# Clinical trial results:
# A phase III, randomized, double-blind, placebo-controlled multi-center study of subcutaneous secukinumab (150 mg and 300 mg) in prefilled syringe to demonstrate efficacy (including inhibition of structural damage), safety, and tolerability up to 2 years in subjects with active psoriatic arthritis (FUTURE 5)

## Summary

| | |
|---|---|
| EudraCT number | 2015-000050-38 |
| Trial protocol | LT IE HU NL ES DE IT AT LV DK CZ FI EE GR |
| Global end of trial date | 24 January 2019 |

**Results information**

| | |
|---|---|
| Result version number | v1 (current) |
| This version publication date | 09 February 2020 |
| First version publication date | 09 February 2020 |

## Trial information

**Trial identification**

| | |
|---|---|
| Sponsor protocol code | CAIN457F2342 |

**Additional study identifiers**

| | |
|---|---|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02404350 |
| WHO universal trial number (UTN) | - |

Notes:

**Sponsors**

| | |
|---|---|
| Sponsor organisation name | Novartis PharmaAG |
| Sponsor organisation address | CH-4002, Basel, Switzerland, |
| Public contact | Clinical Disclosure Office, Novartis PharmaAG, 41 613241111, novartis.email@novartis.com |
| Scientific contact | Clinical Disclosure Office, Novartis PharmaAG, 41 613241111, Novartis.email@novartis.com |

Notes:

**Paediatric regulatory details**

| | |
|---|---|
| Is trial part of an agreed paediatric investigation plan (PIP) | No |
| Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial? | No |
| Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial? | No |

Notes:

## Results analysis stage

| | |
|---|---|
| Analysis stage | Final |
| Date of interim/final analysis | 07 August 2019 |
| Is this the analysis of the primary completion data? | Yes |
| Primary completion date | 31 August 2017 |
| Global end of trial reached? | Yes |
| Global end of trial date | 24 January 2019 |
| Was the trial ended prematurely? | No |

Notes:

## General information about the trial

Main objective of the trial:

The primary objective was to demonstrate that the efficacy of secukinumab 150 mg sc (with or without loading regimen), or 300 mg sc with loading regimen, at Week 16 is superior to placebo based on proportion of patients with active psoriatic arthritis (PsA) achieving American College of Rheumatology 20 (ACR20) response.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and the International Conference on Harmonization (ICH) Good Clinical Practice (GCP) guidelines. All the local regulatory requirements pertinent to safety of trial subjects were also followed during the conduct of the trial.

Background therapy: -

Evidence for comparator: -

| | |
|---|---|
| Actual start date of recruitment | 31 August 2015 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | Yes |

Notes:

## Population of trial subjects

### Subjects enrolled per country

| | |
|---|---|
| Country: Number of subjects enrolled | Austria: 30 |
| Country: Number of subjects enrolled | Latvia: 8 |
| Country: Number of subjects enrolled | Lithuania: 52 |
| Country: Number of subjects enrolled | Hungary: 36 |
| Country: Number of subjects enrolled | Spain: 65 |
| Country: Number of subjects enrolled | United States: 103 |
| Country: Number of subjects enrolled | Russian Federation: 123 |
| Country: Number of subjects enrolled | Estonia: 15 |
| Country: Number of subjects enrolled | Italy: 10 |
| Country: Number of subjects enrolled | Netherlands: 13 |
| Country: Number of subjects enrolled | Czech Republic: 80 |
| Country: Number of subjects enrolled | United Kingdom: 98 |
| Country: Number of subjects enrolled | Germany: 59 |
| Country: Number of subjects enrolled | Canada: 35 |
| Country: Number of subjects enrolled | Denmark: 2 |
| Country: Number of subjects enrolled | Finland: 15 |
| Country: Number of subjects enrolled | Greece: 22 |
| Country: Number of subjects enrolled | Israel: 41 |

| | |
|---|---|
| Country: Number of subjects enrolled | Thailand: 13 |
| Country: Number of subjects enrolled | Vietnam: 27 |
| Country: Number of subjects enrolled | Philippines: 23 |
| Country: Number of subjects enrolled | Sweden: 4 |
| Country: Number of subjects enrolled | Mexico: 34 |
| Country: Number of subjects enrolled | Ireland: 4 |
| Country: Number of subjects enrolled | India: 38 |
| Country: Number of subjects enrolled | Chile: 23 |
| Country: Number of subjects enrolled | Guatemala: 12 |
| Country: Number of subjects enrolled | Argentina: 11 |
| Worldwide total number of subjects | 996 |
| EEA total number of subjects | 513 |

Notes:

| **Subjects enrolled per age group** | |
|---|---|
| In utero | 0 |
| Preterm newborn - gestational age < 37 wk | 0 |
| Newborns (0-27 days) | 0 |
| Infants and toddlers (28 days-23 months) | 0 |
| Children (2-11 years) | 0 |
| Adolescents (12-17 years) | 0 |
| Adults (18-64 years) | 900 |
| From 65 to 84 years | 96 |
| 85 years and over | 0 |

## Subject disposition

### Recruitment

Recruitment details:

Study was conducted at 173 centers in 28 countries.

### Pre-assignment

Screening details:

999 were randomized and 996 were randomized and dosed, of which 932 participants completed 24 weeks of treatment. Out of the 64 participants who discontinued the most common reasons were participant/guardian decision (32) and adverse events (16).

### Period 1

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

Blinding implementation details:

double-blind

### Arms

| | |
|---|---|
| Are arms mutually exclusive? | Yes |
| **Arm title** | Secukinumab 150 mg Without Load |

Arm description:

Participants were subcutaneously (s.c.) administered with 150 milligrams (mg) of secukinumab as 1 milliliter (mL) Pre-Filled Syringe (PFS) and secukinumab matching placebo (1 mL PFS) at baseline. Participants received secukinumab matching placebo (2*1 mL PFS) at Weeks 1, 2 and 3. From week 4 participants received secukinumab 150 mg (1 mL PFS) and secukinumab matching placebo (1 mL PFS) every four weeks up to 100 weeks.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | Secukinumab |
| Investigational medicinal product code | |
| Other name | AIN457F |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Secukinumab 150 mg Without Load sc

| | |
|---|---|
| **Arm title** | Secukinumab 150 mg With Load |

Arm description:

Participants were s.c. administered with 150 mg of secukinumab as 1 mL PFS and secukinumab matching placebo (1 mL PFS) at baseline, weeks 1, 2 and 3, followed by dosing every four weeks starting at Week 4 up to 100.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | secukinumab |
| Investigational medicinal product code | |
| Other name | AIN457F |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Secukinumab 150 mg With Load

| | |
|---|---|
| **Arm title** | Secukinumab 300 mg With Load |

Arm description:

Participants were s.c. administered with 300 mg of secukinumab as 2*1 mL PFS (150 mg dose) at baseline, weeks 1, 2 and 3, followed by dosing every four weeks starting at Week 4 up to 100 weeks.

| | |
|---|---|
| Arm type | Experimental |
| Investigational medicinal product name | secukinumab |
| Investigational medicinal product code | |
| Other name | AIN457F |
| Pharmaceutical forms | Injection |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Secukinumab 300 mg With Load sc

| | |
|---|---|
| **Arm title** | Placebo |

Arm description:

Participants were s.c. administered with secukinumab matching placebo (2*1 mL PFS) at baseline, weeks 1, 2 and 3, followed by dosing every four weeks starting at Week 4. Participants were further randomized to two different treatment sequences in 1:1 ratio at baseline as secukinumab matching placebo till Week 16/24 followed by secukinumab 150 mg every 4 weeks starting at Week 16/24 up to 100 weeks and secukinumab matching placebo till Week 16/24 followed by secukinumab 300 mg every 4 weeks starting at Week 16/24 up to 100 weeks.

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

Dosage and administration details:

sc

| **Number of subjects in period 1** | Secukinumab 150 mg Without Load | Secukinumab 150 mg With Load | Secukinumab 300 mg With Load |
|---|---|---|---|
| Started | 222 | 220 | 222 |
| Completed | 207 | 214 | 216 |
| Not completed | 15 | 6 | 6 |
| Due to Technical problems | - | - | - |
| Consent withdrawn by subject | 7 | 3 | 3 |
| Physician decision | 1 | - | - |
| Due to Non-compliance with treatment | - | - | - |
| Adverse event, non-fatal | 2 | 2 | 3 |
| Pregnancy | - | - | - |
| Lost to follow-up | 2 | - | - |
| Lack of efficacy | 3 | 1 | - |

| **Number of subjects in period 1** | Placebo |
|---|---|
| Started | 332 |
| Completed | 295 |
| Not completed | 37 |

| | |
|---|---|
| Due to Technical problems | 1 |
| Consent withdrawn by subject | 19 |
| Physician decision | 2 |
| Due to Non-compliance with treatment | 1 |
| Adverse event, non-fatal | 9 |
| Pregnancy | 1 |
| Lost to follow-up | 1 |
| Lack of efficacy | 3 |

## Baseline characteristics

| Reporting groups | |
|---|---|
| Reporting group title | Secukinumab 150 mg Without Load |
| Reporting group description: | |
| Participants were subcutaneously (s.c.) administered with 150 milligrams (mg) of secukinumab as 1 milliliter (mL) Pre-Filled Syringe (PFS) and secukinumab matching placebo (1 mL PFS) at baseline. Participants received secukinumab matching placebo (2*1 mL PFS) at Weeks 1, 2 and 3. From week 4 participants received secukinumab 150 mg (1 mL PFS) and secukinumab matching placebo (1 mL PFS) every four weeks up to 100 weeks. | |
| Reporting group title | Secukinumab 150 mg With Load |
| Reporting group description: | |
| Participants were s.c. administered with 150 mg of secukinumab as 1 mL PFS and secukinumab matching placebo (1 mL PFS) at baseline, weeks 1, 2 and 3, followed by dosing every four weeks starting at Week 4 up to 100. | |
| Reporting group title | Secukinumab 300 mg With Load |
| Reporting group description: | |
| Participants were s.c. administered with 300 mg of secukinumab as 2*1 mL PFS (150 mg dose) at baseline, weeks 1, 2 and 3, followed by dosing every four weeks starting at Week 4 up to 100 weeks. | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Participants were s.c. administered with secukinumab matching placebo (2*1 mL PFS) at baseline, weeks 1, 2 and 3, followed by dosing every four weeks starting at Week 4. Participants were further randomized to two different treatment sequences in 1:1 ratio at baseline as secukinumab matching placebo till Week 16/24 followed by secukinumab 150 mg every 4 weeks starting at Week 16/24 up to 100 weeks and secukinumab matching placebo till Week 16/24 followed by secukinumab 300 mg every 4 weeks starting at Week 16/24 up to 100 weeks. | |

| Reporting group values | Secukinumab 150 mg Without Load | Secukinumab 150 mg With Load | Secukinumab 300 mg With Load |
|---|---|---|---|
| Number of subjects | 222 | 220 | 222 |
| Age categorical<br>Units: Subjects | | | |
| In utero | 0 | 0 | 0 |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | 0 |
| Newborns (0-27 days) | 0 | 0 | 0 |
| Infants and toddlers (28 days-23 months) | 0 | 0 | 0 |
| Children (2-11 years) | 0 | 0 | 0 |
| Adolescents (12-17 years) | 0 | 0 | 0 |
| Adults (18-64 years) | 204 | 193 | 202 |
| From 65-84 years | 18 | 27 | 20 |
| 85 years and over | 0 | 0 | 0 |
| Age Continuous<br>Units: years | | | |
| arithmetic mean | 48.8 | 48.4 | 48.9 |
| standard deviation | ± 11.82 | ± 12.87 | ± 12.80 |
| Sex: Female, Male<br>Units: | | | |
| Female | 102 | 109 | 114 |
| Male | 120 | 111 | 108 |

| | | | |
|---|---|---|---|
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 25 | 30 | 31 |
| Not Hispanic or Latino | 180 | 160 | 174 |
| Unknown or Not Reported | 17 | 30 | 17 |
| Participants with psoriasis of hands and feet<br>Units: Subjects | | | |
| Yes | 133 | 135 | 127 |
| No | 89 | 85 | 95 |
| Subjects with psoriasis of nail<br>Units: Subjects | | | |
| Yes | 153 | 135 | 144 |
| No | 69 | 85 | 78 |
| Subjects with psoriasis ≥ 3% of BSA<br>Units: Subjects | | | |
| Yes | 117 | 125 | 110 |
| No | 105 | 95 | 112 |

| **Reporting group values** | Placebo | Total | |
|---|---|---|---|
| Number of subjects | 332 | 996 | |
| Age categorical<br>Units: Subjects | | | |
| In utero | 0 | 0 | |
| Preterm newborn infants (gestational age < 37 wks) | 0 | 0 | |
| Newborns (0-27 days) | 0 | 0 | |
| Infants and toddlers (28 days-23 months) | 0 | 0 | |
| Children (2-11 years) | 0 | 0 | |
| Adolescents (12-17 years) | 0 | 0 | |
| Adults (18-64 years) | 301 | 900 | |
| From 65-84 years | 31 | 96 | |
| 85 years and over | 0 | 0 | |
| Age Continuous<br>Units: years | | | |
| arithmetic mean | 49.0 | | |
| standard deviation | ± 12.12 | - | |
| Sex: Female, Male<br>Units: | | | |
| Female | 171 | 496 | |
| Male | 161 | 500 | |
| Ethnicity (NIH/OMB)<br>Units: Subjects | | | |
| Hispanic or Latino | 51 | 137 | |
| Not Hispanic or Latino | 251 | 765 | |
| Unknown or Not Reported | 30 | 94 | |
| Participants with psoriasis of hands and feet<br>Units: Subjects | | | |
| Yes | 174 | 569 | |
| No | 158 | 427 | |

| | | | |
|---|---|---|---|
| Subjects with psoriasis of nail<br>Units: Subjects | | | |
| Yes | 231 | 663 | |
| No | 101 | 333 | |
| Subjects with psoriasis ≥ 3% of BSA<br>Units: Subjects | | | |
| Yes | 162 | 514 | |
| No | 170 | 482 | |

## End points reporting groups

| Reporting group title | Secukinumab 150 mg Without Load |
|---|---|
| Reporting group description: | |
| Participants were subcutaneously (s.c.) administered with 150 milligrams (mg) of secukinumab as 1 milliliter (mL) Pre-Filled Syringe (PFS) and secukinumab matching placebo (1 mL PFS) at baseline. Participants received secukinumab matching placebo (2*1 mL PFS) at Weeks 1, 2 and 3. From week 4 participants received secukinumab 150 mg (1 mL PFS) and secukinumab matching placebo (1 mL PFS) every four weeks up to 100 weeks. | |
| Reporting group title | Secukinumab 150 mg With Load |
| Reporting group description: | |
| Participants were s.c. administered with 150 mg of secukinumab as 1 mL PFS and secukinumab matching placebo (1 mL PFS) at baseline, weeks 1, 2 and 3, followed by dosing every four weeks starting at Week 4 up to 100. | |
| Reporting group title | Secukinumab 300 mg With Load |
| Reporting group description: | |
| Participants were s.c. administered with 300 mg of secukinumab as 2*1 mL PFS (150 mg dose) at baseline, weeks 1, 2 and 3, followed by dosing every four weeks starting at Week 4 up to 100 weeks. | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Participants were s.c. administered with secukinumab matching placebo (2*1 mL PFS) at baseline, weeks 1, 2 and 3, followed by dosing every four weeks starting at Week 4. Participants were further randomized to two different treatment sequences in 1:1 ratio at baseline as secukinumab matching placebo till Week 16/24 followed by secukinumab 150 mg every 4 weeks starting at Week 16/24 up to 100 weeks and secukinumab matching placebo till Week 16/24 followed by secukinumab 300 mg every 4 weeks starting at Week 16/24 up to 100 weeks. | |

## Primary: Percentage of Participants With Active Psoriatic Arthritis (PsA) Achieving an American College of Rheumatology Response 20 (ACR20) at Week 16

| End point title | Percentage of Participants With Active Psoriatic Arthritis (PsA) Achieving an American College of Rheumatology Response 20 (ACR20) at Week 16 |
|---|---|
| End point description: | |
| ACR20 response was defined as having a positive clinical response to treatment (individual improvement) in disease activity if the participant had at least 20% improvement based on tender 78-joint count, swollen 76-joint count and at least 20% improvement in 3 of the following 5 measures: participant's assessment of PsA pain, patient’s global assessment of disease activity, physician’s global assessment of disease activity, participant's self-assessed disability (Health Assessment Questionnaire Disability Index (HAQ-DI) score), and acute phase reactant evaluated as (high sensitivity c-reactive protein (hsCRP) or erythrocyte sedimentation rate (ESR)). | |
| End point type | Primary |
| End point timeframe: | |
| Week 16 | |

| End point values | Secukinumab 150 mg Without Load | Secukinumab 150 mg With Load | Secukinumab 300 mg With Load | Placebo |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 222 | 220 | 222 | 332 |
| Units: percentage of participants | | | | |
| number (not applicable) | 59.5 | 55.5 | 62.6 | 27.4 |

## Statistical analyses

| **Statistical analysis title** | Secukinumab 150 mg Without Load, Placebo |
|---|---|
| Statistical analysis description: | |
| Statistical values were calculated from a logistic regression model with treatment and randomization stratum (TNF-a status -naive or Incidence Rate) as factors and baseline weight as a covariate. | |
| Comparison groups | Secukinumab 150 mg Without Load v Placebo |
| Number of subjects included in analysis | 554 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 4.02 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.78 |
| upper limit | 5.79 |

| **Statistical analysis title** | Secukinumab 150 mg With Load |
|---|---|
| Statistical analysis description: | |
| Statistical values were calculated from a logistic regression model with treatment and randomization stratum (TNF-a status -naive or Incidence Rate) as factors and baseline weight as a covariate. | |
| Comparison groups | Secukinumab 150 mg With Load v Placebo |
| Number of subjects included in analysis | 552 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 3.38 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.35 |
| upper limit | 4.87 |

| **Statistical analysis title** | Secukinumab 300 mg With Load |
|---|---|
| Statistical analysis description: | |
| Statistical values were calculated from a logistic regression model with treatment and randomization | |

stratum (TNF-a status -naive or Incidence Rate) as factors and baseline weight as a covariate.

| | |
|---|---|
| Comparison groups | Secukinumab 300 mg With Load v Placebo |
| Number of subjects included in analysis | 554 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 4.58 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.16 |
| upper limit | 6.63 |

## Secondary: Change from baseline to Week 24 with secukinumab compared with placebo for joint/bone structural damage (using van der Heijde modified total Sharp score (mTSS))

| | |
|---|---|
| End point title | Change from baseline to Week 24 with secukinumab compared with placebo for joint/bone structural damage (using van der Heijde modified total Sharp score (mTSS)) |

End point description:

PsA modified vdH-mTSS scoring method was used to assess bone erosion & joint space narrowing (JSN) in hands & feet; that included the 2nd through 5th distal interphalangeal (DIP) joints of each hand. Maximum score for erosions was 5 in joints of the hands and 10 in joints of the feet with 0=no erosions, 1=discrete erosion, 2=large erosion not passing the mid-line, and 3=large erosion passing the mid-line. JSN is: 0=normal, 1=asymmetrical or minimal narrowing up to a maximum of 25%, 2 = definite narrowing with loss of up to 50% of the normal space, 3 = definite narrowing with loss of 50–99% of the normal space, and 4 = absence of a joint space. Maximum erosion score is 320 (200 for the hands and 120 for the feet), and the max total JSN score is 208 (160 for the hands and 48 for the feet). Total radiographic score (hands & feet combined) ranges from 0 to 528, where higher scores indicate more articular damage

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

End point timeframe:

Baseline, Week 24

| End point values | Secukinumab 150 mg Without Load | Secukinumab 150 mg With Load | Secukinumab 300 mg With Load | Placebo |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 222 | 220 | 222 | 332[1] |
| Units: Sharp score | | | | |
| arithmetic mean (standard error) | -0.10 (± 0.22) | 0.13 (± 0.13) | 0.02 (± 0.13) | 0.50 (± 0) |

Notes:

[1] - Placebo cannot be compared to itself

## Statistical analyses

No statistical analyses for this end point

## Secondary: Count and Percentage of patients achieving Psoriatic Area and Severity Index 75 (PASI75) response

| | |
|---|---|
| End point title | Count and Percentage of patients achieving Psoriatic Area and Severity Index 75 (PASI75) response |

End point description:

The efficacy of secukinumab 150 mg (with or without loading regimen), or 300 mg (with loading regimen) at Week 16 compared with placebo based on the proportion of patients achieving Psoriatic Area and Severity Index 75 (PASI75) response.

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

End point timeframe:

Week 16

| **End point values** | Secukinumab 150 mg Without Load | Secukinumab 150 mg With Load | Secukinumab 300 mg With Load | Placebo |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 117 | 125 | 110 | 162 |
| Units: participants | 68 | 75 | 77 | 20 |

### Statistical analyses

| **Statistical analysis title** | Secukinumab 150 mg Without Load |
|---|---|

Statistical analysis description:

Odds ratio, 95% confidence interval, and p-value are from a logistic regression model with treatment and randomization stratum (TNF-alpha status -naïve or IR) as factors and baseline weight as a covariate.

| | |
|---|---|
| Comparison groups | Secukinumab 150 mg Without Load v Placebo |
| Number of subjects included in analysis | 279 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 10.15 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 5.52 |
| upper limit | 18.63 |

| **Statistical analysis title** | Secukinumab 150 mg With Load |
|---|---|

Statistical analysis description:

Odds ratio, 95% confidence interval, and p-value are from a logistic regression model with treatment and randomization stratum (TNF-alpha status -naïve or IR) as factors and baseline weight as a covariate.

| | |
|---|---|
| Comparison groups | Secukinumab 150 mg With Load v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 287 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 11.66 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 6.37 |
| upper limit | 21.37 |

| **Statistical analysis title** | Secukinumab 300 mg With Load |
|---|---|

Statistical analysis description:

Odds ratio, 95% confidence interval, and p-value are from a logistic regression model with treatment and randomization stratum (TNF-alpha status -naïve or IR) as factors and baseline weight as a covariate.

| | |
|---|---|
| Comparison groups | Secukinumab 300 mg With Load v Placebo |
| Number of subjects included in analysis | 272 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 18.06 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 9.56 |
| upper limit | 34.12 |

## Secondary: Count and Percentage of patients achieving Psoriatic Area and Severity Index 90 (PASI90) response

| | |
|---|---|
| End point title | Count and Percentage of patients achieving Psoriatic Area and Severity Index 90 (PASI90) response |

End point description:

The efficacy of secukinumab 150 mg (with or without loading regimen), or 300 mg (with loading regimen) at Week 16 compared with placebo based on the proportion of patients achieving Psoriatic Area and Severity Index 90 (PASI90) response.

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

End point timeframe:

16 weeks

| End point values | Secukinumab 150 mg Without Load | Secukinumab 150 mg With Load | Secukinumab 300 mg With Load | Placebo |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 117 | 125 | 110 | 162 |
| Units: participants | 37 | 46 | 59 | 15 |

**Statistical analyses**

| Statistical analysis title | Secukinumab 150 mg Without Load |
|---|---|
| Statistical analysis description: | |
| Odds ratio, 95% confidence interval, and p-value are from a logistic regression model with treatment and randomization stratum (TNF-alpha status -naïve or IR) as factors and baseline weight as a covariate. Missing responses are imputed as non-responders. | |
| Comparison groups | Secukinumab 150 mg Without Load v Placebo |
| Number of subjects included in analysis | 279 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 4.51 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 2.31 |
| upper limit | 8.83 |

| Statistical analysis title | Secukinumab 150 mg With Load |
|---|---|
| Statistical analysis description: | |
| Odds ratio, 95% confidence interval, and p-value are from a logistic regression model with treatment and randomization stratum (TNF-alpha status -naïve or IR) as factors and baseline weight as a covariate. Missing responses are imputed as non-responders. | |
| Comparison groups | Secukinumab 150 mg With Load v Placebo |
| Number of subjects included in analysis | 287 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 6.14 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.18 |
| upper limit | 11.87 |

| **Statistical analysis title** | Secukinumab 300 mg With Load |
|---|---|

Statistical analysis description:

Odds ratio, 95% confidence interval, and p-value are from a logistic regression model with treatment and randomization stratum (TNF-alpha status -naïve or IR) as factors and baseline weight as a covariate. Missing responses are imputed as non-responders.

| | |
|---|---|
| Comparison groups | Secukinumab 300 mg With Load v Placebo |
| Number of subjects included in analysis | 272 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 12.55 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 6.43 |
| upper limit | 24.48 |

## Secondary: Count and Percentage of patients achieving an ACR50 response

| End point title | Count and Percentage of patients achieving an ACR50 response |
|---|---|

End point description:

ACR 50 Response is a measure based on American College of Rheumatology criteria of at least a 50% improvement in the number of tender and swollen joints, and a 50% improvement in at least 3 of the following: the patient’s global assessment of disease status; the patient’s assessment of pain; the patient’s assessment of function measured using the Stanford Health Assessment Questionnaire the physician’s global assessment of disease status; serum C-reactive protein levels.

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

End point timeframe:

16 weeks

| **End point values** | Secukinumab 150 mg Without Load | Secukinumab 150 mg With Load | Secukinumab 300 mg With Load | Placebo |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 222 | 220 | 222 | 332 |
| Units: participants | 71 | 79 | 88 | 27 |

## Statistical analyses

| **Statistical analysis title** | Secukinumab 150 mg Without Load |
|---|---|

Statistical analysis description:

Odds ratio, 95% confidence interval, and p-value are from a logistic regression model with treatment and randomization stratum (TNF-alpha status -naïve or IR) as factors and baseline weight as a covariate.

| | |
|---|---|
| Comparison groups | Secukinumab 150 mg Without Load v Placebo |
| Number of subjects included in analysis | 554 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Log odds ratio |
| Point estimate | 5.37 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.3 |
| upper limit | 8.73 |

| **Statistical analysis title** | Secukinumab 150 mg With Load |
|---|---|

Statistical analysis description:

Odds ratio, 95% confidence interval, and p-value are from a logistic regression model with treatment and randomization stratum (TNF-alpha status -naïve or IR) as factors and baseline weight as a covariate.

| | |
|---|---|
| Comparison groups | Secukinumab 150 mg With Load v Placebo |
| Number of subjects included in analysis | 552 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 6.37 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 3.93 |
| upper limit | 10.32 |

| **Statistical analysis title** | Secukinumab 300 mg With Load |
|---|---|

Statistical analysis description:

Odds ratio, 95% confidence interval, and p-value are from a logistic regression model with treatment and randomization stratum (TNF-alpha status -naïve or IR) as factors and baseline weight as a covariate.

| | |
|---|---|
| Comparison groups | Secukinumab 300 mg With Load v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 554 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 7.43 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 4.61 |
| upper limit | 12 |

## Secondary: Change from baseline in HAQ-DI© score

| | |
|---|---|
| End point title | Change from baseline in HAQ-DI© score |

End point description:

The change (within treatment) on secukinumab 150 mg (with or without loading regimen), or 300 mg (with loading regimen), at Week 16 compared with placebo for the disease activity assessed by the changes in The Health Assessment Questionnaire disability index (HAQ-DI) relative to baseline.

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

End point timeframe:

16 weeks

| End point values | Secukinumab 150 mg Without Load | Secukinumab 150 mg With Load | Secukinumab 300 mg With Load | Placebo |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 211 | 210 | 211 | 300 |
| Units: scores on a scale | | | | |
| least squares mean (standard error) | -0.45 (± 0.035) | -0.44 (± 0.035) | -0.55 (± 0.035) | -0.21 (± 0.029) |

### Statistical analyses

| Statistical analysis title | Secukinumab 150 mg Without Load |
|---|---|
| Comparison groups | Secukinumab 150 mg Without Load v Placebo |
| Number of subjects included in analysis | 511 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | < 0.0001 |
| Method | Mixed models analysis |
| Parameter estimate | Treatment contrast in LS mean (Change) |
| Point estimate | -0.24 |

| | |
|---|---|
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.32 |
| upper limit | -0.15 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.045 |

| **Statistical analysis title** | Secukinumab 150 mg With Load |
|---|---|
| Comparison groups | Secukinumab 150 mg With Load v Placebo |
| Number of subjects included in analysis | 510 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Mixed models analysis |
| Parameter estimate | Treatment Contrast in LS mean (Change) |
| Point estimate | -0.23 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.32 |
| upper limit | -0.14 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.045 |

| **Statistical analysis title** | Secukinumab 300 mg With Load |
|---|---|
| Comparison groups | Secukinumab 300 mg With Load v Placebo |
| Number of subjects included in analysis | 511 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Mixed models analysis |
| Parameter estimate | Treatment Contrast inj LS mean (Change) |
| Point estimate | -0.33 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.42 |
| upper limit | -0.24 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.045 |

**Secondary: Change from baseline in Disease Activity Score for 28 joints (DAS28-CRP) (utilizing High sensitivity C-Reactive Protein (hsCRP))**

| End point title | Change from baseline in Disease Activity Score for 28 joints (DAS28-CRP) (utilizing High sensitivity C-Reactive Protein (hsCRP)) |
|---|---|

End point description:

The improvement on secukinumab 150 mg (with or without loading regimen), or 300 mg (with loading regimen) at Week 16 compared with placebo for the disease activity assessed by the changes in Disease Activity Score for 28 joints (DAS28-CRP) (utilizing High sensitivity C-Reactive Protein (hsCRP)) relative to baseline.

Scores range from 0 (no difficulty) to 3 (unable to do)

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

End point timeframe:

16 weeks

| **End point values** | Secukinumab 150 mg Without Load | Secukinumab 150 mg With Load | Secukinumab 300 mg With Load | Placebo |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 210 | 208 | 209 | 297 |
| Units: scores on a scale | | | | |
| least squares mean (standard error) | -1.29 (± 0.074) | -1.29 (± 0.075) | -1.49 (± 0.074) | -0.63 (± 0.062) |

**Statistical analyses**

| **Statistical analysis title** | Secukinumab 150 mg Without Load |
|---|---|

Statistical analysis description:

Mixed model with treatment regimen, analysis visit and randomization stratum (TNF-alpha status -naïve or IR) as factors, weight and baseline score as continuous covariates, and treatment by analysis visit and baseline score by analysis visit as interaction terms, using an unstructured covariance structure

| Comparison groups | Secukinumab 150 mg Without Load v Placebo |
|---|---|
| Number of subjects included in analysis | 507 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Mixed models analysis |
| Parameter estimate | Treatment contrast in LS mean (Change) |
| Point estimate | -0.66 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.85 |
| upper limit | -0.47 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.096 |

| **Statistical analysis title** | Secukinumab 150 mg With Load |
|---|---|

Statistical analysis description:

Mixed model with treatment regimen, analysis visit and randomization stratum (TNF-alpha status -naïve or IR) as factors, weight and baseline score as continuous covariates, and treatment by analysis visit and baseline score by analysis visit as interaction terms, using an unstructured covariance structure

| | |
|---|---|
| Comparison groups | Secukinumab 150 mg With Load v Placebo |
| Number of subjects included in analysis | 505 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Mixed models analysis |
| Parameter estimate | Treatment Contrast in LS Mean (Change) |
| Point estimate | -0.66 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -0.85 |
| upper limit | -0.47 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.096 |

| **Statistical analysis title** | Secukinumab 300 mg With Load |
|---|---|

Statistical analysis description:

Mixed model with treatment regimen, analysis visit and randomization stratum (TNF-alpha status -naïve or IR) as factors, weight and baseline score as continuous covariates, and treatment by analysis visit and baseline score by analysis visit as interaction terms, using an unstructured covariance structure

| | |
|---|---|
| Comparison groups | Secukinumab 300 mg With Load v Placebo |
| Number of subjects included in analysis | 506 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Mixed models analysis |
| Parameter estimate | Treatment contrast in LS mean (Change) |
| Point estimate | -0.86 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | -1.05 |
| upper limit | -0.67 |
| Variability estimate | Standard error of the mean |
| Dispersion value | 0.096 |

## Secondary: Count and Percentage of patients with enthesitis in the subset of patients who had enthesitis at baseline

| End point title | Count and Percentage of patients with enthesitis in the subset of patients who had enthesitis at baseline |
|---|---|

End point description:

The efficacy of secukinumab pooled regimen (150 mg with or without loading regimen, and 300 mg with loading regimen) at Week 16 compared with placebo based on the
proportion of patients with enthesitis in the subset of patients who had enthesitis at

baseline

| | |
|---|---|
| End point type | Secondary |
| End point timeframe: 16 weeks | |

| End point values | Secukinumab 150 mg Without Load | Secukinumab 150 mg With Load | Secukinumab 300 mg With Load | Placebo |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 129 | 141 | 140 | 192 |
| Units: participants | 75 | 64 | 62 | 124 |

**Statistical analyses**

| Statistical analysis title | Secukinumab 150 mg Without Load |
|---|---|
| Comparison groups | Secukinumab 150 mg Without Load v Placebo |
| Number of subjects included in analysis | 321 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.225 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.75 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.47 |
| upper limit | 1.19 |

| Statistical analysis title | Secukinumab 150 mg With Load |
|---|---|
| Comparison groups | Secukinumab 150 mg With Load v Placebo |
| Number of subjects included in analysis | 333 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0004 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.45 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.29 |
| upper limit | 0.7 |

| Statistical analysis title | Secukinumab 300 mg With Load |
|---|---|
| Comparison groups | Secukinumab 300 mg With Load v Placebo |
| Number of subjects included in analysis | 332 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0004 |
| Method | Regression, Logistic |
| Parameter estimate | Log odds ratio |
| Point estimate | 0.44 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.28 |
| upper limit | 0.69 |

## Secondary: Count and Percentage of Participants with dactylitis in the subset of patients who have dactylitis at baseline

| End point title | Count and Percentage of Participants with dactylitis in the subset of patients who have dactylitis at baseline |
|---|---|

End point description:

The efficacy of secukinumab pooled regimen (150 mg with or without loading regimen, and 300 mg with loading regimen) at Week 16 compared with placebo based on the proportion of patients with dactylitis in the subset of patients who have dactylitis at baseline

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

End point timeframe:

16 weeks

| End point values | Secukinumab 150 mg Without Load | Secukinumab 150 mg With Load | Secukinumab 300 mg With Load | Placebo |
|---|---|---|---|---|
| Subject group type | Reporting group | Reporting group | Reporting group | Reporting group |
| Number of subjects analysed | 103 | 80 | 82 | 124 |
| Units: Participants | 45 | 34 | 28 | 84 |

### Statistical analyses

| Statistical analysis title | Secukinumab 150 mg Without Load |
|---|---|
| Comparison groups | Secukinumab 150 mg Without Load v Placebo |

| | |
|---|---|
| Number of subjects included in analysis | 227 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0004 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.37 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.22 |
| upper limit | 0.65 |

| **Statistical analysis title** | Secukinumab 150 mg With Load |
|---|---|
| Comparison groups | Secukinumab 150 mg With Load v Placebo |
| Number of subjects included in analysis | 204 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | = 0.0003 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.34 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.19 |
| upper limit | 0.6 |

| **Statistical analysis title** | Secukinumab 300 mg With Load |
|---|---|
| Comparison groups | Secukinumab 300 mg With Load v Placebo |
| Number of subjects included in analysis | 206 |
| Analysis specification | Pre-specified |
| Analysis type | superiority |
| P-value | < 0.0001 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 0.24 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.13 |
| upper limit | 0.44 |

## Adverse events

### Adverse events information

Timeframe for reporting adverse events:

AEs & SAEs were collected for maximum duration of treatment & follow up for a participant per protocol for approximately 24 weeks. All cause mortality was collected for as long as participants could be contacted from FPFV until LPLV up to a max of 24 wks

Adverse event reporting additional description:

An Adverse Event (AE) is any sign or symptom that occurs during the study treatment plus 28 days post treatment

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

### Dictionary used

| | |
|---|---|
| Dictionary name | MedDRA |
| Dictionary version | 20.0 |

### Reporting groups

| | |
|---|---|
| Reporting group title | Secukinumab 150 mg Without Load |

Reporting group description:

Participants were s.c. administered with 150 milligrams (mg) of secukinumab as 1 mL PFS and secukinumab matching placebo (1.0 mL PFS) at baseline. Participants received secukinumab matching placebo (2*1 mL PFS) at Weeks 1, 2 and 3. From week 4 participants received secukinumab 150 mg (1 mL PFS) and secukinumab matching placebo (1 mL PFS) every four weeks up to 100 weeks.

| | |
|---|---|
| Reporting group title | Secukinumab 150 mg With Load |

Reporting group description:

Participants were s.c. administered with 150 mg of secukinumab as 1 mL PFS and secukinumab matching placebo (1.0 mL PFS) at baseline, weeks 1, 2 and 3, followed by dosing every four weeks starting at Week 4 up to 100.

| | |
|---|---|
| Reporting group title | Secukinumab 300 mg With Load |

Reporting group description:

Participants were s.c. administered with 300 mg of secukinumab as 2*1 mL PFS (150 mg dose) at baseline, weeks 1, 2 and 3, followed by dosing every four weeks starting at Week 4 up to 100 weeks.

| | |
|---|---|
| Reporting group title | Secukinumab Total |

Reporting group description:

Participants were s.c. administered with secukinumab and secukinumab matching placebo at baseline, weeks 1, 2 and 3, followed by dosing every four weeks starting at Week 4 up to 100.

| | |
|---|---|
| Reporting group title | Placebo |

Reporting group description:

Participants were s.c. administered with secukinumab matching placebo (2*1 mL PFS) at baseline, weeks 1, 2 and 3, followed by dosing every four weeks starting at Week 4. Participants were further randomized to two different treatment sequences in 1:1 ratio at baseline as secukinumab matching placebo till Week 16/24 followed by secukinumab 150 mg every 4 weeks starting at Week 16/24 up to 100 weeks and secukinumab matching placebo till Week 16/24 followed by secukinumab 300 mg every 4 weeks starting at Week 16/24 up to 100 weeks.

| Serious adverse events | Secukinumab 150 mg Without Load | Secukinumab 150 mg With Load | Secukinumab 300 mg With Load |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 6 / 222 (2.70%) | 9 / 220 (4.09%) | 7 / 222 (3.15%) |
| number of deaths (all causes) | 0 | 0 | 0 |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |

| | | | |
|---|---|---|---|
| Basal cell carcinoma | | | |
| subjects affected / exposed | 1 / 222 (0.45%) | 0 / 220 (0.00%) | 0 / 222 (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 |
| Malignant melanoma | | | |
| subjects affected / exposed | 1 / 222 (0.45%) | 0 / 220 (0.00%) | 0 / 222 (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 |
| Vascular disorders | | | |
| Circulatory collapse | | | |
| subjects affected / exposed | 1 / 222 (0.45%) | 0 / 220 (0.00%) | 0 / 222 (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 |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (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 |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 1 / 220 (0.45%) | 0 / 222 (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 |
| Ectopic pregnancy | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 1 / 220 (0.45%) | 0 / 222 (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 |
| General disorders and administration site conditions | | | |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 1 / 222 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 1 / 222 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| 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 / 222 (0.45%) | 0 / 220 (0.00%) | 0 / 222 (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 |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (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 | | | |
| Suicidal ideation | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 1 / 220 (0.45%) | 0 / 222 (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 |
| Investigations | | | |
| Computerised tomogram thorax abnormal | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 1 / 220 (0.45%) | 0 / 222 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Injury, poisoning and procedural complications | | | |
| Ankle fracture | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 1 / 222 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Concussion | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 1 / 222 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Foreign body | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 222 (0.00%) | 1 / 220 (0.45%) | 0 / 222 (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 |
| Hip fracture | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 1 / 220 (0.45%) | 0 / 222 (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 |
| Humerus fracture | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 1 / 220 (0.45%) | 0 / 222 (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 |
| Road traffic accident | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (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 |
| Tibia fracture | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 1 / 222 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Ulna fracture | | | |
| subjects affected / exposed | 1 / 222 (0.45%) | 0 / 220 (0.00%) | 0 / 222 (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 |
| Cardiac disorders | | | |
| Coronary artery disease | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 1 / 220 (0.45%) | 0 / 222 (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 |
| Myocardial infarction | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 1 / 220 (0.45%) | 0 / 222 (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 |
| Nervous system disorders | | | |

| | | | |
|---|---|---|---|
| Carotid artery stenosis | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (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 |
| Polyneuropathy | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (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 / 222 (0.00%) | 1 / 220 (0.45%) | 0 / 222 (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 |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 1 / 222 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Blood and lymphatic system disorders | | | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Gastrointestinal disorders | | | |
| Colitis ulcerative | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 1 / 220 (0.45%) | 0 / 222 (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 |
| Crohn's disease | | | |
| subjects affected / exposed | 1 / 222 (0.45%) | 0 / 220 (0.00%) | 0 / 222 (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 |
| Diverticulum | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (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 |

| | | | |
|---|---|---|---|
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (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 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (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 | | | |
| Renal colic | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (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 | | | |
| Arthritis | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (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 |
| Chondropathy | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (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 chest pain | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 1 / 222 (0.45%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 1 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (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 |
| Synovitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (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 | | | |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (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 |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (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 |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 222 (0.45%) | 0 / 220 (0.00%) | 0 / 222 (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 |
| Typhoid fever | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 1 / 220 (0.45%) | 0 / 222 (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 |
| Viral infection | | | |
| subjects affected / exposed | 0 / 222 (0.00%) | 0 / 220 (0.00%) | 0 / 222 (0.00%) |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | 0 / 0 |

| **Serious adverse events** | Secukinumab Total | Placebo | |
|---|---|---|---|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 25 / 822 (3.04%) | 12 / 332 (3.61%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | | | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Basal cell carcinoma | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Malignant melanoma | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Circulatory collapse | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Deep vein thrombosis | | | |
| subjects affected / exposed | 0 / 822 (0.00%) | 1 / 332 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pregnancy, puerperium and perinatal conditions | | | |
| Abortion spontaneous | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ectopic pregnancy | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| General disorders and administration site conditions | | | |
| Non-cardiac chest pain | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Immune system disorders | | | |
| Anaphylactic reaction | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Chronic obstructive pulmonary disease | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pulmonary embolism | | | |
| subjects affected / exposed | 0 / 822 (0.00%) | 1 / 332 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Psychiatric disorders | | | |
| Suicidal ideation | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Investigations | | | |
| Computerised tomogram thorax abnormal | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Injury, poisoning and procedural complications | | | |
| Ankle fracture | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Concussion | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Foreign body | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Hip fracture | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Humerus fracture | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Road traffic accident | | | |
| subjects affected / exposed | 0 / 822 (0.00%) | 1 / 332 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tibia fracture | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Ulna fracture | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| **Cardiac disorders** | | | |
| Coronary artery disease | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Myocardial infarction | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| **Nervous system disorders** | | | |

| | | | |
|---|---|---|---|
| Carotid artery stenosis | | | |
| subjects affected / exposed | 0 / 822 (0.00%) | 1 / 332 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Polyneuropathy | | | |
| subjects affected / exposed | 0 / 822 (0.00%) | 1 / 332 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Sciatica | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Transient ischaemic attack | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Blood and lymphatic system disorders | | | |
| Thrombocytopenia | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Colitis ulcerative | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Crohn's disease | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulum | | | |
| subjects affected / exposed | 0 / 822 (0.00%) | 1 / 332 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|---|---|---|
| Rectal haemorrhage | | | |
| subjects affected / exposed | 0 / 822 (0.00%) | 1 / 332 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Skin and subcutaneous tissue disorders | | | |
| Psoriasis | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Renal and urinary disorders | | | |
| Renal colic | | | |
| subjects affected / exposed | 0 / 822 (0.00%) | 1 / 332 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 1 / 1 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthritis | | | |
| subjects affected / exposed | 0 / 822 (0.00%) | 1 / 332 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Chondropathy | | | |
| subjects affected / exposed | 0 / 822 (0.00%) | 1 / 332 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal chest pain | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Rotator cuff syndrome | | | |
| subjects affected / exposed | 0 / 822 (0.00%) | 1 / 332 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Synovitis | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 0 / 822 (0.00%) | 1 / 332 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Cellulitis | | | |
| subjects affected / exposed | 0 / 822 (0.00%) | 2 / 332 (0.60%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 2 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Otitis externa | | | |
| subjects affected / exposed | 0 / 822 (0.00%) | 1 / 332 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Tonsillitis | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Typhoid fever | | | |
| subjects affected / exposed | 1 / 822 (0.12%) | 0 / 332 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Viral infection | | | |
| subjects affected / exposed | 0 / 822 (0.00%) | 1 / 332 (0.30%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

Frequency threshold for reporting non-serious adverse events: 2 %

| **Non-serious adverse events** | Secukinumab 150 mg Without Load | Secukinumab 150 mg With Load | Secukinumab 300 mg With Load |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 95 / 222 (42.79%) | 82 / 220 (37.27%) | 83 / 222 (37.39%) |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 3 / 222 (1.35%) | 5 / 220 (2.27%) | 2 / 222 (0.90%) |
| occurrences (all) | 3 | 5 | 2 |

| | | | |
|---|---|---|---|
| Fall | | | |
| subjects affected / exposed | 5 / 222 (2.25%) | 1 / 220 (0.45%) | 0 / 222 (0.00%) |
| occurrences (all) | 5 | 1 | 0 |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 9 / 222 (4.05%) | 5 / 220 (2.27%) | 8 / 222 (3.60%) |
| occurrences (all) | 9 | 5 | 8 |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 8 / 222 (3.60%) | 9 / 220 (4.09%) | 5 / 222 (2.25%) |
| occurrences (all) | 8 | 9 | 5 |
| Blood and lymphatic system disorders | | | |
| Leukopenia | | | |
| subjects affected / exposed | 1 / 222 (0.45%) | 1 / 220 (0.45%) | 6 / 222 (2.70%) |
| occurrences (all) | 0 | 0 | 0 |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 4 / 222 (1.80%) | 4 / 220 (1.82%) | 4 / 222 (1.80%) |
| occurrences (all) | 4 | 4 | 4 |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 7 / 222 (3.15%) | 4 / 220 (1.82%) | 9 / 222 (4.05%) |
| occurrences (all) | 7 | 4 | 9 |
| Nausea | | | |
| subjects affected / exposed | 7 / 222 (3.15%) | 4 / 220 (1.82%) | 3 / 222 (1.35%) |
| occurrences (all) | 7 | 4 | 3 |
| Vomiting | | | |
| subjects affected / exposed | 3 / 222 (1.35%) | 6 / 220 (2.73%) | 2 / 222 (0.90%) |
| occurrences (all) | 3 | 6 | 2 |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 7 / 222 (3.15%) | 2 / 220 (0.91%) | 4 / 222 (1.80%) |
| occurrences (all) | 7 | 2 | 4 |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 5 / 222 (2.25%) | 5 / 220 (2.27%) | 5 / 222 (2.25%) |
| occurrences (all) | 5 | 5 | 5 |
| Skin and subcutaneous tissue disorders | | | |

| | | | |
|---|---|---|---|
| Pruritus | | | |
| subjects affected / exposed | 2 / 222 (0.90%) | 11 / 220 (5.00%) | 3 / 222 (1.35%) |
| occurrences (all) | 2 | 11 | 3 |
| Psoriasis | | | |
| subjects affected / exposed | 3 / 222 (1.35%) | 3 / 220 (1.36%) | 3 / 222 (1.35%) |
| occurrences (all) | 3 | 3 | 3 |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 1 / 222 (0.45%) | 5 / 220 (2.27%) | 0 / 222 (0.00%) |
| occurrences (all) | 1 | 5 | 0 |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 3 / 222 (1.35%) | 4 / 220 (1.82%) | 4 / 222 (1.80%) |
| occurrences (all) | 3 | 4 | 4 |
| Back pain | | | |
| subjects affected / exposed | 8 / 222 (3.60%) | 4 / 220 (1.82%) | 4 / 222 (1.80%) |
| occurrences (all) | 8 | 4 | 4 |
| Psoriatic arthropathy | | | |
| subjects affected / exposed | 3 / 222 (1.35%) | 3 / 220 (1.36%) | 0 / 222 (0.00%) |
| occurrences (all) | 3 | 3 | 0 |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 3 / 222 (1.35%) | 1 / 220 (0.45%) | 8 / 222 (3.60%) |
| occurrences (all) | 3 | 1 | 8 |
| Influenza | | | |
| subjects affected / exposed | 2 / 222 (0.90%) | 4 / 220 (1.82%) | 5 / 222 (2.25%) |
| occurrences (all) | 2 | 4 | 5 |
| Oral herpes | | | |
| subjects affected / exposed | 3 / 222 (1.35%) | 0 / 220 (0.00%) | 5 / 222 (2.25%) |
| occurrences (all) | 3 | 0 | 5 |
| Rhinitis | | | |
| subjects affected / exposed | 2 / 222 (0.90%) | 2 / 220 (0.91%) | 7 / 222 (3.15%) |
| occurrences (all) | 2 | 2 | 7 |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 14 / 222 (6.31%) | 17 / 220 (7.73%) | 7 / 222 (3.15%) |
| occurrences (all) | 14 | 17 | 7 |

| | | | |
|---|---|---|---|
| Urinary tract infection | | | |
| subjects affected / exposed | 6 / 222 (2.70%) | 8 / 220 (3.64%) | 6 / 222 (2.70%) |
| occurrences (all) | 6 | 8 | 6 |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 13 / 222 (5.86%) | 15 / 220 (6.82%) | 14 / 222 (6.31%) |
| occurrences (all) | 13 | 15 | 14 |
| Metabolism and nutrition disorders | | | |
| Dyslipidaemia | | | |
| subjects affected / exposed | 8 / 222 (3.60%) | 4 / 220 (1.82%) | 8 / 222 (3.60%) |
| occurrences (all) | 8 | 4 | 8 |
| Hypercholesterolaemia | | | |
| subjects affected / exposed | 8 / 222 (3.60%) | 9 / 220 (4.09%) | 3 / 222 (1.35%) |
| occurrences (all) | 8 | 9 | 3 |
| Hyperlipidaemia | | | |
| subjects affected / exposed | 1 / 222 (0.45%) | 5 / 220 (2.27%) | 3 / 222 (1.35%) |
| occurrences (all) | 1 | 5 | 3 |

| **Non-serious adverse events** | Secukinumab Total | Placebo | |
|---|---|---|---|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 275 / 822 (33.45%) | 127 / 332 (38.25%) | |
| Injury, poisoning and procedural complications | | | |
| Contusion | | | |
| subjects affected / exposed | 10 / 822 (1.22%) | 1 / 332 (0.30%) | |
| occurrences (all) | 10 | 1 | |
| Fall | | | |
| subjects affected / exposed | 6 / 822 (0.73%) | 2 / 332 (0.60%) | |
| occurrences (all) | 6 | 2 | |
| Vascular disorders | | | |
| Hypertension | | | |
| subjects affected / exposed | 22 / 822 (2.68%) | 10 / 332 (3.01%) | |
| occurrences (all) | 22 | 10 | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 23 / 822 (2.80%) | 13 / 332 (3.92%) | |
| occurrences (all) | 23 | 13 | |
| Blood and lymphatic system disorders | | | |

| | | | |
|---|---|---|---|
| Leukopenia | | | |
| subjects affected / exposed | 11 / 822 (1.34%) | 1 / 332 (0.30%) | |
| occurrences (all) | 0 | 0 | |
| General disorders and administration site conditions | | | |
| Fatigue | | | |
| subjects affected / exposed | 12 / 822 (1.46%) | 8 / 332 (2.41%) | |
| occurrences (all) | 12 | 8 | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 21 / 822 (2.55%) | 22 / 332 (6.63%) | |
| occurrences (all) | 21 | 22 | |
| Nausea | | | |
| subjects affected / exposed | 14 / 822 (1.70%) | 12 / 332 (3.61%) | |
| occurrences (all) | 14 | 12 | |
| Vomiting | | | |
| subjects affected / exposed | 12 / 822 (1.46%) | 2 / 332 (0.60%) | |
| occurrences (all) | 12 | 2 | |
| Respiratory, thoracic and mediastinal disorders | | | |
| Cough | | | |
| subjects affected / exposed | 14 / 822 (1.70%) | 6 / 332 (1.81%) | |
| occurrences (all) | 14 | 6 | |
| Oropharyngeal pain | | | |
| subjects affected / exposed | 16 / 822 (1.95%) | 6 / 332 (1.81%) | |
| occurrences (all) | 16 | 6 | |
| Skin and subcutaneous tissue disorders | | | |
| Pruritus | | | |
| subjects affected / exposed | 16 / 822 (1.95%) | 4 / 332 (1.20%) | |
| occurrences (all) | 16 | 4 | |
| Psoriasis | | | |
| subjects affected / exposed | 11 / 822 (1.34%) | 12 / 332 (3.61%) | |
| occurrences (all) | 11 | 12 | |
| Psychiatric disorders | | | |
| Anxiety | | | |
| subjects affected / exposed | 6 / 822 (0.73%) | 1 / 332 (0.30%) | |
| occurrences (all) | 6 | 1 | |
| Musculoskeletal and connective tissue disorders | | | |

| | | | |
|---|---|---|---|
| Arthralgia | | | |
| subjects affected / exposed | 12 / 822 (1.46%) | 10 / 332 (3.01%) | |
| occurrences (all) | 12 | 10 | |
| Back pain | | | |
| subjects affected / exposed | 16 / 822 (1.95%) | 12 / 332 (3.61%) | |
| occurrences (all) | 16 | 12 | |
| Psoriatic arthropathy | | | |
| subjects affected / exposed | 7 / 822 (0.85%) | 7 / 332 (2.11%) | |
| occurrences (all) | 7 | 7 | |
| Infections and infestations | | | |
| Bronchitis | | | |
| subjects affected / exposed | 12 / 822 (1.46%) | 2 / 332 (0.60%) | |
| occurrences (all) | 12 | 2 | |
| Influenza | | | |
| subjects affected / exposed | 12 / 822 (1.46%) | 3 / 332 (0.90%) | |
| occurrences (all) | 12 | 3 | |
| Oral herpes | | | |
| subjects affected / exposed | 8 / 822 (0.97%) | 4 / 332 (1.20%) | |
| occurrences (all) | 8 | 4 | |
| Rhinitis | | | |
| subjects affected / exposed | 11 / 822 (1.34%) | 3 / 332 (0.90%) | |
| occurrences (all) | 11 | 3 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 38 / 822 (4.62%) | 11 / 332 (3.31%) | |
| occurrences (all) | 38 | 11 | |
| Urinary tract infection | | | |
| subjects affected / exposed | 20 / 822 (2.43%) | 8 / 332 (2.41%) | |
| occurrences (all) | 20 | 8 | |
| Viral upper respiratory tract infection | | | |
| subjects affected / exposed | 44 / 822 (5.35%) | 29 / 332 (8.73%) | |
| occurrences (all) | 44 | 29 | |
| Metabolism and nutrition disorders | | | |
| Dyslipidaemia | | | |
| subjects affected / exposed | 23 / 822 (2.80%) | 11 / 332 (3.31%) | |
| occurrences (all) | 23 | 11 | |
| Hypercholesterolaemia | | | |

| | | | |
|---|---|---|---|
| subjects affected / exposed | 20 / 822 (2.43%) | 2 / 332 (0.60%) | |
| occurrences (all) | 20 | 2 | |
| Hyperlipidaemia | | | |
| subjects affected / exposed | 9 / 822 (1.09%) | 2 / 332 (0.60%) | |
| occurrences (all) | 9 | 2 | |

## More information

## Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

| Date | Amendment |
|---|---|
| 14 February 2018 | After a full review of the data, it was confirmed that nineteen patients were impacted by the mapping error, of which, only 10 (1.1%) of the evaluable 936 patients met the criteria of inclusion in the analysis by having both a baseline and post-baseline X-ray. The remaining 9 patients had only baseline X-rays and thus were not included in the radiographic treatment comparison analyses. All possible preventive actions to ensure that this situation will not occur in the future have been taken up with the external radiographic vendor.<br>The purpose of this addendum is to evaluate the effect of using radiographic data from reread X-ray assessments compared to the data from the first read X-rays in patients with inter-reader difference of vdH-mTSS > 8 points between the 2 blinded independent readers. This new analysis was performed after an export mapping error of the 2 sets of X-ray assessments by the external radiographic vendor was identified after Week 24 interim analysis. |

Notes:

## Interruptions (globally)

Were there any global interruptions to the trial? No

## Limitations and caveats

None reported