



## Clinical trial results:

### A Phase 2a, Multicenter, Randomized, Double-blind Study Evaluating the Efficacy and Safety of Subcutaneously Administered Guselkumab and Golimumab Combination Therapy in Participants with Active Psoriatic Arthritis

#### Summary

|                          |                |
|--------------------------|----------------|
| EudraCT number           | 2021-002012-31 |
| Trial protocol           | ES IT DK HU FR |
| Global end of trial date | 06 August 2024 |

#### Results information

|                                |                |
|--------------------------------|----------------|
| Result version number          | v1 (current)   |
| This version publication date  | 16 August 2025 |
| First version publication date | 16 August 2025 |

#### Trial information

##### Trial identification

|                       |                 |
|-----------------------|-----------------|
| Sponsor protocol code | CNT01959PSA2003 |
|-----------------------|-----------------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT05071664 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |   |
|------------------------------|---|
| Sponsor organisation name    | Janssen Research & Development LLC  |
| Sponsor organisation address | Turnhoutseweg 30, Beerse, Belgium, B-2340   |
| 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                       | 06 August 2024 |
| Is this the analysis of the primary completion data? | No             |
| Global end of trial reached?                         | Yes            |
| Global end of trial date                             | 06 August 2024 |
| 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 efficacy of combination therapy with guselkumab plus golimumab versus guselkumab monotherapy in subjects with active psoriatic arthritis (PsA) and inadequate response (IR) to prior anti-tumor necrosis factor-alpha (anti-TNF-alpha) therapies by assessing clinical response.

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                          | 25 October 2021 |
| 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 | Denmark: 12           |
| Country: Number of subjects enrolled | France: 1             |
| Country: Number of subjects enrolled | Hungary: 6            |
| Country: Number of subjects enrolled | Italy: 10             |
| Country: Number of subjects enrolled | Poland: 2             |
| Country: Number of subjects enrolled | Russian Federation: 4 |
| Country: Number of subjects enrolled | Spain: 22             |
| Country: Number of subjects enrolled | Ukraine: 3            |
| Country: Number of subjects enrolled | United States: 31     |
| Worldwide total number of subjects   | 91                    |
| EEA total number of subjects         | 53                    |

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)                     | 91 |
| From 65 to 84 years                      | 0  |
| 85 years and over                        | 0  |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 91 adult subjects were randomised (2:1 ratio) and treated either in Group 1 (guselkumab plus golimumab) or Group 2 (guselkumab plus placebo). Out of which 76 subjects completed the study.

### Period 1

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

### Arms

|                              |                                     |
|------------------------------|-------------------------------------|
| Are arms mutually exclusive? | Yes                                 |
| <b>Arm title</b>             | Group 1 : Guselkumab Plus Golimumab |

Arm description:

Subjects received guselkumab and golimumab using single-use prefilled syringes, once every 4 weeks (q4w; at Weeks 0, 4, 8, 12, 16, and 20).

|  |  |
|--|--|
| Arm type                               | Experimental                                 |
| Investigational medicinal product name | Golimumab                                    |
| Investigational medicinal product code |  |
| Other name                             | SIMPONI, CNTO148                             |
| Pharmaceutical forms                   | Solution for injection in pre-filled syringe |
| Routes of administration               | Subcutaneous use                             |

Dosage and administration details:

Subjects received golimumab SC injection q4w at Weeks 0, 4, 8, 12, 16, and 20.

|  |  |
|--|--|
| Investigational medicinal product name | Guselkumab                                   |
| Investigational medicinal product code |  |
| Other name                             | TREMFYA, CNTO1959                            |
| Pharmaceutical forms                   | Solution for injection in pre-filled syringe |
| Routes of administration               | Subcutaneous use                             |

Dosage and administration details:

Subjects received guselkumab SC injection q4w at Weeks 0, 4, 8, 12, 16, and 20.

|                  |                                  |
|------------------|----------------------------------|
| <b>Arm title</b> | Group 2: Guselkumab Plus Placebo |
|------------------|----------------------------------|

Arm description:

Subjects received guselkumab and placebo using single-use prefilled syringes q4w (q4w; at Weeks 0, 4, 8, 12, 16, and 20).

|  |  |
|--|--|
| Arm type                               | Active comparator                            |
| 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:

Subjects received placebo (matched golimumab) SC injection q4w at Weeks 0, 4, 8, 12, 16, and 20.

|  |  |
|--|--|
| Investigational medicinal product name | Guselkumab                                   |
| Investigational medicinal product code |  |
| Other name                             | TREMFYA, CNT01959                            |
| Pharmaceutical forms                   | Solution for injection in pre-filled syringe |
| Routes of administration               | Subcutaneous use                             |

Dosage and administration details:

Subjects received guselkumab SC injection q4w at Weeks 0, 4, 8, 12, 16, and 20.

| <b>Number of subjects in period 1</b> | Group 1 :<br>Guselkumab Plus<br>Golimumab | Group 2:<br>Guselkumab Plus<br>Placebo |
|---------------------------------------|---|--|
| Started                               | 59  | 32                                     |
| Completed                             | 48  | 28                                     |
| Not completed                         | 11  | 4                                      |
| Consent withdrawn by subject          | 3   | 3                                      |
| Unspecified                           | 5   | 1                                      |
| Lost to follow-up                     | 3   | -                                      |

## Baseline characteristics

### Reporting groups

|   |                                     |
|---|-------------------------------------|
| Reporting group title   | Group 1 : Guselkumab Plus Golimumab |
| Reporting group description:  |                                     |
| Subjects received guselkumab and golimumab using single-use prefilled syringes, once every 4 weeks (q4w; at Weeks 0, 4, 8, 12, 16, and 20). |                                     |
| Reporting group title   | Group 2: Guselkumab Plus Placebo    |
| Reporting group description:  |                                     |
| Subjects received guselkumab and placebo using single-use prefilled syringes q4w (q4w; at Weeks 0, 4, 8, 12, 16, and 20).                   |                                     |

| Reporting group values             | Group 1 :<br>Guselkumab Plus<br>Golimumab | Group 2:<br>Guselkumab Plus<br>Placebo | Total |
|------------------------------------|---|--|-------|
| Number of subjects                 | 59  | 32                                     | 91    |
| Age Categorical<br>Units: Subjects |   |  |       |

|   |                 |                 |    |
|---|-----------------|-----------------|----|
| Age continuous<br>Units: years<br>arithmetic mean<br>standard deviation | 50.2<br>± 10.53 | 47.7<br>± 10.34 | -  |
| Gender categorical<br>Units: Subjects                                   |                 |                 |    |
| Male  | 23              | 12              | 35 |
| Female  | 36              | 20              | 56 |
| Race<br>Units: Subjects   |                 |                 |    |
| American Indian or Alaska Native  | 0               | 0               | 0  |
| Asian   | 0               | 0               | 0  |
| Black or African American   | 0               | 0               | 0  |
| Native Hawaiian or other Pacific Islander                               | 0               | 0               | 0  |
| White   | 57              | 32              | 89 |
| Multiple  | 0               | 0               | 0  |
| Not Reported  | 1               | 0               | 1  |
| Unknown   | 1               | 0               | 1  |
| Ethnicity<br>Units: Subjects  |                 |                 |    |
| Hispanic or Latino  | 18              | 5               | 23 |
| Not Hispanic or Latino  | 38              | 26              | 64 |
| Not Reported  | 2               | 1               | 3  |
| Unknown   | 1               | 0               | 1  |

## End points

### End points reporting groups

|   |                                     |
|---|-------------------------------------|
| Reporting group title   | Group 1 : Guselkumab Plus Golimumab |
| Reporting group description:<br>Subjects received guselkumab and golimumab using single-use prefilled syringes, once every 4 weeks (q4w; at Weeks 0, 4, 8, 12, 16, and 20). |                                     |
| Reporting group title   | Group 2: Guselkumab Plus Placebo    |
| Reporting group description:<br>Subjects received guselkumab and placebo using single-use prefilled syringes q4w (q4w; at Weeks 0, 4, 8, 12, 16, and 20).                   |                                     |

### Primary: Percentage of Subjects who Achieved Minimal Disease Activity (MDA) at Week 24

|   |   |
|---|---|
| End point title   | Percentage of Subjects who Achieved Minimal Disease Activity (MDA) at Week 24 |
| End point description:<br>MDA: measured to indicate disease remission based on composite score of 7 domains. Subjects achieved MDA if fulfilled at least 5 of the 7 criteria: tender joint count (0 to 68 joints) less than or equal to ( $\leq$ ) 1, swollen joint count (0-66 joints) $\leq$ 1, psoriasis area and severity index (PASI) $\leq$ 1 (scale 0 [no] to 72 [maximal disease]) or body surface area (BSA) $\leq$ 3 percent (%); Patient's Global Assessment of Pain $\leq$ 15 scale 0 (no) to 100 (severe pain); Patient's Global Assessment of Disease Activity $\leq$ 20 scale 0 (very well) to 100 (very poor); Disability Index of the Health Assessment Questionnaire (HAQ-DI) score $\leq$ 0.5, HAQ-DI score ranged 0 (no difficulty) to 3 (maximum difficulty); Leeds Enthesitis Index score $\leq$ 1 for subjects with enthesitis at baseline. Full analysis set (FAS) included all subjects who were randomised in this study. |   |
| End point type  | Primary   |
| End point timeframe:<br>Week 24   |   |

| End point values              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed   | 59   | 32                                     |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 28.8   | 21.9                                   |  |  |

### Statistical analyses

|                            |  |
|----------------------------|--|
| Statistical analysis title | Statistical Analysis -1  |
| Comparison groups          | Group 2: Guselkumab Plus Placebo v Group 1 : Guselkumab Plus Golimumab |

|   |                      |
|---|----------------------|
| Number of subjects included in analysis | 91                   |
| Analysis specification                  | Pre-specified        |
| Analysis type                           | superiority          |
| P-value                                 | = 0.557              |
| Method                                  | Regression, Logistic |
| Parameter estimate                      | Odds ratio (OR)      |
| Point estimate                          | 1.4                  |
| Confidence interval                     |                      |
| level                                   | 90 %                 |
| sides                                   | 2-sided              |
| lower limit                             | 0.6                  |
| upper limit                             | 3.3                  |

### Secondary: Percentage of Subjects who Achieved American College of Rheumatology (ACR) 50 at Week 24

|  |  |
|--|--|
| End point title  | Percentage of Subjects who Achieved American College of Rheumatology (ACR) 50 at Week 24 |
| End point description:   |  |
| ACR 50 response, defined as greater than or equal to ( $\geq$ ) 50% improvement from baseline in both swollen joint (66 joints) and tender joint counts (68 joints) and $\geq$ 50% improvement from baseline in 3 of 5 ( $\geq$ 3) assessments: Physician global assessment of disease activity (0 to 100 millimetres [mm] visual analog scale [VAS; 0 = no; 100 = severe symptoms]), Patient global assessment of disease activity (arthritis) (100 mm VAS [0 = no limitation of normal activities; 100 = very poor]), Patient's global assessment of pain (100 mm VAS [0 = no pain; 100 = most severe pain]), HAQ-DI assessed degree of difficulty experienced in 8 domains of daily living activities (20 questions), total score (0 to 3) computed from item scores, lower scores indicated less disability and high-sensitivity C-reactive protein (hsCRP). FAS included all subjects who were randomised in study. |  |
| End point type   | Secondary  |
| End point timeframe:   |  |
| Week 24  |  |

| End point values              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed   | 59   | 32                                     |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 44.1   | 21.9                                   |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects who Achieved Minimal Disease Activity (MDA) at Week 16

|                 |   |
|-----------------|---|
| End point title | Percentage of Subjects who Achieved Minimal Disease Activity (MDA) at Week 16 |
|-----------------|---|



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**End point description:**

MDA: measured to indicate disease remission based on composite score of 7 domains. Subjects achieved MDA if fulfilled at least 5 of the 7 criteria: tender joint count (0 to 68 joints)  $\leq 1$ , swollen joint count (0-66 joints)  $\leq 1$ , psoriasis area and severity index (PASI)  $\leq 1$  (scale 0 [no] to 72 [maximal disease]) or body surface area (BSA)  $\leq 3$  percent (%); Patient's Global Assessment of Pain  $\leq 15$  scale 0 (no) to 100 (severe pain); Patient's Global Assessment of Disease Activity  $\leq 20$  scale 0 (very well) to 100 (very poor); Disability Index of the Health Assessment Questionnaire (HAQ-DI) score  $\leq 0.5$ , HAQ-DI score ranged 0 (no difficulty) to 3 (maximum difficulty); Leeds Enthesitis Index score  $\leq 1$  for subjects with enthesitis at baseline. FAS included all subjects who were randomised in this study.

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

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End point timeframe:

Week 16

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| End point values              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed   | 59   | 32                                     |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 32.2   | 12.5                                   |  |  |

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**Statistical analyses**

No statistical analyses for this end point

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**Secondary: Percentage of Subjects who Achieved Psoriasis Area and Severity Index (PASI) 90 Response at Week 24 Among the Subjects with  $\geq 3\%$  Body Surface Area (BSA) Psoriatic Involvement and an Investigator Global Assessment (IGA) Score of  $\geq 2$  (Mild) at Baseline**

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|                 |   |
|-----------------|---|
| End point title | Percentage of Subjects who Achieved Psoriasis Area and Severity Index (PASI) 90 Response at Week 24 Among the Subjects with $\geq 3\%$ Body Surface Area (BSA) Psoriatic Involvement and an Investigator Global Assessment (IGA) Score of $\geq 2$ (Mild) at Baseline |
|-----------------|---|

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End point description:

PASI 90 response was defined as at least a 90% reduction in PASI relative to baseline. PASI was a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body was divided into 4 regions: head and neck, trunk (including axillae and groin), upper extremities, and lower extremities (included buttocks). Each of these areas was assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90 to 100% involvement), and erythema, induration and scaling, each rated on a scale of 0 to 4. The PASI produces a numeric score range from 0 (no psoriasis) to 72 (worst condition). Higher scores indicated more severe disease. Population included all subjects with  $\geq 3\%$  BSA and IGA  $\geq 2$  at baseline.

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

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End point timeframe:

Week 24

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| End point values              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed   | 22   | 13                                     |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 54.5   | 38.5                                   |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects who Achieved PASI 100 Response at Week 24 Among the Subjects with $\geq 3\%$ BSA Psoriatic involvement and an IGA Score of $\geq 2$ (Mild) at Baseline

|  |   |
|--|---|
| End point title  | Percentage of Subjects who Achieved PASI 100 Response at Week 24 Among the Subjects with $\geq 3\%$ BSA Psoriatic involvement and an IGA Score of $\geq 2$ (Mild) at Baseline |
| End point description:<br>PASI 100 response was defined as at least a 100% reduction in PASI relative to baseline. PASI was a system used for assessing and grading the severity of psoriatic lesions and their response to therapy. In the PASI system, the body was divided into 4 regions: head and neck, trunk (including axillae and groin), upper extremities, and lower extremities (included buttocks). Each of these areas was assessed separately for the percentage of the area involved, which translates to a numeric score that ranges from 0 (indicates no involvement) to 6 (90 to 100% involvement), and erythema, induration and scaling, each rated on a scale of 0 to 4. The PASI produces a numeric score range from 0 (no psoriasis) to 72 (worst condition). Higher scores indicate more severe disease. Population included all subjects with $\geq 3\%$ BSA and IGA $\geq 2$ at baseline. |   |
| End point type   | Secondary   |
| End point timeframe:<br>Week 24  |   |

| End point values              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed   | 22   | 13                                     |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 31.8   | 30.8                                   |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects with an IGA-psoriasis Response at Week 24 Among Subjects with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of $\geq 2$ (Mild) at Baseline

|  |   |
|--|---|
| End point title  | Percentage of Subjects with an IGA-psoriasis Response at Week 24 Among Subjects with $\geq 3\%$ BSA Psoriatic Involvement and an IGA Score of $\geq 2$ (Mild) at Baseline |
| End point description:<br>IGA psoriasis response is defined as an IGA psoriasis score of 0 (cleared) or 1 (minimal) and $\geq 2$ grade reduction from baseline in the IGA psoriasis score. The IGA documents the investigator's assessment of the subject's psoriasis at a given time point. Overall lesions were graded for induration, erythema, and scaling. The subject's psoriasis was assessed as clear (0), minimal (1), mild (2), moderate (3), and severe (4) scale. The IGA score of psoriasis is based upon the average of induration, erythema, and scaling scores. The subject's psoriasis is assessed as cleared (0), minimal (1), mild (2), moderate (3), or severe (4). The IGA response was defined as a score of 0 (clear) or 1 (almost clear) with at least a 2-category improvement relative to baseline. Population included all subjects with $\geq 3\%$ BSA and IGA $\geq 2$ at baseline. |   |
| End point type   | Secondary   |
| End point timeframe:<br>Week 24  |   |

| End point values              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed   | 22   | 13                                     |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 54.5   | 61.5                                   |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Mean Change from Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) at Week 24

|  |   |
|--|---|
| End point title  | Mean Change from Baseline in Health Assessment Questionnaire-Disability Index (HAQ-DI) at Week 24 |
| End point description:<br>Mean change from baseline in HAQ-DI score was a measure of the change in the physical function. It consists of a 20-questions instrument that assesses the degree of difficulty a person has in accomplishing tasks in 8 functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping, and activities of daily living). Responses in each functional area were scored from 0 = no difficulty to 3 = inability to perform a task. Scores on each task are summed and averaged to provide an overall HAQ-DI total score ranging from 0 (least difficulty) to 3 (extreme difficulty). Lower scores were indicated of better functioning. Negative change from baseline indicates improvement of physical function. FAS included all subjects who were randomised in study. |   |
| End point type   | Secondary   |
| End point timeframe:<br>Baseline (Week 0), Week 24   |   |

| End point values                             | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|--|--|--|--|--|
| Subject group type                           | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed                  | 59   | 32                                     |  |  |
| Units: Units on a scale                      |  |  |  |  |
| least squares mean (confidence interval 90%) | -0.39 (-0.51 to -0.28)                       | -0.26 (-0.42 to -0.10)                 |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects Who had Resolution of Enthesitis at Week 24 Among the Subjects With Enthesitis at Baseline

|  |   |
|--|---|
| End point title  | Percentage of Subjects Who had Resolution of Enthesitis at Week 24 Among the Subjects With Enthesitis at Baseline |
| End point description:   |   |
| Enthesitis was an important feature of psoriatic arthritis and other spondyloarthropathies. Enthesitis assessed using the Leeds Enthesitis Index (LEI), a tool developed to assess enthesitis in subjects with PsA and evaluates the presence (score of 1) or absence (score of 0) of pain by applying local pressure to the following entheses: left and right lateral epicondyle humerus, left and right medial femoral condyle, and left and right achilles tendon insertion. The enthesitis index score was a total score of the 6 evaluated sites from 0 (0 sites with tenderness) to 6 (worst possible score; 6 sites with tenderness). A LEI score of 0 at a post baseline visit indicates resolution of enthesitis when baseline LEI >0. Population included all subjects with Enthesitis (LEI>0) at baseline. |   |
| End point type   | Secondary   |
| End point timeframe:   |   |
| Week 24  |   |

| End point values              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed   | 35   | 21                                     |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 48.6   | 52.4                                   |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects who Achieved Resolution of Dactylitis Response at Week 24 Among the Subjects with Dactylitis at Baseline

|                 |   |
|-----------------|---|
| End point title | Percentage of Subjects who Achieved Resolution of Dactylitis Response at Week 24 Among the Subjects with Dactylitis at Baseline |
|-----------------|---|

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**End point description:**

Dactylitis was characterised by swelling in both hands and feet. The severity of dactylitis is scored on a scale from 0 to 3 (0-no dactylitis, 1-mild dactylitis, 2-moderate dactylitis, and 3-severe dactylitis) for each digit. The results for each digit summed to produce final dactylitis score which is from 0 to 60. Higher score indicates more severe dactylitis. Dactylitis count was derived based on dactylitis score, each score was recorded to 0 or 1 from 0 to 3, where any score >0 was recorded as 1. For resolution of dactylitis, it was defined as subjects who had a dactylitis score greater than 0 at baseline and a score of 0 at the analysis visit. Population included all subjects with Dactylitis at baseline.

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

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End point timeframe:

Week 24

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| End point values              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed   | 13   | 8                                      |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 61.5   | 87.5                                   |  |  |

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**Statistical analyses**

No statistical analyses for this end point

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**Secondary: Mean Change from Baseline in Short Form Health Survey (SF-36) Physical Component Score (PCS) at Week 24**

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|                 |   |
|-----------------|---|
| End point title | Mean Change from Baseline in Short Form Health Survey (SF-36) Physical Component Score (PCS) at Week 24 |
|-----------------|---|

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End point description:

SF-36 was a multi-domain instrument with 36 items to evaluate health status and quality of life. It included 8 subscales (physical functioning, physical role functioning, bodily pain, general health perception, vitality, social functioning, emotional role functioning, and mental health). The scores for the 8 domains were combined into two summary scores: the physical component summary (PCS) score and the mental component summary (MCS) score. Domains 1 to 4 primarily contribute to the PCS score of the SF-36. Domains 5-8 primarily contributes to the MCS score of the SF-36. Each of the 8 domain scores and the component summary score range from 0=worst to 100=best. Higher scores represent better health status. A positive change indicates improvement while a negative change indicates worsening of health status and quality of life. FAS included all subjects who were randomised in study.

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

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End point timeframe:

Baseline (Week 0), Week 24

---

| End point values                             | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|--|--|--|--|--|
| Subject group type                           | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed                  | 59   | 32                                     |  |  |
| Units: Score on a scale                      |  |  |  |  |
| least squares mean (confidence interval 90%) | 8.84 (6.88 to 10.80)                         | 3.59 (0.92 to 6.26)                    |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects with Treatment-emergent Serious Adverse Events (TESAEs)

|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects with Treatment-emergent Serious Adverse Events (TESAEs) |
|-----------------|--|

End point description:

SAE was defined as any untoward medical occurrence that resulted in death, was life-threatening, required inpatient hospitalisation or prolongation of existing hospitalisation, resulted in persistent or significant disability/incapacity, led to a congenital anomaly/birth defect in the offspring of a subject, or was an important medical event. TESAEs were any SAE occurred at or after the initial administration of study intervention through the day of last dose plus 16 weeks. The safety analysis set included all subjects who were randomised in the study and received at least one (complete or partial) administration of study intervention.

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

End point timeframe:

From baseline (Week 0) up to Week 36

| End point values              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed   | 59   | 32                                     |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 6.8  | 0                                      |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects with Treatment-emergent Adverse Events (TEAEs)

|                 |   |
|-----------------|---|
| End point title | Percentage of Subjects with Treatment-emergent Adverse Events (TEAEs) |
|-----------------|---|

**End point description:**

An adverse event (AE) was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product. An AE does not necessarily have a causal relationship with the intervention. TEAEs were any AE occurred at or after the initial administration of study intervention through the day of last dose plus 16 weeks. The safety analysis set included all subjects who were randomised in the study and received at least one (complete or partial) administration of study intervention.

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

**End point timeframe:**

From baseline (Week 0) up to Week 36

| End point values              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed   | 59   | 32                                     |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 71.2   | 56.3                                   |  |  |

**Statistical analyses**

No statistical analyses for this end point

**Secondary: Percentage of Subjects with Reasonably Related Adverse Events (AEs)**

|                 |   |
|-----------------|---|
| End point title | Percentage of Subjects with Reasonably Related Adverse Events (AEs) |
|-----------------|---|

**End point description:**

Percentage of subjects with reasonably related AEs were reported. An AE was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product. AE reasonably related to guselkumab or golimumab are AEs classified by the investigator as related to study agent. The safety analysis set included all subjects who were randomised in the study and received at least one (complete or partial) administration of study intervention.

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

**End point timeframe:**

From baseline (Week 0) up to Week 36

| End point values              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed   | 59   | 32                                     |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 35.6   | 21.9                                   |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects With AEs Leading to Discontinuation of Study Intervention

|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects With AEs Leading to Discontinuation of Study Intervention |
|-----------------|--|

End point description:

Percentage of subjects with AEs leading to discontinuation of study intervention were reported. AE was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product. An AE does not necessarily have a causal relationship with the intervention. The safety analysis set included all subjects who were randomised in the study and received at least one (complete or partial) administration of study intervention.

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

End point timeframe:

From baseline (Week 0) to Week 24

| End point values              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed   | 59   | 32                                     |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 3.4  | 0                                      |  |  |

## Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects With Infections

|                 |  |
|-----------------|--|
| End point title | Percentage of Subjects With Infections |
|-----------------|--|

End point description:

Percentage of subjects with infections were reported. Investigators evaluate subjects for any signs or symptoms of infection at every scheduled visit. An AE was any untoward medical occurrence in a clinical study subject administered a pharmaceutical (investigational or non-investigational) product. The safety analysis set included all subjects who were randomised in the study and received at least one (complete or partial) administration of study intervention.

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

End point timeframe:

From baseline (Week 0) up to Week 36



| End point values              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed   | 59   | 32                                     |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 32.2   | 40.6                                   |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Percentage of Subjects With Injection-site Reactions

|  |  |
|--|--|
| End point title  | Percentage of Subjects With Injection-site Reactions |
| End point description:   |  |
| Percentage of subjects with injection-site reaction were reported. A study intervention injection-site reaction was any adverse reaction at a subcutaneous study intervention injection-site. The injection sites were evaluated for reactions, and any injection-site reaction was recorded as an AE. Injection site reactions were significant bruising, erythema, hemorrhage, irritation, pain, and pruritus. The safety analysis set included all subjects who received at least one dose of study intervention. |  |
| End point type   | Secondary  |
| End point timeframe:   |  |
| From baseline (Week 0) up to Week 36   |  |

| End point values              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed   | 59   | 32                                     |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 10.2   | 3.1                                    |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Serum Concentration of Golimumab

|   |   |
|---|---|
| End point title   | Serum Concentration of Golimumab <sup>[1]</sup> |
| End point description:  |   |
| Serum concentration of golimumab was reported. Pharmacokinetics (PK) analysis set included all subjects who were randomised in the study and received at least one (complete) administration of study |   |

intervention and had at least one valid post-injection blood sample drawn for PK analysis. Here, 'n' (number analysed) signifies number of subjects evaluable for specified time points. Result was planned to be reported for the specified arm only.

|                                       |           |
|---------------------------------------|-----------|
| End point type                        | Secondary |
| End point timeframe:                  |           |
| Weeks 0, 4, 8, 12, 16, 20, 24, and 36 |           |

Notes:

[1] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period. Justification: This endpoint was planned to be analysed for specified arms only.

|                                      |  |  |  |  |
|--------------------------------------|--|--|--|--|
| <b>End point values</b>              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab |  |  |  |
| Subject group type                   | Reporting group                              |  |  |  |
| Number of subjects analysed          | 59   |  |  |  |
| Units: Micrograms per millilitre     |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Week 0 (n=59)                        | 0.02 (± 0.136)                               |  |  |  |
| Week 4 (n=49)                        | 0.78 (± 1.749)                               |  |  |  |
| Week 8 (n=47)                        | 0.68 (± 0.670)                               |  |  |  |
| Week 12 (n=38)                       | 0.97 (± 2.316)                               |  |  |  |
| Week 16 (n=33)                       | 0.73 (± 0.646)                               |  |  |  |
| Week 20 (n=27)                       | 0.57 (± 0.399)                               |  |  |  |
| Week 24 (n=25)                       | 0.56 (± 0.424)                               |  |  |  |
| Week 36 (n=23)                       | 0.06 (± 0.250)                               |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Secondary: Serum Concentration of Guselkumab

|  |                                   |
|--|-----------------------------------|
| End point title  | Serum Concentration of Guselkumab |
| End point description:   |                                   |
| Serum concentration of guselkumab was reported. The PK analysis set included all subjects who were randomised in the study and received at least one (complete) administration of study intervention and had at least one valid post-injection blood sample drawn for PK analysis. Here, 'n' (number analysed) signifies number of subjects evaluable for specified time points. |                                   |
| End point type   | Secondary                         |
| End point timeframe:   |                                   |
| Weeks 0, 4, 8, 12, 16, 20, 24, and 36  |                                   |

| End point values                     | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|--------------------------------------|--|--|--|--|
| Subject group type                   | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed          | 59   | 32                                     |  |  |
| Units: Micrograms per milliliter     |  |  |  |  |
| arithmetic mean (standard deviation) |  |  |  |  |
| Week 0 (n=59, 32)                    | 0.05 (± 0.288)                               | 0.00 (± 0.000)                         |  |  |
| Week 4 (n=49, 28)                    | 2.34 (± 1.338)                               | 2.41 (± 1.527)                         |  |  |
| Week 8 (n=47, 24)                    | 3.36 (± 2.266)                               | 3.56 (± 2.370)                         |  |  |
| Week 12 (n=38, 21)                   | 3.62 (± 2.342)                               | 4.04 (± 2.785)                         |  |  |
| Week 16 (n=33, 20)                   | 3.95 (± 2.188)                               | 4.19 (± 2.963)                         |  |  |
| Week 20 (n=27, 18 )                  | 3.85 (± 2.214)                               | 4.13 (± 2.954)                         |  |  |
| Week 24 (n=26,16)                    | 3.96 (± 2.297)                               | 3.64 (± 2.850)                         |  |  |
| Week 36 (n=23, 16)                   | 0.95 (± 1.587)                               | 1.00 (± 1.764)                         |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects with Anti-Guselkumab Antibodies

|  |  |
|--|--|
| End point title  | Percentage of Subjects with Anti-Guselkumab Antibodies |
| End point description:<br>Percentage of subjects with anti-guselkumab antibodies were reported. The immunogenicity analysis set included all subjects who were randomised in the study and received at least one (complete) administration of study intervention and had appropriate samples for antibodies to guselkumab and golimumab detection. |  |
| End point type   | Secondary  |
| End point timeframe:<br>From baseline (Week 0) up to Week 36   |  |

| End point values              | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab | Group 2:<br>Guselkumab<br>Plus Placebo |  |  |
|-------------------------------|--|--|--|--|
| Subject group type            | Reporting group                              | Reporting group                        |  |  |
| Number of subjects analysed   | 59   | 32                                     |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 11.9   | 15.6                                   |  |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Subjects with Anti-Golimumab Antibodies

|  |  |
|--|--|
| End point title  | Percentage of Subjects with Anti-Golimumab Antibodies <sup>[2]</sup> |
| End point description:   |  |
| Percentage of subjects with anti-golimumab antibodies were reported. The immunogenicity analysis set included all subjects who were randomised in the study and received at least one (complete) administration of study intervention and had appropriate samples for antibodies to guselkumab and golimumab detection. As planned, results data were analysed and reported for the specified arm for this endpoint. |  |
| End point type   | Secondary  |
| End point timeframe:   |  |
| From baseline (Week 0) up to Week 36   |  |

Notes:

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.

Justification: This endpoint was planned to be analysed for specified arms only.

|                               |  |  |  |  |
|-------------------------------|--|--|--|--|
| <b>End point values</b>       | Group 1 :<br>Guselkumab<br>Plus<br>Golimumab |  |  |  |
| Subject group type            | Reporting group                              |  |  |  |
| Number of subjects analysed   | 59   |  |  |  |
| Units: Percentage of Subjects |  |  |  |  |
| number (not applicable)       | 67.8   |  |  |  |

## Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

All-cause mortality: From screening (Week -6) up to Week 36; SAE and non-serious AEs: From baseline (Week 0) up to Week 36

Adverse event reporting additional description:

The safety analysis set included all subjects who received at least one dose of study intervention.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 27.0 |
|--------------------|------|

### Reporting groups

|                       |                                  |
|-----------------------|----------------------------------|
| Reporting group title | Group 2: Guselkumab Plus Placebo |
|-----------------------|----------------------------------|

Reporting group description:

Subjects received SC injection of guselkumab 100 mg and placebo (matched to golimumab) using single-use prefilled syringe, once q4w (at Weeks 0, 4, 8, 12, 16, and 20).

|                       |                                     |
|-----------------------|-------------------------------------|
| Reporting group title | Group 1 : Guselkumab Plus Golimumab |
|-----------------------|-------------------------------------|

Reporting group description:

Subjects received guselkumab and golimumab using single-use prefilled syringes, once every 4 weeks (q4w; at Weeks 0, 4, 8, 12, 16, and 20).

| Serious adverse events  | Group 2:<br>Guselkumab Plus<br>Placebo | Group 1 :<br>Guselkumab Plus<br>Golimumab |  |
|---|--|---|--|
| Total subjects affected by serious adverse events                   |  |   |  |
| subjects affected / exposed   | 0 / 32 (0.00%)                         | 4 / 59 (6.78%)                            |  |
| number of deaths (all causes)                                       | 0                                      | 0   |  |
| number of deaths resulting from adverse events                      | 0                                      | 0   |  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |  |   |  |
| Neuroendocrine Tumour   |  |   |  |
| subjects affected / exposed   | 0 / 32 (0.00%)                         | 1 / 59 (1.69%)                            |  |
| occurrences causally related to treatment / all                     | 0 / 0                                  | 0 / 1                                     |  |
| deaths causally related to treatment / all                          | 0 / 0                                  | 0 / 0                                     |  |
| Respiratory, thoracic and mediastinal disorders                     |  |   |  |
| Chronic Obstructive Pulmonary Disease                               |  |   |  |
| subjects affected / exposed   | 0 / 32 (0.00%)                         | 1 / 59 (1.69%)                            |  |
| occurrences causally related to treatment / all                     | 0 / 0                                  | 0 / 1                                     |  |
| deaths causally related to treatment / all                          | 0 / 0                                  | 0 / 0                                     |  |
| Infections and infestations   |  |   |  |
| Covid-19  |  |   |  |

|   |                |                |  |
|---|----------------|----------------|--|
| subjects affected / exposed                     | 0 / 32 (0.00%) | 1 / 59 (1.69%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 0 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |
| <b>Pneumonia Mycoplasmal</b>                    |                |                |  |
| subjects affected / exposed                     | 0 / 32 (0.00%) | 1 / 59 (1.69%) |  |
| occurrences causally related to treatment / all | 0 / 0          | 1 / 1          |  |
| deaths causally related to treatment / all      | 0 / 0          | 0 / 0          |  |

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

| <b>Non-serious adverse events</b>                            | <b>Group 2:<br/>Guselkumab Plus<br/>Placebo</b> | <b>Group 1 :<br/>Guselkumab Plus<br/>Golimumab</b> |  |
|--|---|--|--|
| <b>Total subjects affected by non-serious adverse events</b> |   |  |  |
| subjects affected / exposed                                  | 10 / 32 (31.25%)                                | 25 / 59 (42.37%)                                   |  |
| <b>Nervous system disorders</b>                              |   |  |  |
| Headache   |   |  |  |
| subjects affected / exposed                                  | 1 / 32 (3.13%)                                  | 7 / 59 (11.86%)                                    |  |
| occurrences (all)  | 1   | 7  |  |
| <b>General disorders and administration site conditions</b>  |   |  |  |
| Injection Site Reaction                                      |   |  |  |
| subjects affected / exposed                                  | 0 / 32 (0.00%)                                  | 3 / 59 (5.08%)                                     |  |
| occurrences (all)  | 0   | 4  |  |
| <b>Gastrointestinal disorders</b>                            |   |  |  |
| Nausea   |   |  |  |
| subjects affected / exposed                                  | 0 / 32 (0.00%)                                  | 4 / 59 (6.78%)                                     |  |
| occurrences (all)  | 0   | 4  |  |
| Diarrhoea  |   |  |  |
| subjects affected / exposed                                  | 0 / 32 (0.00%)                                  | 7 / 59 (11.86%)                                    |  |
| occurrences (all)  | 0   | 10   |  |
| <b>Musculoskeletal and connective tissue disorders</b>       |   |  |  |
| Back Pain  |   |  |  |
| subjects affected / exposed                                  | 0 / 32 (0.00%)                                  | 4 / 59 (6.78%)                                     |  |
| occurrences (all)  | 0   | 4  |  |
| Psoriatic Arthropathy  |   |  |  |

|  |                     |                     |  |
|--|---------------------|---------------------|--|
| subjects affected / exposed<br>occurrences (all) | 0 / 32 (0.00%)<br>0 | 5 / 59 (8.47%)<br>5 |  |
| Infections and infestations                      |                     |                     |  |
| Oral Candidiasis                                 |                     |                     |  |
| subjects affected / exposed                      | 2 / 32 (6.25%)      | 0 / 59 (0.00%)      |  |
| occurrences (all)                                | 2                   | 0                   |  |
| Upper Respiratory Tract Infection                |                     |                     |  |
| subjects affected / exposed                      | 2 / 32 (6.25%)      | 3 / 59 (5.08%)      |  |
| occurrences (all)                                | 2                   | 3                   |  |
| Urinary Tract Infection                          |                     |                     |  |
| subjects affected / exposed                      | 2 / 32 (6.25%)      | 0 / 59 (0.00%)      |  |
| occurrences (all)                                | 2                   | 0                   |  |
| Influenza  |                     |                     |  |
| subjects affected / exposed                      | 2 / 32 (6.25%)      | 2 / 59 (3.39%)      |  |
| occurrences (all)                                | 2                   | 2                   |  |
| Covid-19   |                     |                     |  |
| subjects affected / exposed                      | 2 / 32 (6.25%)      | 5 / 59 (8.47%)      |  |
| occurrences (all)                                | 2                   | 5                   |  |
| Nasopharyngitis                                  |                     |                     |  |
| subjects affected / exposed                      | 3 / 32 (9.38%)      | 5 / 59 (8.47%)      |  |
| occurrences (all)                                | 3                   | 7                   |  |

## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date            | Amendment  |
|-----------------|--|
| 06 October 2021 | The purpose of this amendment was to address health authority feedback regarding washout periods for prohibited medications, provide further clarification on recurrent or chronic serious infections, testing for antibodies to both golimumab and guselkumab, and gadolinium administration. |
| 19 August 2022  | The purpose of this amendment was to proposed changes to the protocol, including changes to inclusion and exclusion criteria to facilitate recruitment of subjects and to ensure a broader and more representative population was included in the study.                                       |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported