NOVARTIS

Clinical Trial Results Website

Sponsor

Novartis Pharmaceuticals

Generic Drug Name

Secukinumab

Trial Indication(s)

Moderate to severe chronic plaque-type psoriasis

Protocol Number

CAIN457A2318

Protocol Title

A randomized, double-blind, placebo controlled, multicenter study of subcutaneous secukinumab, to demonstrate efficacy after twelve weeks of treatment and to assess safety, tolerability and long-term efficacy up to one year in subjects with moderate to severe chronic plaque-type psoriasis with or without psoriatic arthritis comorbidity

Clinical Trial Phase

Phase 3

Phase of Drug Development

Phase III

Study Start/End Dates

Study Start Date: February 2017 (Actual)
Primary Completion Date: December 2017 (Actual)
Study Completion Date: November 2018 (Actual)

Reason for Termination (If applicable)

Study Design/Methodology

multicenter, randomized, double-blind, placebo-controlled, parallel-group study

Centers

32 centers in 6 countries: Malaysia(2), China(17), Hungary(3), Turkey(5), Thailand(3), Philippines(2)

Objectives:

Primary objective(s)

To demonstrate the superiority of secukinumab in subjects with moderate to severe chronic plaque-type psoriasis in terms of both PASI 75 and IGA mod 2011 0 or 1 response (co-primary endpoints) at Week 12 compared to placebo.

Secondary objectives

- To demonstrate the superiority of secukinumab in terms of PASI 90 response at Week 12 compared to placebo.
- To assess the efficacy of secukinumab in maintaining PASI 75 response at Week 52 in subjects who were PASI 75 responders at Week 12 or IGA mod 2011 0 or 1 response at Week 52 in subjects who were IGA mod 2011 0 or 1 responders at Week 12.
- To assess the efficacy of secukinumab in terms of PASI score, IGA mod 2011 score, PASI 50/75/90/100 and IGA mod 2011 0 or 1 response over time up to Week 12 compared to placebo and over time up to Week 52.
- To assess the efficacy of secukinumab in terms of time to PASI 75 response up to Week 12 compared to placebo.
- To investigate the clinical safety and tolerability of secukinumab, as assessed by vital signs, clinical laboratory variables, electrocardiogram (ECG) and adverse events monitoring compared to placebo.
- To assess the efficacy of secukinumab in treating psoriatic arthritis in subjects with this comorbidity at Baseline in terms of American College of Rheumatology (ACR) 20/50/70 response over time up to Week 52.

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

Secukinumab 150 mg 1 mL solution in a pre-filled syringe (PFS) for subcutaneous (sc) injection

Statistical Methods

The co-primary endpoints (PASI 75 and IGA mod 2011 0 or 1 response at Week 12) were evaluated using a logistic regression model with treatment group, baseline body weight category, geographical region, and baseline PASI score as explanatory variables. PASI 90 response at Week 12 was evaluated analogously to PASI 75 and IGA mod 2011 0 or 1 response at Week 12 (i.e., logistic regression analysis).

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:
1. Subjects must give a written, signed and dated informed consent.
2. Men or women at least 18 years of age at time of screening.
3. Chronic plaque-type psoriasis present for at least 6 months and diagnosed before Baseline.
4. Moderate to severe psoriasis as defined at Baseline by:
• PASI score of 12 or greater, and
• IGA mod 2011 score of 3 or greater (based on a static 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 Baseline.
2. Drug-induced psoriasis.
3. Ongoing use of prohibited treatments.
4. Previous exposure to secukinumab (AIN457) or any other biologic drug directly targeting IL-17 or the IL-17 receptor.
5. 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.
6. 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.

Participant Flow Table

INDUCTION

	Secukinumab 150mg	Secukinumab 300mg	placebo	Placebo - secukinumab 300mg	Total
Arm/Group Description	Secukinumab 150mg s.c.	Secukinumab 300mg s.c.	Placebo	patients switched to AIN457 at week 12	
Started	136	272	135	0	543
Completed	134	270	133	0	537
Not Completed	2	2	2	0	6
Pregnancy	0	0	1	0	1
Lack of Efficacy	0	0	1	0	1
Adverse Event	2	2	0	0	4

MAINTENANCE

	Secukinumab 150mg	Secukinumab 300mg	placebo	Placebo - secukinumab 300mg	Total
Arm/Group Description	Secukinumab 150mg s.c.	Secukinumab 300mg s.c.	Placebo	patients switched to AIN457 at week 12	
Started	134	270	4	129	537
Completed	127	266	2	126	521
Not Completed	7	4	2	3	16

Adverse Event	0	0	0	1	1
Withdrawal by Subject	4	2	1	1	8
Lost to Follow-up	0	1	1	0	2
Pregnancy	1	0	0	0	1
Lack of Efficacy	2	1	0	1	4

OVERALL STUDY

	Secukinumab 150mg	Secukinumab 300mg	placebo	Placebo - secukinumab 300mg	Total
Arm/Group Description	Secukinumab 150mg s.c.	Secukinumab 300mg s.c.	Placebo	patients switched to AIN457 at week 12	
Started	136	272	6	129	543
Completed	126	264	2	124	516
Not Completed	10	8	4	5	27
Adverse Event	2	2	0	1	5
Withdrawal by Subject	4	2	1	2	9
Lost to Follow-up	1	1	1	1	4
Pregnancy	1	0	1	0	2
Lack of Efficacy	2	1	1	1	5

discontinued follow up	0	2	0	0	2

Baseline Characteristics

	Secukinumab 150mg	Secukinumab 300mg	placebo	Total
Arm/Group Description	Secukinumab 150mg s.c.	Secukinumab 300mg s.c.	Placebo	
Number of Participants [units: participants]	136	272	135	543
Age Continuous (units: years) Mean ± Standard Deviation				
	41±11.39	39.9±12.35	40.1±11.01	40.2±11.78
Sex: Female, Male (units: participants) Count of Participants (Not Applicable)				
Female	37	67	27	131
Male	99	205	108	412
Race/Ethnicity, Customized[1] (units: participants) Count of Participants (Not Applicable)				
East Asian	109	220	109	438
Southeast Asian	19	32	16	67
South Asian	1	0	0	1
West Asian	0	3	0	3
other	6	17	10	33
not reported	1	0	0	1

Race/Ethnicity, Customized[2]
(units: participants)
Count of Participants (Not Applicable)

Caucasian	7	20	10	37
Asian	129	252	125	506

[1] Ethnicity
[2] Race

Summary of Efficacy

Primary Outcome Result(s)

Psoriasis Area and Severity Index (PASI) 75 (multiple imputation)
(Time Frame: Week 12)

	Secukinumab 150mg	Secukinumab 300mg	placebo
Arm/Group Description	Secukinumab 150mg s.c.	Secukinumab 300mg s.c.	Placebo
Number of Participants Analyzed [units: participants]	136	272	135
Psoriasis Area and Severity Index (PASI) 75 (multiple imputation) (units: participants) Count of Participants (Not Applicable)			
PASI 75	112	254	6

Statistical Analysis

Groups	Secukinumab 150mg, placebo	PASI 75

P Value	<0.0001
Method	Regression, Logistic
Odds Ratio (OR)	153.94
95 % Confidence Interval 2-Sided	54.02 to 438.67

Statistical Analysis

Groups	Secukinumab 300mg, placebo	PASI 75
P Value	<0.0001	
Method	Regression, Logistic	
Odds Ratio (OR)	557.98	
95 % Confidence Interval 2-Sided	187.2 to 1663.4	

Investigator`s Global Assessment (IGA) mod 2011 0/1 (multiple imputation)

(Time Frame: Week 12)

	Secukinumab 150mg	**Secukinumab 300mg**	**placebo**
Arm/Group Description	Secukinumab 150mg s.c.	Secukinumab 300mg s.c.	Placebo
Number of Participants Analyzed [units: participants]	136	272	135
Investigator`s Global Assessment (IGA) mod 2011 0/1 (multiple imputation)			

(units: participants) Count of Participants (Not Applicable)			
IGA 0/1	92	214	4

Statistical Analysis

Groups	Secukinumab 150mg, placebo	IGA
P Value	<0.0001	
Method	Regression, Logistic	
Odds Ratio (OR)	75.82	
95 % Confidence Interval 2-Sided	25.81 to 222.72	

Statistical Analysis

Groups	Secukinumab 300mg, placebo	IGA
P Value	<0.0001	
Method	Regression, Logistic	
Odds Ratio (OR)	149.71	
95 % Confidence Interval 2-Sided	51.83 to 432.42	

Secondary Outcome Result(s)

Psoriasis Area and Severity Index (PASI) 90 (multiple imputation)

(Time Frame: Week 12)

	Secukinumab 150mg	Secukinumab 300mg	placebo
Arm/Group Description	Secukinumab 150mg s.c.	Secukinumab 300mg s.c.	Placebo
Number of Participants Analyzed [units: participants]	136	272	135
Psoriasis Area and Severity Index (PASI) 90 (multiple imputation) (units: participants) Count of Participants (Not Applicable)			
PASI 90	85	210	2

Statistical Analysis

Groups	Secukinumab 150mg, placebo	PASI 90
P Value	<0.0001	
Method	Regression, Logistic	
Odds Ratio (OR)	114.85	
95 % Confidence Interval 2-Sided	26.94 to 489.59	

Statistical Analysis

Groups	Secukinumab 300mg, placebo	PASI 90

P Value	<0.0001
Method	Regression, Logistic
Odds Ratio (OR)	246.12
95 % Confidence Interval 2-Sided	58.41 to 1037.1

efficacy of secukinumab in maintaining PASI 75 response at Week 52 in subjects who were PASI 75 responders at Week 12 (multiple imputation)

(Time Frame: Week 52)

	Secukinumab 150mg	Secukinumab 300mg
Arm/Group Description	Secukinumab 150mg s.c.	Secukinumab 300mg s.c.
Number of Participants Analyzed [units: participants]	136	272
(n=110,242)		
efficacy of secukinumab in maintaining PASI 75 response at Week 52 in subjects who were PASI 75 responders at Week 12 (multiple imputation) (units: participants) Count of Participants (Not Applicable)		
	94	235

efficacy of secukinumab in maintaining IGA mod 2011 0 or 1 response at Week 52 in subjects who were IGA mod 2011 0 or 1 responders at Week 12 (multiple imputation)

(Time Frame: Week 52)

	Secukinumab 150mg	Secukinumab 300mg
Arm/Group Description	Secukinumab 150mg s.c.	Secukinumab 300mg s.c.
Number of Participants Analyzed [units: participants]	136	272
(n=91,206)		
efficacy of secukinumab in maintaining IGA mod 2011 0 or 1 response at Week 52 in subjects who were IGA mod 2011 0 or 1 responders at Week 12 (multiple imputation) (units: participants) Count of Participants (Not Applicable)		
	65	162

PASI 50/75/90/100 and IGA mod 2011 0 or 1 response over time (multiple imputation)

(Time Frame: week 1, week 12, week 24, week 52)

	Secukinumab 150mg	Secukinumab 300mg	placebo	Placebo - AIN457 300 mg
Arm/Group Description	Secukinumab 150mg s.c.	Secukinumab 300mg s.c.	Placebo	patients switched to AIN457 at week 12
Number of Participants Analyzed [units: participants]	136	272	135	129
PASI 50/75/90/100 and IGA mod 2011 0 or 1 response over time (multiple imputation) (units: participants) Count of Participants (Not Applicable)				

Week 1 IGA 0/1	0	1	0	0
Week 1 PASI 50	5	25	1	0
Week 1 PASI 75	0	0	0	0
Week 1 PASI 90	0	0	0	0
Week 1 PASI 100	0	0	0	0
Week 12 IGA 0/1	92	214	4	0
Week 12 PASI 50	130	267	16	0
Week 12 PASI 75	112	254	6	0
Week 12 PASI 90	85	210	2	0
Week 12 PASI 100	28	81	1	0
Week 16 IGA 0/1	100	219	2	32
Week 16 PASI 50	134	270	4	108
Week 16 PASI 75	124	261	3	72
Week 16 PASI 90	98	233	2	22
Week 16 PASI 100	39	99	0	3
Week 24 IGA 0/1	91	217	1	88
Week 24 PASI 50	135	271	4	123
Week 24 PASI 75	123	257	2	113
Week 24 PASI 90	93	230	2	94
Week 24 PASI 100	47	107	0	31
Week 52 IGA 0/1	79	194	0	96
Week 52 PASI 50	128	269	4	126
Week 52 PASI 75	111	259	4	119
Week 52 PASI 90	86	218	1	101
Week 52 PASI 100	42	110	1	55

American Collage of Rheumatology (ACR) Response 20/50/70

(Time Frame: week 12, week 24, week 52)

	Secukinumab 150mg	Secukinumab 300mg	placebo	Placebo - AIN457 300 mg
Arm/Group Description	Secukinumab 150mg s.c.	Secukinumab 300mg s.c.	Placebo	patients switched to AIN457 at week 12
Number of Participants Analyzed [units: participants]	7	17	4	4
American Collage of Rheumatology (ACR) Response 20/50/70 (units: participants) Count of Participants (Not Applicable)				
Week 12 ACR 20	4	13	0	0
Week 12 ACR 50	3	12	0	0
Week 12 ACR 70	2	6	0	0
Week 24 ACR 20	5	14	0	2
Week 24 ACR 50	4	10	0	1
Week 24 ACR 70	2	6	0	1
Week 52 ACR 20	4	13	0	3
Week 52 ACR 50	3	11	0	2
Week 52 ACR 70	2	8	0	0

Time to PASI 75 response up to Week 12

(Time Frame: week 12)

	Secukinumab 150mg	Secukinumab 300mg
Arm/Group Description	Secukinumab 150mg s.c.	Secukinumab 300mg s.c.

Number of Participants Analyzed [units: participants]	136	272
Time to PASI 75 response up to Week 12 (units: days) Median (95% Confidence Interval)		
	57 (51 to 57)	55 (29 to 57)

Summary of Safety

Safety Results

All-Cause Mortality

	AIN457 150 mg N = 136	AIN457 300 mg N = 272	Any AIN457 300 mg N = 401	Any AIN457 dose N = 537	Placebo N = 135
Arm/Group Description	AIN457 150 mg	AIN457 300 mg	Any AIN457 300 mg	Any AIN457 dose	Placebo
Total participants affected	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Serious Adverse Events by System Organ Class

Time Frame 12 months

Additional Description	Adverse Events and deaths occurring in this on-treatment period plus follow up (+30 days or +5 half- lives) are reported in the Adverse Event Information Tables.
Source Vocabulary for Table Default	MedDRA (21.1)
Assessment Type for Table Default	Systematic Assessment

	AIN457 150 mg N = 136	AIN457 300 mg N = 272	Any AIN457 300 mg N = 401	Any AIN457 dose N = 537	Placebo N = 135
Arm/Group Description	AIN457 150 mg	AIN457 300 mg	Any AIN457 300 mg	Any AIN457 dose	Placebo
Total participants affected	5 (3.68%)	9 (3.31%)	14 (3.49%)	19 (3.54%)	2 (1.48%)
Cardiac disorders					
Angina unstable	1 (0.74%)	0 (0.00%)	0 (0.00%)	1 (0.19%)	0 (0.00%)
Arteriosclerosis coronary artery	1 (0.74%)	0 (0.00%)	1 (0.25%)	2 (0.37%)	0 (0.00%)
Coronary artery disease	0 (0.00%)	1 (0.37%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Eye disorders					
Diabetic retinopathy	0 (0.00%)	0 (0.00%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Gastrointestinal disorders					
Crohn's disease	1 (0.74%)	0 (0.00%)	0 (0.00%)	1 (0.19%)	0 (0.00%)
Enteritis	0 (0.00%)	1 (0.37%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Haemorrhoids	0 (0.00%)	0 (0.00%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Mouth ulceration	0 (0.00%)	0 (0.00%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Tooth impacted	1 (0.74%)	0 (0.00%)	0 (0.00%)	1 (0.19%)	0 (0.00%)

Hepatobiliary disorders					
Cholecystitis acute	0 (0.00%)	0 (0.00%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Cholelithiasis	0 (0.00%)	0 (0.00%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Hepatic mass	0 (0.00%)	0 (0.00%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Hepatic steatosis	0 (0.00%)	0 (0.00%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Infections and infestations					
Appendicitis	0 (0.00%)	2 (0.74%)	2 (0.50%)	2 (0.37%)	0 (0.00%)
Bronchitis	0 (0.00%)	1 (0.37%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Erysipelas	0 (0.00%)	1 (0.37%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Peritonitis	0 (0.00%)	1 (0.37%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Tonsillitis	1 (0.74%)	0 (0.00%)	0 (0.00%)	1 (0.19%)	0 (0.00%)
Injury, poisoning and procedural complications					
Comminuted fracture	0 (0.00%)	1 (0.37%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Forearm fracture	0 (0.00%)	1 (0.37%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Tibia fracture	0 (0.00%)	1 (0.37%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Musculoskeletal and connective tissue disorders					
Intervertebral disc protrusion	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.74%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)					
Colon adenoma	1 (0.74%)	0 (0.00%)	0 (0.00%)	1 (0.19%)	0 (0.00%)

Nervous system disorders					
Cerebral infarction	0 (0.00%)	1 (0.37%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Diabetic neuropathy	0 (0.00%)	0 (0.00%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Renal and urinary disorders					
Glomerulonephritis chronic	0 (0.00%)	1 (0.37%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Nephrolithiasis	0 (0.00%)	1 (0.37%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Ureterolithiasis	0 (0.00%)	1 (0.37%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Skin and subcutaneous tissue disorders					
Erythrodermic psoriasis	1 (0.74%)	0 (0.00%)	0 (0.00%)	1 (0.19%)	0 (0.00%)
Psoriasis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (0.74%)
Vascular disorders					
Deep vein thrombosis	0 (0.00%)	0 (0.00%)	1 (0.25%)	1 (0.19%)	0 (0.00%)
Diabetic vascular disorder	0 (0.00%)	0 (0.00%)	1 (0.25%)	1 (0.19%)	0 (0.00%)

Other Adverse Events by System Organ Class

Time Frame	12 months
Additional Description	Adverse Events and deaths occurring in this on-treatment period plus follow up (+30 days or +5 half- lives) are reported in the Adverse Event Information Tables.
Source Vocabulary for Table Default	MedDRA (21.1)
Assessment Type for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	3%

	AIN457 150 mg N = 136	AIN457 300 mg N = 272	Any AIN457 300 mg N = 401	Any AIN457 dose N = 537	Placebo N = 135
Arm/Group Description	AIN457 150 mg	AIN457 300 mg	Any AIN457 300 mg	Any AIN457 dose	Placebo
Total participants affected	115 (84.56%)	221 (81.25%)	312 (77.81%)	427 (79.52%)	71 (52.59%)
Gastrointestinal disorders					
Diarrhoea	13 (9.56%)	31 (11.40%)	42 (10.47%)	55 (10.24%)	12 (8.89%)
General disorders and administration site conditions					
Pyrexia	4 (2.94%)	14 (5.15%)	18 (4.49%)	22 (4.10%)	1 (0.74%)
Hepatobiliary disorders					
Hepatic function abnormal	9 (6.62%)	18 (6.62%)	22 (5.49%)	31 (5.77%)	4 (2.96%)
Infections and infestations					
Folliculitis	6 (4.41%)	18 (6.62%)	26 (6.48%)	32 (5.96%)	0 (0.00%)
Influenza	17 (12.50%)	28 (10.29%)	38 (9.48%)	55 (10.24%)	4 (2.96%)
Nasopharyngitis	15 (11.03%)	44 (16.18%)	57 (14.21%)	72 (13.41%)	5 (3.70%)
Pharyngitis	14 (10.29%)	24 (8.82%)	35 (8.73%)	49 (9.12%)	7 (5.19%)
Rhinitis	2 (1.47%)	14 (5.15%)	16 (3.99%)	18 (3.35%)	1 (0.74%)
Tinea pedis	5 (3.68%)	20 (7.35%)	25 (6.23%)	30 (5.59%)	1 (0.74%)
Tonsillitis	5 (3.68%)	14 (5.15%)	16 (3.99%)	21 (3.91%)	1 (0.74%)
Upper respiratory tract infection	41 (30.15%)	67 (24.63%)	97 (24.19%)	138 (25.70%)	13 (9.63%)

Investigations					
Blood uric acid increased	4 (2.94%)	4 (1.47%)	6 (1.50%)	10 (1.86%)	5 (3.70%)
C-reactive protein increased	7 (5.15%)	11 (4.04%)	13 (3.24%)	20 (3.72%)	3 (2.22%)
Gamma-glutamyltransferase increased	2 (1.47%)	10 (3.68%)	12 (2.99%)	14 (2.61%)	1 (0.74%)
Metabolism and nutrition disorders					
Dyslipidaemia	0 (0.00%)	2 (0.74%)	2 (0.50%)	2 (0.37%)	5 (3.70%)
Hyperlipidaemia	11 (8.09%)	22 (8.09%)	23 (5.74%)	34 (6.33%)	11 (8.15%)
Hyperuricaemia	25 (18.38%)	56 (20.59%)	76 (18.95%)	101 (18.81%)	17 (12.59%)
Musculoskeletal and connective tissue disorders					
Arthralgia	4 (2.94%)	11 (4.04%)	12 (2.99%)	16 (2.98%)	3 (2.22%)
Nervous system disorders					
Headache	4 (2.94%)	10 (3.68%)	10 (2.49%)	14 (2.61%)	2 (1.48%)
Respiratory, thoracic and mediastinal disorders					
Cough	13 (9.56%)	17 (6.25%)	25 (6.23%)	38 (7.08%)	2 (1.48%)
Oropharyngeal pain	16 (11.76%)	25 (9.19%)	32 (7.98%)	48 (8.94%)	3 (2.22%)
Skin and subcutaneous tissue disorders					
Eczema	10 (7.35%)	20 (7.35%)	25 (6.23%)	35 (6.52%)	0 (0.00%)
Pruritus	12 (8.82%)	32 (11.76%)	36 (8.98%)	48 (8.94%)	11 (8.15%)
Psoriasis	6 (4.41%)	3 (1.10%)	3 (0.75%)	9 (1.68%)	0 (0.00%)

Urticaria	12 (8.82%)	24 (8.82%)	30 (7.48%)	42 (7.82%)	0 (0.00%)
Vascular disorders					
Hypertension	5 (3.68%)	19 (6.99%)	22 (5.49%)	27 (5.03%)	4 (2.96%)

Other Relevant Findings

Conclusion:

The study results demonstrated that both doses of secukinumab (150 mg and 300 mg) were superior to placebo in the treatment of patients with moderate to severe chronic plaque-type psoriasis. The efficacy achieved by both doses of secukinumab was maintained up to Week 52. The secukinumab 300 mg did show greater efficacy and faster onset of response than the secukinumab 150 mg dose in all efficacy endpoints, with no dose-dependent increases in the incidence of AEs. Secukinumab was well tolerated at both doses (150 mg and 300 mg). The safety profile of secukinumab in this study was consistent with the known safety profile of secukinumab and showed no new or unexpected safety signals.

Date of Clinical Trial Report

18 July 2019