Clinical trial results:
A Phase II, randomized, double-blind, placebo-controlled repeated-dose study to evaluate the efficacy, safety, tolerability, and PK/PD of intravenously administered MOR106 in adult subjects with moderate to severe atopic dermatitis

Summary

EudraCT number	2017-001142-10
Trial protocol	DE GB HU PL SK
Global end of trial date	03 March 2020

Results information

Result version number	v1 (current)
This version publication date	23 December 2020
First version publication date	23 December 2020

Trial information

Trial identification

Sponsor protocol code	MOR106-CL-201

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03568071
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Galapagos NV
Sponsor organisation address	Generaal De Wittelaan L11 A3, Mechelen, Belgium, 2800
Public contact	Galapagos Medical Information, Galapagos NV, medicalinfo@glpg.com
Scientific contact	Galapagos Medical Information, Galapagos NV, medicalinfo@glpg.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 March 2020
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 March 2020
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The primary objective of the study was to assess the clinical efficacy of repeated intravenous (IV) doses of MOR106 as assessed by percentage change from baseline in Eczema Area and Severity Index (EASI) score at Day 85 visit in adult subjects with moderate to severe atopic dermatitis (AD).

Protection of trial subjects:

The study was performed in accordance with the ethical principles that have their origin in the "Declaration of Helsinki" and its amendments in force at the time of the study. It was also carried out in conformity with the protocol and International Council for Harmonisation Guideline for Good Clinical Practice (ICH-GCP) (EMA, 2002).

The investigator informed the participants of the risks and benefits of the study. The participants were informed that they could withdraw from the study at any time for any reason. Consent was obtained in writing prior to any study-related activities; the investigator retained the inform consent forms (ICFs), which were available to Galapagos for inspection. In the case of the optional substudies (skin biopsy, target lesion photography, and genetic research), participant were be informed that choosing not to participate, will not affect their participation in the main study.

The participant was given sufficient time to read the ICF and to ask additional questions. After this explanation and before entry in the clinical study, consent was appropriately recorded by means of the participant's personally dated signature and by the investigator's signature. After having obtained the consent, a copy of the signed and dated informed consent(s) was given to the participant.

The participants were covered by Galapagos insurance according to local legal requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 April 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	Germany: 17
Country: Number of subjects enrolled	Hungary: 35
Country: Number of subjects enrolled	Poland: 150
Country: Number of subjects enrolled	United Kingdom: 5
Worldwide total number of subjects	207
EEA total number of subjects	207

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)	205
From 65 to 84 years	2
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Subjects were enrolled at study sites in Poland, Hungary, Germany, and United Kingdom. The first subject was screened on 26 April 2018 and the last study visit happened on 03 March 2020.

Pre-assignment

Screening details:

A total of 270 subjects were screened of which 207 were randomized and enrolled in the study.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Placebo Q2W

Arm description:

Subjects received MOR106 matching placebo, IV infusions, every 2 weeks (Q2W) up to Week 12.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subject received Placebo Q2W up to Week 12.

Arm title	MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1

Arm description:

Subjects received MOR106 1 milligram per kilogram (mg/kg), IV infusions, every 4 weeks (Q4W) up to Week 12. A loading dose (LD) of 2 mg/kg was administered on Day 1.

Arm type	Experimental
Investigational medicinal product name	MOR106
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received MOR106 1 mg/kg IV infusions, Q4W up to Week 12.

Arm title	MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1

Arm description:

Subjects received MOR106 3 mg/kg IV infusions, Q4W up to Week 12. A LD of 6 mg/kg was administered on Day 1.

Arm type	Experimental

Investigational medicinal product name	MOR106
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received MOR106 3 mg/kg IV infusions, Q4W up to Week 12.

Arm title	MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1

Arm description:

Subjects received MOR106 1 mg/kg IV infusions, Q2W up to Week 12. A LD of 2 mg/kg was administered on Day 1.

Arm type	Experimental
Investigational medicinal product name	MOR106
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received MOR106 1 mg/kg IV infusions, Q2W up to Week 12.

Arm title	MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1

Arm description:

Subjects received MOR106 3 mg/kg IV infusions, Q2W up to Week 12. A LD of 6 mg/kg was administered on Day 1.

Arm type	Experimental
Investigational medicinal product name	MOR106
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received MOR106 3 mg/kg IV infusions, Q2W up to Week 12.

Arm title	MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1

Arm description:

Subjects received MOR106 10 mg/kg IV infusions, Q2W up to Week 12. A LD of 20 mg/kg was administered on Day 1.

Arm type	Experimental
Investigational medicinal product name	MOR106
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received MOR106 10 mg/kg IV infusions, Q2W up to Week 12.

Number of subjects in period 1	Placebo Q2W	MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1	MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Started	37	30	30
Completed	24	19	19
Not completed	13	11	11
Physician decision	1	-	1
Consent withdrawn by subject	9	5	4
Adverse event, non-fatal	1	3	5
Other	2	2	-
Lost to follow-up	-	1	-
Lack of efficacy	-	-	1

Number of subjects in period 1	MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1	MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1	MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Started	36	38	36
Completed	20	25	27
Not completed	16	13	9
Physician decision	-	1	-
Consent withdrawn by subject	9	9	6
Adverse event, non-fatal	4	2	1
Other	2	1	1
Lost to follow-up	1	-	-
Lack of efficacy	-	-	1

Baseline characteristics

Reporting groups	
Reporting group title	Placebo Q2W
Reporting group description:	
Subjects received MOR106 matching placebo, IV infusions, every 2 weeks (Q2W) up to Week 12.	
Reporting group title	MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1
Reporting group description:	
Subjects received MOR106 1 milligram per kilogram (mg/kg), IV infusions, every 4 weeks (Q4W) up to Week 12. A loading dose (LD) of 2 mg/kg was administered on Day 1.	
Reporting group title	MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Reporting group description:	
Subjects received MOR106 3 mg/kg IV infusions, Q4W up to Week 12. A LD of 6 mg/kg was administered on Day 1.	
Reporting group title	MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Reporting group description:	
Subjects received MOR106 1 mg/kg IV infusions, Q2W up to Week 12. A LD of 2 mg/kg was administered on Day 1.	
Reporting group title	MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1
Reporting group description:	
Subjects received MOR106 3 mg/kg IV infusions, Q2W up to Week 12. A LD of 6 mg/kg was administered on Day 1.	
Reporting group title	MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Reporting group description:	
Subjects received MOR106 10 mg/kg IV infusions, Q2W up to Week 12. A LD of 20 mg/kg was administered on Day 1.	

Reporting group values	Placebo Q2W	MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1	MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Number of subjects	37	30	30
Age categorical Units: Subjects			
>=18 to <25	5	6	8
>=25 to <40	18	13	14
>=40 to <65	13	11	8
>=65	1	0	0
Age continuous Units: years			
arithmetic mean	38.1	35.6	33.7
standard deviation	± 12.67	± 12.49	± 12.24
Gender categorical Units: Subjects			
Female	18	17	17
Male	19	13	13
Race Units: Subjects			
Asian	0	1	0
White	37	29	30
Ethnicity Units: Subjects			

Non Hispanic or Latino	37	30	30

Eczema Area and Severity Index (EASI) Units: scores on scale			
arithmetic mean	29.201	28.482	27.372
standard deviation	± 13.5282	± 11.1545	± 8.9842
Scoring Atopic Dermatitis (SCORAD) Score Units: scores on scale			
arithmetic mean	67.662	67.087	60.800
standard deviation	± 14.1537	± 13.5887	± 9.9124

Reporting group values	MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1	MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1	MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Number of subjects	36	38	36
Age categorical Units: Subjects			
>=18 to <25	12	7	8
>=25 to <40	11	21	18
>=40 to <65	13	9	10
>=65	0	1	0
Age continuous Units: years			
arithmetic mean	35.1	35.0	33.8
standard deviation	± 15.41	± 12.58	± 11.31
Gender categorical Units: Subjects			
Female	20	19	10
Male	16	19	26
Race Units: Subjects			
Asian	0	0	0
White	36	38	36
Ethnicity Units: Subjects			
Non Hispanic or Latino	36	38	36
Eczema Area and Severity Index (EASI) Units: scores on scale			
arithmetic mean	28.956	28.962	34.264
standard deviation	± 10.7465	± 11.5183	± 15.4456
Scoring Atopic Dermatitis (SCORAD) Score Units: scores on scale			
arithmetic mean	66.248	63.907	68.624
standard deviation	± 11.0225	± 12.3086	± 13.5505

Reporting group values	Total		
Number of subjects	207		

Age categorical Units: Subjects			
>=18 to <25	46		
>=25 to <40	95		
>=40 to <65	64		
>=65	2		
Age continuous Units: years arithmetic mean standard deviation	 -		
Gender categorical Units: Subjects			
Female	101		
Male	106		
Race Units: Subjects			
Asian	1		
White	206		
Ethnicity Units: Subjects			
Non Hispanic or Latino	207		
Eczema Area and Severity Index (EASI) Units: scores on scale arithmetic mean standard deviation	 -		
Scoring Atopic Dermatitis (SCORAD) Score Units: scores on scale arithmetic mean standard deviation	 -		

End points

End points reporting groups

Reporting group title	Placebo Q2W
Reporting group description:	
Subjects received MOR106 matching placebo, IV infusions, every 2 weeks (Q2W) up to Week 12.	
Reporting group title	MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1
Reporting group description:	
Subjects received MOR106 1 milligram per kilogram (mg/kg), IV infusions, every 4 weeks (Q4W) up to Week 12. A loading dose (LD) of 2 mg/kg was administered on Day 1.	
Reporting group title	MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Reporting group description:	
Subjects received MOR106 3 mg/kg IV infusions, Q4W up to Week 12. A LD of 6 mg/kg was administered on Day 1.	
Reporting group title	MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Reporting group description:	
Subjects received MOR106 1 mg/kg IV infusions, Q2W up to Week 12. A LD of 2 mg/kg was administered on Day 1.	
Reporting group title	MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1
Reporting group description:	
Subjects received MOR106 3 mg/kg IV infusions, Q2W up to Week 12. A LD of 6 mg/kg was administered on Day 1.	
Reporting group title	MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Reporting group description:	
Subjects received MOR106 10 mg/kg IV infusions, Q2W up to Week 12. A LD of 20 mg/kg was administered on Day 1.	

Primary: Percent Change From Baseline in EASI score At Day 85

End point title	Percent Change From Baseline in EASI score At Day 85

End point description:

The EASI is used to assess the severity and extent of AD. Four AD disease characteristics (erythema, induration/papulation, excoriation, and lichenification) is assessed for severity on a scale of 0 (absent) to 3 (severe). The area of AD involvement is assessed as a percentage by body area of head, trunk, arms, and legs, and converted to a score of 0 (0 percent [%]) to 6 (90-100%). The total EASI score for each region is calculated by multiplying the severity score by the area score. The EASI score ranges are between 0 and 72, where higher scores represent worse outcome. The EASI is assessed by the investigator or adequately qualified and trained designee at all timepoints. The full analysis set (FAS) included all randomized subjects who received/used at least 1 dose of investigational medicinal product (IMP), and had at least 1 post baseline efficacy assessment. FAS population with subjects available at specified time point.

End point type	Primary

End point timeframe:

Baseline and Day 85

End point values	Placebo Q2W	MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1	MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1	MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	20	25	22	25
Units: percent change				
least squares mean (standard error)	-22.09 (± 9.447)	-36.24 (± 9.065)	-32.60 (± 9.494)	-42.97 (± 8.942)

End point values	MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1	MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	24	26		
Units: percent change				
least squares mean (standard error)	-40.18 (± 9.130)	-37.00 (± 8.902)		

Statistical analyses

Statistical analysis title	Day 85: MOR106 1 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a mixed effect model repeat measurement (MMRM) approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2488
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-14.15
Confidence interval	
level	95 %
sides	2-sided
lower limit	-38.29
upper limit	10
Variability estimate	Standard error of the mean
Dispersion value	12.22

Statistical analysis title	Day 85: MOR106 3 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and

country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Number of subjects included in analysis	42
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4021
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-10.51
Confidence interval	
level	95 %
sides	2-sided
lower limit	-35.23
upper limit	14.2
Variability estimate	Standard error of the mean
Dispersion value	12.511

Statistical analysis title	Day 85: MOR106 1 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Number of subjects included in analysis	45
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0842
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-20.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	-44.62
upper limit	2.85
Variability estimate	Standard error of the mean
Dispersion value	12.014

Statistical analysis title	Day 85: MOR106 3 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1

Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1396
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-18.09
Confidence interval	
level	95 %
sides	2-sided
lower limit	-42.14
upper limit	5.97
Variability estimate	Standard error of the mean
Dispersion value	12.179

Statistical analysis title	Day 85: MOR106 10 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Number of subjects included in analysis	46
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2179
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-14.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	-38.71
upper limit	8.89
Variability estimate	Standard error of the mean
Dispersion value	12.05

Secondary: Percentage of Subjects who Achieved >=50% Overall improvement in EASI Score From Baseline

End point title	Percentage of Subjects who Achieved >=50% Overall improvement in EASI Score From Baseline

End point description:

Percentage of participants who achieved at least a 50% improvement in EASI score were reported. The EASI is used to assess the severity and extent of AD. Four AD disease characteristics (erythema, induration/papulation, excoriation, and lichenification) is assessed for severity on a scale of 0 (absent) to 3 (severe). The area of AD involvement is assessed as a percentage by body area of head, trunk, arms, and legs, and converted to a score of 0 (0%) to 6 (90-100%). The total EASI score for each region is calculated by multiplying the severity score by the area score. The EASI score ranges are between 0 and 72, where higher scores represent worse outcome. The EASI is assessed by the investigator or adequately qualified and trained designee at all timepoints. FAS population with subjects

available at specified time point.

End point type	Secondary

End point timeframe:

Baseline, Day 15, Day 29, Day 43, Day 57, Day 71, and Day 85

End point values	Placebo Q2W	MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1	MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1	MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	30	30	36
Units: percentage of subjects				
number (not applicable)				
Day 15 (n= 35, 30, 30, 36, 35, 35)	11.4	13.3	3.3	8.3
Day 29 (n= 33, 28, 28, 33, 33, 35)	18.2	17.9	25.0	30.3
Day 43 (n= 27, 28, 26, 31, 31, 28)	14.8	32.1	34.6	29.0
Day 57 (n= 25, 27, 24, 29, 27, 27)	28.0	40.7	41.7	34.5
Day 71 (n= 23, 26, 23, 27, 24, 25)	34.8	50.0	65.2	55.6
Day 85 (n= 20, 25, 22, 25, 24, 26)	40.0	48.0	63.6	64.0

End point values	MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1	MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	35		
Units: percentage of subjects				
number (not applicable)				
Day 15 (n= 35, 30, 30, 36, 35, 35)	8.6	14.3		
Day 29 (n= 33, 28, 28, 33, 33, 35)	24.2	34.3		
Day 43 (n= 27, 28, 26, 31, 31, 28)	41.9	32.1		
Day 57 (n= 25, 27, 24, 29, 27, 27)	59.3	63		
Day 71 (n= 23, 26, 23, 27, 24, 25)	62.5	56		
Day 85 (n= 20, 25, 22, 25, 24, 26)	66.7	61.5		

Statistical analyses

Statistical analysis title	Day 15: MOR106 1 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a generalized estimating equations (GEE) model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1

Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7669
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	1.25
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.28
upper limit	5.53

Statistical analysis title	Day 15: MOR106 3 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.27
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	0.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.03
upper limit	2.68

Statistical analysis title	Day 15: MOR106 1 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6946
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	0.73

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.15
upper limit	3.53

Statistical analysis title	Day 15: MOR106 3 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7149
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	0.75
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.16
upper limit	3.55

Statistical analysis title	Day 15: MOR106 10 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6402
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	1.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.34
upper limit	5.75

Statistical analysis title	Day 29: MOR106 1 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9308
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	0.94
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.25
upper limit	3.51

Statistical analysis title	Day 29: MOR106 3 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5636
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	1.44
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	4.99

Statistical analysis title	Day 29: MOR106 1 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit

link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2882
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	1.88
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	6.06

Statistical analysis title	Day 29: MOR106 3 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1 v Placebo Q2W
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5885
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	1.39
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.42
upper limit	4.62

Statistical analysis title	Day 29: MOR106 10 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1125
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	2.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.8
upper limit	7.89

Statistical analysis title	Day 43: MOR106 1 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1643
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	2.52
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	9.31

Statistical analysis title	Day 43: MOR106 3 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1385
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	2.7

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	10.05

Statistical analysis title	Day 43: MOR106 1 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2456
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	2.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.59
upper limit	7.68

Statistical analysis title	Day 43: MOR106 3 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0442
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	3.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.03
upper limit	12.57

Statistical analysis title	Day 43: MOR106 10 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1623
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	2.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	8.58

Statistical analysis title	Day 57: MOR106 1 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2401
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	1.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	6.1

Statistical analysis title	Day 57: MOR106 3 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit

link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.316
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	1.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.57
upper limit	5.76

Statistical analysis title	Day 57: MOR106 1 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5219
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	1.46
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.46
upper limit	4.65

Statistical analysis title	Day 57: MOR106 3 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0482
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	3.12
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.01
upper limit	9.63

Statistical analysis title	Day 57: MOR106 10 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0232
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	3.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	1.19
upper limit	11.27

Statistical analysis title	Day 71: MOR106 1 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2087
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	2.02

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.68
upper limit	6.03

Statistical analysis title	Day 71: MOR106 3 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0726
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	2.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.91
upper limit	8.15

Statistical analysis title	Day 71: MOR106 1 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1735
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	2.1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	6.11

Statistical analysis title	Day 71: MOR106 3 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.137
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	2.28
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.77
upper limit	6.79

Statistical analysis title	Day 71: MOR106 10 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1921
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	2.05
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	6.01

Statistical analysis title	Day 85: MOR106 1 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit

link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4846
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	1.5
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.48
upper limit	4.74

Statistical analysis title	Day 85: MOR106 3 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2074
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	2.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.66
upper limit	6.71

Statistical analysis title	Day 85: MOR106 1 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1

Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1725
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	2.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	6.34

Statistical analysis title	Day 85: MOR106 3 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1671
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	2.3
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	7.51

Statistical analysis title	Day 85: MOR106 10 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a GEE model for binary data using SAS GENMOD procedure with a logit link, binomial distribution and independent within-subject correlation matrix with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline EASI score and country as covariates and treatment-visit as interaction terms. The model was implemented with multiple imputation for missing data in all participants of the FAS.

Comparison groups	Placebo Q2W v MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1622
Method	GEE model
Parameter estimate	Odds ratio (OR)
Point estimate	2.23

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.72
upper limit	6.9

Secondary: Percentage of Subjects who Achieved an Investigators' Global Assessment (IGA) score of 0 or 1

End point title	Percentage of Subjects who Achieved an Investigators' Global Assessment (IGA) score of 0 or 1

End point description:

The IGA is used to assess the severity of AD and clinical response to treatment based on a 5-point scale ranging from 0 to 4, where 0: clear (no inflammatory signs of AD), 1: almost clear (just perceptible erythema and just perceptible papulation/infiltration), 2: mild (mild erythema and mild papulation/infiltration), 3: moderate (moderate erythema and moderate papulation/infiltration), and 4: severe (severe erythema and severe papulation/infiltration with or without oozing/crusting). The EASI is assessed by the investigator or adequately qualified and trained designee at all timepoints. The percentage of subjects with a score of 0 or 1 is reported. FAS population with subjects available at specified timepoint.

End point type	Secondary

End point timeframe:

Day 15, Day 29, Day 43, Day 57, Day 71, and Day 85

End point values	Placebo Q2W	MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1	MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1	MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	30	30	36
Units: percentage of subjects				
number (not applicable)				
Day 15 (n= 35, 30, 30, 36, 35, 35)	2.9	0	0	0
Day 29 (n= 33, 28, 28, 33, 33, 35)	3.0	0	0	0
Day 43 (n= 27, 28, 26, 31, 31, 28)	0	0	3.8	0
Day 57 (n= 25, 27, 24, 29, 27, 27)	4.4	0	12.5	6.9
Day 71 (n= 23, 26, 23, 27, 24, 25)	4.3	7.7	13	11.1
Day 85 (n= 20, 25, 22, 25, 24, 26)	20.0	20.0	31.8	12.0

End point values	MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1	MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	35		
Units: percentage of subjects				
number (not applicable)				

Day 15 (n= 35, 30, 30, 36, 35, 35)	0	0		
Day 29 (n= 33, 28, 28, 33, 33, 35)	0	2.9		
Day 43 (n= 27, 28, 26, 31, 31, 28)	0	14.3		
Day 57 (n= 25, 27, 24, 29, 27, 27)	0	14.8		
Day 71 (n= 23, 26, 23, 27, 24, 25)	8.3	16.0		
Day 85 (n= 20, 25, 22, 25, 24, 26)	11.5	11.5		

Statistical analyses

No statistical analyses for this end point

Secondary: Percent Change From Baseline in SCORAD Score

End point title	Percent Change From Baseline in SCORAD Score

End point description:

The SCORAD is used to evaluate extent and severity of AD. Extent of AD is assessed as percentage of each defined body area and reported as sum of all areas, with maximum score of 100% (A in overall SCORAD calculation). The severity of 6 specific symptoms of AD is assessed using following scale: none (0), mild (1), moderate (2), or severe (3) (for a maximum of 18 total points, B in overall SCORAD calculation). Subjective assessment of itch and sleeplessness is recorded for each symptom by the subject/relative on a visual analogue scale, where 0 is no itch (or sleeplessness) and 10 is worst imaginable itch (or sleeplessness), with a maximum possible score of 20 (C in overall SCORAD calculation). The SCORAD is calculated as: A/5 + 7B/2 + C and ranges between 0 and 103, where higher scores represent worse outcome. The SCORAD is assessed by the investigator or adequately qualified and trained designee at all timepoints. FAS population with subjects available at specified timepoints.

End point type	Secondary

End point timeframe:

Baseline, Day 15, Day 29, Day 43, Day 57, Day 71, and Day 85

End point values	Placebo Q2W	MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1	MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1	MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	35	30	30	36
Units: percent change				
least squares mean (standard error)				
Day 15 (n= 35, 30, 30, 36, 35, 35)	-2.13 (± 3.811)	-9.93 (± 4.019)	-3.36 (± 3.984)	-5.47 (± 3.930)
Day 29 (n= 33, 28, 28, 33, 33, 35)	-8.70 (± 4.450)	-8.40 (± 4.679)	-11.67 (± 4.706)	-13.08 (± 4.541)
Day 43 (n= 27, 28, 26, 31, 31, 28)	-10.01 (± 5.130)	-14.01 (± 5.156)	-11.88 (± 5.293)	-16.48 (± 5.036)
Day 57 (n= 25, 27, 24, 29, 27, 27)	-16.0 (± 5.686)	-25.22 (± 5.596)	-16.62 (± 5.828)	-19.79 (± 5.488)
Day 71 (n= 23, 26, 23, 27, 24, 25)	-18.55 (± 6.291)	-30.50 (± 6.112)	-24.51 (± 6.397)	-26.69 (± 6.002)
Day 85 (n= 20, 25, 22, 25, 24, 26)	-23.49 (± 6.658)	-31.90 (± 6.372)	-29.18 (± 6.669)	-32.94 (± 6.286)

End point values	MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1	MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	35	35		
Units: percent change				
least squares mean (standard error)				
Day 15 (n= 35, 30, 30, 36, 35, 35)	-2.24 (± 3.949)	-8.41 (± 3.825)		
Day 29 (n= 33, 28, 28, 33, 33, 35)	-11.39 (± 4.533)	-17.99 (± 4.362)		
Day 43 (n= 27, 28, 26, 31, 31, 28)	-19.97 (± 5.012)	-19.64 (± 5.015)		
Day 57 (n= 25, 27, 24, 29, 27, 27)	-29.81 (± 5.544)	-30.22 (± 5.504)		
Day 71 (n= 23, 26, 23, 27, 24, 25)	-26.22 (± 6.148)	-30.99 (± 6.054)		
Day 85 (n= 20, 25, 22, 25, 24, 26)	-33.54 (± 6.410)	-28.97 (± 6.235)		

Statistical analyses

Statistical analysis title	Day 15: MOR106 1 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0874
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-7.81
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.77
upper limit	1.16
Variability estimate	Standard error of the mean
Dispersion value	4.544

Statistical analysis title	Day 15: MOR106 3 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7885
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-1.23
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.29
upper limit	7.82
Variability estimate	Standard error of the mean
Dispersion value	4.591

Statistical analysis title	Day 15: MOR106 1 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4422
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-3.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.91
upper limit	5.22
Variability estimate	Standard error of the mean
Dispersion value	4.342

Statistical analysis title	Day 15: MOR106 3 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9793
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-0.11
Confidence interval	
level	95 %
sides	2-sided
lower limit	-8.75
upper limit	8.53
Variability estimate	Standard error of the mean
Dispersion value	4.381

Statistical analysis title	Day 15: MOR106 10 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1514
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-6.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.9
upper limit	2.32
Variability estimate	Standard error of the mean
Dispersion value	4.365

Statistical analysis title	Day 29: MOR106 1 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1

Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9583
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	0.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-10.75
upper limit	11.34
Variability estimate	Standard error of the mean
Dispersion value	5.598

Statistical analysis title	Day 29: MOR106 3 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5996
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-2.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.13
upper limit	8.18
Variability estimate	Standard error of the mean
Dispersion value	5.655

Statistical analysis title	Day 29: MOR106 1 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1

Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4157
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-4.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.98
upper limit	6.22
Variability estimate	Standard error of the mean
Dispersion value	0.4157

Statistical analysis title	Day 29: MOR106 3 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6185
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-2.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-13.32
upper limit	7.95
Variability estimate	Standard error of the mean
Dispersion value	5.391

Statistical analysis title	Day 29: MOR106 10 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0829
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-9.29
Confidence interval	
level	95 %
sides	2-sided
lower limit	-19.8
upper limit	1.22
Variability estimate	Standard error of the mean
Dispersion value	5.328

Statistical analysis title	Day 43: MOR106 1 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5383
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-4.01
Confidence interval	
level	95 %
sides	2-sided
lower limit	-16.83
upper limit	8.82
Variability estimate	Standard error of the mean
Dispersion value	6.496

Statistical analysis title	Day 43: MOR106 3 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1

Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7779
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-1.87
Confidence interval	
level	95 %
sides	2-sided
lower limit	-14.95
upper limit	11.21
Variability estimate	Standard error of the mean
Dispersion value	6.626

Statistical analysis title	Day 43: MOR106 1 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3057
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-6.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-18.92
upper limit	5.97
Variability estimate	Standard error of the mean
Dispersion value	6.305

Statistical analysis title	Day 43: MOR106 3 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1165
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-9.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.42
upper limit	2.5
Variability estimate	Standard error of the mean
Dispersion value	6.313

Statistical analysis title	Day 43: MOR106 10 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1312
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-9.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.18
upper limit	2.9
Variability estimate	Standard error of the mean
Dispersion value	6.354

Statistical analysis title	Day 57: MOR106 1 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1

Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2069
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-9.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.54
upper limit	5.14
Variability estimate	Standard error of the mean
Dispersion value	7.258

Statistical analysis title	Day 57: MOR106 3 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9359
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-15.32
upper limit	14.12
Variability estimate	Standard error of the mean
Dispersion value	7.455

Statistical analysis title	Day 57: MOR106 1 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1

Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5959
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-3.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	-17.77
upper limit	10.24
Variability estimate	Standard error of the mean
Dispersion value	7.09

Statistical analysis title	Day 57: MOR106 3 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0561
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-13.79
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.93
upper limit	0.36
Variability estimate	Standard error of the mean
Dispersion value	7.165

Statistical analysis title	Day 57: MOR106 10 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0488
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-14.2
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.32
upper limit	-0.08
Variability estimate	Standard error of the mean
Dispersion value	7.152

Statistical analysis title	Day 71: MOR106 1 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1428
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-11.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.98
upper limit	4.08
Variability estimate	Standard error of the mean
Dispersion value	8.113

Statistical analysis title	Day 71: MOR106 3 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1

Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4757
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-5.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.44
upper limit	10.51
Variability estimate	Standard error of the mean
Dispersion value	8.341

Statistical analysis title	Day 71: MOR106 1 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3076
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-8.14
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.85
upper limit	7.57
Variability estimate	Standard error of the mean
Dispersion value	7.954

Statistical analysis title	Day 71: MOR106 3 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3442
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-7.68
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.66
upper limit	8.31
Variability estimate	Standard error of the mean
Dispersion value	8.093

Statistical analysis title	Day 71: MOR106 10 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1233
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-12.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-28.32
upper limit	3.42
Variability estimate	Standard error of the mean
Dispersion value	8.033

Statistical analysis title	Day 85: MOR106 1 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1

Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3304
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-8.4
Confidence interval	
level	95 %
sides	2-sided
lower limit	-25.41
upper limit	8.6
Variability estimate	Standard error of the mean
Dispersion value	8.607

Statistical analysis title	Day 85: MOR106 3 mg/kg Q4W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Number of subjects included in analysis	65
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.521
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-5.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	-23.16
upper limit	11.78
Variability estimate	Standard error of the mean
Dispersion value	8.845

Statistical analysis title	Day 85: MOR106 1 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1

Number of subjects included in analysis	71
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2665
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-9.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	-26.18
upper limit	7.29
Variability estimate	Standard error of the mean
Dispersion value	8.472

Statistical analysis title	Day 85: MOR106 3 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1
Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2441
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-10.04
Confidence interval	
level	95 %
sides	2-sided
lower limit	-27.01
upper limit	6.92
Variability estimate	Standard error of the mean
Dispersion value	8.588

Statistical analysis title	Day 85: MOR106 10 mg/kg Q2W vs Placebo Q2W

Statistical analysis description:

The analysis is performed with a MMRM approach using SAS mixed procedure, with treatment and visit up to Day 85 (defined by the time windows) as categorical fixed effects, baseline SCORAD score and country as covariates, treatment-visit as interaction terms and unstructured within-subject correlation matrix.

Comparison groups	Placebo Q2W v MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1

Number of subjects included in analysis	70
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5195
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-5.48
Confidence interval	
level	95 %
sides	2-sided
lower limit	-22.23
upper limit	11.28
Variability estimate	Standard error of the mean
Dispersion value	8.482

Secondary: Number of Subjects With Treatment-Emergent Adverse Events (TEAEs), Adverse Event of Special Interest (AESIs), Serious Adverse Events (SAEs), and Discontinuations Due to Adverse Events (AEs)

End point title	Number of Subjects With Treatment-Emergent Adverse Events (TEAEs), Adverse Event of Special Interest (AESIs), Serious Adverse Events (SAEs), and Discontinuations Due to Adverse Events (AEs)

End point description:

Adverse events of special interest (AESIs) were defined as skin-related events (SRE) (except exacerbation and infective exacerbation of AD) or infusion-related reactions (IRR) (common terminology criteria for adverse events [CTCAE] Grade 2 to 5). The safety analysis population included all randomized subjects who received/used at least 1 dose of IMP or placebo.

End point type	Secondary

End point timeframe:

Baseline up to Day 197/early discontinuation (ED)

End point values	Placebo Q2W	MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1	MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1	MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	30	30	36
Units: subjects				
TEAE	26	27	22	22
IRR	0	1	0	1
SRE	1	4	3	1
SAE	2	5	3	4
Discontinuation due to AEs	3	4	6	5

End point values	MOR106 3	MOR106 10		

	mg/kg Q2W + 6 mg/kg LD Day 1	mg/kg Q2W + 20 mg/kg LD Day 1		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	36		
Units: subjects				
TEAE	29	26		
IRR	0	1		
SRE	7	8		
SAE	1	2		
Discontinuation due to AEs	2	2		

Statistical analyses

No statistical analyses for this end point

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

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

End point description:

Subjects with ADAs were reported. Safety Population.

End point type	Secondary

End point timeframe:

Baseline up to Day 197/early discontinuation (ED)

End point values	Placebo Q2W	MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1	MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1	MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	37	30	30	36
Units: subjects	0	0	0	0

End point values	MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1	MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	38	36		
Units: subjects	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: Area Under the Concentration-time Curve From Zero to Infinity (AUC0-inf) for MOR106

End point title	Area Under the Concentration-time Curve From Zero to Infinity (AUC0-inf) for MOR106[1]

End point description:

The pharmacokinetic (PK) analysis population was a subset of safety analysis set and included all subjects who had available and evaluable serum concentration data.

End point type	Secondary

End point timeframe:

Day 1 to 197: Pre-infusion and 1 hour post-infusion

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: This endpoint was assessed only for the reporting groups in which participants received MOR106.

End point values	MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1	MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1	MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1	MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[2]	0[3]	0[4]	0[5]
Units: nanogram*hour per milliliter (ng*hr/mL)				
arithmetic mean (standard deviation)	()	()	()	()

Notes:

[2] - Study treatment was discontinued prematurely, hence derivation of PK parameters was not performed.
[3] - Study treatment was discontinued prematurely, hence derivation of PK parameters was not performed.
[4] - Study treatment was discontinued prematurely, hence derivation of PK parameters was not performed.
[5] - Study treatment was discontinued prematurely, hence derivation of PK parameters was not performed.

End point values	MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1			
Subject group type	Reporting group			
Number of subjects analysed	0[6]			
Units: nanogram*hour per milliliter (ng*hr/mL)				
arithmetic mean (standard deviation)	()			

Notes:

[6] - Study treatment was discontinued prematurely, hence derivation of PK parameters was not performed.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events: Day 1 up to Day 197/ED	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.1

Reporting groups	
Reporting group title	MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1
Reporting group description: Subjects received MOR106 1 mg/kg IV infusions, Q2W up to Week 12. A LD of 2 mg/kg was administered on Day 1.	
Reporting group title	MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1
Reporting group description: Subjects received MOR106 1 mg/kg, IV infusions, Q4W up to Week 12. A LD of 2 mg/kg was administered on Day 1.	
Reporting group title	MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Reporting group description: Subjects received MOR106 10 mg/kg IV infusions, Q2W up to Week 12. A LD of 20 mg/kg was administered on Day 1.	
Reporting group title	MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1
Reporting group description: Subjects received MOR106 3 mg/kg IV infusions, Q2W up to Week 12. A LD of 6 mg/kg was administered on Day 1.	
Reporting group title	MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1
Reporting group description: Subjects received MOR106 3 mg/kg IV infusions, Q4W up to Week 12. A LD of 6 mg/kg was administered on Day 1.	
Reporting group title	Placebo Q2W
Reporting group description: Subjects received MOR106 matching placebo, IV infusions, Q2W up to Week 12.	

Serious adverse events	MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1	MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1	MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 36 (11.11%)	5 / 30 (16.67%)	2 / 36 (5.56%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	1 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (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
Respiratory, thoracic and mediastinal disorders			
Tonsillar hypertrophy			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (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			
Dermatitis atopic			
subjects affected / exposed	2 / 36 (5.56%)	2 / 30 (6.67%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	1 / 2	1 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis exfoliative generalised			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (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
Musculoskeletal and connective tissue disorders			
Connective tissue inflammation			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (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
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (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 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (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	MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1	MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1	Placebo Q2W
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 38 (2.63%)	3 / 30 (10.00%)	2 / 37 (5.41%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Tonsillar hypertrophy			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Dermatitis atopic			
subjects affected / exposed	1 / 38 (2.63%)	2 / 30 (6.67%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	1 / 1	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dermatitis exfoliative generalised			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Connective tissue inflammation			

subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Appendicitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eczema herpeticum			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	0 / 37 (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

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

Non-serious adverse events	MOR106 1 mg/kg Q2W + 2 mg/kg LD Day 1	MOR106 1 mg/kg Q4W + 2 mg/kg LD Day 1	MOR106 10 mg/kg Q2W + 20 mg/kg LD Day 1
Total subjects affected by non-serious adverse events			
subjects affected / exposed	23 / 36 (63.89%)	26 / 30 (86.67%)	28 / 36 (77.78%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Seborrhoeic keratosis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Skin papilloma			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Hypertension			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Thrombophlebitis			

subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Varicose vein			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Fatigue			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Induration			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Influenza like illness			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Localised oedema			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	2 / 36 (5.56%)	1 / 30 (3.33%)	2 / 36 (5.56%)
occurrences (all)	2	2	2
Pain			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Soft tissue inflammation			

subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Cough			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Nasal congestion			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Nasal polyps			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Nasal septum deviation			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal pain			
subjects affected / exposed	1 / 36 (2.78%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Rhinitis allergic			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Rhinorrhoea			
subjects affected / exposed	1 / 36 (2.78%)	1 / 30 (3.33%)	1 / 36 (2.78%)
occurrences (all)	1	1	2
Sinus pain			

subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Sneezing			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Tonsillar inflammation			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Psychiatric disorders			
Depressed mood			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Generalised anxiety disorder			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Insomnia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Blood bilirubin increased			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Blood creatinine increased			
subjects affected / exposed	2 / 36 (5.56%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	2	0	0
Blood immunoglobulin E increased			

subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Blood phosphorus increased			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Blood potassium increased			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Blood pressure increased			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Blood triglycerides increased			
subjects affected / exposed	1 / 36 (2.78%)	1 / 30 (3.33%)	1 / 36 (2.78%)
occurrences (all)	1	2	2
Blood uric acid increased			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Body temperature increased			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
C-reactive protein abnormal			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	3
Electrocardiogram ST segment depression			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram ST-T segment depression			

subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Eosinophil count increased			
subjects affected / exposed	1 / 36 (2.78%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	2	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 36 (0.00%)	2 / 30 (6.67%)	0 / 36 (0.00%)
occurrences (all)	0	3	0
Heart rate increased			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Lymphocyte count decreased			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	1 / 36 (2.78%)
occurrences (all)	0	3	1
N-terminal prohormone brain natriuretic peptide increased			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Platelet count increased			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Protein urine			
subjects affected / exposed	2 / 36 (5.56%)	1 / 30 (3.33%)	1 / 36 (2.78%)
occurrences (all)	3	1	2
Red blood cells urine			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	2
Red blood cells urine positive			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
White blood cell count decreased			

subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
White blood cell count increased			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
White blood cells urine positive			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Fibula fracture			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Joint dislocation			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Ligament sprain			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Nail injury			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Procedural nausea			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Procedural pain			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Road traffic accident			

subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Traumatic haematoma			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Arrhythmia supraventricular			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Bradycardia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Conduction disorder			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Sinus bradycardia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Headache			
subjects affected / exposed	1 / 36 (2.78%)	4 / 30 (13.33%)	2 / 36 (5.56%)
occurrences (all)	2	5	2
Paraesthesia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Syncope			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Eosinophilia			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Iron deficiency anaemia			

subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Leukopenia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Lymphadenopathy			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Lymphopenia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Neutropenia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Ear discomfort			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
External ear inflammation			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Swelling of eyelid			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 36 (2.78%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Abdominal pain upper			

subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	2	0	0
Cheilosis			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	1 / 36 (2.78%)	1 / 30 (3.33%)	1 / 36 (2.78%)
occurrences (all)	2	1	1
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Inguinal hernia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Irritable bowel syndrome			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Noninfective gingivitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Toothache			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Vomiting			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Hepatobiliary disorders			
Gallbladder polyp			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Acne			

subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	2 / 36 (5.56%)
occurrences (all)	0	1	2
Alopecia			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Dermatitis			
subjects affected / exposed	1 / 36 (2.78%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Dermatitis allergic			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Dermatitis atopic			
subjects affected / exposed	9 / 36 (25.00%)	10 / 30 (33.33%)	17 / 36 (47.22%)
occurrences (all)	15	17	19
Dermatitis contact			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Ecchymosis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Eczema			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Hyperhidrosis			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Onychoclasis			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Pruritus			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	2 / 36 (5.56%)
occurrences (all)	0	1	2
Rash			

subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Rash erythematous			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Skin burning sensation			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Bladder pain			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Leukocyturia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Proteinuria			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Axillary mass			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Back pain			
subjects affected / exposed	0 / 36 (0.00%)	2 / 30 (6.67%)	2 / 36 (5.56%)
occurrences (all)	0	2	2
Bursitis			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Foot deformity			

subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Groin pain			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Joint swelling			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Musculoskeletal chest pain			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Myalgia			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	2 / 36 (5.56%)
occurrences (all)	0	1	2
Osteoarthritis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Bronchitis			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	1	0	1
Bronchitis viral			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	3 / 36 (8.33%)
occurrences (all)	0	0	3
Cystitis			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0

Ear infection			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Erysipelas			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Eyelid infection			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	2 / 36 (5.56%)	0 / 30 (0.00%)	3 / 36 (8.33%)
occurrences (all)	2	0	4
Furuncle			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Gastroenteritis			
subjects affected / exposed	1 / 36 (2.78%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Herpes simplex			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Hordeolum			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Impetigo			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	2	0	0
Influenza			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Laryngitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Mastitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0

Nasopharyngitis			
subjects affected / exposed	6 / 36 (16.67%)	4 / 30 (13.33%)	6 / 36 (16.67%)
occurrences (all)	6	4	8
Onychomycosis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Oral herpes			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Otitis media			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Pharyngitis			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	3 / 36 (8.33%)
occurrences (all)	1	0	3
Pulpitis dental			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Rhinitis			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Sinusitis			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Skin bacterial infection			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Soft tissue infection			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Staphylococcal infection			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1

Superinfection			
subjects affected / exposed	0 / 36 (0.00%)	2 / 30 (6.67%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Superinfection bacterial			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Tonsillitis			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Tracheitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Upper respiratory tract infection			
subjects affected / exposed	3 / 36 (8.33%)	3 / 30 (10.00%)	2 / 36 (5.56%)
occurrences (all)	4	3	4
Urinary tract infection			
subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Vaginal infection			
subjects affected / exposed	0 / 36 (0.00%)	1 / 30 (3.33%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
Glucose tolerance impaired			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hyperkalaemia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	3 / 36 (8.33%)
occurrences (all)	0	0	4
Hyperuricaemia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			

subjects affected / exposed	1 / 36 (2.78%)	0 / 30 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	MOR106 3 mg/kg Q2W + 6 mg/kg LD Day 1	MOR106 3 mg/kg Q4W + 6 mg/kg LD Day 1	Placebo Q2W
Total subjects affected by non-serious adverse events			
subjects affected / exposed	29 / 38 (76.32%)	22 / 30 (73.33%)	26 / 37 (70.27%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Seborrhoeic keratosis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Skin papilloma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hypertension			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Thrombophlebitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
Varicose vein			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Tooth extraction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Fatigue			

subjects affected / exposed	1 / 38 (2.63%)	1 / 30 (3.33%)	1 / 37 (2.70%)
occurrences (all)	1	2	2
Induration			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Influenza like illness			
subjects affected / exposed	2 / 38 (5.26%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	2	0	0
Localised oedema			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Oedema peripheral			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Peripheral swelling			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Soft tissue inflammation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Immune system disorders			
Seasonal allergy			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Reproductive system and breast disorders			
Dysmenorrhoea			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Asthma			
subjects affected / exposed	2 / 38 (5.26%)	0 / 30 (0.00%)	3 / 37 (8.11%)
occurrences (all)	2	0	3
Cough			

subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Nasal polyps			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nasal septum deviation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Oropharyngeal pain			
subjects affected / exposed	2 / 38 (5.26%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	2	0	0
Rhinitis allergic			
subjects affected / exposed	0 / 38 (0.00%)	2 / 30 (6.67%)	1 / 37 (2.70%)
occurrences (all)	0	2	1
Rhinorrhoea			
subjects affected / exposed	2 / 38 (5.26%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	2	0	0
Sinus pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Sneezing			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Tonsillar inflammation			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Upper respiratory tract inflammation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Depressed mood			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

Generalised anxiety disorder			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	2 / 37 (5.41%)
occurrences (all)	1	0	2
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	2 / 37 (5.41%)
occurrences (all)	3	0	2
Aspartate aminotransferase increased			
subjects affected / exposed	2 / 38 (5.26%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	2	0	1
Blood bilirubin increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
Blood immunoglobulin E increased			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
Blood phosphorus increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood potassium increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood pressure increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood triglycerides increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood uric acid increased			

subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Body temperature increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
C-reactive protein abnormal			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
C-reactive protein increased			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	2 / 37 (5.41%)
occurrences (all)	0	1	3
Electrocardiogram ST segment depression			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Electrocardiogram ST segment elevation			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram ST-T segment depression			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Electrocardiogram T wave inversion			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Eosinophil count increased			
subjects affected / exposed	1 / 38 (2.63%)	2 / 30 (6.67%)	1 / 37 (2.70%)
occurrences (all)	1	2	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Heart rate increased			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Lymphocyte count decreased			

subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
N-terminal prohormone brain natriuretic peptide increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Platelet count increased			
subjects affected / exposed	1 / 38 (2.63%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Protein urine			
subjects affected / exposed	1 / 38 (2.63%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Red blood cells urine			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Red blood cells urine positive			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
White blood cell count decreased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
White blood cell count increased			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
White blood cells urine positive			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Contusion			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Fibula fracture			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Infusion related reaction			

subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Joint dislocation			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Ligament sprain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Nail injury			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Procedural nausea			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Procedural pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Road traffic accident			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Traumatic haematoma			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Arrhythmia supraventricular			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Bradycardia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Conduction disorder			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Sinus bradycardia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	0	1	0

Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Headache			
subjects affected / exposed	4 / 38 (10.53%)	7 / 30 (23.33%)	4 / 37 (10.81%)
occurrences (all)	6	8	9
Paraesthesia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Eosinophilia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Iron deficiency anaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Lymphadenopathy			
subjects affected / exposed	2 / 38 (5.26%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	3	0	0
Lymphopenia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Neutropenia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Ear and labyrinth disorders			
Cerumen impaction			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Ear discomfort			

subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
External ear inflammation			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Conjunctivitis allergic			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Swelling of eyelid			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	2	0	1
Abdominal pain upper			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Cheilosis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Constipation			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	1 / 38 (2.63%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Inguinal hernia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Irritable bowel syndrome			

subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Noninfective gingivitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Vomiting			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Hepatobiliary disorders			
Gallbladder polyp			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Skin and subcutaneous tissue disorders			
Acne			
subjects affected / exposed	1 / 38 (2.63%)	2 / 30 (6.67%)	0 / 37 (0.00%)
occurrences (all)	1	4	0
Alopecia			
subjects affected / exposed	1 / 38 (2.63%)	1 / 30 (3.33%)	1 / 37 (2.70%)
occurrences (all)	1	1	1
Dermatitis			
subjects affected / exposed	2 / 38 (5.26%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	3	0	0
Dermatitis allergic			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Dermatitis atopic			
subjects affected / exposed	13 / 38 (34.21%)	14 / 30 (46.67%)	10 / 37 (27.03%)
occurrences (all)	20	22	20
Dermatitis contact			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Ecchymosis			

subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	1 / 38 (2.63%)	1 / 30 (3.33%)	1 / 37 (2.70%)
occurrences (all)	1	1	1
Folliculitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Hyperhidrosis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Onychoclasis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 38 (0.00%)	2 / 30 (6.67%)	0 / 37 (0.00%)
occurrences (all)	0	2	0
Rash			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Rash erythematous			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Seborrhoeic dermatitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Skin burning sensation			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Bladder pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Leukocyturia			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	0	1	0

Proteinuria			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
Axillary mass			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Bursitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Foot deformity			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Groin pain			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Joint swelling			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal chest pain			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	2	0	0
Myalgia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	2
Osteoarthritis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Pain in extremity			

subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Bronchitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
Bronchitis viral			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Conjunctivitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Cystitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Ear infection			
subjects affected / exposed	1 / 38 (2.63%)	2 / 30 (6.67%)	0 / 37 (0.00%)
occurrences (all)	1	2	0
Erysipelas			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Eyelid infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Folliculitis			
subjects affected / exposed	3 / 38 (7.89%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	4	1	0
Furuncle			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Gastroenteritis			
subjects affected / exposed	1 / 38 (2.63%)	1 / 30 (3.33%)	1 / 37 (2.70%)
occurrences (all)	1	1	1

Herpes simplex			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Hordeolum			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Impetigo			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Influenza			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	1 / 37 (2.70%)
occurrences (all)	0	3	1
Laryngitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Mastitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Nasopharyngitis			
subjects affected / exposed	5 / 38 (13.16%)	1 / 30 (3.33%)	7 / 37 (18.92%)
occurrences (all)	7	1	9
Onychomycosis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Oral herpes			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	6
Otitis media			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Pharyngitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	1 / 37 (2.70%)
occurrences (all)	0	1	1
Pulpitis dental			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0

Respiratory tract infection			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	0	1	0
Rhinitis			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	2	0	0
Sinusitis			
subjects affected / exposed	0 / 38 (0.00%)	1 / 30 (3.33%)	3 / 37 (8.11%)
occurrences (all)	0	1	3
Skin bacterial infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Soft tissue infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Staphylococcal infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Superinfection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Superinfection bacterial			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Tonsillitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Tracheitis			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Upper respiratory tract infection			
subjects affected / exposed	1 / 38 (2.63%)	1 / 30 (3.33%)	3 / 37 (8.11%)
occurrences (all)	2	2	4
Urinary tract infection			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	2 / 37 (5.41%)
occurrences (all)	2	0	2

Vaginal infection			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Glucose tolerance impaired			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	1	0	0
Hyperkalaemia			
subjects affected / exposed	1 / 38 (2.63%)	1 / 30 (3.33%)	0 / 37 (0.00%)
occurrences (all)	1	1	0
Hypertriglyceridaemia			
subjects affected / exposed	1 / 38 (2.63%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	1	0	1
Hyperuricaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	1 / 37 (2.70%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 38 (0.00%)	0 / 30 (0.00%)	0 / 37 (0.00%)
occurrences (all)	0	0	0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 October 2018	The changes included: -Updates related to sample size: increased from 180 to 240 subjects in order to increase the precision for the planned population based pharmacokinetic/pharmacodynamic (PK/PD) model used for Phase 3 dose selection. – Update to clarify that subjects who experienced any episode or recurrence of Herpes Zoster infection within 1 year before the screening visit must be excluded (Exclusion Criterion 5). – Deletion of Exclusion Criterion 6, related to tuberculosis testing by Quantiferon TB Gold test, as the exclusion of a history of tuberculosis is in general covered by Exclusion Criterion 4. – Several simplification and clarification in the statistical section as well as some adjustments for consistency with other studies. – Definition of AESIs was updated to indicate that AESI only occur after IMP administration. – Update to add wording related to the new General Data Protection Regulation, which became effective on 25-May-2018.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? Yes

Date	Interruption	Restart date
28 October 2019	On 28-Oct-2019, it was announced that the further development of MOR106 in the indication of moderate to severe AD would not be continuing. This was based on a futility analysis of efficacy data of the interim analysis of the current study. There were no concerns related to safety and tolerability after administration of MOR106. Based on this assessment it was decided, with immediate effect, to stop treatment of participants in all ongoing studies with MOR106. As a consequence of study treatment termination, participants who were in treatment were requested to stop treatment immediately, complete the early treatment discontinuation visit and then start with the 16-week follow-up period.	-

Notes:

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

Participant numbers decreased due to early treatment termination for primary and secondary efficacy endpoints. High placebo values as well as the low participant number at later timepoints should be taken into account when interpreting the result.

Notes: