



Clinical trial results:

A randomized, double-blind, placebo-controlled multicenter study of subcutaneous secukinumab to demonstrate efficacy in the treatment of enthesitis at the Achilles tendon up to 1 year in adult patients with active Psoriatic Arthritis (PsA) and axial Spondyloarthritis (axSpA) (ACHILLES)
Summary

| | |
|--------------------------|-------------------------|
| EudraCT number | 2016-000972-91 |
| Trial protocol | DE GB ES SK CZ GR BG IT |
| Global end of trial date | 11 December 2019 |

Results information

| | |
|--------------------------------|------------------|
| Result version number | v1 (current) |
| This version publication date | 19 December 2020 |
| First version publication date | 19 December 2020 |

Trial information

Trial identification

| | |
|-----------------------|--------------|
| Sponsor protocol code | CAIN457F3301 |
|-----------------------|--------------|

Additional study identifiers

| | |
|------------------------------------|-------------|
| ISRCTN number | - |
| ClinicalTrials.gov id (NCT number) | NCT02771210 |
| WHO universal trial number (UTN) | - |

Notes:

Sponsors

| | |
|------------------------------|---|
| Sponsor organisation name | Novartis Pharmaceuticals |
| Sponsor organisation address | CH-4200, Basel, Switzerland, |
| Public contact | Clinical Disclosure Office, Novartis Pharma AG, 41 613241111, novartis.email@novartis.com |
| Scientific contact | Study Director, Novartis Pharmaceuticals, 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 | 18 September 2020 |
| Is this the analysis of the primary completion data? | No |
| Global end of trial reached? | Yes |
| Global end of trial date | 11 December 2019 |
| Was the trial ended prematurely? | No |

Notes:

General information about the trial

Main objective of the trial:

The primary objective of this study was to demonstrate that the efficacy of secukinumab was superior to placebo based on the percentage of patients with resolution of Achilles tendon enthesitis as assessed by the respective subcomponent of the Leeds enthesitis index (LEI) at 24 weeks in patients with active PsA and axSpA.

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 | 30 August 2016 |
| Long term follow-up planned | No |
| Independent data monitoring committee (IDMC) involvement? | No |

Notes:

Population of trial subjects

Subjects enrolled per country

| | |
|--------------------------------------|--------------------|
| Country: Number of subjects enrolled | Bulgaria: 21 |
| Country: Number of subjects enrolled | Czechia: 40 |
| Country: Number of subjects enrolled | Germany: 54 |
| Country: Number of subjects enrolled | Greece: 11 |
| Country: Number of subjects enrolled | Italy: 15 |
| Country: Number of subjects enrolled | Slovakia: 2 |
| Country: Number of subjects enrolled | Spain: 36 |
| Country: Number of subjects enrolled | United Kingdom: 25 |
| Worldwide total number of subjects | 204 |
| EEA total number of subjects | 204 |

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) | 192 |
| From 65 to 84 years | 12 |
| 85 years and over | 0 |

Subject disposition

Recruitment

Recruitment details:

304 patients were screened. Of these, 94 patients discontinued during screening phase, 6 patients were re-screened and 204 patients completed the screening phase and were randomized in the trial.

Pre-assignment

Screening details:

A total of 175 patients (85.8%) completed treatment period 1 (up to Week 24); 29 patients (14.2%) discontinued study treatment in treatment period 1. A total of 170 patients (83.3%) completed treatment period 2 (up to Week 52); 5 patients (2.5%) discontinued in treatment period 2.

Period 1

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

Arms

| | |
|------------------------------|-------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Secukinumab |

Arm description:

Secukinumab 150 mg or 300 mg s.c., administered at baseline, weeks 1, 2, 3, 4 and every 4 weeks until week 24, respective dose was assigned according to underlying condition, in case of PsA according to severity of concomitant Psoriasis or preexposure to anti-TNF α

| | |
|--|--|
| Arm type | Experimental |
| Investigational medicinal product name | AIN457 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution and suspension for suspension for injection in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Secukinumab as one (1.0 mL PFS of 150 mg dose) or two (2 × 1.0 mL PFS of 150 mg dose, 300 mg) s.c. injections according to axSpA or PsA disease at Baseline, Week 1, Week 2, and Week 3, followed by administration every 4 weeks starting at Week 4.

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

Arm description:

Placebo 150 mg or 300 mg s.c., administered at baseline, weeks 1, 2, 3, 4 and every 4 weeks until week 24, respective dose was assigned according to underlying condition, in case of PsA according to severity of concomitant Psoriasis or preexposure to anti-TNF α

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

Dosage and administration details:

Placebo as one (1.0 mL PFS of 150 mg dose) or two (2 × 1.0 mL PFS of 150 mg dose, 300 mg) s.c. injections according to axSpA or PsA disease at Baseline, Week 1, Week 2, and Week 3, followed by administration every 4 weeks starting at Week 4.

| Number of subjects in period 1 | Secukinumab | Placebo |
|---------------------------------------|-------------|---------|
| Started | 102 | 102 |
| Completed | 91 | 84 |
| Not completed | 11 | 18 |
| Physician decision | - | 1 |
| Consent withdrawn by subject | - | 3 |
| Adverse event, non-fatal | 5 | 3 |
| Lost to follow-up | 2 | - |
| Withdrawal of informed consent | 1 | 5 |
| Lack of efficacy | 3 | 6 |

Period 2

| | |
|------------------------------|-------------------------|
| Period 2 title | Period 2 |
| Is this the baseline period? | No |
| Allocation method | Randomised - controlled |
| Blinding used | Not blinded |

Blinding implementation details:

Period 2 has no loading and all patients received Secukinumab - no Placebo in this period. Open-label

Arms

| | |
|------------------------------|-------------|
| Are arms mutually exclusive? | Yes |
| Arm title | Secukinumab |

Arm description:

From week 24 Secukinumab 150 mg or 300 mg s.c. was administered every 4 weeks; respective dose was assigned according to underlying condition, in case of PsA according to severity of concomitant Psoriasis or preexposure to anti-TNFα

| | |
|--|---|
| Arm type | Experimental |
| Investigational medicinal product name | AIN457 |
| Investigational medicinal product code | |
| Other name | |
| Pharmaceutical forms | Solution for injection/infusion in pre-filled syringe |
| Routes of administration | Subcutaneous use |

Dosage and administration details:

Secukinumab as one (1.0 mL PFS of 150 mg dose) or two (2 × 1.0 mL PFS of 150 mg dose, 300 mg) s.c. injections according to axSpA or PsA disease at Baseline, Week 1, Week 2, and Week 3, followed by administration every 4 weeks starting at Week 4.

| | |
|------------------|---------------------|
| Arm title | Placebo/Secukinumab |
|------------------|---------------------|

Arm description:

From week 24 Secukinumab 150 mg or 300 mg s.c. was administered every 4 weeks; respective dose was assigned according to underlying condition, in case of PsA according to severity of concomitant Psoriasis or preexposure to anti-TNFα

| | |
|----------|---------|
| Arm type | Placebo |
|----------|---------|

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

Dosage and administration details:

placebo as one (1.0 mL PFS of 150 mg dose) or two (2 × 1.0 mL PFS of 150 mg dose, 300 mg) s.c. injections according to axSpA or PsA disease at Baseline, Week 1, Week 2, and Week 3, followed by administration every 4 weeks starting at Week 4.

| Number of subjects in period 2 | Secukinumab | Placebo/Secukinumab |
|---------------------------------------|-------------|---------------------|
| Started | 91 | 84 |
| Completed | 89 | 81 |
| Not completed | 2 | 3 |
| Consent withdrawn by subject | 1 | - |
| Adverse event, non-fatal | 1 | - |
| Withdrawal of informed consent | - | 2 |
| Lack of efficacy | - | 1 |

Baseline characteristics

Reporting groups

| | |
|--|-------------|
| Reporting group title | Secukinumab |
| Reporting group description: | |
| Secukinumab 150 mg or 300 mg s.c., administered at baseline, weeks 1, 2, 3, 4 and every 4 weeks until week 24, respective dose was assigned according to underlying condition, in case of PsA according to severity of concomitant Psoriasis or preexposure to anti-TNF α | |
| Reporting group title | Placebo |
| Reporting group description: | |
| Placebo 150 mg or 300 mg s.c., administered at baseline, weeks 1, 2, 3, 4 and every 4 weeks until week 24, respective dose was assigned according to underlying condition, in case of PsA according to severity of concomitant Psoriasis or preexposure to anti-TNF α | |

| Reporting group values | Secukinumab | Placebo | Total |
|---|-------------|-------------|-------|
| Number of subjects | 102 | 102 | 204 |
| Age Categorical | | | |
| Number of participants in each age group | | | |
| Units: Participants | | | |
| <=18 years | 0 | 0 | 0 |
| Between 18 and 65 years | 97 | 95 | 192 |
| >=65 years | 5 | 7 | 12 |
| Age Continuous | | | |
| Mean age of participants in each group | | | |
| Units: Years | | | |
| arithmetic mean | 47.8 | 47.7 | |
| standard deviation | ± 11.33 | ± 11.02 | - |
| Sex/Gender, Customized | | | |
| Number of males vs females in Randomized set | | | |
| Units: Participants | | | |
| Female | 58 | 55 | 113 |
| Male | 44 | 47 | 91 |
| Race/Ethnicity, Customized | | | |
| Number of participants (Randomized set) by race | | | |
| Units: Subjects | | | |
| Caucasian | 99 | 99 | 198 |
| Black | 0 | 0 | 0 |
| Asian | 2 | 1 | 3 |
| Other | 1 | 2 | 3 |

End points

End points reporting groups

| | |
|--|---------------------|
| Reporting group title | Secukinumab |
| Reporting group description: Secukinumab 150 mg or 300 mg s.c., administered at baseline, weeks 1, 2, 3, 4 and every 4 weeks until week 24, respective dose was assigned according to underlying condition, in case of PsA according to severity of concomitant Psoriasis or preexposure to anti-TNFα | |
| Reporting group title | Placebo |
| Reporting group description: Placebo 150 mg or 300 mg s.c., administered at baseline, weeks 1, 2, 3, 4 and every 4 weeks until week 24, respective dose was assigned according to underlying condition, in case of PsA according to severity of concomitant Psoriasis or preexposure to anti-TNFα | |
| Reporting group title | Secukinumab |
| Reporting group description: From week 24 Secukinumab 150 mg or 300 mg s.c. was administered every 4 weeks; respective dose was assigned according to underlying condition, in case of PsA according to severity of concomitant Psoriasis or preexposure to anti-TNFα | |
| Reporting group title | Placebo/Secukinumab |
| Reporting group description: From week 24 Secukinumab 150 mg or 300 mg s.c. was administered every 4 weeks; respective dose was assigned according to underlying condition, in case of PsA according to severity of concomitant Psoriasis or preexposure to anti-TNFα | |

Primary: Number (%) of patients with resolution of Achilles tendon enthesitis

| | |
|--|--|
| End point title | Number (%) of patients with resolution of Achilles tendon enthesitis |
| End point description: Number (%) of patients with resolution of Achilles tendon enthesitis (affected foot) as assessed by respective subcomponent of Leeds enthesitis index (LEI) at Week 24. The primary analysis was performed via a logistic regression model with the factors treatment, country, and stratification factor diagnosis (PsA or axSpA); patients with a missing assessment were considered as responders if they had already met the response criterion at the time of last assessment. | |
| End point type | Primary |
| End point timeframe: Week 24 | |

| End point values | Secukinumab | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 102 | 102 | | |
| Units: Participants | 43 | 32 | | |

Statistical analyses

| | |
|----------------------------|--|
| Statistical analysis title | Resolution of achilles tendon enthesitis |
|----------------------------|--|

Statistical analysis description:

The primary analysis was performed via a logistic regression model with the factors treatment, country, and stratification factor diagnosis (PsA or axSpA); patients with a missing assessment were considered as responders if they had already met the response criterion at the time of last assessment.

| | |
|---|-----------------------|
| Comparison groups | Secukinumab v Placebo |
| Number of subjects included in analysis | 204 |
| Analysis specification | Pre-specified |
| Analysis type | |
| P-value | = 0.136 |
| Method | Regression, Logistic |
| Parameter estimate | Odds ratio (OR) |
| Point estimate | 1.63 |
| Confidence interval | |
| level | 95 % |
| sides | 2-sided |
| lower limit | 0.87 |
| upper limit | 3.08 |

Secondary: Mean change of heel pain

| | |
|---|--------------------------|
| End point title | Mean change of heel pain |
| End point description: | |
| Mean change of heel pain from baseline to Week 24 measured by Numeric Rating Scale (NRS) ranging from 0 to 10, with 0 representing no pain and 10 representing worst pain (e.g. "pain as bad as you can imagine" or "worst pain imaginable"). | |
| End point type | Secondary |
| End point timeframe: | |
| Week 24 | |

| | | | | |
|--------------------------------------|-----------------|-----------------|--|--|
| End point values | Secukinumab | Placebo | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 87 | 85 | | |
| Units: Mean | | | | |
| arithmetic mean (standard deviation) | -2.8 (± 2.99) | -1.9 (± 2.69) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number (%) of patients with improvement of bone marrow edema

| | |
|---|--|
| End point title | Number (%) of patients with improvement of bone marrow edema |
| End point description: | |
| Number (%) of patients with an improvement of bone marrow edema from baseline to Week 24 as assessed by the respective subcomponent of the Psoriatic Arthritis Magnetic Resonance Imaging Score (PsAMRIS) in the affected foot. | |

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 24 | |

| End point values | Secukinumab | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 44 | 36 | | |
| Units: Participants | 17 | 12 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number (%) of patients with resolution of enthesitis as assessed by LEI

| | |
|--|---|
| End point title | Number (%) of patients with resolution of enthesitis as assessed by LEI |
| End point description: | |
| Number (%) of patients with resolution of enthesitis as assessed by the Leeds enthesitis index (LEI) at Week 24. | |
| End point type | Secondary |
| End point timeframe: | |
| Week 24 | |

| End point values | Secukinumab | Placebo | | |
|-----------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 102 | 102 | | |
| Units: Participants | 31 | 21 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change of physician's global assessment (PhGA) of disease activity

| | |
|--|---|
| End point title | Mean change of physician's global assessment (PhGA) of disease activity |
| End point description: | |
| Mean change of physician's global assessment (PhGA) of disease activity from baseline to Week 24 measured by Visual Analog Scale (VAS) ranging from 0 to 100, with 0 representing not severe and 100 representing very severe. | |
| End point type | Secondary |

End point timeframe:

Week 24

| End point values | Secukinumab | Placebo | | |
|--------------------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 88 | 85 | | |
| Units: mm | | | | |
| arithmetic mean (standard deviation) | -34.88 (\pm 25.927) | -18.93 (\pm 26.257) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change of patient's global assessment (PGA) of disease activity

| | |
|-----------------|--|
| End point title | Mean change of patient's global assessment (PGA) of disease activity |
|-----------------|--|

End point description:

Mean change of patient's global assessment (PGA) of disease activity from baseline to Week 24 measured by Visual Analog Scale (VAS) ranging from 0 to 100, with 0 representing not severe and 100 representing very severe.

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

End point timeframe:

Week 24

| End point values | Secukinumab | Placebo | | |
|--------------------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 82 | 80 | | |
| Units: mm | | | | |
| arithmetic mean (standard deviation) | -25.87 (\pm 31.108) | -16.61 (\pm 29.235) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change of physician's assessment of heel enthesopathy activity

| | |
|-----------------|---|
| End point title | Mean change of physician's assessment of heel enthesopathy activity |
|-----------------|---|

End point description:

Mean change of physician's assessment of heel enthesopathy activity from baseline to Week 24 measured by Visual Analog Scale (VAS) ranging from 0 to 100, with 0 representing not severe and 100 representing very severe.

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 24 | |

| End point values | Secukinumab | Placebo | | |
|--------------------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 88 | 85 | | |
| Units: mm | | | | |
| arithmetic mean (standard deviation) | -38.40 (\pm 24.244) | -25.19 (\pm 25.250) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change of patient's assessment of heel enthesopathy activity

| | |
|--|---|
| End point title | Mean change of patient's assessment of heel enthesopathy activity |
| End point description: | |
| Mean change of patient's assessment of heel enthesopathy activity from baseline to Week 24 measured by Visual Analog Scale (VAS) ranging from 0 to 100, with 0 representing not severe and 100 representing very severe. | |
| End point type | Secondary |
| End point timeframe: | |
| Week 24 | |

| End point values | Secukinumab | Placebo | | |
|--------------------------------------|------------------------|------------------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 86 | 84 | | |
| Units: mm | | | | |
| arithmetic mean (standard deviation) | -31.05 (\pm 29.135) | -20.77 (\pm 30.417) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change in Short Form-36 (SF-36) v2

| | |
|--|---|
| End point title | Mean change in Short Form-36 (SF-36) v2 |
| End point description: | |
| Mean change in Short Form-36 (SF-36) v2 as an indicator of overall health status | |

The SF-36 has eight scaled scores; the scores are weighted sums of the questions in each section.
Lower scores = more disability, higher scores = less disability

| | |
|----------------------|-----------|
| End point type | Secondary |
| End point timeframe: | |
| Week 24 | |

| | | | | |
|--------------------------------------|---------------------|---------------------|--|--|
| End point values | Secukinumab | Placebo | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 87 | 85 | | |
| Units: scores on a scale | | | | |
| arithmetic mean (standard deviation) | 8.29 (\pm 9.759) | 5.28 (\pm 7.285) | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Number (%) of patients with resolution of achilles tendon enthesitis after switching from placebo to secukinumab

| | |
|--|--|
| End point title | Number (%) of patients with resolution of achilles tendon enthesitis after switching from placebo to secukinumab |
| End point description: | |
| To describe the increase in percentage of patients with resolution of achilles tendon enthesitis (affected foot) after switching from placebo to secukinumab at Week 24. | |
| End point type | Secondary |
| End point timeframe: | |
| Weeks 24 and 52 | |

| | | | | |
|-----------------------------|-----------------|-----------------|--|--|
| End point values | Secukinumab | Placebo | | |
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 102 | 102 | | |
| Units: Participants | | | | |
| Week 24 | 43 | 32 | | |
| Week 52 | 66 | 55 | | |

Statistical analyses

No statistical analyses for this end point

Secondary: Mean change of heel pain after switching from placebo to secukinumab

| | |
|-----------------|--|
| End point title | Mean change of heel pain after switching from placebo to secukinumab |
|-----------------|--|

End point description:

To describe the increase in mean change of heel pain after switching from placebo to secukinumab at Week 24.

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

End point timeframe:

Weeks 24 and 52

| End point values | Secukinumab | Placebo | | |
|--------------------------------------|-----------------|-----------------|--|--|
| Subject group type | Reporting group | Reporting group | | |
| Number of subjects analysed | 80 | 79 | | |
| Units: Mean | | | | |
| arithmetic mean (standard deviation) | -0.70 (± 2.291) | -1.43 (± 2.251) | | |

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Adverse events were collected from first dose of study treatment until end of study at week 52

Adverse event reporting additional description:

Adverse Events (AEs) are any untoward sign or symptom that occurs during the study treatment. Where a patient reported more than 1 AE with the same preferred term, the AE was counted only once; and where a patient reported more than 1 AE within the same primary system organ class, patient was counted only once at the system organ class level.

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

Dictionary used

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

| | |
|--------------------|------|
| Dictionary version | 22.1 |
|--------------------|------|

Reporting groups

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

Reporting group description:

Secukinumab

| | |
|-----------------------|-----------------------------|
| Reporting group title | Placebo/Placebo-Secukinumab |
|-----------------------|-----------------------------|

Reporting group description:

Placebo/Placebo-Secukinumab

| Serious adverse events | Secukinumab | Placebo/Placebo-Secukinumab | |
|---|-----------------|-----------------------------|--|
| Total subjects affected by serious adverse events | | | |
| subjects affected / exposed | 7 / 102 (6.86%) | 6 / 102 (5.88%) | |
| number of deaths (all causes) | 0 | 0 | |
| number of deaths resulting from adverse events | 0 | 0 | |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | | | |
| Invasive breast carcinoma | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 102 (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 / 102 (0.98%) | 0 / 102 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Uterine cancer | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 102 (0.98%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

| | | | |
|---|-----------------|-----------------|--|
| Injury, poisoning and procedural complications | | | |
| Lower limb fracture | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 102 (0.98%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Stress fracture | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 102 (0.98%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Vascular disorders | | | |
| Venous thrombosis limb | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 102 (0.98%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Cardiac disorders | | | |
| Atrial fibrillation | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 1 / 102 (0.98%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Nervous system disorders | | | |
| Cauda equina syndrome | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 102 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Migraine with aura | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 102 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Gastrointestinal disorders | | | |
| Abdominal adhesions | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 102 (0.98%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Inflammatory bowel disease | | | |

| | | | |
|---|-----------------|-----------------|--|
| subjects affected / exposed | 1 / 102 (0.98%) | 1 / 102 (0.98%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Large intestinal stenosis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 102 (0.98%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Endocrine disorders | | | |
| Goitre | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 102 (0.98%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Musculoskeletal and connective tissue disorders | | | |
| Intervertebral disc protrusion | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 102 (0.00%) | |
| occurrences causally related to treatment / all | 0 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Infections and infestations | | | |
| Cellulitis | | | |
| subjects affected / exposed | 1 / 102 (0.98%) | 0 / 102 (0.00%) | |
| occurrences causally related to treatment / all | 1 / 1 | 0 / 0 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Diverticulitis | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 102 (0.98%) | |
| occurrences causally related to treatment / all | 0 / 0 | 0 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |
| Pyelonephritis acute | | | |
| subjects affected / exposed | 0 / 102 (0.00%) | 1 / 102 (0.98%) | |
| occurrences causally related to treatment / all | 0 / 0 | 1 / 1 | |
| deaths causally related to treatment / all | 0 / 0 | 0 / 0 | |

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

| Non-serious adverse events | Secukinumab | Placebo/Placebo-Secukinumab | |
|---|-------------------|-----------------------------|--|
| Total subjects affected by non-serious adverse events | | | |
| subjects affected / exposed | 33 / 102 (32.35%) | 34 / 102 (33.33%) | |
| Nervous system disorders | | | |
| Headache | | | |
| subjects affected / exposed | 6 / 102 (5.88%) | 10 / 102 (9.80%) | |
| occurrences (all) | 8 | 16 | |
| Gastrointestinal disorders | | | |
| Diarrhoea | | | |
| subjects affected / exposed | 8 / 102 (7.84%) | 5 / 102 (4.90%) | |
| occurrences (all) | 8 | 5 | |
| Musculoskeletal and connective tissue disorders | | | |
| Arthralgia | | | |
| subjects affected / exposed | 7 / 102 (6.86%) | 5 / 102 (4.90%) | |
| occurrences (all) | 8 | 8 | |
| Infections and infestations | | | |
| Nasopharyngitis | | | |
| subjects affected / exposed | 13 / 102 (12.75%) | 22 / 102 (21.57%) | |
| occurrences (all) | 18 | 28 | |
| Upper respiratory tract infection | | | |
| subjects affected / exposed | 6 / 102 (5.88%) | 5 / 102 (4.90%) | |
| occurrences (all) | 6 | 5 | |

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported