

**Clinical trial results:**

A Phase-IV, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Trial to Evaluate the Efficacy and Safety of Golimumab (MK-8259 [SCH900259]) After Treatment Withdrawal, Compared With Continued Treatment (Either Full- or Reduced-Treatment Regimen), In Subjects With Non-Radiographic Axial Spondyloarthritis

Summary

| | |
|--------------------------|-------------------|
| EudraCT number | 2015-004020-65 |
| Trial protocol | DE CZ ES NL PL RO |
| Global end of trial date | 17 March 2021 |

Results information

| | |
|--------------------------------|---------------|
| Result version number | v2 (current) |
| This version publication date | 12 June 2022 |
| First version publication date | 30 March 2022 |
| Version creation reason | |

Trial information**Trial identification**

| | |
|-----------------------|----------|
| Sponsor protocol code | 8259-038 |
|-----------------------|----------|

Additional study identifiers

| | |
|------------------------------------|---------------------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03253796 |
| WHO universal trial number (UTN) | - |
| Other trial identifiers | GO-BACK: Merck study name |

Notes:

Sponsors

| | |
|------------------------------|--|
| Sponsor organisation name | Merck Sharp & Dohme LLC |
| Sponsor organisation address | 126 E. Lincoln Avenue, Rahway, NJ, United States, 07065 |
| Public contact | Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@merck.com |
| Scientific contact | Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@merck.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 | 17 March 2021 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 17 March 2021 |
| Global end of trial reached? | Yes |
| Global end of trial date | 17 March 2021 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to evaluate the effect of treatment withdrawal vs continued treatment with golimumab (GLM) administered by subcutaneous (SC) injection on the incidence of a "flare" in non-radiographic axial spondyloarthritis over up to 12 months. The primary hypothesis is that continued treatment with golimumab is superior to treatment withdrawal, based on the percentage of participants without a "flare" during up to 12 months of blinded therapy.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

| | |
|---|------------------|
| Actual start date of recruitment | 07 November 2017 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|------------------------|
| Country: Number of subjects enrolled | Czechia: 80 |
| Country: Number of subjects enrolled | Germany: 19 |
| Country: Number of subjects enrolled | Netherlands: 3 |
| Country: Number of subjects enrolled | Poland: 75 |
| Country: Number of subjects enrolled | Romania: 24 |
| Country: Number of subjects enrolled | Russian Federation: 30 |
| Country: Number of subjects enrolled | Spain: 5 |
| Country: Number of subjects enrolled | Ukraine: 67 |
| Country: Number of subjects enrolled | Turkey: 20 |
| Worldwide total number of subjects | 323 |
| EEA total number of subjects | 206 |

Notes:

Subjects enrolled per age group

| | |
|--|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 | 0 |

| | |
|--|-----|
| wk | |
| 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) | 323 |
| From 65 to 84 years | 0 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Adult subjects with active non-radiographic axial spondyloarthritis (nr-AxSpA), who had objective signs of inflammation and intolerance or inadequate response to non-steroidal anti-inflammatory drugs (NSAIDs), were enrolled in this trial.

Period 1

| | |
|------------------------------|------------------|
| Period 1 title | Period 1: Run-In |
| Is this the baseline period? | Yes |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|-----------|--------------------------------|
| Arm title | Open-Label Run-In Golimumab QM |
|-----------|--------------------------------|

Arm description:

Participants were treated with open-label subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 10 months. Participants with a body weight greater than 100 kg may have received 100 mg injections of golimumab at the discretion of the investigator.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | golimumab |
| Investigational medicinal product code | |
| Other name | MK-8259 Simponi® |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 10 months. Participants with a body weight greater than 100 kg may have received 100 mg injections of golimumab at the discretion of the investigator.

| Number of subjects in period 1 | Open-Label Run-In Golimumab QM |
|--------------------------------|--------------------------------|
| Started | 323 |
| Completed | 207 |
| Not completed | 116 |
| Consent withdrawn by subject | 8 |
| Adverse event, non-fatal | 4 |
| Lack of Qualifying Event | 98 |
| Lack of efficacy | 1 |
| Protocol deviation | 5 |

Period 2

| | |
|------------------------------|--------------------------------------|
| Period 2 title | Period 2: Withdrawal vs Continued Tx |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator |

Arms

| | |
|------------------------------|-----|
| Are arms mutually exclusive? | Yes |
|------------------------------|-----|

| | |
|------------------|---------------------------------------|
| Arm title | Golimumab QM (Full Treatment Regimen) |
|------------------|---------------------------------------|

Arm description:

Participants were treated with double-blinded SC injections of 50 mg golimumab QM for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | golimumab |
| Investigational medicinal product code | |
| Other name | MK-8259 Simponi® |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

| | |
|------------------|---|
| Arm title | Golimumab Q2M (Reduced Treatment Regimen) |
|------------------|---|

Arm description:

Participants were treated with double-blinded SC injections of 50 mg golimumab every other month (Q2M) alternating with matching placebo to golimumab every other month for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | golimumab |
| Investigational medicinal product code | |
| Other name | MK-8259 Simponi® |
| Pharmaceutical forms | Solution for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Double-blinded SC injections of 50 mg golimumab every other month (Q2M) for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

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

Dosage and administration details:

Double-blinded SC injections of placebo to golimumab every other month (Q2M) for up to 12 months.

| | |
|------------------|--|
| Arm title | Placebo (Treatment Withdrawal Regimen) |
|------------------|--|

Arm description:

Participants were treated with double-blinded SC injections of placebo for up to 12 months. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded

treatment and were retreated with open-label golimumab.

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

Dosage and administration details:

Double-blinded SC injections of placebo to golimumab once a month (QM) for up to 12 months.

| Number of subjects in period 2 ^[1] | Golimumab QM (Full Treatment Regimen) | Golimumab Q2M (Reduced Treatment Regimen) | Placebo (Treatment Withdrawal Regimen) |
|--|---------------------------------------|---|--|
| | | | |
| Started | 63 | 64 | 62 |
| Completed | 53 | 43 | 21 |
| Not completed | 10 | 21 | 41 |
| Disease Flare, moved to Open-label retreatment | 10 | 15 | 38 |
| Physician decision | - | 1 | - |
| Consent withdrawn by subject | - | 2 | 3 |
| Adverse event, non-fatal | - | 2 | - |
| Did not attain inactive disease in Period 1 | - | 1 | - |

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: Participants who experienced disease flare discontinued double-blind treatment and entered open-label retreatment

Period 3

| | |
|------------------------------|----------------------------------|
| Period 3 title | Period 2: Open-Label Retreatment |
| Is this the baseline period? | No |
| Allocation method | Not applicable |
| Blinding used | Not blinded |

Arms

| | |
|------------------|------------------------|
| Arm title | Open-Label Retreatment |
|------------------|------------------------|

Arm description:

Participants who experienced a disease flare were treated with open-label SC injections of 50 mg golimumab QM for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | golimumab |
| Investigational medicinal product code | |
| Other name | Simponi® |
| Pharmaceutical forms | Solution for injection in pre-filled pen |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 12 months. Participants

with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

| Number of subjects in period 3^[2] | Open-Label Retreatment |
|---|---------------------------|
| Started | 63 |
| Completed | 58 |
| Not completed | 5 |
| Consent withdrawn by subject | 5 |

Notes:

[2] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.

Justification: 18 participants did not continue into Period 2

Baseline characteristics

Reporting groups

| | |
|-----------------------|--------------------------------|
| Reporting group title | Open-Label Run-In Golimumab QM |
|-----------------------|--------------------------------|

Reporting group description:

Participants were treated with open-label subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 10 months. Participants with a body weight greater than 100 kg may have received 100 mg injections of golimumab at the discretion of the investigator.

| Reporting group values | Open-Label Run-In Golimumab QM | Total | |
|--|--------------------------------|-------|--|
| Number of subjects | 323 | 323 | |
| Age categorical Units: Subjects | | | |
| In utero | | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | | 0 | |
| Newborns (0-27 days) | | 0 | |
| Infants and toddlers (28 days-23 months) | | 0 | |
| Children (2-11 years) | | 0 | |
| Adolescents (12-17 years) | | 0 | |
| Adults (18-64 years) | | 0 | |
| From 65-84 years | | 0 | |
| 85 years and over | | 0 | |
| Age Continuous Units: years | | | |
| arithmetic mean | 32.5 | | |
| standard deviation | ± 7.2 | - | |
| Sex: Female, Male Units: Participants | | | |
| Female | 109 | 109 | |
| Male | 214 | 214 | |
| Race (NIH/OMB) Units: Subjects | | | |
| American Indian or Alaska Native | 0 | 0 | |
| Asian | 0 | 0 | |
| Native Hawaiian or Other Pacific Islander | 0 | 0 | |
| Black or African American | 0 | 0 | |
| White | 323 | 323 | |
| More than one race | 0 | 0 | |
| Unknown or Not Reported | 0 | 0 | |
| Ethnicity (NIH/OMB) Units: Subjects | | | |
| Hispanic or Latino | 2 | 2 | |
| Not Hispanic or Latino | 321 | 321 | |
| Unknown or Not Reported | 0 | 0 | |
| C-Reactive Protein (CRP) Category at Enrollment Units: Subjects | | | |

| | | | |
|----------|-----|-----|--|
| > 6 mg/L | 196 | 196 | |
| ≤ 6 mg/L | 127 | 127 | |

Subject analysis sets

| | |
|----------------------------|--|
| Subject analysis set title | Golimumab QM (Full Treatment Regimen) - baseline reporting |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

Subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

| | |
|----------------------------|--|
| Subject analysis set title | Golimumab Q2M (Reduced Treatment Regimen) - baseline reporting |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

Double-blinded SC injections of 50 mg golimumab every other month (Q2M) for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

| | |
|----------------------------|---|
| Subject analysis set title | Placebo (Treatment Withdrawal Regimen) - baseline reporting |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

Double-blinded SC injections of placebo to golimumab once a month (QM) for up to 12 months.

| | |
|----------------------------|---|
| Subject analysis set title | Open-Label Retreatment - baseline reporting |
| Subject analysis set type | Safety analysis |

Subject analysis set description:

Participants who experienced a disease flare were treated with open-label SC injections of 50 mg golimumab QM for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

| | |
|----------------------------|---|
| Subject analysis set title | Golimumab Q2M and Placebo (Withdrawal Regimens) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Participants were treated with double-blinded SC injections of 50 mg golimumab Q2M alternating with matching placebo to golimumab every other month or with placebo for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

| Reporting group values | Golimumab QM (Full Treatment Regimen) - baseline reporting | Golimumab Q2M (Reduced Treatment Regimen) - baseline reporting | Placebo (Treatment Withdrawal Regimen) - baseline reporting |
|--|--|--|---|
| Number of subjects | 63 | 64 | 62 |
| Age categorical Units: Subjects | | | |
| In utero | | | |
| Preterm newborn infants (gestational age < 37 wks) | | | |
| Newborns (0-27 days) | | | |
| Infants and toddlers (28 days-23 months) | | | |
| Children (2-11 years) | | | |
| Adolescents (12-17 years) | | | |
| Adults (18-64 years) | | | |
| From 65-84 years | | | |
| 85 years and over | | | |

| | | | |
|---|----------------------------------|----------------------------------|----------------------------------|
| Age Continuous Units: years arithmetic mean standard deviation | 31.4 ± 8.0 | 30.8 ± 6.7 | 32.9 ± 6.8 |
| Sex: Female, Male Units: Participants | | | |
| Female Male | 19 44 | 21 43 | 16 46 |
| Race (NIH/OMB) Units: Subjects | | | |
| American Indian or Alaska Native Asian Native Hawaiian or Other Pacific Islander Black or African American White More than one race Unknown or Not Reported | 0 0 0 0 63 0 0 | 0 0 0 0 64 0 0 | 0 0 0 0 62 0 0 |
| Ethnicity (NIH/OMB) Units: Subjects | | | |
| Hispanic or Latino Not Hispanic or Latino Unknown or Not Reported | 0 63 0 | 0 64 0 | 0 62 0 |
| C-Reactive Protein (CRP) Category at Enrollment Units: Subjects | | | |
| > 6 mg/L ≤ 6 mg/L | 40 23 | 40 24 | 39 23 |

| Reporting group values | Open-Label Retreatment - baseline reporting | Golimumab Q2M and Placebo (Withdrawal Regimens) | |
|---|---|---|--|
| Number of subjects | 63 | 125 | |
| Age categorical Units: Subjects | | | |
| In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over | | | |
| Age Continuous Units: years arithmetic mean standard deviation | 33.4 ± 6.7 | ± | |
| Sex: Female, Male Units: Participants | | | |
| Female Male | 20 43 | | |

| | | | |
|---|----|--|--|
| Race (NIH/OMB) | | | |
| Units: Subjects | | | |
| American Indian or Alaska Native | 0 | | |
| Asian | 0 | | |
| Native Hawaiian or Other Pacific Islander | 0 | | |
| Black or African American | 0 | | |
| White | 63 | | |
| More than one race | 0 | | |
| Unknown or Not Reported | 0 | | |
| Ethnicity (NIH/OMB) | | | |
| Units: Subjects | | | |
| Hispanic or Latino | 0 | | |
| Not Hispanic or Latino | 63 | | |
| Unknown or Not Reported | 0 | | |
| C-Reactive Protein (CRP) Category at Enrollment | | | |
| Units: Subjects | | | |
| > 6 mg/L | 38 | | |
| ≤ 6 mg/L | 25 | | |

End points

End points reporting groups

| | |
|--|--|
| Reporting group title | Open-Label Run-In Golimumab QM |
| Reporting group description: Participants were treated with open-label subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 10 months. Participants with a body weight greater than 100 kg may have received 100 mg injections of golimumab at the discretion of the investigator. | |
| Reporting group title | Golimumab QM (Full Treatment Regimen) |
| Reporting group description: Participants were treated with double-blinded SC injections of 50 mg golimumab QM for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab. | |
| Reporting group title | Golimumab Q2M (Reduced Treatment Regimen) |
| Reporting group description: Participants were treated with double-blinded SC injections of 50 mg golimumab every other month (Q2M) alternating with matching placebo to golimumab every other month for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab. | |
| Reporting group title | Placebo (Treatment Withdrawal Regimen) |
| Reporting group description: Participants were treated with double-blinded SC injections of placebo for up to 12 months. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab. | |
| Reporting group title | Open-Label Retreatment |
| Reporting group description: Participants who experienced a disease flare were treated with open-label SC injections of 50 mg golimumab QM for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study. | |
| Subject analysis set title | Golimumab QM (Full Treatment Regimen) - baseline reporting |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study. | |
| Subject analysis set title | Golimumab Q2M (Reduced Treatment Regimen) - baseline reporting |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Double-blinded SC injections of 50 mg golimumab every other month (Q2M) for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study. | |
| Subject analysis set title | Placebo (Treatment Withdrawal Regimen) - baseline reporting |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Double-blinded SC injections of placebo to golimumab once a month (QM) for up to 12 months. | |
| Subject analysis set title | Open-Label Retreatment - baseline reporting |
| Subject analysis set type | Safety analysis |
| Subject analysis set description: Participants who experienced a disease flare were treated with open-label SC injections of 50 mg golimumab QM for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of | |

the study.

| | |
|----------------------------|---|
| Subject analysis set title | Golimumab Q2M and Placebo (Withdrawal Regimens) |
| Subject analysis set type | Full analysis |

Subject analysis set description:

Participants were treated with double-blinded SC injections of 50 mg golimumab Q2M alternating with matching placebo to golimumab every other month or with placebo for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

Primary: Percentage of Participants Without a Disease Activity Flare During Period 2

| | |
|-----------------|---|
| End point title | Percentage of Participants Without a Disease Activity Flare During Period 2 |
|-----------------|---|

End point description:

Disease flare is defined as Ankylosing Spondylitis Disease Activity Score (ASDAS) at 2 consecutive visits that both show either score ≥ 2.1 or a post-withdrawal increase of ≥ 1.1 relative to baseline prior to the first dose in Period 2. ASDAS is a composite index assessing disease activity in axial spondyloarthropathies consisting of 4 self-assessed parameters and 1 laboratory parameter. The parameters of back pain, duration of morning stiffness, Patient Global Disease Assessment (PGDn), and peripheral pain/swelling are scored on a numeric scale of 0 (low activity/impact) to 10 (high activity/impact). The self-assessed criteria and the laboratory value of CRP are combined to provide the total ASDAS score, which has a lower limit of 0.6 and no defined upper limit. A higher score indicates greater disease activity. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥ 1 dose of double-blind study intervention.

| | |
|----------------|---------|
| End point type | Primary |
|----------------|---------|

End point timeframe:

Up to 12 months

| End point values | Golimumab QM (Full Treatment Regimen) | Golimumab Q2M (Reduced Treatment Regimen) | Placebo (Treatment Withdrawal Regimen) | |
|-----------------------------------|---------------------------------------|---|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 63 | 63 | 62 | |
| Units: Percentage of participants | | | | |
| number (not applicable) | 84.1 | 68.3 | 33.9 | |

Statistical analyses

| | |
|----------------------------|-----------------------------------|
| Statistical analysis title | Full Treatment Regimen vs Placebo |
|----------------------------|-----------------------------------|

Statistical analysis description:

Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor

| | |
|---|--|
| Comparison groups | Golimumab QM (Full Treatment Regimen) v Placebo (Treatment Withdrawal Regimen) |
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in percentage |
| Point estimate | 50.2 |

| | |
|---------------------|---------|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 34.1 |
| upper limit | 63.6 |

| | |
|-----------------------------------|--------------------------------------|
| Statistical analysis title | Reduced Treatment Regimen vs Placebo |
|-----------------------------------|--------------------------------------|

Statistical analysis description:

Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor

| | |
|---|--|
| Comparison groups | Golimumab Q2M (Reduced Treatment Regimen) v Placebo (Treatment Withdrawal Regimen) |
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in percentage |
| Point estimate | 34.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 17 |
| upper limit | 49.7 |

Secondary: Percentage of Participants with a Flare Who Show a Clinical Response Within 3 Months of Open-Label Golimumab Retreatment

| | |
|-----------------|--|
| End point title | Percentage of Participants with a Flare Who Show a Clinical Response Within 3 Months of Open-Label Golimumab Retreatment |
|-----------------|--|

End point description:

Clinical response is defined as BASDAI (Bath Ankylosing Spondylitis Disease Assessment Index) score improvement of ≥ 2.0 or $\geq 50\%$ improvement within 3 months of the start of retreatment, relative to the mean of the 2 consecutive BASDAI scores that defined the flare. Sustained clinical response is clinical response and maintenance of BASDAI criteria during 3-month retreatment period. BASDAI is a summary of 6 participant-assessed measures rated on scales of 0 (none) to 10 (very severe): fatigue, spinal pain, joint pain/swelling, tenderness, morning stiffness, and duration of morning stiffness [0 (0 hours) to 10 (2 or more hours)]. BASDAI score is the mean of responses to the 6 questions (range of 0 to 10). A higher score indicates greater disease activity. The population is all participants who had inactive disease in Period 1, were randomized to reduced-treatment regimen or placebo in Period 2, received ≥ 1 dose of double-blind study intervention, and had disease flare in Period 2.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to 3 months following start of retreatment

| | | | | |
|-----------------------------------|---------------------------|--|--|--|
| End point values | Open-Label Retreatment | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 53 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | | | | |
| Within 1 month of retreatment | 90.6 (79.3 to 96.9) | | | |
| Within 2 months of retreatment | 96.2 (87.0 to 99.5) | | | |
| Within 3 months of retreatment | 96.2 (87.0 to 99.5) | | | |
| Sustained clinical response | 71.7 (57.7 to 83.2) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Time to First Disease Flare

| | |
|---|-----------------------------|
| End point title | Time to First Disease Flare |
| End point description: | |
| The Kaplan-Meier analysis of time to first "flare" in Period 2 is represented by the percentage of participants who experienced a disease flare relative to baseline prior to the first dose of double-blind treatment in Period 2. Disease flare is defined as ASDAS at two consecutive visits that both show either absolute score ≥ 2.1 or a post-withdrawal increase of ≥ 1.1 . The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥ 1 dose of double-blind study intervention. | |
| End point type | Secondary |
| End point timeframe: | |
| Month 3, Month 6, Month 9, and Month 12 | |

| | | | | |
|-----------------------------------|---|--|---|--|
| End point values | Golimumab QM (Full Treatment Regimen) | Golimumab Q2M (Reduced Treatment Regimen) | Placebo (Treatment Withdrawal Regimen) | |
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 63 | 63 | 62 | |
| Units: Percentage of participants | | | | |
| number (not applicable) | | | | |
| Month 3 | 14.3 | 7.9 | 41.9 | |
| Month 6 | 14.3 | 17.5 | 58.1 | |
| Month 9 | 14.3 | 20.6 | 61.3 | |
| Month 12 | 15.9 | 23.8 | 61.3 | |

Statistical analyses

Secondary: Percentage of Participants Achieving ASAS20 (Assessment in SpondyloArthritis international Society) Response (Double-blind treatment)

| | |
|-----------------|---|
| End point title | Percentage of Participants Achieving ASAS20 (Assessment in SpondyloArthritis international Society) Response (Double-blind treatment) |
|-----------------|---|

End point description:

ASAS20 is 20% improvement in response (per the Assessment in Ankylosing Spondylitis International Working Group) meeting 2 criteria: 1) improvement of $\geq 20\%$ from Baseline and an improvement from Baseline of ≥ 1.0 in at least 3 of 4 domains, and 2) absence of deterioration from Baseline (defined as a $\geq 20\%$ worsening and an absolute worsening of ≥ 1.0) in the potential remaining domain. Baseline is defined as the last ASAS score prior to the first dose of double-blind treatment in Period 2. The ASAS consists of 4 domains: the PGDn, total back pain, Bath Ankylosing Spondylitis Functional Index (BASFI), and morning stiffness (mean of questions 5 and 6 of BASDAI). Each domain is measured on a 10-point scale from 0=no disease symptoms/impact to 10=extreme disease symptoms/impact. A higher score indicates more severe impairment. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥ 1 dose of double-blind study intervention.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to 12 months

| End point values | Golimumab QM (Full Treatment Regimen) | Golimumab Q2M (Reduced Treatment Regimen) | Placebo (Treatment Withdrawal Regimen) | |
|-----------------------------------|---------------------------------------|---|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 63 | 63 | 62 | |
| Units: Percentage of participants | | | | |
| number (not applicable) | 9.5 | 3.2 | 0.0 | |

Statistical analyses

| | |
|----------------------------|--------------------------------------|
| Statistical analysis title | Reduced Treatment Regimen vs Placebo |
|----------------------------|--------------------------------------|

Statistical analysis description:

Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor

| | |
|---|--|
| Comparison groups | Golimumab Q2M (Reduced Treatment Regimen) v Placebo (Treatment Withdrawal Regimen) |
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Difference in percentage |
| Point estimate | 3.2 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -2.8 |
| upper limit | 10.9 |

| | |
|---|--|
| Statistical analysis title | Full Treatment Regimen vs Placebo |
| Statistical analysis description: | |
| Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor | |
| Comparison groups | Golimumab QM (Full Treatment Regimen) v Placebo (Treatment Withdrawal Regimen) |
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Difference in percentage |
| Point estimate | 9.5 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.3 |
| upper limit | 19.4 |

Secondary: Percentage of Participants Achieving ASAS20 Response (Open-label retreatment)

| | |
|--|---|
| End point title | Percentage of Participants Achieving ASAS20 Response (Open-label retreatment) |
| End point description: | |
| ASAS20 is 20% improvement in response (per the Assessment in Ankylosing Spondylitis International Working Group) meeting 2 criteria: 1) improvement of ≥20% from Baseline and an improvement from Baseline of ≥1.0 in at least 3 of 4 domains, and 2) absence of deterioration from Baseline (defined as a ≥20% worsening and an absolute worsening of ≥1.0) in the potential remaining domain. Baseline is defined as the last ASAS score prior to the first dose of double-blind treatment in Period 2. The ASAS consists of 4 domains: the PGDn, total back pain, BASFI, and morning stiffness (mean of questions 5 and 6 of BASDAI). Each domain is measured on a 10-point scale from 0=no disease symptoms/impact to 10=extreme disease symptoms/impact. A higher score indicates more severe impairment. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥1 dose of double-blind study intervention. | |
| End point type | Secondary |
| End point timeframe: | |
| Up to 12 months | |

| | | | | |
|-----------------------------------|------------------------|--|--|--|
| End point values | Open-Label Retreatment | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 53 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 94.3 (84.3 to 98.8) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving ASAS40 Response (Double-blind treatment)

| | |
|--|---|
| End point title | Percentage of Participants Achieving ASAS40 Response (Double-blind treatment) |
| End point description: ASAS40 is 40% improvement in response (per the Assessment in Ankylosing Spondylitis International Working Group) meeting 2 criteria: 1) improvement of $\geq 40\%$ from Baseline and an improvement from Baseline of ≥ 2.0 in at least 3 of 4 domains, and 2) no deterioration from in the potential remaining domain. Baseline is defined as the last ASAS score prior to the first dose of double-blind treatment in Period 2. The ASAS consists of 4 domains: the PGDn, total back pain, BASFI, and morning stiffness (mean of questions 5 and 6 of BASDAI). Each domain is measured on a 10-point scale from 0=no disease symptoms/impact to 10=extreme disease symptoms/impact. A higher score indicates more severe impairment. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥ 1 dose of double-blind study intervention. | |
| End point type | Secondary |
| End point timeframe: Up to 12 months | |

| End point values | Golimumab QM (Full Treatment Regimen) | Golimumab Q2M (Reduced Treatment Regimen) | Placebo (Treatment Withdrawal Regimen) | |
|-----------------------------------|---------------------------------------|---|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 63 | 63 | 62 | |
| Units: Percentage of participants | 0 | 0 | 0 | |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Reduced Treatment Regimen vs Placebo |
| Statistical analysis description: Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor | |
| Comparison groups | Golimumab Q2M (Reduced Treatment Regimen) v Placebo (Treatment Withdrawal Regimen) |
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Difference in percentage |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.9 |
| upper limit | 5.8 |

| | |
|---|--|
| Statistical analysis title | Full Treatment Regimen vs Placebo |
| Statistical analysis description: | |
| Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor | |
| Comparison groups | Golimumab QM (Full Treatment Regimen) v Placebo (Treatment Withdrawal Regimen) |
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Difference in percentage |
| Point estimate | 0 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -5.9 |
| upper limit | 5.8 |

Secondary: Percentage of Participants Achieving ASAS40 Response (Open-label retreatment)

| | |
|---|---|
| End point title | Percentage of Participants Achieving ASAS40 Response (Open-label retreatment) |
| End point description: | |
| ASAS40 is 40% improvement in response (per the Assessment in Ankylosing Spondylitis International Working Group) meeting 2 criteria: 1) improvement of ≥40% from Baseline and an improvement from Baseline of ≥2.0 in at least 3 of 4 domains, and 2) no deterioration from in the potential remaining domain. Baseline is defined as the last ASAS score prior to the first dose of double-blind treatment in Period 2. The ASAS consists of 4 domains: the PGDn, total back pain, BASFI, and morning stiffness (mean of questions 5 and 6 of BASDAI). Each domain is measured on a 10-point scale from 0=no disease symptoms/impact to 10=extreme disease symptoms/impact. A higher score indicates more severe impairment. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥1 dose of double-blind study intervention. | |
| End point type | Secondary |
| End point timeframe: | |
| Up to 12 months | |

| | | | | |
|-----------------------------------|------------------------|--|--|--|
| End point values | Open-Label Retreatment | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 53 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 90.6 (79.3 to 96.9) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving ASAS Partial Remission (Double-blind treatment)

| | |
|-----------------|--|
| End point title | Percentage of Participants Achieving ASAS Partial Remission (Double-blind treatment) |
|-----------------|--|

End point description:

ASAS partial remission is defined as a score of ≤ 2 in all 4 ASAS domains. Baseline for this analysis is defined as the ASAS score prior to the first dose of double-blind treatment in Period 2. The ASAS consists of 4 domains: Patient Global Disease Assessment (PGDn), total back pain, function (Bath Ankylosing Spondylitis Functional Index [BASFI]), and morning stiffness (mean of questions 5 and 6 of Bath Ankylosing Spondylitis Disease Activity Index [BASDAI]). Each domain is measured on a 10-point numeric scale from 0=no disease symptoms/impact to 10=extreme disease symptoms/impact, with a higher score indicating more severe impairment. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥ 1 dose of double-blind study intervention.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Up to 12 months | |

| End point values | Golimumab QM (Full Treatment Regimen) | Golimumab Q2M (Reduced Treatment Regimen) | Placebo (Treatment Withdrawal Regimen) | |
|-----------------------------------|---------------------------------------|---|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 63 | 63 | 62 | |
| Units: Percentage of participants | | | | |
| number (not applicable) | 85.7 | 85.7 | 71.0 | |

Statistical analyses

| | |
|----------------------------|-----------------------------------|
| Statistical analysis title | Full Treatment Regimen vs Placebo |
|----------------------------|-----------------------------------|

Statistical analysis description:

Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor

| | |
|---|--|
| Comparison groups | Golimumab QM (Full Treatment Regimen) v Placebo (Treatment Withdrawal Regimen) |
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Difference in percentage |
| Point estimate | 14.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 29 |

| | |
|----------------------------|--------------------------------------|
| Statistical analysis title | Reduced Treatment Regimen vs Placebo |
|----------------------------|--------------------------------------|

Statistical analysis description:

Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor

| | |
|---|--|
| Comparison groups | Golimumab Q2M (Reduced Treatment Regimen) v Placebo (Treatment Withdrawal Regimen) |
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Difference in percentage |
| Point estimate | 14.7 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.2 |
| upper limit | 29.1 |

Secondary: Percentage of Participants Achieving ASAS Partial Remission (Open-label retreatment)

| | |
|-----------------|--|
| End point title | Percentage of Participants Achieving ASAS Partial Remission (Open-label retreatment) |
|-----------------|--|

End point description:

ASAS partial remission is defined as a score of ≤2 in all 4 ASAS domains. Baseline for this analysis is defined as the ASAS score prior to the first dose of open-label retreatment in Period 2. The ASAS consists of 4 domains: Patient Global Disease Assessment (PGDn), total back pain, function (Bath Ankylosing Spondylitis Functional Index [BASFI]), and morning stiffness (mean of questions 5 and 6 of Bath Ankylosing Spondylitis Disease Activity Index [BASDAI]). Each domain is measured on a 10-point numeric scale from 0=no disease symptoms/impact to 10=extreme disease symptoms/impact, with a higher score indicating more severe impairment. The population is all participants who had inactive disease in Period 1, were randomized to reduced-treatment regimen or placebo in Period 2, received ≥1 dose of double-blind study intervention, and experienced disease flare in Period 2.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to 12 months

| | | | | |
|-----------------------------------|------------------------|--|--|--|
| End point values | Open-Label Retreatment | | | |
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 53 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 92.5 (81.8 to 97.9) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving BASDAI50 Response (Double-blind Treatment)

| | |
|---|---|
| End point title | Percentage of Participants Achieving BASDAI50 Response (Double-blind Treatment) |
| End point description: BASDAI50 is defined as $\geq 50\%$ improvement from baseline in the Bath Ankylosing Spondylitis Disease Assessment Index (BASDAI) score. Baseline for BASDAI50 analysis is defined as the last BASDAI score prior to the first dose of double-blind treatment in Period 2. The BASDAI is a summary of 6 participant-assessed measures rated on scales of 0 (none) to 10 (very severe): fatigue, spinal pain, joint pain/swelling, tenderness, morning stiffness, and duration of morning stiffness [0 (zero) to 10 (2 or more hours)]. The BASDAI score is the mean of responses to the 6 questions with a minimum of 0 and a maximum of 10. A higher score indicates greater disease activity. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥ 1 dose of double-blind study intervention. | |
| End point type | Secondary |
| End point timeframe: Up to 12 months | |

| End point values | Golimumab QM (Full Treatment Regimen) | Golimumab Q2M (Reduced Treatment Regimen) | Placebo (Treatment Withdrawal Regimen) | |
|-----------------------------------|---------------------------------------|---|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 63 | 63 | 62 | |
| Units: Percentage of participants | | | | |
| number (not applicable) | 49.2 | 30.2 | 24.2 | |

Statistical analyses

| | |
|--|--|
| Statistical analysis title | Reduced Treatment Regimen vs Placebo |
| Statistical analysis description: Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor | |
| Comparison groups | Golimumab Q2M (Reduced Treatment Regimen) v Placebo (Treatment Withdrawal Regimen) |
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Difference in percentage |
| Point estimate | 5.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -9.9 |
| upper limit | 21.3 |

| | |
|--|-----------------------------------|
| Statistical analysis title | Full Treatment Regimen vs Placebo |
| Statistical analysis description: Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor | |

| | |
|---|--|
| Comparison groups | Golimumab QM (Full Treatment Regimen) v Placebo (Treatment Withdrawal Regimen) |
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Difference in percentage |
| Point estimate | 24.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 8.5 |
| upper limit | 40.3 |

Secondary: Percentage of Participants Achieving BASDAI50 Response (Open-label Retreatment)

| | |
|---|---|
| End point title | Percentage of Participants Achieving BASDAI50 Response (Open-label Retreatment) |
| End point description: | |
| BASDAI50 is defined as $\geq 50\%$ improvement from baseline in the Bath Ankylosing Spondylitis Disease Assessment Index (BASDAI) score. Baseline for BASDAI50 analysis is defined as the last BASDAI score prior to the first dose of open-label retreatment in Period 2. The BASDAI is a summary of 6 participant-assessed measures rated on scales of 0 (none) to 10 (very severe): fatigue, spinal pain, joint pain/swelling, tenderness, morning stiffness, and duration of morning stiffness [0 (zero) to 10 (2 or more hours)]. The BASDAI score is the mean of responses to the 6 questions with a minimum of 0 and a maximum of 10. A higher score indicates greater disease activity. The population is all participants who had inactive disease in Period 1, were randomized to reduced-treatment regimen or placebo in Period 2, received ≥ 1 dose of double-blind study intervention, and experienced disease flare in Period 2. | |
| End point type | Secondary |
| End point timeframe: | |
| Up to 12 months | |

| End point values | Open-Label Retreatment | | | |
|-----------------------------------|------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 53 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 98.1 (89.9 to 100.0) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Achieving Inactive Disease Status (Double-Blind Treatment)

| | |
|-----------------|---|
| End point title | Percentage of Participants Achieving Inactive Disease Status (Double-Blind Treatment) |
|-----------------|---|

End point description:

Inactive disease status is defined as an ASDAS score <1.3. The ASDAS is a composite index assessing disease activity in axial spondyloarthropathies that consists of 4 self-assessed parameters and 1 laboratory parameter. The self-assessed parameters of back pain, duration of morning stiffness, Patient Global Disease Assessment (PGDn), and peripheral pain/swelling are individually scored on a numeric scale of 0 to 10, with 0 being low activity/impact and 10 being high activity/impact. The self-assessed criteria and the laboratory value of CRP are combined to provide the total ASDAS score, which has a lower limit of 0.6 and no defined upper limit. A higher score indicates greater disease activity. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥ 1 dose of double-blind study intervention.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to 12 months

| End point values | Golimumab QM (Full Treatment Regimen) | Golimumab Q2M (Reduced Treatment Regimen) | Placebo (Treatment Withdrawal Regimen) | |
|-----------------------------------|---------------------------------------|---|--|--|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 63 | 63 | 62 | |
| Units: Percentage of participants | | | | |
| number (not applicable) | 85.7 | 84.1 | 61.3 | |

Statistical analyses

| | |
|-----------------------------------|-----------------------------------|
| Statistical analysis title | Full Treatment Regimen vs Placebo |
|-----------------------------------|-----------------------------------|

Statistical analysis description:

Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor

| | |
|---|--|
| Comparison groups | Golimumab QM (Full Treatment Regimen) v Placebo (Treatment Withdrawal Regimen) |
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Difference in percentage |
| Point estimate | 24.4 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 9.1 |
| upper limit | 39 |

| | |
|-----------------------------------|--------------------------------------|
| Statistical analysis title | Reduced Treatment Regimen vs Placebo |
|-----------------------------------|--------------------------------------|

Statistical analysis description:

Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor

| | |
|-------------------|--|
| Comparison groups | Golimumab Q2M (Reduced Treatment Regimen) v Placebo (Treatment Withdrawal Regimen) |
|-------------------|--|

| | |
|---|--------------------------|
| Number of subjects included in analysis | 125 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| Parameter estimate | Difference in percentage |
| Point estimate | 22.8 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 7.3 |
| upper limit | 37.7 |

Secondary: Percentage of Participants Achieving Inactive Disease Status (Open-label retreatment)

| | |
|-----------------|---|
| End point title | Percentage of Participants Achieving Inactive Disease Status (Open-label retreatment) |
|-----------------|---|

End point description:

Inactive disease status is defined as an ASDAS score <1.3. The ASDAS is a composite index assessing disease activity in axial spondyloarthropathies that consists of 4 self-assessed parameters and 1 laboratory parameter. The self-assessed parameters of back pain, duration of morning stiffness, Patient Global Disease Assessment (PGDn), and peripheral pain/swelling are individually scored on a numeric scale of 0 to 10, with 0 being low activity/impact and 10 being high activity/impact. The self-assessed criteria and the laboratory value of CRP are combined to provide the total ASDAS score, which has a lower limit of 0.6 and no defined upper limit. A higher score indicates greater disease activity. The population is all participants who had inactive disease in Period 1, were randomized to reduced-treatment regimen or placebo in Period 2, received ≥1 dose of double-blind study intervention, and experienced disease flare in Period 2.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to 12 months

| End point values | Open-Label Retreatment | | | |
|-----------------------------------|------------------------|--|--|--|
| Subject group type | Reporting group | | | |
| Number of subjects analysed | 53 | | | |
| Units: Percentage of participants | | | | |
| number (confidence interval 95%) | 90.6 (79.3 to 96.9) | | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Experienced an Adverse Event (AE) in Period 2

| | |
|-----------------|--|
| End point title | Percentage of Participants Who Experienced an Adverse Event (AE) in Period 2 |
|-----------------|--|

End point description:

This endpoint evaluated the safety and tolerability of withdrawing from or continuing treatment with

golimumab in Period 2. An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant administered a study treatment and which does not necessarily have to have a causal relationship with this treatment. An AE could be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a study treatment, whether or not considered related to the study treatment. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a preexisting condition that is temporally associated with the use of study treatment, is also an AE. The analysis includes AEs that occurred through 90 days after the last dose of study treatment. The analysis population consists of all participants who received at least one dose of study intervention in Period 2.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to approximately 15 months

| End point values | Golimumab QM (Full Treatment Regimen) | Open-Label Retreatment | Golimumab Q2M (Reduced Treatment Regimen) | Placebo (Treatment Withdrawal Regimen) |
|-----------------------------------|---------------------------------------|------------------------|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 63 | 63 | 64 | 62 |
| Units: Percentage of participants | | | | |
| number (not applicable) | 46.0 | 41.3 | 46.9 | 32.3 |

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants Who Discontinued Study Treatment Due to an AE in Period 2

| | |
|-----------------|--|
| End point title | Percentage of Participants Who Discontinued Study Treatment Due to an AE in Period 2 |
|-----------------|--|

End point description:

This endpoint evaluated the safety and tolerability of withdrawing from or continuing treatment with golimumab in Period 2. An AE is defined as any untoward medical occurrence in a participant or clinical investigation participant administered a study treatment and which does not necessarily have to have a causal relationship with this treatment. An AE could be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a study treatment, whether or not considered related to the study treatment. Any worsening (i.e., any clinically significant adverse change in frequency and/or intensity) of a preexisting condition that is temporally associated with the use of study treatment, is also an AE. The analysis population consists of all participants who received at least one dose of study intervention in Period 2.

| | |
|----------------|-----------|
| End point type | Secondary |
|----------------|-----------|

End point timeframe:

Up to approximately 12 months

| End point values | Golimumab QM (Full Treatment Regimen) | Open-Label Retreatment | Golimumab Q2M (Reduced Treatment Regimen) | Placebo (Treatment Withdrawal Regimen) |
|-----------------------------------|---------------------------------------|------------------------|---|--|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 63 | 63 | 64 | 62 |
| Units: Percentage of participants | | | | |
| number (not applicable) | 0.0 | 0.0 | 4.7 | 1.6 |

Statistical analyses

No statistical analyses for this end point

Other pre-specified: Percentage of Participants Without a Disease Activity Flare During Period 2 (Full Treatment Regimen versus Withdrawal Regimens)

| | |
|--|---|
| End point title | Percentage of Participants Without a Disease Activity Flare During Period 2 (Full Treatment Regimen versus Withdrawal Regimens) |
| End point description: | |
| Disease flare is defined as Ankylosing Spondylitis Disease Activity Score (ASDAS) at 2 consecutive visits that both show either score ≥ 2.1 or a post-withdrawal increase of ≥ 1.1 relative to baseline prior to the first dose in Period 2. ASDAS is a composite index assessing disease activity in axial spondyloarthropathies consisting of 4 self-assessed parameters and 1 laboratory parameter. The parameters of back pain, duration of morning stiffness, Patient Global Disease Assessment (PGDn), and peripheral pain/swelling are scored on a numeric scale of 0 (low activity/impact) to 10 (high activity/impact). The self-assessed criteria and the laboratory value of CRP are combined to provide the total ASDAS score, which has a lower limit of 0.6 and no defined upper limit. A higher score indicates greater disease activity. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥ 1 dose of double-blind study intervention. | |
| End point type | Other pre-specified |
| End point timeframe: | |
| Up to 12 months | |

| End point values | Golimumab QM (Full Treatment Regimen) | Golimumab Q2M and Placebo (Withdrawal Regimens) | | |
|-----------------------------------|---------------------------------------|---|--|--|
| Subject group type | Reporting group | Subject analysis set | | |
| Number of subjects analysed | 63 | 125 | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | 84.1 | 51.2 | | |

Statistical analyses

| | |
|---|---|
| Statistical analysis title | Full Treatment Regimen vs Withdrawal Regimens |
| Statistical analysis description: | |
| Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L) as a stratification factor | |
| Comparison groups | Golimumab QM (Full Treatment Regimen) v Golimumab Q2M |

| | |
|---|-----------------------------------|
| | and Placebo (Withdrawal Regimens) |
| Number of subjects included in analysis | 188 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.001 |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in percentage |
| Point estimate | 32.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 19.2 |
| upper limit | 44.5 |

Other pre-specified: Percentage of Participants Without a Disease Activity Flare During Period 2 (Full Treatment Regimen versus Reduced Treatment Regimen)

| | |
|-----------------|---|
| End point title | Percentage of Participants Without a Disease Activity Flare During Period 2 (Full Treatment Regimen versus Reduced Treatment Regimen) |
|-----------------|---|

End point description:

Disease flare is defined as Ankylosing Spondylitis Disease Activity Score (ASDAS) at 2 consecutive visits that both show either score ≥ 2.1 or a post-withdrawal increase of ≥ 1.1 relative to baseline prior to the first dose in Period 2. ASDAS is a composite index assessing disease activity in axial spondyloarthritis consisting of 4 self-assessed parameters and 1 laboratory parameter. The parameters of back pain, duration of morning stiffness, Patient Global Disease Assessment (PGDn), and peripheral pain/swelling are scored on a numeric scale of 0 (low activity/impact) to 10 (high activity/impact). The self-assessed criteria and the laboratory value of CRP are combined to provide the total ASDAS score, which has a lower limit of 0.6 and no defined upper limit. A higher score indicates greater disease activity. The analysis population is all participants who had inactive disease in Period 1, were randomized in Period 2, and received ≥ 1 dose of double-blind golimumab.

| | |
|----------------|---------------------|
| End point type | Other pre-specified |
|----------------|---------------------|

End point timeframe:

Up to 12 months

| End point values | Golimumab QM (Full Treatment Regimen) | Golimumab Q2M (Reduced Treatment Regimen) | | |
|-----------------------------------|---------------------------------------|---|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 63 | 63 | | |
| Units: Percentage of participants | | | | |
| number (not applicable) | 84.1 | 68.3 | | |

Statistical analyses

| | |
|----------------------------|-------------------------------------|
| Statistical analysis title | Full Treatment vs Reduced Treatment |
|----------------------------|-------------------------------------|

Statistical analysis description:

Derived based on the stratified Miettinen and Nurminen method with CRP level (>6 mg/L or ≤ 6 mg/L)

as a stratification factor

| | |
|---|---|
| Comparison groups | Golimumab QM (Full Treatment Regimen) v Golimumab Q2M (Reduced Treatment Regimen) |
| Number of subjects included in analysis | 126 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.037 |
| Method | Miettinen and Nurminen |
| Parameter estimate | Difference in percentage |
| Point estimate | 15.9 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.9 |
| upper limit | 30.5 |

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 10 months in Period 1 (Open-Label Run-in) and up to 15 months in Period 2 (Withdrawal vs Continued Treatment) for a total of up to 25 months.

Adverse event reporting additional description:

The safety analysis population includes all participants who received at least one dose of study intervention.

| | |
|-----------------|------------|
| Assessment type | Systematic |
|-----------------|------------|

Dictionary used

| | |
|-----------------|--------|
| Dictionary name | MedDRA |
|-----------------|--------|

| | |
|--------------------|------|
| Dictionary version | 24.0 |
|--------------------|------|

Reporting groups

| | |
|-----------------------|--------------------------------|
| Reporting group title | Open-Label Run-In Golimumab QM |
|-----------------------|--------------------------------|

Reporting group description:

Participants were treated with open-label subcutaneous (SC) injections of 50 mg golimumab once a month (QM) for up to 10 months. Participants with a body weight greater than 100 kg may have received 100 mg injections of golimumab at the discretion of the investigator.

| | |
|-----------------------|---------------------------------------|
| Reporting group title | Golimumab QM (Full Treatment Regimen) |
|-----------------------|---------------------------------------|

Reporting group description:

Participants were treated with double-blinded SC injections of 50 mg golimumab QM for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab.

| | |
|-----------------------|------------------------|
| Reporting group title | Open-Label Retreatment |
|-----------------------|------------------------|

Reporting group description:

Participants who experienced a disease flare were treated with open-label SC injections of 50 mg golimumab QM for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study.

| | |
|-----------------------|--|
| Reporting group title | Placebo (Treatment Withdrawal Regimen) |
|-----------------------|--|

Reporting group description:

Participants were treated with double-blinded SC injections of placebo for up to 12 months. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab.

| | |
|-----------------------|---|
| Reporting group title | Golimumab Q2M (Reduced Treatment Regimen) |
|-----------------------|---|

Reporting group description:

Participants were treated with double-blinded SC injections of 50 mg golimumab every other month (Q2M) alternating with matching placebo to golimumab every other month for up to 12 months. Participants with a body weight greater than 100 kg who had received 100 mg injections of golimumab in Period 1 continued to receive this dosage for the duration of the study. Participants who experienced a disease flare during double-blinded treatment in Period 2 discontinued blinded treatment and were retreated with open-label golimumab.

| Serious adverse events | Open-Label Run-In Golimumab QM | Golimumab QM (Full Treatment Regimen) | Open-Label Retreatment |
|---|--------------------------------|---------------------------------------|------------------------|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 7 / 323 (2.17%) | 1 / 63 (1.59%) | 0 / 63 (0.00%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | 0 | 0 | 0 |

| | | | |
|---|-----------------|----------------|----------------|
| Injury, poisoning and procedural complications | | | |
| Joint injury | | | |
| subjects affected / exposed | 0 / 323 (0.00%) | 1 / 63 (1.59%) | 0 / 63 (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 |
| Meniscus injury | | | |
| subjects affected / exposed | 0 / 323 (0.00%) | 0 / 63 (0.00%) | 0 / 63 (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 |
| Hepatobiliary disorders | | | |
| Cholecystitis chronic | | | |
| subjects affected / exposed | 1 / 323 (0.31%) | 0 / 63 (0.00%) | 0 / 63 (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 |
| Renal and urinary disorders | | | |
| Renal colic | | | |
| subjects affected / exposed | 1 / 323 (0.31%) | 0 / 63 (0.00%) | 0 / 63 (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 | | | |
| Arthritis | | | |
| subjects affected / exposed | 1 / 323 (0.31%) | 0 / 63 (0.00%) | 0 / 63 (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 |
| Exostosis | | | |
| subjects affected / exposed | 1 / 323 (0.31%) | 0 / 63 (0.00%) | 0 / 63 (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 |
| Joint instability | | | |
| subjects affected / exposed | 1 / 323 (0.31%) | 0 / 63 (0.00%) | 0 / 63 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Pilonidal cyst | | | |

| | | | |
|---|-----------------|----------------|----------------|
| subjects affected / exposed | 1 / 323 (0.31%) | 0 / 63 (0.00%) | 0 / 63 (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 |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 0 / 323 (0.00%) | 0 / 63 (0.00%) | 0 / 63 (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 |
| Sinusitis bacterial | | | |
| subjects affected / exposed | 1 / 323 (0.31%) | 0 / 63 (0.00%) | 0 / 63 (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 |

| Serious adverse events | Placebo (Treatment Withdrawal Regimen) | Golimumab Q2M (Reduced Treatment Regimen) | |
|---|--|---|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 62 (1.61%) | 1 / 64 (1.56%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Injury, poisoning and procedural complications | | | |
| Joint injury | | | |
| subjects affected / exposed | 0 / 62 (0.00%) | 0 / 64 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Meniscus injury | | | |
| subjects affected / exposed | 1 / 62 (1.61%) | 0 / 64 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hepatobiliary disorders | | | |
| Cholecystitis chronic | | | |
| subjects affected / exposed | 0 / 62 (0.00%) | 0 / 64 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Renal colic | | | |

| | | | |
|--|----------------|----------------|--|
| subjects affected / exposed | 0 / 62 (0.00%) | 1 / 64 (1.56%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthritis | | | |
| subjects affected / exposed | 0 / 62 (0.00%) | 0 / 64 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Exostosis | | | |
| subjects affected / exposed | 0 / 62 (0.00%) | 0 / 64 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Joint instability | | | |
| subjects affected / exposed | 0 / 62 (0.00%) | 0 / 64 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Pilonidal cyst | | | |
| subjects affected / exposed | 0 / 62 (0.00%) | 0 / 64 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 0 / 62 (0.00%) | 1 / 64 (1.56%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sinusitis bacterial | | | |
| subjects affected / exposed | 0 / 62 (0.00%) | 0 / 64 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Open-Label Run-In Golimumab QM | Golimumab QM (Full Treatment Regimen) | Open-Label Retreatment |
|--|---|---|---|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 79 / 323 (24.46%) | 13 / 63 (20.63%) | 11 / 63 (17.46%) |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) | 24 / 323 (7.43%) 39 | 4 / 63 (6.35%) 8 | 1 / 63 (1.59%) 2 |
| Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Pharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all) | 36 / 323 (11.15%) 39 12 / 323 (3.72%) 14 16 / 323 (4.95%) 24 | 6 / 63 (9.52%) 7 2 / 63 (3.17%) 2 2 / 63 (3.17%) 5 | 4 / 63 (6.35%) 4 1 / 63 (1.59%) 1 5 / 63 (7.94%) 5 |

| Non-serious adverse events | Placebo (Treatment Withdrawal Regimen) | Golimumab Q2M (Reduced Treatment Regimen) | |
|--|---|---|--|
| Total subjects affected by non-serious adverse events subjects affected / exposed | 11 / 62 (17.74%) | 17 / 64 (26.56%) | |
| Nervous system disorders Headache subjects affected / exposed occurrences (all) | 4 / 62 (6.45%) 5 | 2 / 64 (3.13%) 3 | |
| Infections and infestations Nasopharyngitis subjects affected / exposed occurrences (all) Pharyngitis subjects affected / exposed occurrences (all) Upper respiratory tract infection subjects affected / exposed occurrences (all) | 3 / 62 (4.84%) 4 3 / 62 (4.84%) 4 2 / 62 (3.23%) 3 | 6 / 64 (9.38%) 6 6 / 64 (9.38%) 9 3 / 64 (4.69%) 3 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---------------|---|
| 25 April 2017 | Amendment 1 added language regarding male contraception, pregnancy follow-up, and clarified timing of several study procedures. |

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported