NOVARTIS

Clinical Trial Results Website

Sponsor

Novartis Pharmaceuticals

Generic Drug Name

Secukinumab (AIN457)

Trial Indication(s)

Psoriasis

Protocol Number

CAIN457A2325

Protocol Title

Multicenter, rAndomized, double-blind, placebo-conTrolled, 52-week stUdy to demonstRatE the efficacy, safety and tolerability of secukinumab injections with 2 mL auto-injectors (300 mg) in adult subjects with plaque psoriasis

Clinical Trial Phase

Phase 3

Phase of Drug Development

Phase IIIb

Study Start/End Dates

Study Start Date: December 2018 (Actual)
Primary Completion Date: November 2019 (Actual)
Study Completion Date: August 2020 (Actual)

Study Design/Methodology

This was a 52-week multicenter, randomized, double-blind, placebo-controlled, parallel-group trial planned to enroll approximately 120 subjects with moderate to severe plaque-type psoriasis. The study consisted of 3 periods: Screening (of at least 1 week and up to 4 weeks), Treatment period 1 (of 12 weeks) and Treatment period 2 (of 40 weeks).
The Treatment period 1 was defined as Randomization through Week 12 (Week 12 pre-dose). At the start of the Treatment period 1, eligible subjects were randomized at a 2:2:1:1 ratio to one of the four treatment groups:

- Secukinumab 300 mg regimen group (2 mL AI)
- Secukinumab 300 mg regimen group (2 × 1 mL PFS)
- Placebo - Secukinumab 300 mg in 2 mL AI
- Placebo - Secukinumab 300 mg in 2 × 1 mL PFS

The Treatment period 2 was defined as Week 12 through Week 52. Prior to receiving the Week 12 dose, all subjects from the 2 placebo groups, who were PASI 90 non-responders, transitioned to the respective secukinumab 300 mg 2 mL AI OR secukinumab 300 mg 2 × 1 mL PFS group that had been pre-assigned at randomization and self-administered secukinumab at Weeks 12, 13, 14, and 15, thereafter every four weeks starting at Week 16 and up to Week 48.

Subjects who prematurely discontinued the treatment in Treatment period 1 or 2 for any reason were to perform End of Treatment period 1 (EOT1) or EOT2/End of Study approximately 4 weeks after their last dose of study treatment. Any treatment known to worsen psoriasis (e.g. beta-blockers, calcium channel blockers, lithium) was required to be stable for at least 4 weeks before randomization.

After Screening, the use of concomitant medication for psoriasis in all body regions was restricted to bland emollients (not supplied by Novartis) and other non-medicated interventions. Mild to moderate potency topical corticosteroids (TCS) were allowed only during the Screening if used only on the face, scalp, hands and feet and/or genitoanal area. These TCS were required to be stopped at least 12 h before the Randomization Visit. There was no restriction on the use of anti-histamines and on the use of topical corticosteroids in the eye, nose or ear.
Exposure to ultraviolet (UV) light (including sunbathing and/or use of UV tanning devices) was limited to avoid any possible effect on psoriasis.

Centers

22 centers in 6 countries: Germany(4), United States(8), Iceland(1), Canada(2), Poland(2), Spain(5)

Objectives:

The primary objective was to demonstrate the efficacy of secukinumab 300 mg when administered in 2 mL AI in subjects with plaque-type psoriasis with respect to both Psoriasis Area and Severity Index (PASI) 75 and Investigator's Global Assessment modified 2011 (IGA mod 2011) 0 or 1 response (co-primary endpoint) at Week 12, compared to placebo.

The key secondary objective was:
- To demonstrate the efficacy of secukinumab 300 mg when administered in 2 mL AI in subjects with plaque-type psoriasis with respect to PASI 90 at Week 12, compared to placebo.

Other secondary objectives were:
- To assess the efficacy of secukinumab 300 mg when administered in 2 mL AI in subjects with plaque-type psoriasis with respect to PASI score, IGA mod 2011 score, PASI 50 / 75 / 90 / 100 and IGA mod 2011 0 or 1 response up to Week 12 compared to placebo, and over time up to Week 52.
- To investigate the clinical safety and tolerability of secukinumab 300 mg 2 mL AI as assessed by vital signs, clinical laboratory variables, and adverse events monitoring, compared to placebo.
- To assess the subject usability (ability to follow instructions for use and potential use-related hazards) and satisfaction with the new secukinumab 2 mL AI utilizing a self-administered Self-Injection Assessment Questionnaire (SIAQ) and investigator/site staff observation of secukinumab 300 mg 2 mL AI administration.
- To investigate the effects of secukinumab 300 mg when administered in 2 mL AI with respect to Dermatology Life Quality Index (DLQI) 0 or 1 achievement and DLQI changes at Week 12 compared to placebo, and over time up to Week 52.

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

Secukinumab 300 mg in 2 mL Auto-Injector, Secukinumab 150 mg in 1 mL Pre-Filled Syringe, Placebo to Secukinumab 300 mg in 2 mL Auto-Injector, Placebo to Secukinumab 150 mg in 1 mL Pre-Filled Syringe

Statistical Methods

Statistical analyses of efficacy variables were performed on the FAS, involving all subjects who entered into the treatment period. Safety analyses were performed on the safety set, including all subjects who took at least one dose of study treatment during the treatment period.

The co-primary endpoints were PASI 75 response at Week 12 and IGA mod 2011 0 or 1 response at Week 12. The key secondary endpoint was PASI 90 response at Week 12.

The primary analysis method for PASI 75 and IGA mod 2011 0 or 1 response at Week 12 was evaluated using a logistic regression model with treatment group, baseline bodyweight strata and baseline PASI score as explanatory variables. Odds ratios were computed for comparisons of secukinumab dose regimen versus placebo utilizing the logistic regression model fitted.
Response variables based on PASI score and IGA mod 2011 categories were imputed using multiple imputation as the primary imputation method. Within this analysis the PASI score or IGA mod 2011 categories were imputed and response variables were derived based on the imputed scores for each treatment arm.
(Modified) non-responder imputation was used as a sensitivity method: Missing values with respect to response variables based on PASI score and IGA mod 2011 categories were imputed with non-response without regard to the reason for missing data. Summary tables for PASI scores and IGA mod 2011 categories were imputed using multiple imputation. Only PASI and IGA mod 2011 based response variables were imputed with multiple imputation or non-response, other response variables (e.g. DLQI 0 or 1 achievement) were imputed with last observation carried forward (LOCF).

The key secondary efficacy variable, PASI 90 response, was analyzed analogously to the co-primary endpoints. i.e., logistic regression model with treatment group, baseline bodyweight strata, and baseline PASI score as explanatory variables. Odds ratios were computed for comparisons of secukinumab regimen versus placebo utilizing the logistic regression model fitted.

Summary statistics for PASI 50, PASI 75, PASI 90, PASI 100 and IGA mod 2011 0 or 1 responses by visit were presented in contingency tables and included absolute and relative frequencies. The comparisons between 2 mL AI and 2 × 1 mL PFS groups were only descriptive.

For DLQI, missing values were replaced by LOCF. Baseline values were not carried forward. Summaries were based on the FAS and were presented separately for each treatment group. Treatment groups were compared by Fisher's exact test. The number and percentage of subjects who successfully completed each and all of the indicated steps as per the Instruction for Use (IFU) or experienced each and any of the defined possible hazards were summarized by visit and treatment group, including total.
Number and percentage of subjects who passed the self-injection successfully as well as a 2-sided 95% exact CI at Week 1 visit were summarized by visit and treatment group, including total. Missing values with respect to the self-assessment checklist and possible hazard assessment checklist were not imputed while summarizing the answers of each question with frequencies. For SIAQ, summary statistics for the absolute values of the domain scores at Randomization (baseline) were provided by treatment group including total for the PRE-module and the POST-module.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:

Subjects eligible for inclusion in this study must have fulfilled all of the following criteria:

1. Men or Women of at least 18 years of age at time of Screening
2. Subjects able to understand and communicate with the investigator and comply with the requirements of the study and must have given a written, signed and dated informed consent before any study related activity was performed. Where relevant, a legal representative signed the informed study consent according to local laws and regulations.
3. Chronic plaque-type psoriasis present for at least 6 months and diagnosed before Randomization.
4. Moderate to severe psoriasis as defined at Randomization by:
◦PASI score of 12 or greater, and
◦IGA mod 2011 score of 3 or greater (based on a scale of 0 - 4), and
◦Body Surface Area (BSA) affected by plaque-type psoriasis of 10% or greater.
5. Candidate for systemic therapy. This is defined as a subject having moderate to severe chronic plaque-type psoriasis that is inadequately controlled by
◦Topical treatment and/or

◦Phototherapy and/or
◦Previous systemic therapy

Exclusion Criteria:
1. Forms of psoriasis other than chronic plaque-type (e.g., pustular, erythrodermic and guttate psoriasis) at Screening or Randomization.
2. Ongoing use of prohibited treatments. Washout periods detailed in the protocol had to be adhered to. Subjects not willing to limit UV light exposure (e.g., sunbathing and/or the use of tanning devices) during the course of the study were considered not eligible for this study since UV light exposure was prohibited.
Note: administration of live vaccines 6 weeks prior to Randomization or during the study period was also prohibited.
3. Previous exposure to secukinumab (AIN457) or any other biologic drug directly targeting IL-17 or the IL-17 receptor.
4. 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 had returned to baseline, whichever is longer; or longer if required by local regulations.
5. Pregnant or nursing (lactating) women, where pregnancy was defined as the state of a female after conception and until the termination of gestation, confirmed by a positive hCG laboratory test.
6. 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 was evidence of local recurrence or metastases (except for Bowen's disease, or basal cell carcinoma or actinic keratoses that had been treated with no evidence of recurrence in the past 12 weeks; carcinoma in situ of the cervix or non-invasive malignant colon polyps that have been removed).
7. History of hypersensitivity to any of study drug constituent

Participant Flow Table

Treatment Period 1-Randomized Set

	Secukinumab 300 mg (2 mL AI)	Secukinumab 300 mg (2x 1 mL PFS)	Placebo	Placebo-Secukinumab 300 mg (2 mL AI)	Placebo-Secukinumab 300 mg (2 x 1 mL PFS)	Total
Arm/Group Description	Secukinumab 300 mg provided in 2 mL auto-injector form	Secukinumab 300 mg provided as 2x 1 mL prefilled	Placebo to Secukinumab	Placebo patients up to Week 12 who thereafter received secukinumab	Placebo patients up to Week 12 who thereafter received secukinumab	

		syringe of 150 mg/mL		in 2 mL AI up to the end of treatment	in 2 x 1 mL PFS up to the end of treatment	
Started	41	41	40	0	0	122
Completed	41	39	37	0	0	117
Not Completed	0	2	3	0	0	5
Adverse Event	0	1	0	0	0	1
Lack of Efficacy	0	0	2	0	0	2
Lost to Follow-up	0	1	0	0	0	1
Withdrawal by Subject	0	0	1	0	0	1

Treatment Period 2-Randomized Set

	Secukinumab 300 mg (2 mL AI)	**Secukinumab 300 mg (2x 1 mL PFS)**	**Placebo**	**Placebo-Secukinumab 300 mg (2 mL AI)**	**Placebo-Secukinumab 300 mg (2 x 1 mL PFS)**	**Total**
Arm/Group Description	Secukinumab 300 mg provided in 2 mL auto-injector form	Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL	Placebo to Secukinumab	Placebo patients up to Week 12 who thereafter received secukinumab in 2 mL AI up to the end of treatment	Placebo patients up to Week 12 who thereafter received secukinumab in 2 x 1 mL PFS up to the end of treatment	
Started	41	39	4	16	17	117

Completed	40	34	3	16	16	109
Not Completed	1	5	1	0	1	8
Adverse Event	0	1	0	0	0	1
Pregnancy	1	0	0	0	0	1
Lost to Follow-up	0	3	1	0	1	5
Withdrawal by Subject	0	1	0	0	0	1

Baseline Characteristics

	Secukinumab 2 mL auto-injector	**Secukinumab 1 mL prefilled syringe**	**Placebo**	**Total**
Arm/Group Description	Secukinumab 300 mg provided in 2 mL auto-injector form	Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL	Placebo to Secukinumab	
Number of Participants [units: participants]	41	41	40	122
Age, Customized (units: Participants)				
< 65	39	37	36	112
≥ 65	2	4	4	10
Sex: Female, Male (units: Participants) Count of Participants (Not Applicable)				

Female	13	12	12	37
Male	28	29	28	85
Race (NIH/OMB) (units: Participants) Count of Participants (Not Applicable)				
American Indian or Alaska Native	0	1	0	1
Asian	1	1	3	5
Native Hawaiian or Other Pacific Islander	0	0	0	0
Black or African American	1	0	0	1
White	39	39	37	115
More than one race	0	0	0	0
Unknown or Not Reported	0	0	0	0

Primary Outcome Result(s)

PASI 75 response after 12 weeks of treatment

(Time Frame: 12 weeks)

	Secukinumab 2 mL auto-injector	Secukinumab 1 mL prefilled syringe	Placebo
Arm/Group Description	Secukinumab 300 mg provided in 2 mL auto-injector form	Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL	Placebo to secukinumab

Number of Participants Analyzed [units: participants]	41	41	40
PASI 75 response after 12 weeks of treatment (units: Participants)			
	39	34	4

Statistical Analysis

Groups	Secukinumab 2 mL auto-injector, Placebo	PASI 75
P Value	<0.0001	
Method	Regression, Logistic	
Odds Ratio (OR)	1014.07	
95 % Confidence Interval 2-Sided	68.83 to 14940.62	

Statistical Analysis

Groups	Secukinumab 1 mL prefilled syringe, Placebo	PASI 75
P Value	<0.0001	
Method	Regression, Logistic	
Odds Ratio (OR)	96.23	

95 % Confidence Interval 2-Sided	17.22 to 537.78

IGA mod 2011 0 or 1 response after 12 weeks of treatment

(Time Frame: 12 weeks)

	Secukinumab 2 mL auto-injector	Secukinumab 1 mL prefilled syringe	Placebo
Arm/Group Description	Secukinumab 300 mg provided in 2 mL auto-injector form	Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL	Placebo to secukinumab
Number of Participants Analyzed [units: participants]	41	41	40
IGA mod 2011 0 or 1 response after 12 weeks of treatment (units: Participants)			
	31	28	3

Statistical Analysis

Groups	Secukinumab 2 mL auto-injector, Placebo
P Value	<0.0001
Method	Regression, Logistic

Odds Ratio (OR)	51.46
95 % Confidence Interval 2-Sided	11.95 to 221.64

Statistical Analysis

Groups	Secukinumab 1 mL prefilled syringe, Placebo
P Value	<0.0001
Method	Regression, Logistic
Odds Ratio (OR)	29.70
95 % Confidence Interval	7.38 to 119.57

Secondary Outcome Result(s)

PASI 90 response

(Time Frame: 12 weeks)

	Secukinumab 2 mL auto-injector	Secukinumab 1 mL prefilled syringe	Placebo
Arm/Group Description	Secukinumab 300 mg provided in 2 mL auto-injector form	Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL	Placebo to Secukinumab

Number of Participants Analyzed [units: participants]	41	41	40

PASI 90 response (units: Participants)	
	31	26	2

Statistical Analysis

Groups	Secukinumab 2 mL auto-injector, Placebo
P Value	<0.0001
Method	Regression, Logistic
Odds Ratio (OR)	88.46
95 % Confidence Interval 2-Sided	16.15 to 484.52

Statistical Analysis

Groups	Secukinumab 1 mL prefilled syringe, Placebo
P Value	<0.0001
Method	Regression, Logistic
Odds Ratio (OR)	37.90

95 % Confidence Interval 2-Sided	7.60 to 189.01

PASI 50, 75, 90 and 100 and IGA mod 2011 0 or 1 response

(Time Frame: 52 weeks)

	Secukinumab 2 mL auto-injector	Secukinumab 1 mL prefilled syringe	Placebo	Placebo-Secukinumab 300 mg (2 mL auto-injector)	Placebo-Secukinumab 300 mg (2x 1 mL prefilled syringe)
Arm/Group Description	Secukinumab 300 mg provided in 2 mL auto-injector form	Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL	Placebo to secuinumab	Placebo patients up to Week 12 who thereafter received secukinumab in 2 mL aI up to the end of treatment	Placebo patients up to Week 12 who thereafter received secukinumab in 2x 1mL PFS up to the end of treatment
Number of Participants Analyzed [units: participants]	41	41	40	16	17
PASI 50, 75, 90 and 100 and IGA mod 2011 0 or 1 response (units: Participants)					
PASI 50	41	40	4	15	15
PASI 75	38	37	1	13	14
PASI 90	30	28	0	12	14
PASI 100	23	18	0	11	11
IGA 0/1	30	33	0	12	13

Successful self-injection

(Time Frame: From randomization until Week 28)

	PRE- Module by Visit	POST-module by Visit	Absolute Change POST Module -PRE Module
Arm/Group Description	PRE- Module by Visit score- Entire Treatment Period (Safety set)	POST-Module by Visit score- Entire Treatment Period (Safety Set)	Absolute Change POST Module -PRE Module scores
Number of Participants Analyzed [units: participants]	122	122	122
Successful self-injection (units: Scores on a scale) Mean ± Standard Deviation			
Baseline	5.75 ± 2.442		
Baseline (1) =POST-module at baseline visit	5.75 ± 2.452	7.52 ± 2.046	1.77 ± 2.789
Week 1	5.72 ± 2.463	8.11 ± 1.759	2.39 ± 3.169
Week 4	5.70 ± 2.495	8.27 ± 1.731	2.57 ± 3.080
Week 8	5.68 ± 2.490	8.62 ± 1.545	2.94 ± 2.869
Week 12	5.70 ± 2.523	8.56 ± 1.623	2.86 ± 2.985
Week 28	5.62 ± 2.485	8.69 ± 1.681	3.07 ± 3.238

Dermatology Life Quality Index, (DLQI) 0 or 1 score (total score)

(Time Frame: Change from Baseline up to 52 weeks)

	Secukinumab 2 mL auto-injector	Secukinumab 1 mL prefilled syringe	Placebo
Arm/Group Description	Secukinumab 300 mg provided in 2 mL auto-injector form	Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL	Placebo to Secukinumab
Number of Participants Analyzed [units: participants]	41	41	40
Dermatology Life Quality Index, (DLQI) 0 or 1 score (total score) (units: Scores on a Scale) Mean ± Standard Deviation			
Week 12	-13.21 ± 7.701	-11.95 ± 7.861	-1.97 ± 6.966
Week 28	-13.59 ± 7.639	-12.23 ± 8.438	-13.00 ± 12.490
Week 52	-12.44 ± 8.219	-12.23 ± 8.408	-14.33 ± 11.240

Safety Results

All-Cause Mortality

Secukinumab 300 mg (2 mL Auto-Injector) N = 41	Secukinumab 300 mg (2 x 1 mL PFS) N = 41	Any Secukinumab 300 mg (2 mL AI) N = 57	Any Secukinumab 300 mg (2 x 1 mL PFS) N = 58	Placebo N = 40	Any Secukinumab 300 mg N = 115

Arm/Group Description	Secukinumab 300 mg provided in 2 mL auto-injector form	Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL	Any Secukinumab 300 mg (2 mL AI)	Any Secukinumab 300 mg (2 x 1 mL PFS)	Placebo to Secukinumab sub-cutaneous form	Any Secukinumab 300 mg
Total participants affected	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Serious Adverse Events by System Organ Class

Time Frame	Adverse events were collected from first dose of study treatment until end of study treatment (Week 48) plus 4 weeks post treatment..
Additional Description	Any sign or symptom that occurs during the study treatment plus the 4 weeks post treatment.
Source Vocabulary for Table Default	MedDRA (23.0)
Assessment Type for Table Default	Systematic Assessment

	Secukinumab 300 mg (2 mL Auto-Injector) N = 41	**Secukinumab 300 mg (2 x 1 mL PFS) N = 41**	**Any Secukinumab 300 mg (2 mL AI) N = 57**	**Any Secukinumab 300 mg (2 x 1 mL PFS) N = 58**	**Placebo N = 40**	**Any Secukinumab 300 mg N = 115**
Arm/Group Description	Secukinumab 300 mg provided in 2 mL auto-injector form	Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL	Any Secukinumab 300 mg (2 mL AI)	Any Secukinumab 300 mg (2 x 1 mL PFS)	Placebo to Secukinumab sub-cutaneous form	Any Secukinumab 300 mg
Total participants affected	1 (2.44%)	3 (7.32%)	1 (1.75%)	4 (6.90%)	0 (0.00%)	5 (4.35%)

Infections and infestations						
Appendicitis	0 (0.00%)	1 (2.44%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	1 (0.87%)
COVID-19	0 (0.00%)	1 (2.44%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	1 (0.87%)
Device related infection	1 (2.44%)	0 (0.00%)	1 (1.75%)	0 (0.00%)	0 (0.00%)	1 (0.87%)
Injury, poisoning and procedural complications						
Concussion	0 (0.00%)	1 (2.44%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	1 (0.87%)
Head injury	0 (0.00%)	1 (2.44%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	1 (0.87%)
Road traffic accident	0 (0.00%)	1 (2.44%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	1 (0.87%)
Nervous system disorders						
Syncope	0 (0.00%)	1 (2.44%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	1 (0.87%)
Respiratory, thoracic and mediastinal disorders						
Asthma	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.72%)	0 (0.00%)	1 (0.87%)

Other Adverse Events by System Organ Class

Time Frame	Adverse events were collected from first dose of study treatment until end of study treatment (Week 48) plus 4 weeks post treatment..
Additional Description	Any sign or symptom that occurs during the study treatment plus the 4 weeks post treatment.
Source Vocabulary for Table Default	MedDRA (23.0)
Assessment Type for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	5%

	Secukinumab 300 mg (2 mL Auto-Injector) N = 41	Secukinumab 300 mg (2 x 1 mL PFS) N = 41	Any Secukinumab 300 mg (2 mL AI) N = 57	Any Secukinumab 300 mg (2 x 1 mL PFS) N = 58	Placebo N = 40	Any Secukinumab 300 mg N = 115
Arm/Group Description	Secukinumab 300 mg provided in 2 mL auto-injector form	Secukinumab 300 mg provided as 2x 1 mL prefilled syringe of 150 mg/mL	Any Secukinumab 300 mg (2 mL AI)	Any Secukinumab 300 mg (2 x 1 mL PFS)	Placebo to Secukinumab sub-cutaneous form	Any Secukinumab 300 mg
Total participants affected	19 (46.34%)	16 (39.02%)	24 (42.11%)	21 (36.21%)	5 (12.50%)	45 (39.13%)
Gastrointestinal disorders						
Nausea	0 (0.00%)	3 (7.32%)	0 (0.00%)	3 (5.17%)	0 (0.00%)	3 (2.61%)
General disorders and administration site conditions						
Influenza like illness	3 (7.32%)	3 (7.32%)	4 (7.02%)	3 (5.17%)	1 (2.50%)	7 (6.09%)
Infections and infestations						
Nasopharyngitis	6 (14.63%)	6 (14.63%)	8 (14.04%)	8 (13.79%)	0 (0.00%)	16 (13.91%)
Upper respiratory tract infection	3 (7.32%)	4 (9.76%)	4 (7.02%)	6 (10.34%)	1 (2.50%)	10 (8.70%)
Nervous system disorders						
Headache	2 (4.88%)	4 (9.76%)	3 (5.26%)	4 (6.90%)	1 (2.50%)	7 (6.09%)
Skin and subcutaneous tissue disorders						
Pruritus	3 (7.32%)	2 (4.88%)	3 (5.26%)	3 (5.17%)	2 (5.00%)	6 (5.22%)
Vascular disorders						

Hypertension	4 (9.76%)	2 (4.88%)	5 (8.77%)	2 (3.45%)	0 (0.00%)	7 (6.09%)

Conclusion:

Secukinumab 300 mg in 2 mL autoinjector demonstrated a rapid onset of response with significantly superior efficacy over placebo in the treatment of subjects with moderate to severe chronic plaque-type psoriasis, and was comparable to the efficacy shown with secukinumab 300 mg in 2 × 1 mL PFS.
The pattern of efficacy was similar between the 2 mL autoinjector and 2 × 1 mL PFS groups. Numerically, more subjects in the 2 mL AI group achieved both PASI and IGA responses at most time points up to Week 12 compared to the 2 × 1 mL PFS group.

The efficacy was sustained up to Week 52, and was comparable between the 2 secukinumab groups. The mean serum secukinumab concentrations were higher with the 2 mL autoinjector than with 2 × 1 mL PFS, though this difference did not lead to an increased overall incidence of AEs with the 2 mL autoinjector. Both, secukinumab 2 mL autoinjector and 2 × 1 mL PFS treatments were safe, well tolerated and demonstrated a comparable safety profile. No new safety signals were identified during this study; in particular, no new signal related to the use of the 2 mL autoinjector occurred. This study demonstrated the usability of the 2 mL autoinjector for self-administration of secukinumab.

Date of Clinical Trial Report

06-January-2021