# Clinical trial results:
# A Phase 2A Randomized, double-blind, Active-controlled, Parallel-group, Multicenter, Proof-of-concept Clinical Study to Evaluate the Efficacy and safety of Combination Therapy With Guselkumab and Golimumab in Participants With Moderately to Severely Active Ulcerative Colitis

## Summary

| | |
|---|---|
| EudraCT number | 2018-001510-15 |
| Trial protocol | DE PL |
| Global end of trial date | 15 November 2021 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 15 December 2022 |
| First version publication date | 15 December 2022 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | CNTO1959UCO2002 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT03662542 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Janssen Research & Development, LLC |
| Sponsor organisation address | 920 Route 202 South, Raritan, United States, 08869 |
| Public contact | Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.com |
| Scientific contact | Clinical Registry Group, Janssen Research & Development, LLC, ClinicalTrialsEU@its.jnj.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 | 15 November 2021 |
| Is this the analysis of the primary completion data? | No |

| | |
|---|---|
| Global end of trial reached? | Yes |
| Global end of trial date | 15 November 2021 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The main objective of this trial was to evaluate the clinical efficacy and safety of combination therapy with guselkumab and golimumab in subjects with moderately to severely active ulcerative colitis (UC).

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 20 November 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 | Argentina: 4 |
| Country: Number of subjects enrolled | Australia: 4 |
| Country: Number of subjects enrolled | Brazil: 9 |
| Country: Number of subjects enrolled | Germany: 2 |
| Country: Number of subjects enrolled | Mexico: 4 |
| Country: Number of subjects enrolled | Poland: 40 |
| Country: Number of subjects enrolled | Russian Federation: 71 |
| Country: Number of subjects enrolled | Ukraine: 68 |
| Country: Number of subjects enrolled | United States: 12 |
| Worldwide total number of subjects | 214 |
| EEA total number of subjects | 42 |

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) | 213 |
| From 65 to 84 years | 1 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 214 subjects were enrolled and received guselkumab and/or golimumab.

### Period 1

| | |
|---|---|
| Period 1 title | Combination Phase (Through Week 12) |
| Is this the baseline period? | Yes |
| Allocation method | Randomised - controlled |
| Blinding used | Double blind |
| Roles blinded | Subject, Investigator |

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Arm 1: Golimumab Monotherapy |

Arm description:

Subjects received golimumab 200 milligrams (mg) as subcutaneous (SC) injection at Week 0, followed by golimumab 100 mg at Weeks 2, 6 and 10. Subjects received placebo as intravenous (IV) infusion at Weeks 0, 4 and 8.

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Subjects received placebo as intravenous (IV) infusion at Weeks 0, 4 and 8.

| | |
|---|---|
| Investigational medicinal product name | Golimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received golimumab 200 mg as SC injection at Week 0, followed by golimumab 100 mg at Weeks 2, 6 and 10.

| | |
|---|---|
| **Arm title** | Arm 2: Guselkumab Monotherapy |

Arm description:

Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4 and 8. Subjects received placebo as SC injection at Weeks 0, 2, 6, and 10.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received placebo as SC injection at Weeks 0, 2, 6, and 10.

| | |
|---|---|
| Investigational medicinal product name | Guselkumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4 and 8.

| **Arm title** | Arm 3: Combination Therapy |
|---|---|

Arm description:

Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4, and 8. Subjects received golimumab 200 mg as SC injection at Week 0, followed by golimumab 100 mg as SC injection at Weeks 2, 6, and 10.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Golimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received golimumab 200 mg as SC injection at Week 0, followed by golimumab 100 mg as SC injection at Weeks 2, 6, and 10.

| | |
|---|---|
| Investigational medicinal product name | Guselkumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion |
| Routes of administration | Intravenous use |

Dosage and administration details:

Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4, and 8.

| **Number of subjects in period 1** | Arm 1: Golimumab Monotherapy | Arm 2: Guselkumab Monotherapy | Arm 3: Combination Therapy |
|---|---|---|---|
| Started | 72 | 71 | 71 |
| Completed | 67 | 70 | 71 |
| Not completed | 5 | 1 | 0 |
| Consent withdrawn by subject | 3 | - | - |
| Adverse event, non-fatal | - | 1 | - |
| Unspecified | 2 | - | - |

## Period 2

| | |
|---|---|
| Period 2 title | Monotherapy Phase (Week 12 to Week 38) |
| 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** | Arm 1: Golimumab Monotherapy |

Arm description:

Subjects received golimumab 100 mg at Weeks 14, 18, 22, 26, 30, and 34 and placebo as SC injection at Weeks 16, 24, and 32.

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received placebo as SC injection at Weeks 16, 24, and 32.

| | |
|---|---|
| Investigational medicinal product name | Golimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received golimumab 100 mg at Weeks 14, 18, 22, 26, 30, and 34.

| | |
|---|---|
| **Arm title** | Arm 2: Guselkumab Monotherapy |

Arm description:

Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24, and 32 and placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34.

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Guselkumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24, and 32.

| | |
|---|---|
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects received placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34.

| | |
|---|---|
| **Arm title** | Arm 3: Combination Therapy |

Arm description:

Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24 and 32 and placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Placebo |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

| | |
|---|---|
| Dosage and administration details:<br>Subjects received placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34. | |
| Investigational medicinal product name | Guselkumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |
| Dosage and administration details:<br>Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24 and 32. | |

| **Number of subjects in period 2** | Arm 1: Golimumab Monotherapy | Arm 2: Guselkumab Monotherapy | Arm 3: Combination Therapy |
|---|---|---|---|
| Started | 67 | 70 | 71 |
| Completed | 62 | 67 | 65 |
| Not completed | 5 | 3 | 6 |
| Consent withdrawn by subject | 4 | 1 | 1 |
| Adverse event, non-fatal | - | - | 2 |
| Death | - | - | 1 |
| Unspecified | - | 1 | 2 |
| Lost to follow-up | 1 | 1 | - |

| **Period 3** | |
|---|---|
| Period 3 title | Safety Follow-up Phase (Week 38- EOS) |
| 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** | Arm 1: Golimumab Monotherapy |
| Arm description:<br>Subjects were followed up after Week 38 to Week 50 (end of study [EOS]) and did not receive any additional medication in the safety follow-up phase. | |
| Arm type | Active comparator |
| Investigational medicinal product name | Golimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |
| Dosage and administration details:<br>Subjects did not receive any additional medication in the safety follow-up phase. | |
| **Arm title** | Arm 2: Guselkumab Monotherapy |

Arm description:

Subjects were followed up after Week 38 to Week 50 (EOS) and did not receive any additional medication in the safety follow-up phase.

| | |
|---|---|
| Arm type | Active comparator |
| Investigational medicinal product name | Guselkumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion, Injection |
| Routes of administration | Intravenous use, Subcutaneous use |

Dosage and administration details:

Subjects did not receive any additional medication in the safety follow-up phase.

| | |
|---|---|
| **Arm title** | Arm 3: Combination Therapy |

Arm description:

Subjects were followed up after Week 38 to Week 50 (EOS) and did not receive any additional medication in the safety follow-up phase.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Guselkumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for infusion, Injection |
| Routes of administration | Subcutaneous use, Intravenous use |

Dosage and administration details:

Subjects did not receive any additional medication in the safety follow-up phase.

| | |
|---|---|
| Investigational medicinal product name | Golimumab |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Subjects did not receive any additional medication in the safety follow-up phase.

| **Number of subjects in period 3[1]** | Arm 1: Golimumab Monotherapy | Arm 2: Guselkumab Monotherapy | Arm 3: Combination Therapy |
|---|---|---|---|
| Started | 58 | 65 | 60 |
| Completed | 55 | 58 | 55 |
| Not completed | 3 | 7 | 5 |
| Consent withdrawn by subject | 1 | - | 2 |
| Death | - | 1 | - |
| Unspecified | 1 | 6 | 2 |
| Lost to follow-up | 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: Out of 194 subjects (who completed Period-2 [monotherapy phase]), 183 subjects started the Period-3 (safety follow-up phase).

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Arm 1: Golimumab Monotherapy |
| Reporting group description: | |
| Subjects received golimumab 200 milligrams (mg) as subcutaneous (SC) injection at Week 0, followed by golimumab 100 mg at Weeks 2, 6 and 10. Subjects received placebo as intravenous (IV) infusion at Weeks 0, 4 and 8. | |
| Reporting group title | Arm 2: Guselkumab Monotherapy |
| Reporting group description: | |
| Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4 and 8. Subjects received placebo as SC injection at Weeks 0, 2, 6, and 10. | |
| Reporting group title | Arm 3: Combination Therapy |
| Reporting group description: | |
| Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4, and 8. Subjects received golimumab 200 mg as SC injection at Week 0, followed by golimumab 100 mg as SC injection at Weeks 2, 6, and 10. | |

| Reporting group values | Arm 1: Golimumab Monotherapy | Arm 2: Guselkumab Monotherapy | Arm 3: Combination Therapy |
|---|---|---|---|
| Number of subjects | 72 | 71 | 71 |
| Title for AgeCategorical<br>Units: subjects | | | |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 72 | 70 | 71 |
| From 65 to 84 years | 0 | 1 | 0 |
| 85 years and over | 0 | 0 | 0 |
| Title for AgeContinuous<br>Units: years | | | |
| arithmetic mean | 38.1 | 39.1 | 37.8 |
| standard deviation | ± 10.47 | ± 13.67 | ± 11.69 |
| Title for Gender<br>Units: subjects | | | |
| Female | 30 | 31 | 37 |
| Male | 42 | 40 | 34 |

| Reporting group values | Total | | |
|---|---|---|---|
| Number of subjects | 214 | | |
| Title for AgeCategorical<br>Units: subjects | | | |
| Children (2-11 years) | 0 | | |
| Adolescents (12-17 years) | 0 | | |
| Adults (18-64 years) | 213 | | |
| From 65 to 84 years | 1 | | |
| 85 years and over | 0 | | |
| Title for AgeContinuous<br>Units: years | | | |
| arithmetic mean | | | |
| standard deviation | - | | |

| Title for Gender<br>Units: subjects | | | |
|---|---|---|---|
| Female | 98 | | |
| Male | 116 | | |

## End points

### End points reporting groups

| Reporting group title | Arm 1: Golimumab Monotherapy |
|---|---|
| Reporting group description: | |
| Subjects received golimumab 200 milligrams (mg) as subcutaneous (SC) injection at Week 0, followed by golimumab 100 mg at Weeks 2, 6 and 10. Subjects received placebo as intravenous (IV) infusion at Weeks 0, 4 and 8. | |
| Reporting group title | Arm 2: Guselkumab Monotherapy |
| Reporting group description: | |
| Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4 and 8. Subjects received placebo as SC injection at Weeks 0, 2, 6, and 10. | |
| Reporting group title | Arm 3: Combination Therapy |
| Reporting group description: | |
| Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4, and 8. Subjects received golimumab 200 mg as SC injection at Week 0, followed by golimumab 100 mg as SC injection at Weeks 2, 6, and 10. | |
| Reporting group title | Arm 1: Golimumab Monotherapy |
| Reporting group description: | |
| Subjects received golimumab 100 mg at Weeks 14, 18, 22, 26, 30, and 34 and placebo as SC injection at Weeks 16, 24, and 32. | |
| Reporting group title | Arm 2: Guselkumab Monotherapy |
| Reporting group description: | |
| Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24, and 32 and placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34. | |
| Reporting group title | Arm 3: Combination Therapy |
| Reporting group description: | |
| Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24 and 32 and placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34. | |
| Reporting group title | Arm 1: Golimumab Monotherapy |
| Reporting group description: | |
| Subjects were followed up after Week 38 to Week 50 (end of study [EOS]) and did not receive any additional medication in the safety follow-up phase. | |
| Reporting group title | Arm 2: Guselkumab Monotherapy |
| Reporting group description: | |
| Subjects were followed up after Week 38 to Week 50 (EOS) and did not receive any additional medication in the safety follow-up phase. | |
| Reporting group title | Arm 3: Combination Therapy |
| Reporting group description: | |
| Subjects were followed up after Week 38 to Week 50 (EOS) and did not receive any additional medication in the safety follow-up phase. | |

### Primary: Percentage of Subjects Who Achieved Clinical Response at Week 12

| End point title | Percentage of Subjects Who Achieved Clinical Response at Week 12[1] |
|---|---|
| End point description: | |
| Clinical response is defined as a decrease from baseline in the Mayo score greater than or equal to (>=) 30 percent (%) and >=3 points with either a decrease from baseline in the rectal bleeding subscore (RBS) >=1 or a RBS of 0 or 1. The Mayo score was calculated as the sum of 4 subscores (stool frequency, rectal bleeding, physician's global assessment, and endoscopy findings - each with score range of 0 (normal activity) to 3 (severe activity) and a total score range of 0 to 12 points. A score of 3 to 5 points indicates mildly active disease, a score of 6 to 10 points indicates moderately active disease, and a score of 11 to 12 points indicates severely active disease. Efficacy analyses were based on the Full Analysis Set (FAS), which included all randomised subjects who received at least 1 (partial or complete) | |

dose of study intervention.

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

End point timeframe:

Week 12

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: No inferential statistics was done. Only descriptive statistics was performed.

| **End point values** | Arm 1: Golimumab Monotherapy | Arm 2: Guselkumab Monotherapy | Arm 3: Combination Therapy | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 72 | 71 | 71 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | 61.1 | 74.6 | 83.1 | |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects Who Achieved Clinical Remission at Week 12

| End point title | Percentage of Subjects Who Achieved Clinical Remission at Week 12 |
|---|---|

End point description:

Clinical remission (legacy definition) is defined as the Mayo score less than or equal to (<=) 2 with no individual subscore greater than (>) 1. The Mayo score was calculated as the sum of 4 subscores (stool frequency, rectal bleeding, physician's global assessment, and endoscopy findings) each with score range of 0 (normal activity) to 3 (severe activity) and a total score range of 0 to 12 points. A score of 3 to 5 points indicates mildly active disease, a score of 6 to 10 points indicates moderately active disease, and a score of 11 to 12 points indicates severely active disease. Efficacy analyses were based on the FAS, which included all randomised subjects who received at least 1 (partial or complete) dose of study intervention.

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

End point timeframe:

Week 12

| **End point values** | Arm 1: Golimumab Monotherapy | Arm 2: Guselkumab Monotherapy | Arm 3: Combination Therapy | |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | |
| Number of subjects analysed | 72 | 71 | 71 | |
| Units: Percentage of subjects | | | | |
| number (not applicable) | 22.2 | 21.1 | 36.6 | |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Up to Week 50

Adverse event reporting additional description:

The safety analysis set included all randomised subjects who received at least 1 (partial or complete) dose of study intervention.

| | |
|---|---|
| Assessment type | Non-systematic |

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 24.1 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Combination Phase: Arm 1: Golimumab Monotherapy |

Reporting group description:

Subjects received golimumab 200 milligrams (mg) as subcutaneous (SC) injection at Week 0, followed by golimumab 100 mg at Weeks 2, 6 and 10. Subjects received placebo as intravenous (IV) infusion at Weeks 0, 4 and 8.

| | |
|---|---|
| Reporting group title | Safety Follow-up Phase: Arm 2: Guselkumab Monotherapy |

Reporting group description:

Subjects were followed up after Week 38 to Week 50 (EOS) and did not receive any additional medication in the safety follow-up phase.

| | |
|---|---|
| Reporting group title | Safety Follow-up Phase: Arm 3: Combination Therapy |

Reporting group description:

Subjects were followed up after Week 38 to Week 50 (EOS) and did not receive any additional medication in the safety follow-up phase.

| | |
|---|---|
| Reporting group title | Monotherapy Phase: Arm 3: Combination Therapy |

Reporting group description:

Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24 and 32 and placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34.

| | |
|---|---|
| Reporting group title | Combination Phase: Arm 3: Combination Therapy |

Reporting group description:

Subjects received guselkumab 200 mg as IV infusion at Weeks 0, 4, and 8. Subjects received golimumab 200 mg as SC injection at Week 0, followed by golimumab 100 mg as SC injection at Weeks 2, 6, and 10.

| | |
|---|---|
| Reporting group title | Monotherapy Phase: Arm 1: Golimumab Monotherapy |

Reporting group description:

Subjects received golimumab 100 mg at Week 14, 18, 22, 26, 30, and 34 and placebo as SC injection at Weeks 16, 24, and 32.

| | |
|---|---|
| Reporting group title | Monotherapy Phase: Arm 2: Guselkumab Monotherapy |

Reporting group description:

Subjects received guselkumab 100 mg as SC injection at Weeks 16, 24, and 32 and placebo as SC injection at Weeks 14, 18, 22, 26, 30, and 34.

| | |
|---|---|
| Reporting group title | Safety Follow-up Phase: Arm 1: Golimumab Monotherapy |

Reporting group description:

Subjects were followed up after Week 38 to Week 50 (end of study [EOS]) and did not receive any additional medication in the safety follow-up phase.

| | |
|---|---|
| Reporting group title | Combination Phase: Arm 2: Guselkumab Monotherapy |

Reporting group description:

Subjects received guselkumab 200 mg as IV infusion at Week 0, 4 and 8. Subjects received placebo as SC injection at Weeks 0, 2, 6, and 10.

| **Serious adverse events** | Combination Phase: Arm 1: Golimumab Monotherapy | Safety Follow-up Phase: Arm 2: Guselkumab Monotherapy | Safety Follow-up Phase: Arm 3: Combination Therapy |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 72 (1.39%) | 2 / 65 (3.08%) | 0 / 60 (0.00%) |
| number of deaths (all causes) | 0 | 1 | 0 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adenocarcinoma of Colon | | | |
| subjects affected / exposed | 0 / 72 (0.00%) | 1 / 65 (1.54%) | 0 / 60 (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 |
| Injury, poisoning and procedural complications | | | |
| Poisoning | | | |
| subjects affected / exposed | 0 / 72 (0.00%) | 0 / 65 (0.00%) | 0 / 60 (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 |
| Cardiac disorders | | | |
| Atrial Fibrillation | | | |
| subjects affected / exposed | 0 / 72 (0.00%) | 0 / 65 (0.00%) | 0 / 60 (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 |
| Gastrointestinal disorders | | | |
| Colitis Ulcerative | | | |
| subjects affected / exposed | 1 / 72 (1.39%) | 0 / 65 (0.00%) | 0 / 60 (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 |
| Gastrointestinal Haemorrhage | | | |
| subjects affected / exposed | 0 / 72 (0.00%) | 1 / 65 (1.54%) | 0 / 60 (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 |
| Small Intestinal Obstruction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 72 (0.00%) | 0 / 65 (0.00%) | 0 / 60 (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 | | | |
| Pulmonary Embolism | | | |
| subjects affected / exposed | 0 / 72 (0.00%) | 0 / 65 (0.00%) | 0 / 60 (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 | | | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 72 (0.00%) | 0 / 65 (0.00%) | 0 / 60 (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 |
| Chronic Sinusitis | | | |
| subjects affected / exposed | 0 / 72 (0.00%) | 0 / 65 (0.00%) | 0 / 60 (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 |
| Covid-19 | | | |
| subjects affected / exposed | 0 / 72 (0.00%) | 1 / 65 (1.54%) | 0 / 60 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| Covid-19 Pneumonia | | | |
| subjects affected / exposed | 0 / 72 (0.00%) | 0 / 65 (0.00%) | 0 / 60 (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 |
| Influenza | | | |
| subjects affected / exposed | 0 / 72 (0.00%) | 0 / 65 (0.00%) | 0 / 60 (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 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 72 (0.00%) | 0 / 65 (0.00%) | 0 / 60 (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 |

| | | | |
|---|---|---|---|
| Tuberculosis of Intrathoracic Lymph Nodes | | | |
| subjects affected / exposed | 0 / 72 (0.00%) | 0 / 65 (0.00%) | 0 / 60 (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 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 72 (0.00%) | 0 / 65 (0.00%) | 0 / 60 (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** | Monotherapy Phase: Arm 3: Combination Therapy | Combination Phase: Arm 3: Combination Therapy | Monotherapy Phase: Arm 1: Golimumab Monotherapy |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 3 / 71 (4.23%) | 1 / 71 (1.41%) | 3 / 67 (4.48%) |
| number of deaths (all causes) | 1 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adenocarcinoma of Colon | | | |
| subjects affected / exposed | 0 / 71 (0.00%) | 0 / 71 (0.00%) | 0 / 67 (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 |
| Injury, poisoning and procedural complications | | | |
| Poisoning | | | |
| subjects affected / exposed | 1 / 71 (1.41%) | 0 / 71 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 0 |
| Cardiac disorders | | | |
| Atrial Fibrillation | | | |
| subjects affected / exposed | 0 / 71 (0.00%) | 0 / 71 (0.00%) | 0 / 67 (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 |
| Gastrointestinal disorders | | | |
| Colitis Ulcerative | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 71 (0.00%) | 0 / 71 (0.00%) | 0 / 67 (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 |
| Gastrointestinal Haemorrhage | | | |
| subjects affected / exposed | 0 / 71 (0.00%) | 0 / 71 (0.00%) | 0 / 67 (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 |
| Small Intestinal Obstruction | | | |
| subjects affected / exposed | 0 / 71 (0.00%) | 0 / 71 (0.00%) | 0 / 67 (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 | | | |
| Pulmonary Embolism | | | |
| subjects affected / exposed | 1 / 71 (1.41%) | 0 / 71 (0.00%) | 1 / 67 (1.49%) |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 0 / 71 (0.00%) | 0 / 71 (0.00%) | 0 / 67 (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 |
| Chronic Sinusitis | | | |
| subjects affected / exposed | 0 / 71 (0.00%) | 0 / 71 (0.00%) | 1 / 67 (1.49%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 1 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Covid-19 | | | |
| subjects affected / exposed | 0 / 71 (0.00%) | 0 / 71 (0.00%) | 0 / 67 (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 |
| Covid-19 Pneumonia | | | |
| subjects affected / exposed | 0 / 71 (0.00%) | 0 / 71 (0.00%) | 1 / 67 (1.49%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| | | | |
|---|---|---|---|
| Influenza | | | |
| subjects affected / exposed | 0 / 71 (0.00%) | 1 / 71 (1.41%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 71 (0.00%) | 1 / 71 (1.41%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Tuberculosis of Intrathoracic Lymph Nodes | | | |
| subjects affected / exposed | 1 / 71 (1.41%) | 0 / 71 (0.00%) | 0 / 67 (0.00%) |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 1 / 71 (1.41%) | 0 / 71 (0.00%) | 0 / 67 (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** | Monotherapy Phase: Arm 2: Guselkumab Monotherapy | Safety Follow-up Phase: Arm 1: Golimumab Monotherapy | Combination Phase: Arm 2: Guselkumab Monotherapy |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 1 / 70 (1.43%) | 0 / 58 (0.00%) | 2 / 71 (2.82%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Adenocarcinoma of Colon | | | |
| subjects affected / exposed | 0 / 70 (0.00%) | 0 / 58 (0.00%) | 0 / 71 (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 |
| Injury, poisoning and procedural complications | | | |
| Poisoning | | | |
| subjects affected / exposed | 0 / 70 (0.00%) | 0 / 58 (0.00%) | 0 / 71 (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 |

| | | | |
|---|---|---|---|
| Cardiac disorders | | | |
| Atrial Fibrillation | | | |
| subjects affected / exposed | 0 / 70 (0.00%) | 0 / 58 (0.00%) | 1 / 71 (1.41%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Colitis Ulcerative | | | |
| subjects affected / exposed | 0 / 70 (0.00%) | 0 / 58 (0.00%) | 0 / 71 (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 |
| Gastrointestinal Haemorrhage | | | |
| subjects affected / exposed | 0 / 70 (0.00%) | 0 / 58 (0.00%) | 0 / 71 (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 |
| Small Intestinal Obstruction | | | |
| subjects affected / exposed | 0 / 70 (0.00%) | 0 / 58 (0.00%) | 1 / 71 (1.41%) |
| 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 | | | |
| Pulmonary Embolism | | | |
| subjects affected / exposed | 0 / 70 (0.00%) | 0 / 58 (0.00%) | 0 / 71 (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 | | | |
| Bronchitis | | | |
| subjects affected / exposed | 1 / 70 (1.43%) | 0 / 58 (0.00%) | 0 / 71 (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 |
| Chronic Sinusitis | | | |
| subjects affected / exposed | 0 / 70 (0.00%) | 0 / 58 (0.00%) | 0 / 71 (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 |
| Covid-19 | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 70 (0.00%) | 0 / 58 (0.00%) | 0 / 71 (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 |
| Covid-19 Pneumonia | | | |
| subjects affected / exposed | 0 / 70 (0.00%) | 0 / 58 (0.00%) | 0 / 71 (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 |
| Influenza | | | |
| subjects affected / exposed | 0 / 70 (0.00%) | 0 / 58 (0.00%) | 0 / 71 (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 |
| Sepsis | | | |
| subjects affected / exposed | 0 / 70 (0.00%) | 0 / 58 (0.00%) | 0 / 71 (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 |
| Tuberculosis of Intrathoracic Lymph Nodes | | | |
| subjects affected / exposed | 0 / 70 (0.00%) | 0 / 58 (0.00%) | 0 / 71 (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 |
| Metabolism and nutrition disorders | | | |
| Dehydration | | | |
| subjects affected / exposed | 0 / 70 (0.00%) | 0 / 58 (0.00%) | 0 / 71 (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 |

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

| **Non-serious adverse events** | Combination Phase: Arm 1: Golimumab Monotherapy | Safety Follow-up Phase: Arm 2: Guselkumab Monotherapy | Safety Follow-up Phase: Arm 3: Combination Therapy |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 19 / 72 (26.39%) | 2 / 65 (3.08%) | 0 / 60 (0.00%) |
| Nervous system disorders | | | |

| | | | |
|---|---|---|---|
| Headache | | | |
| subjects affected / exposed | 2 / 72 (2.78%) | 0 / 65 (0.00%) | 0 / 60 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 5 / 72 (6.94%) | 1 / 65 (1.54%) | 0 / 60 (0.00%) |
| occurrences (all) | 5 | 1 | 0 |
| Neutropenia | | | |
| subjects affected / exposed | 2 / 72 (2.78%) | 0 / 65 (0.00%) | 0 / 60 (0.00%) |
| occurrences (all) | 2 | 0 | 0 |
| Gastrointestinal disorders | | | |
| Colitis Ulcerative | | | |
| subjects affected / exposed | 8 / 72 (11.11%) | 1 / 65 (1.54%) | 0 / 60 (0.00%) |
| occurrences (all) | 8 | 1 | 0 |
| Infections and infestations | | | |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 4 / 72 (5.56%) | 0 / 65 (0.00%) | 0 / 60 (0.00%) |
| occurrences (all) | 5 | 0 | 0 |

| **Non-serious adverse events** | Monotherapy Phase: Arm 3: Combination Therapy | Combination Phase: Arm 3: Combination Therapy | Monotherapy Phase: Arm 1: Golimumab Monotherapy |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 14 / 71 (19.72%) | 14 / 71 (19.72%) | 12 / 67 (17.91%) |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 3 / 71 (4.23%) | 4 / 71 (5.63%) | 2 / 67 (2.99%) |
| occurrences (all) | 6 | 8 | 4 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 0 / 71 (0.00%) | 4 / 71 (5.63%) | 2 / 67 (2.99%) |
| occurrences (all) | 0 | 5 | 2 |
| Neutropenia | | | |
| subjects affected / exposed | 2 / 71 (2.82%) | 2 / 71 (2.82%) | 1 / 67 (1.49%) |
| occurrences (all) | 3 | 4 | 1 |
| Gastrointestinal disorders | | | |
| Colitis Ulcerative | | | |
| subjects affected / exposed | 6 / 71 (8.45%) | 4 / 71 (5.63%) | 5 / 67 (7.46%) |
| occurrences (all) | 6 | 4 | 5 |
| Infections and infestations | | | |

| | | | |
|---|---|---|---|
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 6 / 71 (8.45%) | 1 / 71 (1.41%) | 2 / 67 (2.99%) |
| occurrences (all) | 6 | 1 | 2 |

| **Non-serious adverse events** | Monotherapy Phase: Arm 2: Guselkumab Monotherapy | Safety Follow-up Phase: Arm 1: Golimumab Monotherapy | Combination Phase: Arm 2: Guselkumab Monotherapy |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 16 / 70 (22.86%) | 3 / 58 (5.17%) | 16 / 71 (22.54%) |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 5 / 70 (7.14%) | 0 / 58 (0.00%) | 3 / 71 (4.23%) |
| occurrences (all) | 9 | 0 | 3 |
| Blood and lymphatic system disorders | | | |
| Anaemia | | | |
| subjects affected / exposed | 6 / 70 (8.57%) | 0 / 58 (0.00%) | 6 / 71 (8.45%) |
| occurrences (all) | 7 | 0 | 7 |
| Neutropenia | | | |
| subjects affected / exposed | 2 / 70 (2.86%) | 0 / 58 (0.00%) | 4 / 71 (5.63%) |
| occurrences (all) | 2 | 0 | 4 |
| Gastrointestinal disorders | | | |
| Colitis Ulcerative | | | |
| subjects affected / exposed | 4 / 70 (5.71%) | 3 / 58 (5.17%) | 1 / 71 (1.41%) |
| occurrences (all) | 5 | 3 | 1 |
| Infections and infestations | | | |
| Upper Respiratory Tract Infection | | | |
| subjects affected / exposed | 2 / 70 (2.86%) | 0 / 58 (0.00%) | 5 / 71 (7.04%) |
| occurrences (all) | 4 | 0 | 5 |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported