



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 informed 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), participants were 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 |
| Consent withdrawn by subject | 9 | 5 | 4 |
| Physician decision | 1 | - | 1 |
| 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 |
| Consent withdrawn by subject | 9 | 9 | 6 |
| Physician decision | - | 1 | - |
| 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 standard deviation | 38.1 ± 12.67 | 35.6 ± 12.49 | 33.7 ± 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 standard deviation | 29.201 ± 13.5282 | 28.482 ± 11.1545 | 27.372 ± 8.9842 |
| Scoring Atopic Dermatitis (SCORAD) Score Units: scores on scale arithmetic mean standard deviation | 67.662 ± 14.1537 | 67.087 ± 13.5887 | 60.800 ± 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 standard deviation | 35.1 ± 15.41 | 35.0 ± 12.58 | 33.8 ± 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 standard deviation | 28.956 ± 10.7465 | 28.962 ± 11.5183 | 34.264 ± 15.4456 |
| Scoring Atopic Dermatitis (SCORAD) Score Units: scores on scale arithmetic mean standard deviation | 66.248 ± 11.0225 | 63.907 ± 12.3086 | 68.624 ± 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 (\pm 9.447) | -36.24 (\pm 9.065) | -32.60 (\pm 9.494) | -42.97 (\pm 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 (\pm 9.130) | -37.00 (\pm 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 $\geq 50\%$ Overall improvement in EASI Score From Baseline

| | |
|-----------------|---|
| End point title | Percentage of Subjects who Achieved $\geq 50\%$ 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

Secondary: Area Under the Concentration-time Curve From Zero to Infinity (AUC_{0-inf}) for MOR106

| | |
|-----------------|---|
| End point title | Area Under the Concentration-time Curve From Zero to Infinity (AUC _{0-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 occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 30 (0.00%) 0 | 1 / 36 (2.78%) 1 |
| Immune system disorders Seasonal allergy subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Reproductive system and breast disorders Dysmenorrhoea subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 1 / 30 (3.33%) 1 | 0 / 36 (0.00%) 0 |
| Respiratory, thoracic and mediastinal disorders Asthma subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 30 (0.00%) 0 | 2 / 36 (5.56%) 2 |
| Cough subjects affected / exposed occurrences (all) | 1 / 36 (2.78%) 1 | 0 / 30 (0.00%) 0 | 1 / 36 (2.78%) 1 |
| Nasal congestion subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Nasal polyps subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 1 / 30 (3.33%) 2 | 0 / 36 (0.00%) 0 |
| Nasal septum deviation subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Oropharyngeal pain subjects affected / exposed occurrences (all) | 1 / 36 (2.78%) 1 | 1 / 30 (3.33%) 1 | 0 / 36 (0.00%) 0 |
| Rhinitis allergic subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 1 / 30 (3.33%) 1 | 1 / 36 (2.78%) 1 |
| Rhinorrhoea subjects affected / exposed occurrences (all) | 1 / 36 (2.78%) 1 | 1 / 30 (3.33%) 1 | 1 / 36 (2.78%) 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 occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 30 (0.00%) 0 | 1 / 36 (2.78%) 1 |
| White blood cell count increased subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 1 / 30 (3.33%) 1 | 0 / 36 (0.00%) 0 |
| White blood cells urine positive subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Injury, poisoning and procedural complications | | | |
| Contusion subjects affected / exposed occurrences (all) | 1 / 36 (2.78%) 1 | 0 / 30 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Fibula fracture subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Infusion related reaction subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 30 (0.00%) 0 | 1 / 36 (2.78%) 1 |
| Joint dislocation subjects affected / exposed occurrences (all) | 1 / 36 (2.78%) 1 | 0 / 30 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Ligament sprain subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 30 (0.00%) 0 | 1 / 36 (2.78%) 1 |
| Nail injury subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 36 (0.00%) 0 |
| Procedural nausea subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 30 (0.00%) 0 | 1 / 36 (2.78%) 1 |
| Procedural pain subjects affected / exposed occurrences (all) | 0 / 36 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 36 (0.00%) 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 |
| Onychoclasia | | | |
| 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 occurrences (all) | 0 / 38 (0.00%) 0 | 1 / 30 (3.33%) 1 | 0 / 37 (0.00%) 0 |
| Insomnia subjects affected / exposed occurrences (all) | 1 / 38 (2.63%) 1 | 0 / 30 (0.00%) 0 | 2 / 37 (5.41%) 2 |
| Investigations | | | |
| Alanine aminotransferase increased subjects affected / exposed occurrences (all) | 1 / 38 (2.63%) 3 | 0 / 30 (0.00%) 0 | 2 / 37 (5.41%) 2 |
| Aspartate aminotransferase increased subjects affected / exposed occurrences (all) | 2 / 38 (5.26%) 2 | 0 / 30 (0.00%) 0 | 1 / 37 (2.70%) 1 |
| Blood bilirubin increased subjects affected / exposed occurrences (all) | 0 / 38 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 37 (0.00%) 0 |
| Blood creatinine increased subjects affected / exposed occurrences (all) | 0 / 38 (0.00%) 0 | 0 / 30 (0.00%) 0 | 2 / 37 (5.41%) 2 |
| Blood immunoglobulin E increased subjects affected / exposed occurrences (all) | 0 / 38 (0.00%) 0 | 1 / 30 (3.33%) 1 | 1 / 37 (2.70%) 1 |
| Blood phosphorus increased subjects affected / exposed occurrences (all) | 0 / 38 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 37 (0.00%) 0 |
| Blood potassium increased subjects affected / exposed occurrences (all) | 0 / 38 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 37 (0.00%) 0 |
| Blood pressure increased subjects affected / exposed occurrences (all) | 0 / 38 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 37 (0.00%) 0 |
| Blood triglycerides increased subjects affected / exposed occurrences (all) | 0 / 38 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 37 (0.00%) 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%) |
| Blood and lymphatic system disorders | 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 |
| | Eosinophilia | | | |
| | subjects affected / exposed | 0 / 38 (0.00%) | 0 / 30 (0.00%) | 0 / 37 (0.00%) |
| | occurrences (all) | 0 | 0 | 0 |
| | Iron deficiency anaemia | | | |
| Ear and labyrinth disorders | 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 |
| | Cerumen impaction | | | |
| | subjects affected / exposed | 0 / 38 (0.00%) | 0 / 30 (0.00%) | 0 / 37 (0.00%) |
| Ear discomfort | occurrences (all) | 0 | 0 | 0 |
| | | | | |

| | | | |
|--|---------------------|---------------------|---------------------|
| subjects affected / exposed occurrences (all) | 0 / 38 (0.00%) 0 | 0 / 30 (0.00%) 0 | 1 / 37 (2.70%) 1 |
| External ear inflammation subjects affected / exposed occurrences (all) | 1 / 38 (2.63%) 1 | 0 / 30 (0.00%) 0 | 0 / 37 (0.00%) 0 |
| Eye disorders | | | |
| Conjunctivitis allergic subjects affected / exposed occurrences (all) | 1 / 38 (2.63%) 1 | 0 / 30 (0.00%) 0 | 1 / 37 (2.70%) 1 |
| Swelling of eyelid subjects affected / exposed occurrences (all) | 0 / 38 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 37 (0.00%) 0 |
| Gastrointestinal disorders | | | |
| Abdominal pain subjects affected / exposed occurrences (all) | 1 / 38 (2.63%) 2 | 0 / 30 (0.00%) 0 | 1 / 37 (2.70%) 1 |
| Abdominal pain upper subjects affected / exposed occurrences (all) | 0 / 38 (0.00%) 0 | 0 / 30 (0.00%) 0 | 1 / 37 (2.70%) 1 |
| Cheilosis subjects affected / exposed occurrences (all) | 1 / 38 (2.63%) 1 | 0 / 30 (0.00%) 0 | 0 / 37 (0.00%) 0 |
| Constipation subjects affected / exposed occurrences (all) | 1 / 38 (2.63%) 1 | 0 / 30 (0.00%) 0 | 0 / 37 (0.00%) 0 |
| Diarrhoea subjects affected / exposed occurrences (all) | 1 / 38 (2.63%) 1 | 1 / 30 (3.33%) 1 | 0 / 37 (0.00%) 0 |
| Gastrooesophageal reflux disease subjects affected / exposed occurrences (all) | 0 / 38 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 37 (0.00%) 0 |
| Inguinal hernia subjects affected / exposed occurrences (all) | 0 / 38 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 37 (0.00%) 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 |
| Onychoclasia | | | |
| 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 occurrences (all) | 0 / 38 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 37 (0.00%) 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 occurrences (all) | 0 / 38 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 37 (0.00%) 0 |
| Metabolism and nutrition disorders | | | |
| Glucose tolerance impaired subjects affected / exposed occurrences (all) | 1 / 38 (2.63%) 1 | 0 / 30 (0.00%) 0 | 0 / 37 (0.00%) 0 |
| Hyperkalaemia subjects affected / exposed occurrences (all) | 1 / 38 (2.63%) 1 | 1 / 30 (3.33%) 1 | 0 / 37 (0.00%) 0 |
| Hypertriglyceridaemia subjects affected / exposed occurrences (all) | 1 / 38 (2.63%) 1 | 0 / 30 (0.00%) 0 | 1 / 37 (2.70%) 1 |
| Hyperuricaemia subjects affected / exposed occurrences (all) | 0 / 38 (0.00%) 0 | 0 / 30 (0.00%) 0 | 1 / 37 (2.70%) 1 |
| Hypoalbuminaemia subjects affected / exposed occurrences (all) | 0 / 38 (0.00%) 0 | 0 / 30 (0.00%) 0 | 0 / 37 (0.00%) 0 |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|-----------------|--|
| 05 October 2018 | <p>The changes included:</p> <ul style="list-style-type: none">-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 | <p>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.</p> | - |

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: