



## Clinical trial results:

### A 64-Week, Phase 3, Randomized, Placebo-Controlled, Parallel Design Study to Evaluate the Efficacy and Safety/Tolerability of Subcutaneous Tildrakizumab (SCH 900222/MK-3222), Followed by an Optional Long-Term Safety Extension Study, in Subjects With Moderate-to-Severe Chronic Plaque Psoriasis (Protocol No. MK-3222-010)

#### Summary

|                          |                  |
|--------------------------|------------------|
| EudraCT number           | 2012-002255-42   |
| Trial protocol           | GB               |
| Global end of trial date | 10 November 2021 |

#### Results information

|                                |                 |
|--------------------------------|-----------------|
| Result version number          | v1              |
| This version publication date  | 15 October 2023 |
| First version publication date | 15 October 2023 |

#### Trial information

##### Trial identification

|                       |             |
|-----------------------|-------------|
| Sponsor protocol code | MK-3222-010 |
|-----------------------|-------------|

##### Additional study identifiers

|                                    |             |
|------------------------------------|-------------|
| ISRCTN number                      | -           |
| ClinicalTrials.gov id (NCT number) | NCT01722331 |
| WHO universal trial number (UTN)   | -           |

Notes:

#### Sponsors

|                              |  |
|------------------------------|--|
| Sponsor organisation name    | Sun Pharmaceutical Industries Limited  |
| Sponsor organisation address | Sun House, 201 B/1, Western Express Highway, Goregaon (E), Mumbai, India, 400063   |
| Public contact               | Head-Clinical Development, Sun Pharmaceutical Industries Limited, +91 2266455645 ext. 5689, Clinical.Trial@sunpharma.com |
| Scientific contact           | Head-Clinical Development, Sun Pharmaceutical Industries Limited, +91 2266455645 ext. 5689, Clinical.Trial@sunpharma.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:

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**Results analysis stage**

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|  |                  |
|--|------------------|
| Analysis stage                                       | Final            |
| Date of interim/final analysis                       | 28 October 2015  |
| Is this the analysis of the primary completion data? | Yes              |
| Primary completion date                              | 28 October 2015  |
| Global end of trial reached?                         | Yes              |
| Global end of trial date                             | 10 November 2021 |
| Was the trial ended prematurely?                     | No               |

Notes:

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**General information about the trial**

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Main objective of the trial:

Primary Efficacy Objective: To assess the efficacy of tildrakizumab (SCH-900222/MK-3222) (hereafter referred to as MK-3222) compared to placebo in the treatment of moderate-to-severe chronic plaque psoriasis as measured by the proportion of subjects with at least 75% improvement in the Psoriasis Area and Severity Index from baseline (PASI 75 response), and the proportion of subjects with a Physician's Global Assessment (PGA) score of "clear" or "minimal", with at least a 2 grade reduction from baseline, at Week 12.

Primary Safety/Tolerability Objective: To assess the safety/tolerability of tildrakizumab (MK-3222) in subjects with moderate-to-severe chronic plaque psoriasis at Week 12.

Extension Study:

To assess long-term safety and tolerability of tildrakizumab (MK-3222) in subjects with moderate-to-severe chronic plaque psoriasis for a minimum of 4 years.

Protection of trial subjects:

The following provisions are within the study protocol to ensure adequate protection of subjects:

1. Each subject will be monitored for the occurrence of SAEs immediately after signing informed consent and will be followed up for adverse events (AEs, SAEs, ECIs) for upto 20 weeks after the last visit in the treatment period (base or extension)
  2. Subject's right to withdraw his/her consent at any time during the trial with or without a stated reason
  3. It is the right and the duty of the investigator or subinvestigator to stop treatment in any case in which emerging effects are of unacceptable risk to the individual subject
  4. All subjects were screened for presence of latent or untreated TB infections, HIV, hepatitis B surface antigen, hepatitis C virus, chronic disease, organ dysfunction, use of prohibited medications and presence of any other such conditions to ensure to minimize the potential risk to study subjects prior to enrollment
- Every subject will be monitored for the occurrence of SAEs immediately after the subject has signed informed consent form
5. The study has constituted a DSMB for monitoring the safety of the trial subjects during the study

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Background therapy: -

Evidence for comparator: -

|   |                  |
|---|------------------|
| Actual start date of recruitment                          | 10 December 2012 |
| Long term follow-up planned                               | Yes              |
| Long term follow-up rationale                             | Safety           |
| Long term follow-up duration                              | 4 Years          |
| Independent data monitoring committee (IDMC) involvement? | Yes              |

Notes:

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**Population of trial subjects**

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**Subjects enrolled per country**

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|                                      |                    |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | Australia: 88      |
| Country: Number of subjects enrolled | Canada: 192        |
| Country: Number of subjects enrolled | United Kingdom: 8  |
| Country: Number of subjects enrolled | Japan: 158         |
| Country: Number of subjects enrolled | United States: 326 |
| Worldwide total number of subjects   | 772                |
| EEA total number of subjects         | 0                  |

Notes:

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**Subjects enrolled per age group**

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|   |     |
|---|-----|
| 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)                      | 697 |
| From 65 to 84 years                       | 75  |
| 85 years and over                         | 0   |

## Subject disposition

### Recruitment

Recruitment details: -

### Pre-assignment

Screening details:

A total of 977 subjects were screened for the study, of which 205 were not randomized.

### Period 1

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

### Arms

|                              |    |
|------------------------------|----|
| Are arms mutually exclusive? | No |
|------------------------------|----|

|                  |         |
|------------------|---------|
| <b>Arm title</b> | Placebo |
|------------------|---------|

Arm description:

Placebo administered SC once a week at Weeks 0 and 4

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

Dosage and administration details:

Matching placebo to tildrakizumab administered SC

|                  |                   |
|------------------|-------------------|
| <b>Arm title</b> | Tildrakizumab 100 |
|------------------|-------------------|

Arm description:

Tildrakizumab 100 mg administered SC once a week at Weeks 0 and 4 and then every 12 weeks

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

Dosage and administration details:

Tildrakizumab 100 mg administered SC

|                  |                   |
|------------------|-------------------|
| <b>Arm title</b> | Tildrakizumab 200 |
|------------------|-------------------|

Arm description:

Tildrakizumab 200 mg administered subcutaneously (SC) once a week at Weeks 0 and 4 and then every 12 weeks.

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

Dosage and administration details:  
Tildrakizumab 200 mg administered SC

| <b>Number of subjects in period 1</b> | Placebo | Tildrakizumab 100 | Tildrakizumab 200 |
|---------------------------------------|---------|-------------------|-------------------|
| Started                               | 155     | 309               | 308               |
| Completed                             | 124     | 250               | 264               |
| Not completed                         | 31      | 59                | 44                |
| Adverse event, serious fatal          | -       | -                 | 1                 |
| Consent withdrawn by subject          | 10      | 14                | 11                |
| Physician decision                    | 2       | 6                 | 1                 |
| Non-Compliance with Study Drug        | -       | 2                 | 1                 |
| Adverse event, non-fatal              | 1       | 3                 | 10                |
| Progressive Disease                   | 1       | 1                 | -                 |
| Pregnancy                             | 1       | -                 | 1                 |
| Protocol Violation                    | 1       | 1                 | 4                 |
| Other Protocol Specified Criteria     | 3       | 11                | 7                 |
| Lost to follow-up                     | 4       | 9                 | 4                 |
| Lack of efficacy                      | 8       | 12                | 4                 |

## Baseline characteristics

### Reporting groups

|   |                   |
|---|-------------------|
| Reporting group title   | Placebo           |
| Reporting group description:<br>Placebo administered SC once a week at Weeks 0 and 4  |                   |
| Reporting group title   | Tildrakizumab 100 |
| Reporting group description:<br>Tildrakizumab 100 mg administered SC once a week at Weeks 0 and 4 and then every 12 weeks                   |                   |
| Reporting group title   | Tildrakizumab 200 |
| Reporting group description:<br>Tildrakizumab 200 mg administered subcutaneously (SC) once a week at Weeks 0 and 4 and then every 12 weeks. |                   |

| Reporting group values             | Placebo | Tildrakizumab 100 | Tildrakizumab 200 |
|------------------------------------|---------|-------------------|-------------------|
| Number of subjects                 | 155     | 309               | 308               |
| Age categorical<br>Units: Subjects |         |                   |                   |

|  |                  |                  |                  |
|--|------------------|------------------|------------------|
| Age continuous<br>Units: years<br>median<br>full range (min-max) | 47.5<br>19 to 76 | 46.0<br>18 to 82 | 48.0<br>18 to 76 |
| Gender categorical<br>Units: Subjects                            |                  |                  |                  |
| Female   | 55               | 102              | 82               |
| Male   | 100              | 207              | 226              |

| Reporting group values             | Total |  |  |
|------------------------------------|-------|--|--|
| Number of subjects                 | 772   |  |  |
| Age categorical<br>Units: Subjects |       |  |  |

|  |     |  |  |
|--|-----|--|--|
| Age continuous<br>Units: years<br>median<br>full range (min-max) | -   |  |  |
| Gender categorical<br>Units: Subjects                            |     |  |  |
| Female   | 239 |  |  |
| Male   | 533 |  |  |

## End points

### End points reporting groups

|   |                   |
|---|-------------------|
| Reporting group title   | Placebo           |
| Reporting group description:<br>Placebo administered SC once a week at Weeks 0 and 4  |                   |
| Reporting group title   | Tildrakizumab 100 |
| Reporting group description:<br>Tildrakizumab 100 mg administered SC once a week at Weeks 0 and 4 and then every 12 weeks                   |                   |
| Reporting group title   | Tildrakizumab 200 |
| Reporting group description:<br>Tildrakizumab 200 mg administered subcutaneously (SC) once a week at Weeks 0 and 4 and then every 12 weeks. |                   |

### Primary: Percentage of Participants With Psoriasis Area Sensitivity Index 75 (PASI-75) Response at Week 12

|                                 |   |
|---------------------------------|---|
| End point title                 | Percentage of Participants With Psoriasis Area Sensitivity Index 75 (PASI-75) Response at Week 12 |
| End point description:          |   |
| End point type                  | Primary   |
| End point timeframe:<br>Week 12 |   |

| End point values                 | Placebo         | Tildrakizumab 100 | Tildrakizumab 200 |  |
|----------------------------------|-----------------|-------------------|-------------------|--|
| Subject group type               | Reporting group | Reporting group   | Reporting group   |  |
| Number of subjects analysed      | 154             | 309               | 308               |  |
| Units: Percentage of Participant |                 |                   |                   |  |
| number (not applicable)          | 5.8             | 63.8              | 62.3              |  |

### Statistical analyses

|   |  |
|---|--|
| Statistical analysis title              | CMH analysis of PASI75 Response at Week 12 |
| Comparison groups                       | Tildrakizumab 100 v Placebo                |
| Number of subjects included in analysis | 463  |
| Analysis specification                  | Pre-specified                              |
| Analysis type                           | superiority                                |
| P-value                                 | < 0.001                                    |
| Method                                  | Cochran-Mantel-Haenszel                    |

|                            |  |
|----------------------------|--|
| Statistical analysis title | CMH analysis of PASI75 Response at Week 12 |
|----------------------------|--|

|   |                             |
|---|-----------------------------|
| Comparison groups                       | Tildrakizumab 200 v Placebo |
| Number of subjects included in analysis | 462                         |
| Analysis specification                  | Pre-specified               |
| Analysis type                           | superiority                 |
| P-value                                 | < 0.001                     |
| Method                                  | Cochran-Mantel-Haenszel     |

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**Secondary: Percentage of Participants With a Physician's Global Assessment (PGA) Score of Clear or Minimal With at Least a 2 Grade Reduction From Baseline at Week 12**

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants With a Physician's Global Assessment (PGA) Score of Clear or Minimal With at Least a 2 Grade Reduction From Baseline at Week 12 |
|-----------------|--|

End point description:

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: | Week 12   |

| End point values                 | Placebo         | Tildrakizumab 100 | Tildrakizumab 200 |  |
|----------------------------------|-----------------|-------------------|-------------------|--|
| Subject group type               | Reporting group | Reporting group   | Reporting group   |  |
| Number of subjects analysed      | 154             | 309               | 308               |  |
| Units: Percentage of Participant |                 |                   |                   |  |
| number (not applicable)          | 7.1             | 57.9              | 59.1              |  |

**Statistical analyses**

No statistical analyses for this end point

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**Secondary: Percentage of Participants With PASI-90 Response At Week 12**

|                 |   |
|-----------------|---|
| End point title | Percentage of Participants With PASI-90 Response At Week 12 |
|-----------------|---|

End point description:

|                      |           |
|----------------------|-----------|
| End point type       | Secondary |
| End point timeframe: | Week 12   |



| End point values                  | Placebo         | Tildrakizumab 100 | Tildrakizumab 200 |  |
|-----------------------------------|-----------------|-------------------|-------------------|--|
| Subject group type                | Reporting group | Reporting group   | Reporting group   |  |
| Number of subjects analysed       | 154             | 309               | 308               |  |
| Units: Percentage of Participants |                 |                   |                   |  |
| number (not applicable)           | 2.6             | 34.6              | 35.4              |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants with PASI-100 Response at Week 12

|                 |  |
|-----------------|--|
| End point title | Percentage of Participants with PASI-100 Response at Week 12 |
|-----------------|--|

End point description:

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

End point timeframe:

Week 12

| End point values                                | Placebo         | Tildrakizumab 100 | Tildrakizumab 200 |  |
|---|-----------------|-------------------|-------------------|--|
| Subject group type                              | Reporting group | Reporting group   | Reporting group   |  |
| Number of subjects analysed                     | 154             | 309               | 308               |  |
| Units: Percentage of Participants With PASI-100 |                 |                   |                   |  |
| number (not applicable)                         | 1.3             | 13.9              | 14.0              |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Change From Baseline in the Participant DLQI Score at Week 12

|                 |   |
|-----------------|---|
| End point title | Change From Baseline in the Participant DLQI Score at Week 12 |
|-----------------|---|

End point description:

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

End point timeframe:

Week 12

| End point values                             | Placebo             | Tildrakizumab 100    | Tildrakizumab 200     |  |
|--|---------------------|----------------------|-----------------------|--|
| Subject group type                           | Reporting group     | Reporting group      | Reporting group       |  |
| Number of subjects analysed                  | 154                 | 309                  | 308                   |  |
| Units: Score on a scale                      |                     |                      |                       |  |
| least squares mean (confidence interval 95%) | -2.3 (-3.1 to -1.5) | -9.8 (-10.4 to -9.1) | -10.0 (-10.7 to -9.4) |  |

### Statistical analyses

No statistical analyses for this end point

### Secondary: Percentage of Participants with DLQI Score of 0 or 1 at Week 12

|                        |   |
|------------------------|---|
| End point title        | Percentage of Participants with DLQI Score of 0 or 1 at Week 12 |
| End point description: |   |
| End point type         | Secondary   |
| End point timeframe:   |   |
| Week 12                |   |

| End point values                  | Placebo         | Tildrakizumab 100 | Tildrakizumab 200 |  |
|-----------------------------------|-----------------|-------------------|-------------------|--|
| Subject group type                | Reporting group | Reporting group   | Reporting group   |  |
| Number of subjects analysed       | 150             | 304               | 299               |  |
| Units: Percentage of Participants |                 |                   |                   |  |
| number (not applicable)           | 5.3             | 41.5              | 44.2              |  |

### Statistical analyses

No statistical analyses for this end point

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

Up to 84 weeks including a 20-week follow-up period.

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

### Dictionary used

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

|                    |      |
|--------------------|------|
| Dictionary version | 19.1 |
|--------------------|------|

### Reporting groups

|                       |                               |
|-----------------------|-------------------------------|
| Reporting group title | Tildrakizumab 200 mg (Part 1) |
|-----------------------|-------------------------------|

Reporting group description:

Tildrakizumab 200 mg administered once a week at Weeks 0 and 4.

|                       |                               |
|-----------------------|-------------------------------|
| Reporting group title | Tildrakizumab 200 mg (Part 2) |
|-----------------------|-------------------------------|

Reporting group description:

Tildrakizumab 200 mg administered once a week at Week 16 (includes placebo participants re-randomized at Week 12 to receive tildrakizumab 200 mg)

|                       |                               |
|-----------------------|-------------------------------|
| Reporting group title | Tildrakizumab 100 mg (Part 2) |
|-----------------------|-------------------------------|

Reporting group description:

Tildrakizumab 100 mg administered once a week at Week 16 (includes placebo participants re-randomized at Week 12 to receive Tildrakizumab 100 mg). Includes 1 participant who did not enter Part 2, but received an unscheduled dose at Week 12.

|                       |                               |
|-----------------------|-------------------------------|
| Reporting group title | Tildrakizumab 200 mg (Part 3) |
|-----------------------|-------------------------------|

Reporting group description: -

|                       |                               |
|-----------------------|-------------------------------|
| Reporting group title | Tildrakizumab 100 mg (Part 3) |
|-----------------------|-------------------------------|

Reporting group description: -

|                       |                  |
|-----------------------|------------------|
| Reporting group title | Placebo (Part 1) |
|-----------------------|------------------|

Reporting group description:

Placebo administered once a week at Weeks 0 and 4.

|                       |                               |
|-----------------------|-------------------------------|
| Reporting group title | Tildrakizumab 100 mg (Part 1) |
|-----------------------|-------------------------------|

Reporting group description:

Tildrakizumab 100 mg administered once a week at Weeks 0 and 4.

| Serious adverse events  | Tildrakizumab 200 mg (Part 1) | Tildrakizumab 200 mg (Part 2) | Tildrakizumab 100 mg (Part 2) |
|---|-------------------------------|-------------------------------|-------------------------------|
| Total subjects affected by serious adverse events                   |                               |                               |                               |
| subjects affected / exposed   | 8 / 308 (2.60%)               | 8 / 370 (2.16%)               | 7 / 374 (1.87%)               |
| number of deaths (all causes)                                       | 0                             | 0                             | 0                             |
| number of deaths resulting from adverse events                      |                               |                               |                               |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                               |                               |                               |
| Benign biliary neoplasm   |                               |                               |                               |
| subjects affected / exposed   | 0 / 308 (0.00%)               | 0 / 370 (0.00%)               | 0 / 374 (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                         |
| Basal cell carcinoma  |                               |                               |                               |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                           | 0 / 308 (0.00%) | 1 / 370 (0.27%) | 1 / 374 (0.27%) |
| occurrences causally related to treatment / all       | 0 / 0           | 0 / 1           | 0 / 1           |
| deaths causally related to treatment / all            | 0 / 0           | 0 / 0           | 0 / 0           |
| <b>Bowen's disease</b>                                |                 |                 |                 |
| subjects affected / exposed                           | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| <b>Carcinoma in situ of skin</b>                      |                 |                 |                 |
| subjects affected / exposed                           | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| <b>Pancreatic carcinoma</b>                           |                 |                 |                 |
| subjects affected / exposed                           | 0 / 308 (0.00%) | 1 / 370 (0.27%) | 0 / 374 (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           |
| <b>Squamous cell carcinoma of skin</b>                |                 |                 |                 |
| subjects affected / exposed                           | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 1 / 374 (0.27%) |
| occurrences causally related to treatment / all       | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all            | 0 / 0           | 0 / 0           | 0 / 0           |
| <b>Vascular disorders</b>                             |                 |                 |                 |
| <b>Aneurysm</b>                                       |                 |                 |                 |
| subjects affected / exposed                           | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| <b>Deep vein thrombosis</b>                           |                 |                 |                 |
| subjects affected / exposed                           | 0 / 308 (0.00%) | 1 / 370 (0.27%) | 0 / 374 (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           |
| <b>Pregnancy, puerperium and perinatal conditions</b> |                 |                 |                 |
| <b>Abortion spontaneous</b>                           |                 |                 |                 |
| subjects affected / exposed                           | 1 / 308 (0.32%) | 1 / 370 (0.27%) | 0 / 374 (0.00%) |
| occurrences causally related to treatment / all       | 0 / 1           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all            | 0 / 0           | 0 / 0           | 0 / 0           |

|  |                 |                 |                 |
|--|-----------------|-----------------|-----------------|
| General disorders and administration site conditions |                 |                 |                 |
| Non-cardiac chest pain                               |                 |                 |                 |
| subjects affected / exposed                          | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Immune system disorders                              |                 |                 |                 |
| Anaphylactic reaction                                |                 |                 |                 |
| subjects affected / exposed                          | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Reproductive system and breast disorders             |                 |                 |                 |
| Uterine haemorrhage                                  |                 |                 |                 |
| subjects affected / exposed                          | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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      |                 |                 |                 |
| Chronic obstructive pulmonary disease                |                 |                 |                 |
| subjects affected / exposed                          | 1 / 308 (0.32%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Pneumothorax   |                 |                 |                 |
| subjects affected / exposed                          | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Pulmonary embolism                                   |                 |                 |                 |
| subjects affected / exposed                          | 0 / 308 (0.00%) | 1 / 370 (0.27%) | 0 / 374 (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           |
| Sleep apnoea syndrome                                |                 |                 |                 |
| subjects affected / exposed                          | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Psychiatric disorders                                |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Suicide attempt                                 |                 |                 |                 |
| subjects affected / exposed                     | 1 / 308 (0.32%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Injury, poisoning and procedural complications  |                 |                 |                 |
| Lower limb fracture                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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                               |                 |                 |                 |
| Acute myocardial infarction                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Angina pectoris                                 |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Coronary artery disease                         |                 |                 |                 |
| subjects affected / exposed                     | 1 / 308 (0.32%) | 1 / 370 (0.27%) | 0 / 374 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Tachycardia                                     |                 |                 |                 |
| subjects affected / exposed                     | 1 / 308 (0.32%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Nervous system disorders                        |                 |                 |                 |
| Cerebellar infarction                           |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Lacunar infarction                              |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 308 (0.00%) | 1 / 370 (0.27%) | 0 / 374 (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           |
| Presyncope                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Sciatica  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Transient ischaemic attack                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Blood and lymphatic system disorders            |                 |                 |                 |
| Anaemia neonatal                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Eye disorders                                   |                 |                 |                 |
| Cataract  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Macular fibrosis                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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                      |                 |                 |                 |
| Constipation                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 1 / 374 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Diverticulum                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 1 / 374 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Food poisoning                                  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Pancreatitis                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 1 / 374 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Pancreatitis acute                              |                 |                 |                 |
| subjects affected / exposed                     | 1 / 308 (0.32%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Salivary gland enlargement                      |                 |                 |                 |
| subjects affected / exposed                     | 1 / 308 (0.32%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Hepatobiliary disorders                         |                 |                 |                 |
| Cholecystitis                                   |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Cholelithiasis                                  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Skin and subcutaneous tissue disorders          |                 |                 |                 |
| Psoriasis                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 1 / 370 (0.27%) | 0 / 374 (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           |



|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Renal and urinary disorders                     |                 |                 |                 |
| Nephrolithiasis                                 |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Musculoskeletal and connective tissue disorders |                 |                 |                 |
| Rotator cuff syndrome                           |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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                     |                 |                 |                 |
| Epiglottitis                                    |                 |                 |                 |
| subjects affected / exposed                     | 1 / 308 (0.32%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Cellulitis                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |
| Bone tuberculosis                               |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 1 / 370 (0.27%) | 0 / 374 (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           |
| Diverticulitis                                  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 1 / 374 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastroenteritis                                 |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 1 / 374 (0.27%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Gastroenteritis salmonella                      |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Sinusitis                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 308 (0.00%) | 0 / 370 (0.00%) | 0 / 374 (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           |

| <b>Serious adverse events</b>                                       | Tildrakizumab 200 mg (Part 3) | Tildrakizumab 100 mg (Part 3) | Placebo (Part 1) |
|---|-------------------------------|-------------------------------|------------------|
| Total subjects affected by serious adverse events                   |                               |                               |                  |
| subjects affected / exposed   | 21 / 360 (5.83%)              | 14 / 316 (4.43%)              | 1 / 154 (0.65%)  |
| number of deaths (all causes)                                       | 0                             | 1                             | 0                |
| number of deaths resulting from adverse events                      |                               |                               |                  |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) |                               |                               |                  |
| Benign biliary neoplasm   |                               |                               |                  |
| subjects affected / exposed   | 0 / 360 (0.00%)               | 1 / 316 (0.32%)               | 0 / 154 (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            |
| Basal cell carcinoma  |                               |                               |                  |
| subjects affected / exposed   | 0 / 360 (0.00%)               | 2 / 316 (0.63%)               | 0 / 154 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 0                         | 0 / 3                         | 0 / 0            |
| deaths causally related to treatment / all                          | 0 / 0                         | 0 / 0                         | 0 / 0            |
| Bowen's disease   |                               |                               |                  |
| subjects affected / exposed   | 1 / 360 (0.28%)               | 1 / 316 (0.32%)               | 0 / 154 (0.00%)  |
| occurrences causally related to treatment / all                     | 0 / 1                         | 0 / 1                         | 0 / 0            |
| deaths causally related to treatment / all                          | 0 / 0                         | 0 / 0                         | 0 / 0            |
| Carcinoma in situ of skin   |                               |                               |                  |
| subjects affected / exposed   | 0 / 360 (0.00%)               | 1 / 316 (0.32%)               | 0 / 154 (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            |
| Pancreatic carcinoma  |                               |                               |                  |
| subjects affected / exposed   | 1 / 360 (0.28%)               | 0 / 316 (0.00%)               | 0 / 154 (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            |

|  |                 |                 |                 |
|--|-----------------|-----------------|-----------------|
| Squamous cell carcinoma of skin<br>subjects affected / exposed | 2 / 360 (0.56%) | 2 / 316 (0.63%) | 0 / 154 (0.00%) |
| occurrences causally related to<br>treatment / all             | 0 / 2           | 0 / 2           | 0 / 0           |
| deaths causally related to<br>treatment / all                  | 0 / 0           | 0 / 0           | 0 / 0           |
| Vascular disorders   |                 |                 |                 |
| Aneurysm   |                 |                 |                 |
| subjects affected / exposed                                    | 1 / 360 (0.28%) | 0 / 316 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to<br>treatment / all             | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                  | 0 / 0           | 0 / 0           | 0 / 0           |
| Deep vein thrombosis   |                 |                 |                 |
| subjects affected / exposed                                    | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to<br>treatment / all             | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                  | 0 / 0           | 0 / 0           | 0 / 0           |
| Pregnancy, puerperium and perinatal<br>conditions              |                 |                 |                 |
| Abortion spontaneous   |                 |                 |                 |
| subjects affected / exposed                                    | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to<br>treatment / all             | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                  | 0 / 0           | 0 / 0           | 0 / 0           |
| General disorders and administration<br>site conditions        |                 |                 |                 |
| Non-cardiac chest pain   |                 |                 |                 |
| subjects affected / exposed                                    | 2 / 360 (0.56%) | 1 / 316 (0.32%) | 0 / 154 (0.00%) |
| occurrences causally related to<br>treatment / all             | 0 / 2           | 0 / 1           | 0 / 0           |
| deaths causally related to<br>treatment / all                  | 0 / 0           | 0 / 0           | 0 / 0           |
| Immune system disorders  |                 |                 |                 |
| Anaphylactic reaction  |                 |                 |                 |
| subjects affected / exposed                                    | 1 / 360 (0.28%) | 0 / 316 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to<br>treatment / all             | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                  | 0 / 0           | 0 / 0           | 0 / 0           |
| Reproductive system and breast<br>disorders                    |                 |                 |                 |
| Uterine haemorrhage  |                 |                 |                 |
| subjects affected / exposed                                    | 1 / 360 (0.28%) | 0 / 316 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to<br>treatment / all             | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to<br>treatment / all                  | 0 / 0           | 0 / 0           | 0 / 0           |
| Respiratory, thoracic and mediastinal<br>disorders             |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Chronic obstructive pulmonary disease           |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Pneumothorax                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Pulmonary embolism                              |                 |                 |                 |
| subjects affected / exposed                     | 1 / 360 (0.28%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Sleep apnoea syndrome                           |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 1 / 316 (0.32%) | 0 / 154 (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           |
| Psychiatric disorders                           |                 |                 |                 |
| Suicide attempt                                 |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (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  |                 |                 |                 |
| Lower limb fracture                             |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 1 / 316 (0.32%) | 0 / 154 (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           |
| Cardiac disorders                               |                 |                 |                 |
| Acute myocardial infarction                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Angina pectoris                                 |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 1 / 360 (0.28%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Coronary artery disease                         |                 |                 |                 |
| subjects affected / exposed                     | 1 / 360 (0.28%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Tachycardia                                     |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Nervous system disorders                        |                 |                 |                 |
| Cerebellar infarction                           |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 1 / 316 (0.32%) | 0 / 154 (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           |
| Lacunar infarction                              |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Presyncope                                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 1 / 154 (0.65%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 1           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Sciatica  |                 |                 |                 |
| subjects affected / exposed                     | 1 / 360 (0.28%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Transient ischaemic attack                      |                 |                 |                 |
| subjects affected / exposed                     | 1 / 360 (0.28%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Blood and lymphatic system disorders            |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Anaemia neonatal                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 1 / 316 (0.32%) | 0 / 154 (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           |
| Eye disorders                                   |                 |                 |                 |
| Cataract  |                 |                 |                 |
| subjects affected / exposed                     | 1 / 360 (0.28%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Macular fibrosis                                |                 |                 |                 |
| subjects affected / exposed                     | 1 / 360 (0.28%) | 0 / 316 (0.00%) | 0 / 154 (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 disorders                      |                 |                 |                 |
| Constipation                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Diverticulum                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Food poisoning                                  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 1 / 316 (0.32%) | 0 / 154 (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           |
| Pancreatitis                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Pancreatitis acute                              |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (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           |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| Salivary gland enlargement                      |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Hepatobiliary disorders                         |                 |                 |                 |
| Cholecystitis                                   |                 |                 |                 |
| subjects affected / exposed                     | 1 / 360 (0.28%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Cholelithiasis                                  |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 1 / 316 (0.32%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 1           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Skin and subcutaneous tissue disorders          |                 |                 |                 |
| Psoriasis                                       |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Renal and urinary disorders                     |                 |                 |                 |
| Nephrolithiasis                                 |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Musculoskeletal and connective tissue disorders |                 |                 |                 |
| Rotator cuff syndrome                           |                 |                 |                 |
| subjects affected / exposed                     | 1 / 360 (0.28%) | 0 / 316 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 0 / 1           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| Infections and infestations                     |                 |                 |                 |
| Epiglottitis                                    |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| Cellulitis                                      |                 |                 |                 |

|   |                 |                 |                 |
|---|-----------------|-----------------|-----------------|
| subjects affected / exposed                     | 2 / 360 (0.56%) | 0 / 316 (0.00%) | 0 / 154 (0.00%) |
| occurrences causally related to treatment / all | 2 / 2           | 0 / 0           | 0 / 0           |
| deaths causally related to treatment / all      | 0 / 0           | 0 / 0           | 0 / 0           |
| <b>Bone tuberculosis</b>                        |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| <b>Diverticulitis</b>                           |                 |                 |                 |
| subjects affected / exposed                     | 1 / 360 (0.28%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| <b>Gastroenteritis</b>                          |                 |                 |                 |
| subjects affected / exposed                     | 1 / 360 (0.28%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| <b>Gastroenteritis salmonella</b>               |                 |                 |                 |
| subjects affected / exposed                     | 1 / 360 (0.28%) | 0 / 316 (0.00%) | 0 / 154 (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           |
| <b>Sinusitis</b>                                |                 |                 |                 |
| subjects affected / exposed                     | 0 / 360 (0.00%) | 1 / 316 (0.32%) | 0 / 154 (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           |

| <b>Serious adverse events</b>  | <b>Tildrakizumab 100 mg (Part 1)</b> |  |  |
|--|--------------------------------------|--|--|
| <b>Total subjects affected by serious adverse events</b>                   |                                      |  |  |
| subjects affected / exposed  | 5 / 309 (1.62%)                      |  |  |
| number of deaths (all causes)  | 0                                    |  |  |
| number of deaths resulting from adverse events                             |                                      |  |  |
| <b>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</b> |                                      |  |  |
| <b>Benign biliary neoplasm</b>   |                                      |  |  |
| subjects affected / exposed  | 0 / 309 (0.00%)                      |  |  |
| occurrences causally related to treatment / all                            | 0 / 0                                |  |  |
| deaths causally related to treatment / all                                 | 0 / 0                                |  |  |



|   |                 |  |  |
|---|-----------------|--|--|
| Basal cell carcinoma                            |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Bowen's disease                                 |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Carcinoma in situ of skin                       |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Pancreatic carcinoma                            |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Squamous cell carcinoma of skin                 |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Vascular disorders                              |                 |  |  |
| Aneurysm  |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Deep vein thrombosis                            |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Pregnancy, puerperium and perinatal conditions  |                 |  |  |
| Abortion spontaneous                            |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |

|  |                 |  |  |
|--|-----------------|--|--|
| General disorders and administration site conditions |                 |  |  |
| Non-cardiac chest pain                               |                 |  |  |
| subjects affected / exposed                          | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| Immune system disorders                              |                 |  |  |
| Anaphylactic reaction                                |                 |  |  |
| subjects affected / exposed                          | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| Reproductive system and breast disorders             |                 |  |  |
| Uterine haemorrhage                                  |                 |  |  |
| subjects affected / exposed                          | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| Respiratory, thoracic and mediastinal disorders      |                 |  |  |
| Chronic obstructive pulmonary disease                |                 |  |  |
| subjects affected / exposed                          | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| Pneumothorax   |                 |  |  |
| subjects affected / exposed                          | 1 / 309 (0.32%) |  |  |
| occurrences causally related to treatment / all      | 0 / 1           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| Pulmonary embolism                                   |                 |  |  |
| subjects affected / exposed                          | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| Sleep apnoea syndrome                                |                 |  |  |
| subjects affected / exposed                          | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all      | 0 / 0           |  |  |
| deaths causally related to treatment / all           | 0 / 0           |  |  |
| Psychiatric disorders                                |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| Suicide attempt                                 |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Injury, poisoning and procedural complications  |                 |  |  |
| Lower limb fracture                             |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Cardiac disorders                               |                 |  |  |
| Acute myocardial infarction                     |                 |  |  |
| subjects affected / exposed                     | 1 / 309 (0.32%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Angina pectoris                                 |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Coronary artery disease                         |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Tachycardia                                     |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Nervous system disorders                        |                 |  |  |
| Cerebellar infarction                           |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Lacunar infarction                              |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Presyncope                                      |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Sciatica  |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Transient ischaemic attack                      |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Blood and lymphatic system disorders            |                 |  |  |
| Anaemia neonatal                                |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Eye disorders                                   |                 |  |  |
| Cataract  |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Macular fibrosis                                |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Gastrointestinal disorders                      |                 |  |  |
| Constipation                                    |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| Diverticulum                                    |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Food poisoning                                  |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Pancreatitis                                    |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Pancreatitis acute                              |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Salivary gland enlargement                      |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Hepatobiliary disorders                         |                 |  |  |
| Cholecystitis                                   |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Cholelithiasis                                  |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Skin and subcutaneous tissue disorders          |                 |  |  |
| Psoriasis                                       |                 |  |  |
| subjects affected / exposed                     | 1 / 309 (0.32%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| Renal and urinary disorders                     |                 |  |  |
| Nephrolithiasis                                 |                 |  |  |
| subjects affected / exposed                     | 1 / 309 (0.32%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Musculoskeletal and connective tissue disorders |                 |  |  |
| Rotator cuff syndrome                           |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Infections and infestations                     |                 |  |  |
| Epiglottitis                                    |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Cellulitis                                      |                 |  |  |
| subjects affected / exposed                     | 1 / 309 (0.32%) |  |  |
| occurrences causally related to treatment / all | 0 / 1           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Bone tuberculosis                               |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Diverticulitis                                  |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Gastroenteritis                                 |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Gastroenteritis salmonella                      |                 |  |  |

|   |                 |  |  |
|---|-----------------|--|--|
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |
| Sinusitis                                       |                 |  |  |
| subjects affected / exposed                     | 0 / 309 (0.00%) |  |  |
| occurrences causally related to treatment / all | 0 / 0           |  |  |
| deaths causally related to treatment / all      | 0 / 0           |  |  |

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

| <b>Non-serious adverse events</b>                     | Tildrakizumab 200 mg (Part 1) | Tildrakizumab 200 mg (Part 2) | Tildrakizumab 100 mg (Part 2) |
|---|-------------------------------|-------------------------------|-------------------------------|
| Total subjects affected by non-serious adverse events |                               |                               |                               |
| subjects affected / exposed                           | 35 / 308 (11.36%)             | 38 / 370 (10.27%)             | 42 / 374 (11.23%)             |
| Skin and subcutaneous tissue disorders                |                               |                               |                               |
| Psoriasis   |                               |                               |                               |
| subjects affected / exposed                           | 0 / 308 (0.00%)               | 3 / 370 (0.81%)               | 2 / 374 (0.53%)               |
| occurrences (all)                                     | 0                             | 4                             | 2                             |
| Infections and infestations                           |                               |                               |                               |
| Nasopharyngitis                                       |                               |                               |                               |
| subjects affected / exposed                           | 20 / 308 (6.49%)              | 17 / 370 (4.59%)              | 24 / 374 (6.42%)              |
| occurrences (all)                                     | 20                            | 18                            | 24                            |
| Upper respiratory tract infection                     |                               |                               |                               |
| subjects affected / exposed                           | 15 / 308 (4.87%)              | 20 / 370 (5.41%)              | 16 / 374 (4.28%)              |
| occurrences (all)                                     | 15                            | 21                            | 17                            |

| <b>Non-serious adverse events</b>                     | Tildrakizumab 200 mg (Part 3) | Tildrakizumab 100 mg (Part 3) | Placebo (Part 1)  |
|---|-------------------------------|-------------------------------|-------------------|
| Total subjects affected by non-serious adverse events |                               |                               |                   |
| subjects affected / exposed                           | 86 / 360 (23.89%)             | 78 / 316 (24.68%)             | 23 / 154 (14.94%) |
| Skin and subcutaneous tissue disorders                |                               |                               |                   |
| Psoriasis   |                               |                               |                   |
| subjects affected / exposed                           | 9 / 360 (2.50%)               | 9 / 316 (2.85%)               | 8 / 154 (5.19%)   |
| occurrences (all)                                     | 9                             | 9                             | 8                 |
| Infections and infestations                           |                               |                               |                   |
| Nasopharyngitis                                       |                               |                               |                   |
| subjects affected / exposed                           | 44 / 360 (12.22%)             | 48 / 316 (15.19%)             | 8 / 154 (5.19%)   |
| occurrences (all)                                     | 55                            | 66                            | 8                 |

|   |                         |                        |                       |
|---|-------------------------|------------------------|-----------------------|
| Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all) | 37 / 360 (10.28%)<br>43 | 26 / 316 (8.23%)<br>32 | 9 / 154 (5.84%)<br>10 |
|---|-------------------------|------------------------|-----------------------|

|   |  |  |  |
|---|--|--|--|
| <b>Non-serious adverse events</b>   | Tildrakizumab 100 mg (Part 1)                        |  |  |
| Total subjects affected by non-serious adverse events<br>subjects affected / exposed  | 36 / 309 (11.65%)                                    |  |  |
| Skin and subcutaneous tissue disorders<br>Psoriasis<br>subjects affected / exposed<br>occurrences (all)   | 2 / 309 (0.65%)<br>2                                 |  |  |
| Infections and infestations<br>Nasopharyngitis<br>subjects affected / exposed<br>occurrences (all)<br><br>Upper respiratory tract infection<br>subjects affected / exposed<br>occurrences (all) | 24 / 309 (7.77%)<br>26<br><br>10 / 309 (3.24%)<br>10 |  |  |



## More information

### Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date              | Amendment  |
|-------------------|--|
| 12 September 2012 | Tier 2 endpoints revised, PK, ADA timepoints revised |
| 14 January 2014   | New objectives were added                            |
| 08 January 2018   | Other secondary objectives and endpoints were added  |

Notes:

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### Interruptions (globally)

Were there any global interruptions to the trial? No

### Limitations and caveats

None reported