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Sponsor

Novartis Pharmaceuticals

Generic Drug Name

Secukinumab/AIN457

Trial Indication(s)

Plaque psoriasis with concomitant metabolic syndrome

Protocol Number

CAIN457ADE08

Protocol Title

A randomized, multicenter 28 week study to compare the efficacy and safety of combining Cosentyx (Secukinumab) (4-weekly, 300 mg s.c.) with a lifestyle intervention to Cosentyx therapy alone in adult patients with moderate to severe plaque-type psoriasis and concomitant metabolic syndrome, followed by a 28 week extension period

Clinical Trial Phase

Phase 4

Phase of Drug Development

Phase IV

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Study Start/End Dates

Study Start Date: February 28, 2018 (Actual)
Primary Completion Date: November 30, 2021 (Actual)
Study Completion Date: June 03, 2022 (Actual)

Reason for Termination (If applicable)

Not applicable

Study Design/Methodology

This study was a randomized, open-label, parallel-group, active comparator controlled study with two treatment arms.

Core study: After providing informed consent, patients were screened for eligibility for a period of 1 to 4 weeks prior to inclusion in the study. Eligible patients were randomized to one of the two treatment arms, which were the following:

- Arm A: Patients in arm A received a regular induction followed by 4-weekly maintenance treatment with secukinumab 300 mg s.c. until Week 28, where they completed the core study. The last secukinumab injection was to be administered at Week 24.
- Arm B: Patients in arm B received a regular induction followed by 4-weekly maintenance treatment with secukinumab 300 mg s.c. until Week 28. The last secukinumab injection was to be administered at Week 24. In addition to secukinumab treatment, patients in arm B participated in a lifestyle intervention program.

A biomarker sub-study was conducted during the core study in a subgroup of 100 patients (50 from each treatment arm).

The core study ended at Week 28.

Extension period: After 28 weeks, the study continued with an extension period, during which lifestyle intervention was offered to all patients, irrespective of their prior treatment arm. This meant that patients of arm B, who were willing to, could continue their previously started lifestyle intervention program, and patients of arm A, who were willing to, could start the lifestyle intervention program at the beginning of the extension period. All patients, irrespective of their decision whether to start/continue lifestyle intervention or not, had to participate in the extension period and visit their dermatologic study center for scheduled visits. The extension period ended at Week 56, where all patients completed the study. No study drug was

supplied during the extension period. The treating physician could choose psoriasis therapy freely according to their discretion.

Centers

Germany(81)

Publication

No data identified.

Objectives:

The primary objective of the Core Study was to demonstrate that the combination of Secukinumab (300 mg, 4-weekly s.c.) with lifestyle intervention results in higher psoriasis treatment efficacy than Secukinumab alone in psoriasis patients with concomitant metabolic syndrome.

The secondary objectives of the Core Study were as follows:

- To explore treatment efficacy of Secukinumab (300 mg, 4-weekly s.c.) combined with lifestyle intervention in comparison to Secukinumab alone
- To evaluate the effect of Secukinumab (300 mg, 4-weekly s.c.) combined with lifestyle intervention in comparison to Secukinumab alone on systemic inflammation
- To evaluate the effect of Secukinumab (300 mg, 4-weekly s.c.) combined with lifestyle intervention in comparison to Secukinumab alone on glucose metabolism
- To evaluate the effect of Secukinumab (300 mg, 4-weekly s.c.) combined with lifestyle intervention in comparison to Secukinumab alone on lipid metabolism
- To evaluate the effect of Secukinumab (300 mg, 4-weekly s.c.) combined with lifestyle intervention in comparison to Secukinumab alone on body weight and waist circumference
- To evaluate the effect of Secukinumab (300 mg, 4-weekly s.c.) combined with lifestyle intervention in comparison to Secukinumab alone on systolic and diastolic blood pressure
- To evaluate the effect of Secukinumab (300 mg, 4-weekly s.c.) combined with lifestyle intervention in comparison to Secukinumab alone on health-related quality of life, itch, pain and scaling as well as mental well-being

Test Product (s), Dose(s), and Mode(s) of Administration

All patients were assigned secukinumab 300 mg s.c. provided as 2 pre-filled syringes each containing 150 mg secukinumab. These syringes were from commercially available sources and batch numbers were not tracked.

Additionally, patients randomized to Arm B received additional treatment in the form of a lifestyle intervention. This was based on a structured and standardized program, closely guiding patients with metabolic syndrome with the primary goal to improve their metabolic status and to lose weight

Statistical Methods

For the primary analysis, the null hypothesis to be rejected was that the odds of response Week 28 were equal in both treatment groups. The corresponding alternative hypothesis was that the odds of response at Week 28 were higher under secukinumab combined with lifestyle intervention compared to secukinumab alone. The primary analysis was performed on the FAS, comparing treatments with respect to the primary efficacy variable in a logistic regression model with the factors treatment, center and covariate baseline PASI. The odds ratio and its 95% CI and p-value were given. The null hypothesis of equal odds was to be rejected if the 2-sided p-value from the logistic regression model for the factor “treatment” was < 0.05; however, superiority of secukinumab combined with lifestyle intervention was claimed only if the direction was correct, i.e. if the odds of response were larger under secukinumab combined with lifestyle intervention. Sensitivity analysis for the primary endpoint was by means of a Cochran-Mantel-Haenszel (CMH) test using the FAS. This test was stratified by center. Treatment groups were compared with respect to the proportion of responders using the CMH test statistics. The corresponding p-value was based on the CMH statistics, which followed a Chi-square distribution with one degree of freedom.

Absolute scores and values for continuous secondary endpoints were analyzed using a mixed model for repeated measures (MMRM), with factors treatment, center, visit, visit*treatment interaction, and covariate baseline score/value. The raw as well as the adjusted least square means, and their differences between treatment groups, were calculated for each visit together with their corresponding 95% CIs and p-values. The proportion of patients with DLQI 0/1 response was evaluated in both treatment arms and were compared using a logistic regression model with the factors treatment, center, visit, visit*treatment interaction, and covariate baseline DLQI. The odds ratio and its 95% CI and p value were reported.

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Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:

1. Written informed consent must be obtained before any assessment is performed.
2. Men or women of at least 18 years of age at the time of screening.
3. Patients must be able to understand and communicate with the investigator and must be willing and able to comply with all study procedures.
4. Patients with moderate to severe plaque-type psoriasis who are candidates for systemic therapy, diagnosed at least 6 month before randomization and baseline value of
   - PASI > 10 and
   - DLQI > 10 and
   - Body Surface Area (BSA) affected by plaque-type psoriasis ≥ 10%
5. Fulfillment of Metabolic Syndrome definition (Alberti et al., 2009), which means fulfillment of ≥3 of the following criteria at screening visit:
   - Fasting (8 hours) plasma glucose ≥ 100 mg/dl or ongoing antidiabetic drug treatment (defined as: metformin, DPP4 inhibitors, GLP1 analogues, SGLT2 inhibitors)
   - Abdominal obesity defined by elevated waist circumference (measured as defined in section 6.4.5): Male: ≥94 cm, female: ≥80 cm (except for patients of Asian, South or Central American ethnicity, for whom the cut off values are: Male: ≥90 cm, female: ≥80 cm)
   - Fasting (8 hours) triglycerides ≥ 150 mg/dl or ongoing drug treatment for elevated triglycerides (defined as: fibrates or nicotinic acid).
   - Fasting (8 hours) HDL-C < 40 mg/dl in men or < 50 mg/dl in women or ongoing drug treatment for reduced HDL-C (defined as: fibrates, nicotinic acid or statins).
   - Resting blood pressure: Systolic blood pressure ≥ 130 and/ or diastolic blood pressure ≥ 85 mmHg (measured as defined in section 6.4.6) or ongoing antihypertensive drug treatment [defined as: ACE inhibitors, beta blockers, angiotensin receptor antagonists (e.g. Valsartan), aldosterone receptor antagonists, diuretics, nitrates, calcium channel blockers (e.g. Verapamil, Nifedipin), Aliskiren, Clonidin, alpha1 receptor antagonists (e.g. Doxazosin), Dihydralazin, Minoxidil, Moxonidin or Methyldopa].
6. Willingness and motivation to actively participate in a lifestyle intervention, which means patients need to be willing to increase physical activity and to change dietary habits.

Exclusion Criteria:

Patients fulfilling any of the following criteria are not eligible for inclusion in this study. No additional exclusions may be applied by the investigator, in order to ensure that the study population will be representative of all eligible patients.

1. Forms of psoriasis other than chronic plaque-type (e.g. pustular, erythrodermic and guttate psoriasis) at screening.
2. Previous exposure to Secukinumab or any other biologic drug directly targeting IL17A or the IL17A receptor (e.g. Brodalumab, Ixekizumab).

3. Exposure to anti-TNF treatment during 1 year prior to baseline.
4. Drug-induced psoriasis (i.e., new onset or current exacerbation from beta-blockers, calcium channel inhibitors or lithium) at screening.
5. History of hypersensitivity to Secukinumab, trehalose-dihydrate, L-histidine, L-histidinhydrochloride-monohydrate, L-methionine, polysorbate 80, water for injection, or to substances of similar chemical classes.
6. History of latex hypersensitivity.
7. Ongoing participation (including safety follow-up period) in other interventional or non-interventional studies in any dermatological indication
8. Ongoing use of prohibited treatments. Washout periods detailed in the protocol have to be adhered to (Table 5-1). Note: Administration of live vaccines 6 weeks prior to baseline (visit 2) or during the study period is also prohibited.
9. Diagnosis of type 1 diabetes.
10. Patients with diagnosed type 2 diabetes, if they fulfill one or more of the following conditions:
• uncontrolled type 2 diabetes, meaning HbA1c > 8.0%,
• pharmacological therapy with one or more of the following agents: Insulin, sulfonylurea agents/analogues, thiazolidinediones/glitazones
11. Insufficiently controlled, severe arterial hypertension (systolic blood pressure ≥ 160 mmHg and/or diastolic blood pressure ≥ 95 mmHg) with urgent need for therapy initiation or foreseeable need for medication change during the duration of the core study.
12. Use of other investigational drugs at the time of enrollment, or within 5 half-lives of enrollment, or within 30 days until the expected pharmacodynamic effect has returned to baseline, whichever is longer; or longer if required by local regulations.
13. Pregnant or nursing (lactating) women, where pregnancy is defined as the state of a female after conception and until the termination of gestation, confirmed by a positive hCG laboratory test.
14. Active ongoing inflammatory diseases other than psoriasis and psoriatic arthritis (PsA) that might confound the evaluation of the benefit of Secukinumab therapy.
15. Underlying conditions (including, but not limited to metabolic, hematologic, renal, hepatic, pulmonary, neurologic, endocrine, cardiac, infectious or gastrointestinal) which in the opinion of the investigator significantly immunocompromises the subject and/or places the subject at unacceptable risk for receiving an immunomodulatory therapy.
16. Significant, progressive or uncontrolled medical problems at baseline which according to the opinion of the Investigator render the subject unsuitable for the trial - also in regard to participation in the lifestyle intervention - or put the subject at increased risk when participating in the trial (e.g. broken leg, congestive heart failure NYHA III/IV, uncontrolled hypertension with systolic ≥ 160 mmHg and/or diastolic ≥ 95 mmHg, severe uncontrolled asthma)
17. Medical history of myocardial infarction or angina pectoris
18. Any medical or psychiatric condition which, in the Investigator’s opinion, would preclude the participant from adhering to the protocol or completing the study per protocol.
19. Serum creatinine level exceeding 2.0 mg/dl (176.8 µmol/L) at screening

20. Total white blood cell (WBC) count < 2,500/µl, or platelets < 100,000/µl or neutrophils < 1,500/µl or hemoglobin < 8.5 g/dl at screening.
21. Active systemic infections during the last two weeks (exception: common cold) prior to baseline (visit 2) or any infection that reoccurs on a regular basis.
22. History of an ongoing, chronic or recurrent infectious disease, or evidence of tuberculosis infection as defined by a positive QuantiFERON TB-Gold test (QFT) at screening. Subjects with a positive or indeterminate QFT test may participate in the study if full tuberculosis work up (according to local practice/guidelines) was completed within 12 weeks prior to visit 2 and establishes conclusively that the subject has no evidence of active tuberculosis. If presence of latent tuberculosis is established, then appropriate treatment must have been initiated at least 4 weeks prior to baseline (visit 2) and maintained according to local guidelines.
23. Past medical history record or current infection with HIV, hepatitis B or hepatitis C prior to baseline (visit 2).
24. History of lymphoproliferative disease or any known malignancy or history of malignancy of any organ system treated or untreated within the past 5 years, regardless of whether there is evidence of local recurrence or metastases (except for Bowen's disease, or basal cell carcinoma or actinic keratoses that have been treated with no evidence of recurrence in the past 12 weeks prior to baseline (visit 2); carcinoma in situ of the cervix or non-invasive malignant colon polyps that have been removed).
25. Inability or unwillingness to undergo repeated venipuncture (e.g., because of poor tolerability or lack of access to veins).
26. History or evidence of ongoing alcohol or drug abuse, within the last six months before baseline (visit 2).
27. Women of child-bearing potential, defined as all women physiologically capable of becoming pregnant, unless they are using basic methods of contraception during dosing of investigational drug for at least 20 weeks after the end of Secukinumab treatment. Basic contraception methods include:
• Total abstinence (when this is in line with the preferred and usual lifestyle of the subject. Periodic abstinence (e.g., calendar, ovulation, symptothermal, post-ovulation methods) and withdrawal are not acceptable methods of contraception
• Female sterilization (have had surgical bilateral oophorectomy with or without hysterectomy), total hysterectomy or tubal ligation at least six weeks before taking investigational drug. In case of oophorectomy alone, only when the reproductive status of the woman has been confirmed by follow up hormone level assessment
• Male sterilization (at least 6 m prior to screening). For female subjects on the study, the vasectomized male partner should be the sole partner for that subject
• Barrier methods of contraception: Condom or Occlusive cap (diaphragm or cervical/vault caps).
• Use of oral, (estrogen and progesterone), injected or implanted hormonal methods of contraception or other forms of hormonal contraception that have comparable efficacy (failure rate <1%), for example hormone vaginal ring or transdermal hormone contraception or placement of an intrauterine device (IUD) or intrauterine system (IUS)
• In case of use of oral contraception women should have been stable on the same pill for a minimum of 3 months before taking investigational drug.
• Women are considered post-menopausal and not of child bearing potential if they have had 12 months of natural (spontaneous) amenorrhea with an appropriate clinical profile (e.g. age appropriate, history of vasomotor symptoms) or have had surgical bilateral

oophorectomy (with or without hysterectomy), total hysterectomy or tubal ligation at least six weeks ago. In the case of oophorectomy alone, only when the reproductive status of the woman has been confirmed by follow up hormone level assessment is she considered not of child bearing potential.

Participant Flow Table

Overall Study

	Secukinumab 300 mg subcutaneous (s.c.)	Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	Total
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.	
Started	371	410	781
Full Analysis Set (FAS)	371	409	780
Safety Set (SAF)	371	409	780
Completed	342	375	717
Not Completed	29	35	64
Adverse Event	8	7	15
Lack of Efficacy	2	3	5
Non-compliance with study treatment	1	1	2
Protocol Violation	4	4	8
Lost to Follow-up	2	8	10
Physician Decision	2	2	4
Withdrawal by Subject	9	10	19

Subject discontinued the study due to emergency	1	0	1

Baseline Characteristics

	Secukinumab 300 mg subcutaneous (s.c.)	Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	Total
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.	
Number of Participants [units: participants]	371	409	780
Baseline Analysis Population Description	Following the intent-to-treat principle, patients in the Full Analysis Set (FAS) were analyzed according to the treatment assigned at randomization.		
Age Continuous (units: Years) Analysis Population Type: Participants Mean ± Standard Deviation			
	50.4±13.29	50.1±12.48	50.2±12.86
Sex: Female, Male (units: Participants) Analysis Population Type: Participants Count of Participants (Not Applicable)			
Female	105	115	220

Male	266	294	560
Race/Ethnicity, Customized (units: Participants) Analysis Population Type: Participants			
Asian	7	1	8
Caucasian	359	397	756
Black or African American	2	2	4
Other	3	8	11

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Summary of Efficacy

Primary Outcome Result(s)

Percentage of patients achieving Psoriasis Area and Severity Index (PASI) Score of 90 at week 28

Description	The Psoriasis Area and Severity Index (PASI) is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, trunk, upper limbs, lower limbs); each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area * area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 90 represents patients achieving >= 90% improvement (reduction) in PASI score compared to Baseline. Patients with missing PASI at Week 28 were counted as non-responders.
Time Frame	Baseline, Week 28
Analysis Population Description	Full Analysis Set (FAS)

	Secukinumab 300 mg subcutaneous (s.c.)	**Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention**
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
Percentage of patients achieving Psoriasis Area and Severity Index (PASI) Score of 90 at week 28 (units: Participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
	219 (59.03%)	261 (63.81%)

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	Comparison of mean change between treatments in PASI 90 at week 28
Type of Statistical Test	Superiority	
P Value	0.3857	
Method	Regression, Logistic	
Odds Ratio (OR)	1.17	
95 % Confidence Interval 2-Sided	0.82 to 1.67	

Secondary Outcome Result(s)

Percentage of patients achieving Psoriasis Area and Severity Index (PASI) Score of 75 over time

Description	The Psoriasis Area and Severity Index (PASI) is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, trunk, upper limbs, lower limbs); each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area * area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 75 represents patients achieving >= 75% improvement (reduction) in PASI score compared to Baseline.
Time Frame	Baseline, Week 1, Week 2, Week 3, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28
Analysis Population Description	Full Analysis Set (FAS)

	Secukinumab 300 mg subcutaneous (s.c.)	Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention

Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
Percentage of patients achieving Psoriasis Area and Severity Index (PASI) Score of 75 over time (units: Participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Week 1	2 (.54%)	1 (.24%)
Week 2	11 (2.96%)	3 (.73%)
Week 3	50 (13.48%)	56 (13.69%)
Week 4	108 (29.11%)	135 (33.01%)
Week 8	239 (64.42%)	265 (64.79%)
Week 12	241 (64.96%)	276 (67.48%)
Week 16	287 (77.36%)	332 (81.17%)
Week 20	290 (78.17%)	333 (81.42%)
Week 24	285 (76.82%)	333 (81.42%)
Week 28	286 (77.09%)	335 (81.91%)

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	Comparison of mean change between treatments in PASI 75 at Week 28
Type of Statistical Test	Superiority	
P Value	0.0300	
Method	Regression, Logistic	
Odds Ratio (OR)	1.8	
95 % Confidence Interval 2-Sided	1.06 to 3.06	

Percentage of patients achieving Psoriasis Area and Severity Index (PASI) Score of 90 over time

Description	The Psoriasis Area and Severity Index (PASI) is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, trunk, upper limbs, lower limbs); each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area * area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 90 represents patients achieving ≥ 90% improvement (reduction) in PASI score compared to Baseline.
Time Frame	Baseline, Week 1, Week 2, Week 3, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28
Analysis Population Description	Full Analysis Set (FAS)

	Secukinumab 300 mg subcutaneous (s.c.)	Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8,	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8,

	12, 16, 20 and 24 (last injection was performed at week 24).	12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
Percentage of patients achieving Psoriasis Area and Severity Index (PASI) Score of 90 over time (units: Participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Week 1	0 (%)	0 (%)
Week 2	2 (.54%)	0 (%)
Week 3	7 (1.89%)	4 (.98%)
Week 4	25 (6.74%)	30 (7.33%)
Week 8	130 (35.04%)	141 (34.47%)
Week 12	159 (42.86%)	182 (44.5%)
Week 16	215 (57.95%)	241 (58.92%)
Week 20	217 (58.49%)	242 (59.17%)
Week 24	224 (60.38%)	251 (61.37%)
Week 28	219 (59.03%)	261 (63.81%)

Percentage of patients achieving Psoriasis Area and Severity Index (PASI) Score of 100 over time

Description The Psoriasis Area and Severity Index (PASI) is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, trunk, upper limbs, lower limbs); each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each

area * area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). PASI 100 response/remission represents patients achieving complete clearing of psoriasis (PASI = 0) compared to Baseline.

Time Frame: Baseline, Week 1, Week 2, Week 3, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28

Analysis Population Description: Full Analysis Set (FAS)

	Secukinumab 300 mg subcutaneous (s.c.)	**Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention**
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
Percentage of patients achieving Psoriasis Area and Severity Index (PASI) Score of 100 over time (units: Participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Week 1	0 (%)	0 (%)
Week 2	1 (.27%)	0 (%)
Week 3	1 (.27%)	0 (%)
Week 4	5 (1.35%)	4 (.98%)
Week 8	35 (9.43%)	39 (9.54%)
Week 12	48 (12.94%)	71 (17.36%)

Week 16	82 (22.1%)	115 (28.12%)
Week 20	100 (26.95%)	108 (26.41%)
Week 24	101 (27.22%)	115 (28.12%)
Week 28	105 (28.3%)	118 (28.85%)

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	Comparison of mean change between treatments in PASI 100 at Week 28
Type of Statistical Test	Superiority	
P Value	0.4351	
Method	Regression, Logistic	
Odds Ratio (OR)	0.87	
95 % Confidence Interval 2-Sided	0.61 to 1.24	

Mean absolute Psoriasis Area and Severity Index (PASI) Score over time

Description	The Psoriasis Area and Severity Index (PASI) is a combined assessment of lesion severity and affected area into a single score: 0 (no disease) to 72 (maximal disease). Body is divided into 4 areas for scoring (head, trunk, upper limbs, lower limbs); each area is scored by itself and scores are combined for final PASI. For each area, percent of skin involved is estimated: 0 (0%) to 6 (90-100%), and severity is estimated by clinical signs, erythema, induration and desquamation; scale 0 (none) to 4 (maximum). Final PASI = sum of severity parameters for each area * area score weight of section (head: 0.1, arms: 0.2 body: 0.3 legs: 0.4). A negative change in absolute PASI score means that the severity of psoriasis has decreased, indicating an improvement in the patient's condition.
Time Frame	Baseline, Week 1, Week 2, Week 3, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28

Analysis Population Description: Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
Mean absolute Psoriasis Area and Severity Index (PASI) Score over time (units: Unit on a scale)	**Mean ± Standard Error**	**Mean ± Standard Error**
Baseline (n= 371, 409)	19.8 ± 0.39	19.7 ± 0.38
Week 1 (n= 365, 402)	-2.8 ± 0.22	-2.9 ± 0.21
Week 2 (n= 361, 394)	-6.6 ± 0.23	-6.9 ± 0.22
Week 3 (n= 362, 392)	-9.9 ± 0.25	-10.1 ± 0.23
Week 4 (n= 364, 393)	-12.0 ± 0.26	-12.4 ± 0.25
Week 8 (n= 360, 394)	-15.5 ± 0.26	-15.5 ± 0.25
Week 12 (n= 309, 335)	-16.6 ± 0.26	-16.9 ± 0.25
Week 16 (n= 354, 388)	-17.2 ± 0.27	-17.3 ± 0.26
Week 20 (n= 346, 380)	-17.4 ± 0.27	-17.5 ± 0.26
Week 24 (n= 337, 376)	-17.4 ± 0.28	-17.6 ± 0.26
Week 28 (n= 334, 366)	-17.3 ± 0.29	-17.6 ± 0.27

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	Mean change from Baseline in absolute PASI Score at week 28
Type of Statistical Test	Superiority	
P Value	0.5443	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment interaction and covariate baseline PASI
Other least squares (LS) mean change	-0.2	
Standard Error of the mean	0.38	
95 % Confidence Interval 2-Sided	-1.0 to 0.5	

Mean change from Baseline in high-sensitivity C-reactive Protein (hsCRP)

Description	High-sensitivity C-reactive Protein (hsCRP) was evaluated in both treatment arms throughout the duration of the core study and summarized using descriptive statistics.
Time Frame	Baseline, Week 2, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they

		participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	370	409
Mean change from Baseline in high-sensitivity C-reactive Protein (hsCRP) (units: milligram/litre (mg/L))	**Mean** **± Standard Deviation**	**Mean** **± Standard Deviation**
Baseline (n=370, 409)	0.648 ± 0.7565	0.575 ± 0.6239
Change from BL @ Week 2 (n=354, 386)	-0.087 ± 0.7242	-0.124 ± 0.5178
Change from BL @ Week 4 (n=362, 392)	-0.098 ± 0.6860	-0.117 ± 0.5218
Change from BL @ Week 8 (n=357, 392)	-0.117 ± 0.6797	-0.092 ± 0.5733
Change from BL @ Week 12 (n=310, 334)	-0.069 ± 0.7539	-0.078 ± 0.7599
Change from BL @ Week 16 (n=352, 387)	-0.100 ± 0.6654	-0.116 ± 0.4679
Change from BL @ Week 20 (n=345, 378)	-0.074 ± 0.7019	-0.113 ± 0.5109
Change from BL @ Week 24 (n=333, 373)	-0.087 ± 0.7964	-0.097 ± 0.5783
Change from BL @ Week 28 (n=332, 362)	-0.101 ± 0.7694	-0.141 ± 0.4254

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	Comparison of mean change between treatments in hsCRP at week 28
Type of Statistical Test	Superiority	
P Value	0.0057	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment interaction and covariate baseline hsCRP.
Other Comparison of mean change between treatm	-0.114	

95 % Confidence Interval 2-Sided	-0.194 to -0.033

Mean change from Baseline in Hemoglobin A1c (HbA1c)

Description	Hemoglobin A1c (HbA1c) was evaluated in both treatment arms throughout the duration of the core study and summarized using descriptive statistics.
Time Frame	Baseline, Week 8, Week 16, Week 24, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	**Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention**
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	365	402
Mean change from Baseline in Hemoglobin A1c (HbA1c) (units: Percentage (%))	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline (n= 365, 402)	5.69 ± 0.706	5.69 ± 0.694
Change from BL @ Week 8 (n=346, 378)	0.01 ± 0.293	-0.07 ± 0.314
Change from BL @ Week 16 (n=346, 380)	0.03 ± 0.389	-0.06 ± 0.342
Change from BL @ Week 24 (n=180, 180))	0.03 ± 0.388	-0.04 ± 0.332
Change from BL @ Week 28 (n=317, 348)	0.03 ± 0.417	-0.05 ± 0.353

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	HbA1c - Comparison of mean change between treatments at week 28
Type of Statistical Test	Superiority	
P Value	0.0012	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment interaction and covariate baseline values
Other least squares (LS) mean change	-0.09	
Standard Error of the mean	0.027	
95 % Confidence Interval 2-Sided	-0.14 to -0.04	

Mean change from Baseline in Fructosamine

Description	Fructosamine was evaluated in both treatment arms throughout the duration of the core study and summarized using descriptive statistics.
Time Frame	Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they

		participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	365	402
Mean change from Baseline in Fructosamine (units: micromole/liter (µmol/L))	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline (n=365, 402)	270.1 ± 61.62	266.7 ± 61.91
Change from BL @ Week 4 (n=127, 135)	-1.0 ± 43.96	-9.6 ± 43.23
Change from BL @ Week 8 (n=349, 378)	-2.4 ± 41.24	-4.2 ± 48.95
Change from BL @ Week 12 (n=137, 135)	6.6 ± 45.84	-6.4 ± 39.15
Change from BL @ Week 16 (n=346, 381)	0.8 ± 45.17	-0.4 ± 48.15
Change from BL @ Week 20 (n=157, 154)	-0.6 ± 46.43	-6.4 ± 56.76
Change from BL @ Week 24 (n=177, 179)	0.6 ± 44.51	3.9 ± 51.88
Change from BL @ Week 28 (n=317, 347)	2.3 ± 47.29	1.7 ± 48.00

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	Fructosamine - Comparison of mean change between treatments at week 28
Type of Statistical Test	Superiority	
P Value	0.9835	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment interaction and covariate baseline values.
Other least squares (LS) mean change	-0.1	
Standard Error of the mean	3.23	
95 % Confidence Interval 2-Sided	-6.4 to 6.3	

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Mean change from Baseline in Fasting Plasma Glucose (FPG)

Description	Fasting Plasma Glucose (FPG) was evaluated in both treatment arms throughout the duration of the core study and summarized using descriptive statistics.
Time Frame	Baseline, Week 8, Week 16, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	**Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention**
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	366	402
Mean change from Baseline in Fasting Plasma Glucose (FPG) (units: milligram per deciliter (mg/dL))	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline (n=366, 402)	102.8 ± 23.35	103.1 ± 25.61
Change from BL @ Week 8 (n=347, 375)	0.8 ± 17.14	-1.7 ± 16.71
Change from BL @ Week 16 (n=343, 377)	1.9 ± 20.51	-2.1 ± 16.26
Change from BL @ Week 28 (n=320, 347)	2.9 ± 22.29	-0.5 ± 18.60

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	FPG - Comparison of mean change between treatments at week 28

Type of Statistical Test	Superiority	
P Value	0.0086	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment interaction and covariate baseline values
Other least squares (LS) mean change	-3.5	
Standard Error of the mean	1.35	
95 % Confidence Interval 2-Sided	-6.2 to -0.9	

Mean change from Baseline in Total cholesterol

Description	Total cholesterol was evaluated in both treatment arms throughout the duration of the core study and summarized using descriptive statistics.
Time Frame	Baseline, Week 8, Week 16, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	**Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention**
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	370	409
Mean change from Baseline in Total cholesterol (units: milligram per deciliter (mg/dL))	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**

Baseline (n=370, 409)	203.4 ± 42.38	208.2 ± 41.61
Change from BL @ Week 8 (n=355, 394)	1.9 ± 26.75	-2.5 ± 24.84
Change from BL @ Week 16 (n=350, 386)	-0.2 ± 25.33	-1.3 ± 25.30
Change from BL @ Week 28 (n=332, 359)	-0.4 ± 30.13	-3.1 ± 25.45

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	Total cholesterol - Comparison of mean change between treatments at week 28
Type of Statistical Test	Superiority	
P Value	0.2755	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment interaction and covariate baseline values
Other least squares (LS) mean change	-2.3	
Standard Error of the mean	2.08	
95 % Confidence Interval 2-Sided	-6.4 to 1.8	

Mean change from Baseline in Low-Density Lipoprotein (LDL)

Description	Low-Density Lipoprotein (LDL) was evaluated in both treatment arms throughout the duration of the core study and summarized using descriptive statistics.
Time Frame	Baseline, Week 8, Week 16, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	370	409
Mean change from Baseline in Low-Density Lipoprotein (LDL) (units: milligram per deciliter (mg/dL))	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline (n=370, 409)	136.6 ± 39.98	143.3 ± 39.39
Change from BL @ Week 8 (n=355, 394)	1.6 ± 21.53	-2.2 ± 22.00
Change from BL @ Week 16 (n=350, 386)	-1.4 ± 22.67	-0.9 ± 24.14
Change from BL @ Week 28 (n=332, 359)	1.9 ± 25.57	-1.2 ± 25.10

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	LDL - Comparison of mean change between treatments at week 28
Type of Statistical Test	Superiority	
P Value	0.1298	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment interaction and covariate baseline values
Other least squares (LS) mean change	-2.8	
Standard Error of the mean	1.86	

95 % Confidence Interval 2-Sided	-6.5 to 0.8

Mean change from Baseline in High-Density Lipoprotein (HDL)

Description	High-Density Lipoprotein (HDL) was evaluated in both treatment arms throughout the duration of the core study and summarized using descriptive statistics.
Time Frame	Baseline, Week 8, Week 16, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	**Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention**
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	370	409
Mean change from Baseline in High-Density Lipoprotein (HDL) (units: milligram per deciliter (mg/dL))	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline (n=370, 409)	45.5 ± 11.81	46.1 ± 10.62
Change from BL @ Week 8 (n=355, 394)	-0.5 ± 5.29	-1.0 ± 6.20
Change from BL @ Week 16 (n=350, 386)	-0.8 ± 5.92	0.0 ± 6.69
Change from BL @ Week 28 (n=332, 359)	0.0 ± 6.91	0.5 ± 7.29

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	HDL - Comparison of mean change between treatments at week 28
Type of Statistical Test	Superiority	
P Value	0.2084	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment interaction and covariate baseline values
Other least squares (LS) mean change	0.7	
Standard Error of the mean	0.53	
95 % Confidence Interval 2-Sided	-0.4 to 1.7	

Mean change from Baseline in Triglycerides

Description	Triglycerides were evaluated in both treatment arms throughout the duration of the core study and summarized using descriptive statistics.
Time Frame	Baseline, Week 8, Week 16, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they

		participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	370	409
Mean change from Baseline in Triglycerides (units: milligram per deciliter (mg/dL))	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline (n=370, 409)	210.4 ± 169.58	195.8 ± 126.83
Change from BL @ Week 8 (n=355, 394)	2.5 ± 100.55	-2.7 ± 100.29
Change from BL @ Week 16 (n=350, 386)	11.0 ± 146.64	-1.7 ± 111.36
Change from BL @ Week 28 (n=332, 359)	-5.9 ± 187.93	-6.3 ± 98.69

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	TRIG - Comparison of mean change between treatments at week 28
Type of Statistical Test	Superiority	
P Value	0.5187	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment interaction and covariate baseline values
Other least squares (LS) mean change	-5.8	
Standard Error of the mean	8.92	
95 % Confidence Interval 2-Sided	-23.3 to 11.7	

Mean change from Baseline in Waist circumference

Description	Waist circumference was evaluated in both treatment arms throughout the duration of the core study and summarized using descriptive statistics.
Time Frame	Baseline, Week 1, Week 2, Week 3, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28

Analysis Population Description: Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
Mean change from Baseline in Waist circumference (units: Centimeter (cm))	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline (n=371, 409)	115.3 ± 15.10	114.9 ± 13.99
Change from BL @ Week 1 (n=365, 402)	-0.5 ± 2.97	-0.3 ± 3.41
Change from BL @ Week 2 (n=361, 393)	-0.7 ± 3.74	-1.1 ± 4.30
Change from BL @ Week 3 (n=362, 391)	-0.8 ± 3.66	-1.3 ± 4.71
Change from BL @ Week 4 (n=363, 393)	-0.9 ± 3.92	-2.0 ± 4.54
Change from BL @ Week 8 (n=359, 394)	-1.2 ± 4.53	-2.6 ± 5.34
Change from BL @ Week 12 (n=309, 335)	-1.1 ± 4.43	-2.9 ± 5.68
Change from BL @ Week 16 (n=353, 388)	-1.4 ± 5.22	-3.5 ± 6.09
Change from BL @ Week 20 (n=346, 381)	-1.3 ± 5.47	-3.5 ± 6.09
Change from BL @ Week 24 (n=337, 375)	-1.4 ± 5.34	-3.7 ± 6.72
Change from BL @ Week 28 (n=331, 366)	-1.5 ± 5.50	-3.9 ± 7.04

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	Waist circumference - Comparison of mean change between treatments at week 28
Type of Statistical Test	Superiority	
P Value	<0.0001	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment interaction and covariate baseline values
Other least squares (LS) mean change	-2.7	
Standard Error of the mean	0.47	
95 % Confidence Interval 2-Sided	-3.6 to -1.8	

Mean change from Baseline in Body weight

Description	Body weight was evaluated in both treatment arms throughout the duration of the core study and summarized using descriptive statistics.
Time Frame	Baseline, Week 1, Week 2, Week 3, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they

		participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
Mean change from Baseline in Body weight (units: Kilogram (kg))	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline (n=371, 409)	107.16 ± 22.624	107.9 ± 20.765
Change from BL @ Week 1 (n=365, 402)	0.06 ± 2.120	-0.33 ± 1.401
Change from BL @ Week 2 (n=361, 394)	-0.04 ± 1.729	-0.75 ± 1.739
Change from BL @ Week 3 (n=362, 392)	-0.05 ± 2.189	-1.08 ± 2.278
Change from BL @ Week 4 (n=363, 394)	-0.08 ± 2.326	-1.20 ± 2.177
Change from BL @ Week 8 (n=360, 393)	-0.15 ± 2.447	-1.84 ± 3.471
Change from BL @ Week 12 (n=310, 335)	0.02 ± 2.726	-2.38 ± 4.150
Change from BL @ Week 16 (n=355, 388)	-0.21 ± 3.243	-2.65 ± 4.892
Change from BL @ Week 20 (n=346, 381)	-0.36 ± 3.581	-2.72 ± 5.480
Change from BL @ Week 24 (n=337, 376)	-0.30 ± 3.815	-2.86 ± 6.056
Change from BL @ Week 28 (n=334, 366)	-0.17 ± 3.803	-3.03 ± 6.107

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	Body weight - Comparison of mean change between treatments at week 28
Type of Statistical Test	Superiority	
P Value	<0.0001	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment interaction and covariate baseline values
Other least squares (LS) mean change	-2.85	

Standard Error of the mean	0.385
95 % Confidence Interval 2-Sided	-3.61 to -2.09

Mean change from Baseline in Body Mass Index (BMI)

Description	Body Mass Index (BMI) was evaluated in both treatment arms throughout the duration of the core study and summarized using descriptive statistics.
Time Frame	Baseline, Week 1, Week 2, Week 3, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	**Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention**
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
Mean change from Baseline in Body Mass Index (BMI) (units: Kilogram by square meter (kg/m^2))	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline (n=371, 409)	34.788 ± 6.8112	34.631 ± 6.4232
Change from BL @ Week 1 (n=365, 402)	0.015 ± 0.6846	-0.110 ± 0.4515
Change from BL @ Week 2 (n=361, 394)	-0.015 ± 0.5545	-0.240 ± 0.5649
Change from BL @ Week 3 (n=362, 392)	-0.014 ± 0.7076	-0.346 ± 0.7352
Change from BL @ Week 4 (n=363, 394)	-0.027 ± 0.7451	-0.386 ± 0.7128

Change from BL @ Week 8 (n=360, 393)	-0.047 ± 0.7838	-0.582 ± 1.1641
Change from BL @ Week 12 (n=310, 335)	0.009 ± 0.8768	-0.758 ± 1.3522
Change from BL @ Week 16 (n=355, 388)	-0.070 ± 1.0432	-0.843 ± 1.5780
Change from BL @ Week 20 (n=346, 381)	-0.113 ± 1.1627	-0.864 ± 1.7769
Change from BL @ Week 24 (n=337, 376)	-0.094 ± 1.2417	-0.906 ± 1.9591
Change from BL @ Week 28 (n=334, 366)	-0.054 ± 1.2309	-0.961 ± 1.9665

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	BMI - Comparison of mean change between treatments at week 28
Type of Statistical Test	Superiority	
P Value	<0.0001	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment interaction and covariate baseline values
Other least squares (LS) mean change	-0.907	
Standard Error of the mean	0.1243	
95 % Confidence Interval 2-Sided	-1.151 to -0.663	

Mean change from Baseline in Systolic Blood Pressure

Description	Systolic Blood Pressure was evaluated in both treatment arms throughout the duration of the core study and summarized using descriptive statistics.
Time Frame	Baseline, Week 1, Week 2, Week 3, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
Mean change from Baseline in Systolic Blood Pressure (units: millimeter of mercury (mmHg))	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline (n=371, 409)	139.44 ± 11.703	139.19 ± 11.711
Change from BL @ Week 1 (n=365, 402)	-0.66 ± 10.033	-1.44 ± 10.964
Change from BL @ Week 2 (n=361, 394)	-1.24 ± 11.499	-3.12 ± 11.422
Change from BL @ Week 3 (n=362, 392)	-1.05 ± 11.086	-3.67 ± 12.740
Change from BL @ Week 4 (n=362, 394)	-3.02 ± 10.693	-4.33 ± 11.763
Change from BL @ Week 8 (n=360, 394)	-2.52 ± 12.394	-3.88 ± 12.545
Change from BL @ Week 12 (n=310, 335)	-1.64 ± 12.054	-3.65 ± 12.982
Change from BL @ Week 16 (n=354, 388)	-3.03 ± 12.646	-4.33 ± 12.980
Change from BL @ Week 20 (n=346, 381)	-1.65 ± 12.067	-3.70 ± 13.323
Change from BL @ Week 24 (n=337, 376)	-2.53 ± 12.681	-4.35 ± 13.455
Change from BL @ Week 28 (n=334, 366)	-2.56 ± 12.179	-4.28 ± 13.475

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	SYSBP - Comparison of mean change between treatments at week 28
Type of Statistical Test	Superiority	
P Value	0.0204	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment interaction and covariate baseline values
Other least squares (LS) mean change	-2.0	
Standard Error of the mean	0.87	
95 % Confidence Interval 2-Sided	-3.7 to -0.3	

Mean change from Baseline in Diastolic Blood Pressure

Description	Diastolic Blood Pressure was evaluated in both treatment arms throughout the duration of the core study and summarized using descriptive statistics.
Time Frame	Baseline, Week 1, Week 2, Week 3, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they

		participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
Mean change from Baseline in Diastolic Blood Pressure (units: millimeter of mercury (mmHg))	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline (n=371, 409)	86.44 ± 7.116	86.50 ± 7.305
Change from BL @ Week 1 (n=365, 402)	-0.39 ± 6.761	-1.02 ± 7.495
Change from BL @ Week 2 (n=361, 394)	-0.65 ± 7.460	-1.16 ± 7.630
Change from BL @ Week 3 (n=362, 392)	-0.62 ± 7.180	-1.66 ± 8.030
Change from BL @ Week 4 (n=362, 394)	-1.29 ± 7.349	-2.00 ± 7.925
Change from BL @ Week 8 (n=360, 394)	-0.60 ± 7.510	-1.51 ± 7.517
Change from BL @ Week 12 (n=310, 335)	-0.37 ± 7.820	-1.56 ± 8.754
Change from BL @ Week 16 (n=354, 388)	-0.60 ± 7.969	-1.99 ± 8.211
Change from BL @ Week 20 (n=346, 381)	-0.59 ± 8.040	-2.28 ± 8.275
Change from BL @ Week 24 (n=337, 376)	-0.73 ± 8.270	-2.04 ± 8.701
Change from BL @ Week 28 (n=334, 366)	-0.48 ± 8.417	-1.65 ± 8.877

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	DIABP - Comparison of mean change between treatments at week 28
Type of Statistical Test	Superiority	
P Value	0.0652	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment interaction and covariate baseline values
Other least squares (LS) mean change	-1.1	

Standard Error of the mean	0.58
95 % Confidence Interval 2-Sided	-2.2 to 0.1

Dermatology Life Quality Index (DLQI) Total Score over time

Description	The Dermatology life Quality Index (DLQI) is a ten-question questionnaire used to measure the impact of skin disease on the quality of life of an affected person. Each question refers to the impact of the skin disease on the patient's life (symptoms, embarrassment, shopping and home care, clothes, social and leisure, sport, work or study, close relationships, sex, treatment) over the previous week and is scored from 0 to 3, giving a possible score range from 0 (meaning no impact of skin disease on quality of life) to 30 (meaning maximum impact on quality of life).
Time Frame	Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28
Analysis Population Description	Full Analysis Set (FAS).

	Secukinumab 300 mg subcutaneous (s.c.)	**Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention**
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
Dermatology Life Quality Index (DLQI) Total Score over time (units: Unit on a scale)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline (n=371, 409)	19.55 ± 5.124	19.12 ± 5.449
Week 4 (n=366, 394)	8.57 ± 5.932	7.92 ± 6.119
Week 8 (n=360, 395)	5.47 ± 5.725	5.18 ± 5.405
Week 12 (n= 309, 335)	4.29 ± 5.341	4.16 ± 5.100

Week 16 (n= 354, 388)	3.90 ± 5.374	3.73 ± 4.927
Week 20 (n= 346, 380)	3.43 ± 5.101	3.43 ± 5.061
Week 24 (n=337, 378)	3.42 ± 5.261	3.33 ± 4.824
Week 28 (n=334, 366)	3.42 ± 5.242	3.30 ± 5.312

Mean change from Baseline in Dermatology Life Quality Index (DLQI) Total Score over time

Description	The Dermatology life Quality Index (DLQI) is a ten-question questionnaire used to measure the impact of skin disease on the quality of life of an affected person. Each question refers to the impact of the skin disease on the patient's life (symptoms, embarrassment, shopping and home care, clothes, social and leisure, sport, work or study, close relationships, sex, treatment) over the previous week and is scored from 0 to 3, giving a possible score range from 0 (meaning no impact of skin disease on quality of life) to 30 (meaning maximum impact on quality of life).
Time Frame	Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	**Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention**
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
Mean change from Baseline in Dermatology Life Quality Index (DLQI) Total Score over time (units: Unit on a scale)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline (n=371, 409)	19.5 ± 5.12	19.1 ± 5.45

Change from BL @ Week 4 (n=366, 394)	-11.0 ± 6.66	-11.3 ± 6.68
Change from BL @ Week 8 (n=360, 395)	-14.1 ± 6.91	-14.1 ± 6.60
Change from BL @ Week 12 (n=309, 335)	-15.5 ± 6.68	-15.1 ± 6.51
Change from BL @ Week 16 (n=354, 388)	-15.7 ± 6.60	-15.4 ± 6.33
Change from BL @ Week 20 (n=346, 380)	-16.2 ± 6.81	-15.7 ± 6.66
Change from BL @ Week 24 (n=337, 378)	-16.1 ± 6.75	-15.8 ± 6.46
Change from BL @ Week 28 (n=334, 366)	-16.1 ± 6.80	-15.9 ± 6.67

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	DLQI Total Score - Comparison of mean change between treatments at Week 28
Type of Statistical Test	Superiority	
P Value	0.7733	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment interaction and covariate baseline DLQI score.
Other least squares (LS) mean change	-0.12	
Standard Error of the mean	0.41	
95 % Confidence Interval 2-Sided	-0.9 to 0.7	

Percentage of patients with Dermatology Life Quality Index (DLQI) Response

Description	All patients with DLQI score 0 and 1 were considered as responders and patients with DLQI score >=2 were considered as non-responders. Subjects with missing DLQI score were counted as non-responders.
Time Frame	Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28

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Analysis Population Description: Full Analysis Set (FAS)

	Secukinumab 300 mg subcutaneous (s.c.)	Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
Percentage of patients with Dermatology Life Quality Index (DLQI) Response (units: Participants)	**Count of Participants (Not Applicable)**	**Count of Participants (Not Applicable)**
Non-Responders @ Week 4	323 (87.06%)	344 (84.11%)
Responders @ Week 4	43 (11.59%)	50 (12.22%)
Non-Responders @ Week 8	249 (67.12%)	269 (65.77%)
Responders @ Week 8	111 (29.92%)	126 (30.81%)
Non-Responders @ Week 12	179 (48.25%)	192 (46.94%)
Responders @ Week 12	130 (35.04%)	143 (34.96%)
Non-Responders @ Week 16	176 (47.44%)	201 (49.14%)
Responders @ Week 16	178 (47.98%)	187 (45.72%)

Non-Responders @ Week 20	153 (41.24%)	170 (41.56%)
Responders @ Week 20	193 (52.02%)	210 (51.34%)
Non-Responders @ Week 24	148 (39.89%)	175 (42.79%)
Responders @ Week 24	189 (50.94%)	203 (49.63%)
Non-Responders @ Week 28	145 (39.08%)	154 (37.65%)
Responders @ Week 28	189 (50.94%)	212 (51.83%)

World Health Organization Well-Being Index (WHO-5) Total score over time

Description	The 5-item World Health Organization Well-Being Index (WHO-5) is a validated, short questionnaire consisting of 5 simple questions, assessing subjective psychological well-being of the respondents: Felt cheerful and in good spirits, Felt calm and relaxed, Felt active and vigorous, Feeling fresh and rested and Things that interest me in daily life. The recall period is the previous two weeks. Each item has 6 response categories, ranging from 5 (“the whole time”) to 0 (“at no time point”). The raw score ranges from 0 to 25, with 0 representing worst possible and 25 representing best possible quality of life. To obtain a percentage score ranging from 0 to 100, the raw score is multiplied by 4. A percentage score of 0 represents worst possible, whereas a score of 100 represents best possible quality of life.
Time Frame	Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28
Analysis Population Description	Full Analysis Set (FAS)

	Secukinumab 300 mg subcutaneous (s.c.)	**Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention**
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they

		participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
World Health Organization Well-Being Index (WHO-5) Total score over time (units: Unit on a scale)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline (n=371, 409)	10.46 ± 5.208	10.62 ± 5.283
Week 4 (n=365, 394)	14.45 ± 5.236	15.52 ± 4.921
Week 8 (n=360, 395)	15.65 ± 4.889	15.99 ± 4.697
Week 12 (n=309, 335)	15.77 ± 5.083	16.37 ± 4.824
Week 16 (n=353, 388)	15.91 ± 5.334	16.45 ± 4.902
Week 20 (n=346, 379)	16.30 ± 5.364	16.44 ± 4.978
Week 24 (n=337, 378)	16.47 ± 5.173	16.55 ± 4.865
Week 28 (n=334, 366)	16.20 ± 5.583	16.69 ± 4.910

Mean change from Baseline in World Health Organization Well-Being Index (WHO-5) Total score over time

Description	The 5-item World Health Organization Well-Being Index (WHO-5) is a validated, short questionnaire consisting of 5 simple questions, assessing subjective psychological well-being of the respondents: Felt cheerful and in good spirits, Felt calm and relaxed, Felt active and vigorous, Feeling fresh and rested and Things that interest me in daily life. The recall period is the previous two weeks. Each item has 6 response categories, ranging from 5 (“the whole time”) to 0 (“at no time point”). The raw score ranges from 0 to 25, with 0 representing worst possible and 25 representing best possible quality of life. To obtain a percentage score ranging from 0 to 100, the raw score is multiplied by 4. A percentage score of 0 represents worst possible, whereas a score of 100 represents best possible quality of life.
Time Frame	Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	**Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention**

Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
Mean change from Baseline in World Health Organization Well-Being Index (WHO-5) Total score over time (units: Unit on a scale)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Baseline (n=371, 409)	10.5 ± 5.21	10.6 ± 5.28
Week 4 (n= 365, 394)	4.0 ± 5.21	4.9 ± 5.51
Week 8 (n= 360, 395)	5.1 ± 5.61	5.4 ± 5.76
Week 12 (n= 309, 335)	5.2 ± 5.73	5.7 ± 5.95
Week 16 (n= 353, 388)	5.4 ± 5.59	5.8 ± 5.85
Week 20 (n= 346, 379)	5.8 ± 6.08	5.8 ± 5.79
Week 24 (n= 337, 378)	5.9 ± 5.65	5.9 ± 6.19
Week 28 (n= 334, 366)	5.6 ± 6.20	5.9 ± 6.12

Statistical Analysis

Groups	Secukinumab 300 mg subcutaneous (s.c.), Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention	WHO-5 - Comparison of mean change between treatments at week 28
Type of Statistical Test	Superiority	
P Value	0.0982	
Method	Mixed Models Analysis	Mixed model repeated measures (MMRM) with factors treatment, center, visit, visit*treatment

		interaction and covariate baseline WHO-5 total score value
Other least squares (LS) mean change	0.59	
Standard Error of the mean	0.36	
95 % Confidence Interval 2-Sided	-0.1 to 1.3	

Participant's self-assessed pain, itching and scaling over time

Description	A self-administered, 11-point numeric rating scale (NRS, 0-10) was used to evaluate the subject's assessment of their current pain, itching and scaling. Respondents answered the following questions for the assessment of: * Pain: Overall, how severe was your psoriasis-related pain over the past 24 hours * Itching: Overall, how severe was your psoriasis-related itch over the past 24 hours * Scaling: Overall, how severe was your psoriasis-related scaling over the past 24 hours Subjects had to rate their pain, itching, and scaling from 0 to 10 (11-point scale), with the understanding that the 0 represented the absence or null end of the pain, itching, or scale intensity (i.e., no pain, itching or scaling) and the 10 represented the other extreme of pain, itching, or scaling intensity (i.e., pain, itching or scaling as bad as it could be). The number that the patient selected represented his or her intensity score.
Time Frame	Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	**Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention**
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409

Participant's self-assessed pain, itching and scaling over time (units: Unit on a scale)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Pain at Baseline (n=371, 409)	4.9 ± 2.93	4.6 ± 2.87
Pain at week 4 (n= 366, 392)	1.9 ± 2.29	1.7 ± 2.23
Pain at week 8 (n= 359, 394)	1.1 ± 1.88	1.3 ± 2.05
Pain at week 12 (n= 309, 335)	1.2 ± 2.14	1.0 ± 1.84
Pain at week 16 (n= 353, 388)	1.1 ± 2.04	1.1 ± 1.88
Pain at week 20 (n= 346, 380)	1.0 ± 1.93	1.0 ± 1.81
Pain at week 24 (n= 337, 378)	1.0 ± 1.91	1.0 ± 1.85
Pain at week 28 (n= 333, 366)	1.2 ± 2.10	1.0 ± 2.00
Itching at Baseline (n=371, 409)	7.4 ± 2.08	7.1 ± 2.39
Itching at week 4 (n=366, 393)	3.2 ± 2.43	3.0 ± 2.60
Itching at week 8 (n=359, 394)	2.4 ± 2.36	2.3 ± 2.47
Itching at week 12 (n=309, 335)	2.2 ± 2.38	2.0 ± 2.29
Itching at week 16 (n=353, 388)	2.0 ± 2.29	2.0 ± 2.43
Itching at week 20 (n= 346, 380)	1.9 ± 2.23	1.9 ± 2.19
Itching at week 24 (n= 337, 378)	1.9 ± 2.35	1.8 ± 2.23
Itching at week 28 (n=334, 366)	2.0 ± 2.47	1.9 ± 2.38
Scaling at Baseline (n=371, 409)	7.5 ± 2.01	7.3 ± 2.17
Scaling at week 4 (n=366, 393)	2.7 ± 2.18	2.4 ± 2.16
Scaling at week 8 (n=359, 394)	1.7 ± 1.94	1.7 ± 2.03
Scaling at week 12 (n=309, 335)	1.7 ± 2.00	1.6 ± 1.90
Scaling at week 16 (n=353, 388)	1.6 ± 2.10	1.5 ± 1.95
Scaling at week 20 (n=346, 380)	1.6 ± 2.10	1.5 ± 1.98
Scaling at week 24 (n=337, 378)	1.7 ± 2.22	1.4 ± 1.84
Scaling at week 28 (n=334, 366)	1.8 ± 2.28	1.5 ± 2.04

Percentage change from Baseline in Participant's self-assessed pain, itching and scaling

Description	A self-administered, 11-point numeric rating scale (NRS, 0-10) was used to evaluate the subject's assessment of their current pain, itching and scaling. Respondents answered the following questions for the assessment of: * Pain: Overall, how severe was your psoriasis-related pain over the past 24 hours * Itching: Overall, how severe was your psoriasis-related itch over the past 24 hours * Scaling: Overall, how severe was your psoriasis-related scaling over the past 24 hours Subjects had to rate their pain, itching, and scaling from 0 to 10 (11-point scale), with the understanding that the 0 represented the absence or null end of the pain, itching, or scale intensity (i.e., no pain, itching or scaling) and the 10 represented the other extreme of pain, itching, or scaling intensity (i.e., pain, itching or scaling as bad as it could be). The number that the patient selected represented his or her intensity score.
Time Frame	Baseline, Week 4, Week 8, Week 12, Week 16, Week 20, Week 24, Week 28
Analysis Population Description	Full Analysis Set (FAS); only participants with available data for the outcome measure

	Secukinumab 300 mg subcutaneous (s.c.)	**Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention**
Arm/Group Description	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24).	Patients received therapy with Secukinumab 300 mg s.c., which consisted of two injections with 150 mg prefilled syringes at weeks 0, 1, 2, 3, 4, 8, 12, 16, 20 and 24 (last injection was performed at week 24). In addition they participated in a lifestyle intervention program.
Number of Participants Analyzed [units: participants]	371	409
Percentage change from Baseline in Participant's self-assessed pain, itching and scaling (units: Percentage change)	**Mean ± Standard Deviation**	**Mean ± Standard Deviation**
Pain at Baseline (n=371, 409)	4.9 ± 2.93	4.6 ± 2.87
Pain at week 4 (n= 328, 349)	-61.4 ± 44.13	-60.2 ± 59.10
Pain at week 8 (n= 321, 352)	-74.4 ± 44.39	-68.5 ± 53.86
Pain at week 12 (n= 276, 299)	-72.2 ± 54.73	-76.6 ± 40.64

Pain at week 16 (n= 315, 345)	-77.3 ± 38.93	-74.0 ± 46.10
Pain at week 20 (n= 308, 339)	-78.4 ± 41.88	-75.2 ± 43.55
Pain at week 24 (n= 302, 340)	-78.4 ± 41.88	-75.7 ± 47.05
Pain at week 28 (n= 299, 328)	-76.3 ± 42.22	-75.3 ± 52.42
Itching at Baseline (n=371, 409)	7.4 ± 2.08	7.1 ± 2.39
Itching at week 4 (n=365, 386)	-54.1 ± 33.82	-55.8 ± 41.19
Itching at week 8 (n=358, 387)	-63.7 ± 39.78	-66.7 ± 34.31
Itching at week 12 (n=308, 329)	-66.6 ± 40.58	-70.0 ± 33.53
Itching at week 16 (n=352, 381)	-70.6 ± 34.79	-70.0 ± 35.79
Itching at week 20 (n= 345, 373)	-71.1 ± 37.64	-73.0 ± 35.36
Itching at week 24 (n= 326, 374)	-69.6 ± 46.85	-72.6 ± 35.64
Itching at week 28 (n=333, 361)	-68.5 ± 48.46	-72.1 ± 35.97
Scaling at Baseline (n=371, 409)	7.5 ± 2.01	7.3 ± 2.17
Scaling at week 4 (n=366, 389)	-62.2 ± 30.65	-64.9 ± 34.27
Scaling at week 8 (n=359, 390)	-74.9 ± 38.02	-75.1 ± 30.50
Scaling at week 12 (n=309, 332)	-76.5 ± 29.91	-76.9 ± 31.93
Scaling at week 16 (n=353, 384)	-74.3 ± 40.92	-77.2 ± 32.84
Scaling at week 20 (n=346, 376)	-76.4 ± 31.93	-76.2 ± 36.76
Scaling at week 24 (n=337, 375)	-75.4 ± 35.21	-78.2 ± 33.38
Scaling at week 28 (n=334, 362)	-74.3 ± 36.50	-77.7 ± 35.84

Other Pre-Specified Outcome Result(s)

No data identified.

Post-Hoc Outcome Result(s)

No data identified.

Summary of Safety

Safety Results

Time Frame	Adverse events were reported from first dose of secukinumab in the Core Study up to 84 days after the last dose (Week 24). The core study ended at Week 28. The extension period ended at Week 56, where all patients completed the study. No study drug was supplied during the extension period.
Additional Description	The safety analysis were done on the safety population, which included all randomized subjects who received at least one dose of study medication. Any sign or symptom that occurred during the Core Study, with additional AEs from the Extension Period that occurred within 84 days of the last protocol-mandated administration of secukinumab.
Source Vocabulary for Table Default	MedDRA (25.0)
Collection Approach for Table Default	Systematic Assessment

All-Cause Mortality

	Core Study: Secukinumab 300 mg subcutaneous (s.c.) N = 371	**Core Study: Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention N = 409**	**Extension Period: Lifestyle Intervention N = 189**	**Extension Period: Lifestyle Intervention + Secukinumab N = 164**	**Extension Period: Secukinumab N = 427**
Arm/Group Description	Core Study: Secukinumab 300 mg subcutaneous (s.c.) - All AEs that occurred during the Core Study (between week 0 and last injection	Core Study: Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention - All AEs that occurred during the Core Study (between week 0 and last injection	Extension Period: Lifestyle Intervention - All AEs that occurred during the Core Study, with additional AEs from the Extension Period that occurred within 84 days of the last	Extension Period: Lifestyle Intervention + Secukinumab - All AEs that occurred during the Core Study, with additional AEs from the Extension Period that occurred within	Extension Period: Secukinumab - All AEs that occurred during the Core Study, with additional AEs from the Extension Period that occurred within 84 days of the last

	performed at week 24)	performed at week 24)	protocol-mandated administration of secukinumab.	84 days of the last protocol-mandated administration of secukinumab.	protocol-mandated administration of secukinumab.
Total Number Affected	2	0	0	0	2
Total Number At Risk	371	409	189	164	427

Serious Adverse Events

	Core Study: Secukinumab 300 mg subcutaneous (s.c.) N = 371	**Core Study: Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention N = 409**	**Extension Period: Lifestyle Intervention N = 189**	**Extension Period: Lifestyle Intervention + Secukinumab N = 164**	**Extension Period: Secukinumab N = 427**
Arm/Group Description	Core Study: Secukinumab 300 mg subcutaneous (s.c.) - All AEs that occurred during the Core Study (between week 0 and last injection performed at week 24)	Core Study: Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention - All AEs that occurred during the Core Study (between week 0 and last injection performed at week 24)	Extension Period: Lifestyle Intervention - All AEs that occurred during the Core Study, with additional AEs from the Extension Period that occurred within 84 days of the last protocol-mandated administration of secukinumab.	Extension Period: Lifestyle Intervention + Secukinumab - All AEs that occurred during the Core Study, with additional AEs from the Extension Period that occurred within 84 days of the last protocol-mandated administration of secukinumab.	Extension Period: Secukinumab - All AEs that occurred during the Core Study, with additional AEs from the Extension Period that occurred within 84 days of the last protocol-mandated administration of secukinumab.
Total # Affected by any Serious Adverse Event	18	20	11	10	32
Total # at Risk by any Serious Adverse Event	371	409	189	164	427
Cardiac disorders					
Atrial fibrillation	1 (0.27%)	1 (0.24%)	0 (0.00%)	0 (0.00%)	2 (0.47%)

Coronary artery disease	0 (0.00%)	1 (0.24%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Myocardial infarction	0 (0.00%)	1 (0.24%)	0 (0.00%)	0 (0.00%)	2 (0.47%)
Pericarditis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.61%)	0 (0.00%)
Endocrine disorders					
Goitre	0 (0.00%)	1 (0.24%)	0 (0.00%)	1 (0.61%)	0 (0.00%)
Eye disorders					
Endocrine ophthalmopathy	0 (0.00%)	1 (0.24%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Macular oedema	0 (0.00%)	1 (0.24%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Ocular fistula	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Ulcerative keratitis	1 (0.27%)	0 (0.00%)	1 (0.53%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders					
Enterocolitis haemorrhagic	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Femoral hernia	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Gastrointestinal polyp	0 (0.00%)	1 (0.24%)	1 (0.53%)	0 (0.00%)	0 (0.00%)
Hiatus hernia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Hypertrophy of tongue papillae	0 (0.00%)	1 (0.24%)	1 (0.53%)	0 (0.00%)	0 (0.00%)
Inguinal hernia	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Oesophagitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
General disorders and administration site conditions					
Chest discomfort	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Oedema peripheral	2 (0.54%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.47%)
Pyrexia	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Immune system disorders					

Drug hypersensitivity	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Infections and infestations					
Bronchiolitis	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Erysipelas	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.47%)
Gastrointestinal infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Otitis media	0 (0.00%)	1 (0.24%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Pulpitis dental	0 (0.00%)	1 (0.24%)	0 (0.00%)	1 (0.61%)	0 (0.00%)
Tonsillitis	0 (0.00%)	1 (0.24%)	0 (0.00%)	1 (0.61%)	0 (0.00%)
Upper respiratory tract infection	0 (0.00%)	1 (0.24%)	0 (0.00%)	1 (0.61%)	0 (0.00%)
Urinary tract infection	0 (0.00%)	1 (0.24%)	1 (0.53%)	0 (0.00%)	0 (0.00%)
Vestibular neuronitis	0 (0.00%)	1 (0.24%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Injury, poisoning and procedural complications					
Concussion	0 (0.00%)	1 (0.24%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Fall	0 (0.00%)	1 (0.24%)	1 (0.53%)	0 (0.00%)	0 (0.00%)
Foot fracture	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Head injury	0 (0.00%)	1 (0.24%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Pulmonary contusion	0 (0.00%)	1 (0.24%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Reactive gastropathy	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Rib fracture	0 (0.00%)	1 (0.24%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Road traffic accident	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.61%)	0 (0.00%)
Skin laceration	0 (0.00%)	1 (0.24%)	1 (0.53%)	0 (0.00%)	0 (0.00%)
Tendon rupture	2 (0.54%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (0.47%)
Investigations					
Alanine aminotransferase increased	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)

Aspartate aminotransferase increased	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Gamma-glutamyltransferase increased	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Metabolism and nutrition disorders					
Hypercalcaemia	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Musculoskeletal and connective tissue disorders					
Bursitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Intervertebral disc protrusion	1 (0.27%)	0 (0.00%)	1 (0.53%)	0 (0.00%)	1 (0.23%)
Osteoarthritis	2 (0.54%)	1 (0.24%)	0 (0.00%)	1 (0.61%)	3 (0.70%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Bladder cancer	1 (0.27%)	0 (0.00%)	1 (0.53%)	0 (0.00%)	0 (0.00%)
Colorectal adenocarcinoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Malignant melanoma	0 (0.00%)	1 (0.24%)	1 (0.53%)	0 (0.00%)	0 (0.00%)
Metastases to bone	0 (0.00%)	1 (0.24%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Metastases to spine	0 (0.00%)	1 (0.24%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Parathyroid tumour benign	0 (0.00%)	1 (0.24%)	0 (0.00%)	1 (0.61%)	0 (0.00%)
Scrotal cancer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Urethral cancer	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Nervous system disorders					
Cerebral haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Cerebral infarction	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Dizziness	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Paraesthesia	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)

Product issues					
Device loosening	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Psychiatric disorders					
Mania	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Renal and urinary disorders					
Nephrolithiasis	1 (0.27%)	0 (0.00%)	1 (0.53%)	1 (0.61%)	0 (0.00%)
Renal failure	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Reproductive system and breast disorders					
Cystocele	0 (0.00%)	1 (0.24%)	1 (0.53%)	0 (0.00%)	0 (0.00%)
Respiratory, thoracic and mediastinal disorders					
Asthma	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.61%)	0 (0.00%)
Chronic obstructive pulmonary disease	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Dyspnoea	3 (0.81%)	1 (0.24%)	0 (0.00%)	1 (0.61%)	4 (0.94%)
Skin and subcutaneous tissue disorders					
Erythrodermic psoriasis	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Psoriasis	2 (0.54%)	1 (0.24%)	1 (0.53%)	0 (0.00%)	3 (0.70%)
Vascular disorders					
Arteriovenous fistula	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Circulatory collapse	0 (0.00%)	1 (0.24%)	0 (0.00%)	1 (0.61%)	0 (0.00%)
Flushing	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)
Hypertension	1 (0.27%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.23%)

Peripheral arterial occlusive disease	0 (0.00%)	1 (0.24%)	1 (0.53%)	0 (0.00%)	0 (0.00%)
Peripheral ischaemia	0 (0.00%)	1 (0.24%)	0 (0.00%)	1 (0.61%)	0 (0.00%)
Varicose vein	1 (0.27%)	1 (0.24%)	0 (0.00%)	2 (1.22%)	0 (0.00%)

Other (Not Including Serious) Adverse Events

Frequent Event Reporting Threshold 5%

	Core Study: Secukinumab 300 mg subcutaneous (s.c.) N = 371	**Core Study: Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention N = 409**	**Extension Period: Lifestyle Intervention N = 189**	**Extension Period: Lifestyle Intervention + Secukinumab N = 164**	**Extension Period: Secukinumab N = 427**
Arm/Group Description	Core Study: Secukinumab 300 mg subcutaneous (s.c.) - All AEs that occurred during the Core Study (between week 0 and last injection performed at week 24)	Core Study: Secukinumab 300 mg subcutaneous (s.c.) and lifestyle intervention - All AEs that occurred during the Core Study (between week 0 and last injection performed at week 24)	Extension Period: Lifestyle Intervention - All AEs that occurred during the Core Study, with additional AEs from the Extension Period that occurred within 84 days of the last protocol-mandated administration of secukinumab.	Extension Period: Lifestyle Intervention + Secukinumab - All AEs that occurred during the Core Study, with additional AEs from the Extension Period that occurred within 84 days of the last protocol-mandated administration of secukinumab.	Extension Period: Secukinumab - All AEs that occurred during the Core Study, with additional AEs from the Extension Period that occurred within 84 days of the last protocol-mandated administration of secukinumab.
Total # Affected by any Other Adverse Event	178	204	101	103	225
Total # at Risk by any Other Adverse Event	371	409	189	164	427

Gastrointestinal disorders					
Diarrhoea	19 (5.12%)	22 (5.38%)	14 (7.41%)	10 (6.10%)	23 (5.39%)
General disorders and administration site conditions					
Fatigue	14 (3.77%)	10 (2.44%)	2 (1.06%)	9 (5.49%)	16 (3.75%)
Infections and infestations					
Nasopharyngitis	83 (22.37%)	96 (23.47%)	41 (21.69%)	49 (29.88%)	108 (25.29%)
Investigations					
Alanine aminotransferase increased	10 (2.70%)	7 (1.71%)	2 (1.06%)	9 (5.49%)	9 (2.11%)
Musculoskeletal and connective tissue disorders					
Arthralgia	11 (2.96%)	40 (9.78%)	18 (9.52%)	19 (11.59%)	19 (4.45%)
Back pain	23 (6.20%)	22 (5.38%)	19 (10.05%)	9 (5.49%)	23 (5.39%)
Nervous system disorders					
Headache	40 (10.78%)	36 (8.80%)	18 (9.52%)	20 (12.20%)	40 (9.37%)
Respiratory, thoracic and mediastinal disorders					
Oropharyngeal pain	6 (1.62%)	16 (3.91%)	3 (1.59%)	9 (5.49%)	11 (2.58%)
Skin and subcutaneous tissue disorders					
Pruritus	16 (4.31%)	17 (4.16%)	3 (1.59%)	14 (8.54%)	22 (5.15%)
Psoriasis	17 (4.58%)	18 (4.40%)	19 (10.05%)	19 (11.59%)	37 (8.67%)
Vascular disorders					
Hypertension	19 (5.12%)	16 (3.91%)	9 (4.76%)	9 (5.49%)	20 (4.68%)

Other Relevant Findings

None

Conclusion:

Secukinumab therapy is efficacious and safe in patients with psoriasis and concomitant metabolic syndrome. Lifestyle intervention is beneficial in improving symptoms associated with metabolic syndrome in patients with concomitant psoriasis and is safe to use in this patient population. In this study setting, lifestyle intervention did not improve secukinumab performance in patients with psoriasis and concomitant metabolic syndrome.

Date of Clinical Trial Report

31-Mar-2023