0	170.2	
standard deviation	± 9.25	± 9.72	-
Weight			
Units: kilogram(s)			
arithmetic mean	78.7	75.7	
standard deviation	± 15.03	± 15.07	-
Body Mass Index			
Units: kilogram per meter squared			
arithmetic mean	26.2	26.1	
standard deviation	± 4.27	± 4.58	-

End points

End points reporting groups

Reporting group title	Placebo
Reporting group description:	
Subjects randomized to receive matching placebo administered subcutaneously (SC) once every 4 weeks (Q4W) for up to 16 weeks.	
Reporting group title	Etokimab 20 mg Q4W
Reporting group description:	
Subjects randomized to receive etokimab 20 milligrams (mg) administered SC Q4W for up to 16 weeks.	
Reporting group title	Etokimab 300 mg load + 150 mg Q8W
Reporting group description:	
Subjects randomized to receive etokimab 150 mg administered SC once every 8 weeks (Q8W) following an initial 300 mg loading dose for up to 16 weeks.	
Reporting group title	Etokimab 300 mg load + 150 mg Q4W
Reporting group description:	
Subjects randomized to receive etokimab 150 mg administered SC Q4W following an initial 300 mg loading dose for up to 16 weeks.	
Reporting group title	Etokimab 600 mg load + 300 mg Q4W
Reporting group description:	
Subjects randomized to receive etokimab 300 mg administered SC Q4W following an initial 600 mg loading dose for up to 16 weeks.	
Reporting group title	Placebo
Reporting group description:	
Matching placebo was administered SC Q4W for up to 16 weeks.	
Reporting group title	Etokimab 20 mg Q4W
Reporting group description:	
Etokimab 20 mg was administered SC Q4W for up to 16 weeks.	
Reporting group title	Etokimab 300 mg load + 150 mg Q8W
Reporting group description:	
Etokimab 150 mg was administered SC Q8W following an initial 300 mg loading dose for up to 16 weeks. At Weeks 4 and 12, the subjects received a placebo dose.	
Reporting group title	Etokimab 300 mg load + 150 mg Q4W
Reporting group description:	
Etokimab 150 mg was administered SC Q4W following an initial 300 mg loading dose for up to 16 weeks.	
Reporting group title	Etokimab 600 mg load + 300 mg Q4W
Reporting group description:	
Etokimab 300 mg was administered SC Q4W following an initial 600 mg loading dose for up to 16 weeks.	

Primary: Percent Change from Baseline in Eczema Area and Severity Index (EASI) Score

End point title	Percent Change from Baseline in Eczema Area and Severity Index (EASI) Score

End point description:

The EASI is an Investigator assessment measuring the severity of clinical signs in AD. The EASI is considered one of the best validated outcome measures for AD. The EASI score assesses the severity and extent of erythema; induration, papulation, and edema; excoriations; and lichenification. The EASI scores range from 0 to 72, with higher scores indicating greater severity and extent of AD.
The full analysis set included all randomized subjects who received 1 dose of etokimab or placebo and had baseline and post-baseline EASI scores.

End point type	Primary
End point timeframe: Baseline and Week 16	

End point values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W	Etokimab 300 mg load + 150 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	61	59	60
Units: percent				
least squares mean (standard error)	-49.38 (± 7.124)	-41.63 (± 6.707)	-55.70 (± 6.206)	-47.40 (± 6.091)

End point values	Etokimab 600 mg load + 300 mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: percent				
least squares mean (standard error)	-44.56 (± 7.811)			

Statistical analyses

Statistical analysis title	Placebo Vs Etokimab 20 mg Q4W
Statistical analysis description: P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline EASI as covariate.	
Comparison groups	Placebo v Etokimab 20 mg Q4W
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4498
Method	ANCOVA
Parameter estimate	Least squares (LS) mean difference
Point estimate	7.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	-12.4066
upper limit	27.8983
Variability estimate	Standard error of the mean
Dispersion value	10.235

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q8W
Statistical analysis description:	
P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline EASI as covariate.	
Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q8W
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.501
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-6.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	-24.774
upper limit	12.1262
Variability estimate	Standard error of the mean
Dispersion value	9.39

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q4W
Statistical analysis description:	
P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline EASI as covariate.	
Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8349
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	1.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.6037
upper limit	20.5476
Variability estimate	Standard error of the mean
Dispersion value	9.454

Statistical analysis title	Placebo Vs Etokimab 600 mg load + 300 mg Q4W
Statistical analysis description:	
P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline EASI as covariate.	
Comparison groups	Placebo v Etokimab 600 mg load + 300 mg Q4W

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6662
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	4.82
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.1892
upper limit	26.8275
Variability estimate	Standard error of the mean
Dispersion value	11.154

Secondary: Number of Subjects with EASI-50 Responses (≥50% improvement from Baseline)

End point title	Number of Subjects with EASI-50 Responses (≥50% improvement from Baseline)

End point description:

The EASI is an Investigator assessment measuring the severity of clinical signs in AD. The EASI is considered one of the best validated outcome measures for AD. The full analysis set included all randomized subjects who received 1 dose of etokimab or placebo and had baseline and post-baseline EASI scores.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W	Etokimab 300 mg load + 150 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	61	59	60
Units: subjects	21	19	27	21

End point values	Etokimab 600 mg load + 300 mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: subjects	18			

Statistical analyses

Statistical analysis title	Placebo Vs Etokimab 20 mg Q4W

Statistical analysis description:

Inferential statistics from a logistic regression model with treatment as fixed effect and baseline EASI as a covariate.

Comparison groups	Placebo v Etokimab 20 mg Q4W
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7992
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	1.9509

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q8W

Statistical analysis description:

Inferential statistics from a logistic regression model with treatment as fixed effect and baseline EASI as a covariate.

Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q8W
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2197
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.59
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.757
upper limit	3.3572

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q4W

Statistical analysis description:

Inferential statistics from a logistic regression model with treatment as fixed effect and baseline EASI as a covariate.

Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q4W

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7197
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5345
upper limit	2.4774

Statistical analysis title	Placebo Vs Etokimab 600 mg load + 300 mg Q4W

Statistical analysis description:

Inferential statistics from a logistic regression model with treatment as fixed effect and baseline EASI as a covariate.

Comparison groups	Placebo v Etokimab 600 mg load + 300 mg Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6772
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.85
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.391
upper limit	1.8404

Secondary: Number of Subjects with EASI-75 Responses (≥75% improvement from Baseline)

End point title	Number of Subjects with EASI-75 Responses (≥75% improvement from Baseline)

End point description:

The EASI is an Investigator assessment measuring the severity of clinical signs in AD. The EASI is considered one of the best validated outcome measures for AD. The full analysis set included all randomized subjects who received 1 dose of etokimab or placebo and had baseline and post-baseline EASI scores.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W	Etokimab 300 mg load + 150 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	61	59	60
Units: subjects	10	10	14	12

End point values	Etokimab 600 mg load + 300 mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: subjects	11			

Statistical analyses

Statistical analysis title	Placebo Vs Etokimab 20 mg Q4W
Statistical analysis description:	
Inferential statistics from a logistic regression model with treatment as fixed effect and baseline EASI as a covariate.	
Comparison groups	Placebo v Etokimab 20 mg Q4W
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9537
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3922
upper limit	2.6994

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q8W
Statistical analysis description:	
Inferential statistics from a logistic regression model with treatment as fixed effect and baseline EASI as a covariate.	
Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q8W
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3316
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.57

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6323
upper limit	3.8895

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q4W

Statistical analysis description:

Inferential statistics from a logistic regression model with treatment as fixed effect and baseline EASI as a covariate.

Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5166
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5331
upper limit	3.4944

Statistical analysis title	Placebo Vs Etokimab 600 mg load + 300 mg Q4W

Statistical analysis description:

Inferential statistics from a logistic regression model with treatment as fixed effect and baseline EASI as a covariate.

Comparison groups	Placebo v Etokimab 600 mg load + 300 mg Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7426
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4545
upper limit	3.0223

Secondary: Number of Subjects with EASI-90 Responses (>90% improvement from Baseline)

End point title	Number of Subjects with EASI-90 Responses (>90%

	improvement from Baseline)

End point description:

The EASI is an Investigator assessment measuring the severity of clinical signs in AD. The EASI is considered one of the best validated outcome measures for AD. The full analysis set included all randomized subjects who received 1 dose of etokimab or placebo and had baseline and post-baseline EASI scores.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W	Etokimab 300 mg load + 150 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	61	59	60
Units: subjects	3	5	7	7

End point values	Etokimab 600 mg load + 300 mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: subjects	2			

Statistical analyses

Statistical analysis title	Placebo Vs Etokimab 20 mg Q4W

Statistical analysis description:

Inferential statistics from a logistic regression model with treatment as fixed effect and baseline EASI as a covariate.

Comparison groups	Placebo v Etokimab 20 mg Q4W
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4543
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3998
upper limit	7.7615

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q8W

Statistical analysis description:

Inferential statistics from a logistic regression model with treatment as fixed effect and baseline EASI as a covariate.

Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q8W
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1874
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6314
upper limit	10.4827

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q4W

Statistical analysis description:

Inferential statistics from a logistic regression model with treatment as fixed effect and baseline EASI as a covariate.

Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1721
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	2.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6506
upper limit	11.0814

Statistical analysis title	Placebo Vs Etokimab 600 mg load + 300 mg Q4W

Statistical analysis description:

Inferential statistics from a logistic regression model with treatment as fixed effect and baseline EASI as a covariate.

Comparison groups	Placebo v Etokimab 600 mg load + 300 mg Q4W

Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6755
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.1086
upper limit	4.2141

Secondary: Number of Subjects who Achieved Validated Investigator's Global Assessment for Atopic Dermatitis (vIGA-AD) Score Reduction of ≥2

End point title	Number of Subjects who Achieved Validated Investigator's Global Assessment for Atopic Dermatitis (vIGA-AD) Score Reduction of ≥2

End point description:

The vIGA-AD is a static 5-point scale used to evaluate AD disease severity globally:
- 0: Clear - No inflammatory signs of AD (no erythema, no induration/papulation, no lichenification, no oozing/crusting). Post-inflammatory hyperpigmentation and/or hypopigmentation may be present;
- 1: Almost clear - Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting;
- 2: Mild - Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting;
- 3: Moderate - Clearly perceptible erythema (dull red), clearly perceptible induration/papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present;
- 4: Severe - Marked erythema (deep or bright red), marked induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present. Higher scores indicate worse symptoms.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W	Etokimab 300 mg load + 150 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60[1]	61[2]	59[3]	60[4]
Units: subjects	8	7	8	10

Notes:

[1] - Full analysis set.

[2] - Full analysis set.

[3] - Full analysis set.

[4] - Full analysis set.

End point values	Etokimab 600 mg load + 300 mg Q4W			

Subject group type	Reporting group			
Number of subjects analysed	60[5]			
Units: subjects	9			

Notes:

[5] - Full analysis set.

Statistical analyses

Statistical analysis title	Placebo Vs Etokimab 20 mg Q4W

Statistical analysis description:

Inferential statistics based on a Logistic regression model with treatment as fixed effect and baseline test score as covariate.

Comparison groups	Placebo v Etokimab 20 mg Q4W
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6058
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.2481
upper limit	2.2543

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q8W

Statistical analysis description:

Inferential statistics based on a Logistic regression model with treatment as fixed effect and baseline test score as covariate.

Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q8W
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9521
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3356
upper limit	2.7923

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q4W

Statistical analysis description:

Inferential statistics based on a Logistic regression model with treatment as fixed effect and baseline

test score as covariate.

Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6905
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4457
upper limit	3.3878

Statistical analysis title	Placebo Vs Etokimab 600 mg load + 300 mg Q4W

Statistical analysis description:

Inferential statistics based on a Logistic regression model with treatment as fixed effect and baseline test score as covariate.

Comparison groups	Placebo v Etokimab 600 mg load + 300 mg Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9399
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3671
upper limit	2.9518

Secondary: Number of Subjects who Achieved vIGA-AD Response of 0 (Clear) or 1 (Almost Clear)

End point title	Number of Subjects who Achieved vIGA-AD Response of 0 (Clear) or 1 (Almost Clear)

End point description:

The vIGA-AD is a static 5-point scale to evaluate AD disease severity globally.
- 0: Clear - No inflammatory signs of AD (no erythema, no induration/papulation, no lichenification, no oozing/crusting). Post-inflammatory hyperpigmentation and/or hypopigmentation may be present;
- 1: Almost clear - Barely perceptible erythema, barely perceptible induration/papulation, and/or minimal lichenification. No oozing or crusting;
- 2: Mild - Slight but definite erythema (pink), slight but definite induration/papulation, and/or slight but definite lichenification. No oozing or crusting;
- 3: Moderate - Clearly perceptible erythema (dull red), clearly perceptible induration/papulation, and/or clearly perceptible lichenification. Oozing and crusting may be present;
- 4: Severe - Marked erythema (deep or bright red), marked induration/papulation, and/or marked lichenification. Disease is widespread in extent. Oozing or crusting may be present.

Higher scores indicate worst symptoms.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W	Etokimab 300 mg load + 150 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60[6]	61[7]	59[8]	60[9]
Units: subjects	5	5	6	8

Notes:

[6] - Full analysis set.

[7] - Full analysis set.

[8] - Full analysis set.

[9] - Full analysis set.

End point values	Etokimab 600 mg load + 300 mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	60[10]			
Units: subjects	6			

Notes:

[10] - Full analysis set.

Statistical analyses

Statistical analysis title	Placebo Vs Etokimab 20 mg Q4W

Statistical analysis description:

Inferential statistics based on a Logistic regression model with treatment as fixed effect and baseline test score as covariate.

Comparison groups	Placebo v Etokimab 20 mg Q4W
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7659
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.22
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.329
upper limit	4.5268

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q8W

Statistical analysis description:

Inferential statistics based on a Logistic regression model with treatment as fixed effect and baseline

test score as covariate.

Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q8W
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6273
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.36
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3895
upper limit	4.776

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q4W

Statistical analysis description:

Inferential statistics based on a Logistic regression model with treatment as fixed effect and baseline test score as covariate.

Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2967
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5734
upper limit	6.1879

Statistical analysis title	Placebo Vs Etokimab 600 mg load + 300 mg Q4W

Statistical analysis description:

Inferential statistics based on a Logistic regression model with treatment as fixed effect and baseline test score as covariate.

Comparison groups	Placebo v Etokimab 600 mg load + 300 mg Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5544
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.46

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.4152
upper limit	5.1476

Secondary: Number of Subjects who Achieved Numerical Rating System (NRS) for Pruritus Score Reduction from Baseline of ≥4

End point title	Number of Subjects who Achieved Numerical Rating System (NRS) for Pruritus Score Reduction from Baseline of ≥4

End point description:

The NRS for Pruritus is a simple assessment tool that subjects used to report the intensity of their pruritus (itch) during a daily recall period using an ePRO device. Subjects were asked 2 questions:
- For average itch intensity: "On a scale of 0 to 10, with 0 being 'no itch' and 10 being the 'worst imaginable itch', how would you rate your itch overall (on average) during the previous 24 hours?";
- For maximum itch intensity: "On a scale of 0 to 10, with 0 being 'no itch' and 10 being the 'worst imaginable itch', how would you rate your itch at the worst moment during the previous 24 hours?".
The full analysis set included all randomized subjects who received 1 dose of etokimab or placebo and had baseline and post-baseline EASI scores.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W	Etokimab 300 mg load + 150 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	61	59	60
Units: subjects	5	6	8	9

End point values	Etokimab 600 mg load + 300 mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: subjects	9			

Statistical analyses

Statistical analysis title	Placebo Vs Etokimab 20 mg Q4W

Statistical analysis description:

Inferential statistics based on a Logistic regression model with treatment as fixed effect and baseline test score as covariate.

Comparison groups	Placebo v Etokimab 20 mg Q4W

Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.86
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3175
upper limit	3.9513

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q8W

Statistical analysis description:

Inferential statistics based on a Logistic regression model with treatment as fixed effect and baseline test score as covariate.

Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q8W
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3222
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5511
upper limit	6.1214

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q4W

Statistical analysis description:

Inferential statistics based on a Logistic regression model with treatment as fixed effect and baseline test score as covariate.

Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2564
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.98

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.6089
upper limit	6.431

Statistical analysis title	Placebo Vs Etokimab 600 mg load + 300 mg Q4W

Statistical analysis description:

Inferential statistics based on a Logistic regression model with treatment as fixed effect and baseline test score as covariate.

Comparison groups	Placebo v Etokimab 600 mg load + 300 mg Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2912
Method	Regression, Logistic
Parameter estimate	Odds ratio (OR)
Point estimate	1.89
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.5806
upper limit	6.1275

Secondary: Percent Change from Baseline in Peak Weekly Averaged NRS for Pruritus Score

End point title	Percent Change from Baseline in Peak Weekly Averaged NRS for Pruritus Score

End point description:

The NRS for Pruritus is a simple assessment tool that subjects used to report the intensity of their pruritus (itch) during a daily recall period using an ePRO device. Subjects were asked 2 questions:
- For average itch intensity: "On a scale of 0 to 10, with 0 being 'no itch' and 10 being the 'worst imaginable itch', how would you rate your itch overall (on average) during the previous 24 hours?";
- For maximum itch intensity: "On a scale of 0 to 10, with 0 being 'no itch' and 10 being the 'worst imaginable itch', how would you rate your itch at the worst moment during the previous 24 hours?".
The full analysis set included all randomized subjects who received 1 dose of etokimab or placebo and had baseline and post-baseline EASI scores.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W	Etokimab 300 mg load + 150 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	56	58	52	54
Units: percent				
least squares mean (standard error)	-21.13 (± 5.964)	-22.30 (± 6.211)	-17.69 (± 6.530)	-30.39 (± 6.176)

End point values	Etokimab 600 mg load + 300 mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	54			
Units: percent				
least squares mean (standard error)	-27.18 (± 6.192)			

Statistical analyses

Statistical analysis title	Placebo Vs Etokimab 20 mg Q4W
Statistical analysis description:	
P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline Peak Weekly Averaged NRS as covariate.	
Comparison groups	Placebo v Etokimab 20 mg Q4W
Number of subjects included in analysis	114
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8927
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-1.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.2117
upper limit	15.8686
Variability estimate	Standard error of the mean
Dispersion value	8.679

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q8W
Statistical analysis description:	
P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline Peak Weekly Averaged NRS as covariate.	
Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q8W

Number of subjects included in analysis	108
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7035
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	3.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.2767
upper limit	21.1463
Variability estimate	Standard error of the mean
Dispersion value	9.019

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q4W
Statistical analysis description:	
P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline Peak Weekly Averaged NRS as covariate.	
Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q4W
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2819
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-9.27
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.159
upper limit	7.6237
Variability estimate	Standard error of the mean
Dispersion value	8.608

Statistical analysis title	Placebo Vs Etokimab 600 mg load + 300 mg Q4W
Statistical analysis description:	
P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline Peak Weekly Averaged NRS as covariate.	
Comparison groups	Placebo v Etokimab 600 mg load + 300 mg Q4W
Number of subjects included in analysis	110
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4793
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-6.06

Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.8452
upper limit	10.7333
Variability estimate	Standard error of the mean
Dispersion value	8.557

Secondary: Percent Change from Baseline in Severity Scoring of Atopic Dermatitis (SCORAD) Scores

End point title	Percent Change from Baseline in Severity Scoring of Atopic Dermatitis (SCORAD) Scores

End point description:

The SCORAD index, a validated assessment of AD, was developed to standardize the evaluation of the extent and severity of AD.
There are 3 components to the assessment:
- A: extent or affected BSA, assessed as a percentage of each defined body area and reported as the sum of all areas;
- B: severity of 6 specific symptoms of AD (redness, swelling, oozing/crusting, excoriation, skin thickening/lichenification, and dryness) is assessed using the following scale: none (0), mild (1), moderate (2), or severe (3);
- C: subjective assessment of itch and sleeplessness is recorded for each symptom by the subject on a visual analog scale (VAS), where 0 is no itch (or sleeplessness) and 10 is the worst imaginable itch (or sleeplessness).

The SCORAD score is calculated as: A/5 + 7B/2 + C. The maximum score is 103.
The full analysis set included all randomized subjects who received 1 dose of etokimab or placebo and had baseline and post-baseline EASI scores.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W	Etokimab 300 mg load + 150 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	61	59	60
Units: percent				
least squares mean (standard error)	-37.99 (± 4.764)	-31.42 (± 4.605)	-39.22 (± 4.294)	-35.48 (± 4.401)

End point values	Etokimab 600 mg load + 300 mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: percent				
least squares mean (standard error)	-31.23 (± 4.927)			

Statistical analyses

Statistical analysis title	Placebo Vs Etokimab 20 mg Q4W
Statistical analysis description:	
P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline SCORAD as covariate.	
Comparison groups	Placebo v Etokimab 20 mg Q4W
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3262
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	6.57
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.5723
upper limit	19.7054
Variability estimate	Standard error of the mean
Dispersion value	6.677

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q8W
Statistical analysis description:	
P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline SCORAD as covariate.	
Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q8W
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8465
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.7439
upper limit	11.2782
Variability estimate	Standard error of the mean
Dispersion value	6.366

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q4W
Statistical analysis description: P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline SCORAD as covariate.	
Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6947
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	2.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.0587
upper limit	15.082
Variability estimate	Standard error of the mean
Dispersion value	6.396

Statistical analysis title	Placebo Vs Etokimab 600 mg load + 300 mg Q4W
Statistical analysis description: P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline SCORAD as covariate.	
Comparison groups	Placebo v Etokimab 600 mg load + 300 mg Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3288
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	6.76
Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.8451
upper limit	20.3626
Variability estimate	Standard error of the mean
Dispersion value	6.909

Secondary: Change from Baseline in Dermatology Life Quality Index (DLQI)

End point title	Change from Baseline in Dermatology Life Quality Index (DLQI)

End point description:

The DLQI is a 10-item, validated questionnaire used in clinical trials to assess the impact of AD disease symptoms and treatment on quality of life. The format is a simple response (0 to 3 where 0 is "not at all" and 3 is "very much") to 10 questions, which assess quality of life (QoL) over the past week, with an overall scoring system of 0 to 30; a high score is indicative of a poor QoL. The questionnaire was administered only to the subset of subjects who can read and understand a language in which questionnaire is presented (based on availability of validated translations in participating countries). The full analysis set included all randomized subjects who received 1 dose of etokimab or placebo and had baseline and post-baseline EASI scores.

End point type	Secondary

End point timeframe:

Baseline and Week 16

End point values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W	Etokimab 300 mg load + 150 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	61	59	60
Units: units on a scale				
least squares mean (standard error)	-5.61 (± 0.946)	-5.35 (± 0.966)	-6.52 (± 0.945)	-6.05 (± 0.945)

End point values	Etokimab 600 mg load + 300 mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: units on a scale				
least squares mean (standard error)	-5.18 (± 1.036)			

Statistical analyses

Statistical analysis title	Placebo Vs Etokimab 20 mg Q4W

Statistical analysis description:

P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline DLQI score as covariate.

Comparison groups	Placebo v Etokimab 20 mg Q4W
Number of subjects included in analysis	121
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8497
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	0.26

Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.4081
upper limit	2.9218
Variability estimate	Standard error of the mean
Dispersion value	1.355

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q8W
Statistical analysis description:	
P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline DLQI score as covariate.	
Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q8W
Number of subjects included in analysis	119
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5016
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.5636
upper limit	1.7473
Variability estimate	Standard error of the mean
Dispersion value	1.35

Statistical analysis title	Placebo Vs Etokimab 300 mg load + 150 mg Q4W
Statistical analysis description:	
P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline DLQI score as covariate.	
Comparison groups	Placebo v Etokimab 300 mg load + 150 mg Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7511
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	-0.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	-3.167
upper limit	2.287
Variability estimate	Standard error of the mean
Dispersion value	1.386

Statistical analysis title	Placebo Vs Etokimab 600 mg load + 300 mg Q4W
Statistical analysis description:	
P-value is obtained using mixed effect ANCOVA model with treatment as fixed effect and baseline DLQI score as covariate.	
Comparison groups	Placebo v Etokimab 600 mg load + 300 mg Q4W
Number of subjects included in analysis	120
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7558
Method	ANCOVA
Parameter estimate	LS mean difference
Point estimate	0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.3133
upper limit	3.1824
Variability estimate	Standard error of the mean
Dispersion value	1.396

Secondary: Number of Subjects who Experienced an Adverse Event (AE)

End point title	Number of Subjects who Experienced an Adverse Event (AE)

End point description:

An AE is any untoward medical occurrence in a subject or subject, temporally associated with the use of study treatment, whether or not considered related to the study treatment. A treatment-emergent adverse events (TEAEs) is any AE that started or worsened in severity on or after the date and time of the study drug administration. A serious adverse event (SAE) is as any untoward medical occurrence that, at any dose:
- Results in death;
- Is life-threatening;
- Requires inpatient hospitalization or prolongation of existing hospitalization;
- Results in persistent disability/incapacity;
- Is a congenital anomaly/birth defect.

The safety analysis set included all randomized subjects who received 1 dose of etokimab or placebo.

End point type	Secondary

End point timeframe:

Screening up to end of safety follow up period, approximately 24 weeks

End point values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W	Etokimab 300 mg load + 150 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	61	59	60
Units: subjects				
Any non-TEAEs	2	6	16	10
Any TEAEs	38	40	41	42

Any SAEs	1	2	3	3
Any TEAEs leading to discontinuation of study drug	4	9	4	4
Any TEAEs leading to withdrawal from the study	4	7	2	4
Any TEAEs resulting in death	0	0	0	0

End point values	Etokimab 600 mg load + 300 mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: subjects				
Any non-TEAEs	9			
Any TEAEs	43			
Any SAEs	3			
Any TEAEs leading to discontinuation of study drug	7			
Any TEAEs leading to withdrawal from the study	5			
Any TEAEs resulting in death	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Clinically Significant Changes in Vital Signs Measurements

End point title	Number of Subjects with Clinically Significant Changes in Vital Signs Measurements

End point description:

Body temperature, heart rate, blood pressure, respiratory rate, and weight were assessed. Blood pressure and pulse rate measurements were assessed in the seated position with a completely automated device. Manual techniques were used only if an automated device was not available. Blood pressure and pulse rate measurements were preceded by approximately 5 minutes of rest for the subject in a quiet setting without distractions (e.g., television, cell phones etc.).
The safety analysis set included all randomized subjects who received 1 dose of etokimab or placebo.

End point type	Secondary

End point timeframe:

Day 1 up to end of safety follow up period, approximately 24 weeks

End point values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W	Etokimab 300 mg load + 150 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	61	59	60
Units: subjects				
Blood pressure increased	0	0	1	0

Weight decreased	0	1	0	0
Hot flush	1	0	1	0
Hypertension	1	0	1	0
Palpitations	0	0	2	0
Sinus bradycardia	0	0	1	0
Angina pectoris	1	0	0	0

End point values	Etokimab 600 mg load + 300 mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: subjects				
Blood pressure increased	0			
Weight decreased	0			
Hot flush	1			
Hypertension	1			
Palpitations	0			
Sinus bradycardia	0			
Angina pectoris	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Clinically Significant Changes in Clinical Safety Laboratory Tests

End point title	Number of Subjects with Clinically Significant Changes in Clinical Safety Laboratory Tests

End point description:

Hematology, clinical chemistry, serum pregnancy, follicle-stimulating hormone, urine pregnancy, urinalysis, immunoglobulin, drugs of abuse, viral serology, and tuberculosis testing were performed. The Investigator reviewed the laboratory report and record any clinically significant abnormal laboratory findings occurring during the study were reported as an AE or SAE if applicable. Clinically significant abnormal laboratory findings are those that are not associated with the underlying disease, unless judged by the Investigator to be more severe than expected for the subject's condition.
The safety analysis set included all randomized subjects who received 1 dose of etokimab or placebo.

End point type	Secondary

End point timeframe:

Day 1 up to end of safety follow up period, approximately 24 weeks

End point values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W	Etokimab 300 mg load + 150 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	61	59	60
Units: subjects				
Alanine aminotransferase increased	1	0	1	2
Aspartate aminotransferase increased	0	0	1	2
Blood creatine phosphokinase increased	3	1	0	1
Blood lactate dehydrogenase increased	0	0	0	1
Blood uric acid increased	0	0	1	0
Gamma-glutamyltransferase increased	2	0	2	0
Troponin I increased	0	1	0	0
Blood glucose increased	0	0	1	0
Blood immunoglobulin E increased	0	1	0	0
Blood potassium increased	1	1	0	0
Urine ketone body present	0	0	0	0
White blood cell count increased	0	1	0	0
Blood triglycerides increased	1	0	0	0
Lymphopenia	1	1	1	0
White blood cell disorder	0	1	0	0
Hyperlipidaemia	0	0	0	0
Hyperuricaemia	0	0	0	0
Hyponatraemia	0	0	1	0

End point values	Etokimab 600 mg load + 300 mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: subjects				
Alanine aminotransferase increased	1			
Aspartate aminotransferase increased	1			
Blood creatine phosphokinase increased	1			
Blood lactate dehydrogenase increased	1			
Blood uric acid increased	1			
Gamma-glutamyltransferase increased	0			
Troponin I increased	1			
Blood glucose increased	0			
Blood immunoglobulin E increased	0			
Blood potassium increased	0			
Urine ketone body present	1			
White blood cell count increased	0			
Blood triglycerides increased	0			
Lymphopenia	0			
White blood cell disorder	0			
Hyperlipidaemia	1			
Hyperuricaemia	1			
Hyponatraemia	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Clinically Significant Changes in Electrocardiogram (ECG) Parameters

End point title	Number of Subjects with Clinically Significant Changes in Electrocardiogram (ECG) Parameters

End point description:

A single 12-lead ECG was obtained using a validated ECG machine that automatically calculates the heart rate and measures PR, QRS, QT, and QT corrected for heart rate using Fridericia's formula (QTcF) intervals. The ECG was reviewed by the Investigator or authorized representative and assessed for clinical significance.
The safety analysis set included all randomized subjects who received 1 dose of etokimab or placebo.

End point type	Secondary

End point timeframe:

Day 1 up to end of safety follow up period, approximately 24 weeks

End point values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W	Etokimab 300 mg load + 150 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	60	61	59	60
Units: subjects				
Electrocardiogram QT prolonged	0	0	0	0
Electrocardiogram ST segment elevation	0	0	0	1
Electrocardiogram abnormal	0	0	0	0

End point values	Etokimab 600 mg load + 300 mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: subjects				
Electrocardiogram QT prolonged	1			
Electrocardiogram ST segment elevation	0			
Electrocardiogram abnormal	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Subjects with Anti-drug Antibodies (ADA)

End point title	Number of Subjects with Anti-drug Antibodies (ADA)

End point description:

Overall status for subjects without positive baseline ADA or neutralizing ADA (NAb).
The safety analysis set included all randomized subjects who received 1 dose of etokimab or placebo.

End point type	Secondary

End point timeframe:

Baseline up to Week 24

End point values	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W	Etokimab 300 mg load + 150 mg Q4W
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[11]	61	59	60
Units: subjects				
ADA positive post-dose		18	24	29
NAb positive post-dose		0	0	2

Notes:

[11] - ADA results are not applicable for Placebo arm.

End point values	Etokimab 600 mg load + 300 mg Q4W			
Subject group type	Reporting group			
Number of subjects analysed	60			
Units: subjects				
ADA positive post-dose	20			
NAb positive post-dose	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Day 1 up to Week 16	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups	
Reporting group title	Placebo
Reporting group description:	
Matching placebo was administered SC Q4W for up to 16 weeks.	
Reporting group title	Etokimab 20 mg Q4W
Reporting group description:	
Etokimab 20 mg was administered SC Q4W for up to 16 weeks.	
Reporting group title	Etokimab 300 mg load + 150 mg Q8W
Reporting group description:	
Etokimab 150 mg was administered SC Q8W following an initial 300 mg loading dose for up to 16 weeks. At Weeks 4 and 12, the subjects received a placebo dose.	
Reporting group title	Etokimab 300 mg load + 150 mg Q4W
Reporting group description:	
Etokimab 150 mg was administered SC Q4W following an initial 300 mg loading dose for up to 16 weeks.	
Reporting group title	Etokimab 600 mg load + 300 mg Q4W
Reporting group description:	
Etokimab 300 mg was administered SC Q4W following an initial 600 mg loading dose for up to 16 weeks.	

Serious adverse events	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 60 (1.67%)	2 / 61 (3.28%)	3 / 59 (5.08%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Investigations			
Troponin I Increased			
subjects affected / exposed	0 / 60 (0.00%)	1 / 61 (1.64%)	0 / 59 (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
Surgical and medical procedures			
Hysterectomy			

subjects affected / exposed	1 / 60 (1.67%)	0 / 61 (0.00%)	0 / 59 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis Atopic			
subjects affected / exposed	0 / 60 (0.00%)	0 / 61 (0.00%)	2 / 59 (3.39%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis Exfoliative Generalised			
subjects affected / exposed	0 / 60 (0.00%)	0 / 61 (0.00%)	0 / 59 (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
Musculoskeletal and connective tissue disorders			
Joint Instability			
subjects affected / exposed	0 / 60 (0.00%)	0 / 61 (0.00%)	1 / 59 (1.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 60 (0.00%)	1 / 61 (1.64%)	0 / 59 (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
Eczema Herpeticum			
subjects affected / exposed	0 / 60 (0.00%)	0 / 61 (0.00%)	0 / 59 (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	Etokimab 300 mg load + 150 mg Q4W	Etokimab 600 mg load + 300 mg Q4W	
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 60 (5.00%)	3 / 60 (5.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Investigations			
Troponin I Increased			

subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Hysterectomy			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Dermatitis Atopic			
subjects affected / exposed	1 / 60 (1.67%)	3 / 60 (5.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dermatitis Exfoliative Generalised			
subjects affected / exposed	1 / 60 (1.67%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Joint Instability			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Cellulitis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eczema Herpeticum			
subjects affected / exposed	1 / 60 (1.67%)	0 / 60 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Placebo	Etokimab 20 mg Q4W	Etokimab 300 mg load + 150 mg Q8W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	24 / 60 (40.00%)	22 / 61 (36.07%)	23 / 59 (38.98%)
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	3 / 60 (5.00%)	1 / 61 (1.64%)	0 / 59 (0.00%)
occurrences (all)	3	2	0
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 60 (5.00%)	5 / 61 (8.20%)	3 / 59 (5.08%)
occurrences (all)	9	5	4
Dizziness			
subjects affected / exposed	0 / 60 (0.00%)	0 / 61 (0.00%)	1 / 59 (1.69%)
occurrences (all)	0	0	3
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	11 / 60 (18.33%)	12 / 61 (19.67%)	6 / 59 (10.17%)
occurrences (all)	20	15	12
Eczema			
subjects affected / exposed	0 / 60 (0.00%)	1 / 61 (1.64%)	2 / 59 (3.39%)
occurrences (all)	0	4	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	3 / 60 (5.00%)	0 / 61 (0.00%)	1 / 59 (1.69%)
occurrences (all)	3	0	1
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	4 / 60 (6.67%)	4 / 61 (6.56%)	5 / 59 (8.47%)
occurrences (all)	7	4	6
Upper respiratory tract infection			
subjects affected / exposed	3 / 60 (5.00%)	3 / 61 (4.92%)	1 / 59 (1.69%)
occurrences (all)	5	3	2
Oral herpes			
subjects affected / exposed	0 / 60 (0.00%)	0 / 61 (0.00%)	3 / 59 (5.08%)
occurrences (all)	0	0	4
Impetigo			

subjects affected / exposed	1 / 60 (1.67%)	0 / 61 (0.00%)	3 / 59 (5.08%)
occurrences (all)	1	0	3
Conjunctivitis			
subjects affected / exposed	3 / 60 (5.00%)	1 / 61 (1.64%)	1 / 59 (1.69%)
occurrences (all)	4	1	1

Non-serious adverse events	Etokimab 300 mg load + 150 mg Q4W	Etokimab 600 mg load + 300 mg Q4W	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	18 / 60 (30.00%)	26 / 60 (43.33%)	
Investigations			
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 60 (1.67%)	1 / 60 (1.67%)	
occurrences (all)	1	1	
Nervous system disorders			
Headache			
subjects affected / exposed	3 / 60 (5.00%)	1 / 60 (1.67%)	
occurrences (all)	5	2	
Dizziness			
subjects affected / exposed	0 / 60 (0.00%)	3 / 60 (5.00%)	
occurrences (all)	0	3	
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	8 / 60 (13.33%)	9 / 60 (15.00%)	
occurrences (all)	11	11	
Eczema			
subjects affected / exposed	3 / 60 (5.00%)	5 / 60 (8.33%)	
occurrences (all)	4	6	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 60 (3.33%)	1 / 60 (1.67%)	
occurrences (all)	2	1	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	5 / 60 (8.33%)	6 / 60 (10.00%)	
occurrences (all)	8	7	
Upper respiratory tract infection			

subjects affected / exposed	2 / 60 (3.33%)	3 / 60 (5.00%)	
occurrences (all)	4	5	
Oral herpes			
subjects affected / exposed	2 / 60 (3.33%)	1 / 60 (1.67%)	
occurrences (all)	2	1	
Impetigo			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis			
subjects affected / exposed	0 / 60 (0.00%)	0 / 60 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
23 October 2018	Updates included: - Resolution of key comments and requests from respective Regulatory Agencies/Health Authorities; - Procedures were clarified; - Alignment with the Common Protocol Template; - Minor grammatical, editorial, formatting, and administrative changes not affecting the conduct of the study have been incorporated into this amendment for clarification and administrative purposes only.
02 July 2019	Updates to the statistical approach to data analysis included: - Secondary endpoints were reorganized; - Some previously secondary endpoints were reclassified as exploratory; - Some previously exploratory endpoints were reclassified as secondary; - Timepoints were clarified for some endpoints; - An interim analysis was introduced for analysis of efficacy data at Week 16 and safety data collected as of the date of the data cut-off.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported