NOVARTIS

Clinical Trial Results Website

Sponsor

Novartis Pharmaceuticals

Generic Drug Name

Secukinumab / AIN457

Trial Indication(s)

Active psoriatic arthritis

Protocol Number

CAIN457F2366

Protocol Title

A randomized, double-blind, active control, multicenter study to evaluate the efficacy at week 52 of secukinumab monotherapy compared with adalimumab monotherapy in patients with active psoriatic arthritis

Clinical Trial Phase

Phase 3

Phase of Drug Development

Phase IIIb

Study Start/End Dates

Study Start Date: April 2017 (Actual)
Primary Completion Date: December 2019 (Actual)
Study Completion Date: December 2019 (Actual)

Reason for Termination (If applicable)

Not applicable

Study Design/Methodology

This was a randomized, double-blind, active controlled, multicenter, parallel-group study evaluating secukinumab monotherapy and adalimumab monotherapy in approximately 850 patients with active PsA. A screening period of up to 8 weeks before randomization assessed subject/patient eligibility. Efficacy assessments occurred through Study Week 52 with 2 follow-up visits at Week 60 and 68. Thus, the total maximum study duration, including the screening period was up to 76 weeks.

At Baseline, patients whose eligibility was confirmed were randomized to 1 of 2 groups (1:1): Group 1 (secukinumab 300 mg) or Group 2 (adalimumab 40 mg).

In order to maintain the blind, both groups received 1 or 2 placebo s.c. injections to keep consistency in the number of injections at each dosing visit. Secukinumab (300 mg) was available in 2 x 1.0 mL pre-filled syringes (PFS) and adalimumab was available in 1 x 0.4 mL PFS. Placebo (1.0 and 0.5 mL PFS) was also available.

Secukinumab 300 mg s.c injection (2 x 1 mL PFS) was administered at Baseline, Weeks 1, 2, 3 and 4, followed by dosing every 4 weeks to Week 48.

Adalimumab 40 mg (1 x 0.4 mL PFS) was administered at Baseline followed by dosing every 2 weeks until Week 50.

Centers

161 centers in 26 countries: France(7), Spain(20), Germany(14), Slovakia (Slovak Republic)(4), Denmark(1), Netherlands(2), United Kingdom(15), Finland(2), Czech Republic(5), Greece(5), Italy(6), Australia(4), Portugal(5), Hungary(7), Bulgaria(6), Estonia(3), Latvia(2), Russia(10), Iceland(1), Poland(5), Korea, Republic of(1), Israel(7), Lithuania(3), India(4), Canada(3), United States(19)

Objectives:

Primary objective

- To demonstrate that the efficacy of secukinumab monotherapy (300 mg s.c.) at Week 52 is superior to adalimumab monotherapy (40 mg s.c.), based on the proportion of patients achieving an American College of Rheumatology 20 (ACR20) response.

Secondary objectives

- Secukinumab monotherapy (300 mg s.c.) is superior to adalimumab monotherapy (40 mg s.c.) at Week 52, based on the proportion of patients achieving PASI90 response.
- Secukinumab monotherapy (300 mg s.c.) is superior to adalimumab monotherapy (40 mg s.c.) at Week 52, based on the proportion of patients achieving an ACR50 response.
- The improvement (change) from baseline on secukinumab monotherapy (300 mg s.c.) is superior to adalimumab monotherapy (40 mg s.c.) at Week 52, for the Health Assessment Questionnaire – Disability Index (HAQ-DI©) score.
- Secukinumab monotherapy (300 mg s.c.) is superior to adalimumab monotherapy (40 mg s.c.) at Week 52, based on the proportion of patients achieving the resolution of enthesitis based on Leeds Enthesitis Index (LEI).
- An additional secondary objective is to evaluate the safety and tolerability of secukinumab monotherapy (300 mg s.c.) compared with adalimumab monotherapy (40 mg s.c.) as assessed by vital signs, clinical laboratory values, and adverse events (AE) monitoring.

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

Secukinumab (300 mg) s.c. injection was available in 2 x 1.0 mL pre-filled syringes (PFS)

Adalimumab (40 mg) s.c. injection was available in 1 x 0.4 mL PFS.

Placebo (1.0 and 0.5 mL PFS) was also available:

- Group 1 patients received placebo (1 x 1 mL PFS) at given visits in order to maintain the blind.
- Group 2 patients received placebo (1 x 0.5 mL or 2 x 0.5 mL PFS) at given visits in order to maintain the blind.

Statistical Methods

Summary statistics for continuous variables include N, mean, standard deviation, minimum, lower quartile, median, upper quartile, and maximum. For binary or discrete variables the absolute number of patients in each category and relative frequencies were provided.

An inferential efficacy comparison of secukinumab 300 mg with adalimumab 40 mg was performed at Week 52. A sequential hierarchical testing strategy was used to maintain the family-wise 2-sided type I error at 5%. The inferential testing procedure continued if the previous test was rejected at 2-sided 5% level.

The primary efficacy endpoint was a composite endpoint defined as meeting the following three conditions: achieving an ACR20 response, with no permanent study treatment (SEC or ADA) discontinuation before or at Week 50 (the last dosing visit), and no concomitant use of cDMARDs (including MTX) after Week 36 (regardless of the time initiation of csDMARDs). A patient meeting all of these conditions was regarded as a responder, otherwise they were considered as non-responders. All the secondary and exploratory binary endpoints were defined in similar fashion to the primary endpoint.

Efficacy and safety data for the entire treatment period was presented by treatment groups.

Treatment-emergent AEs were summarized by primary system organ class (SOC) and preferred term (PT). In addition, exposure time-adjusted rates (incidence rate) including 95% confidence intervals were provided for the entire treatment period to adjust for differences in exposure. AEs were reported separately by Standard Medical Dictionary for Regulatory Activities (MedDRA) Query (SMQ) according to MedDRA version 22.0.

Study Population: Key Inclusion/Exclusion Criteria

Key Inclusion Criteria:
- Diagnosis of PsA classified by CASPAR
- Rheumatoid factor and anti-CCP antibodies negative
- Diagnosis of active plaque psoriasis, with at least one psoriatic plaque of >= 2cm diameter or nail changes consistent with psoriasis or documented history of plaque psoriasis
- Inadequate control of symptoms with NSAIDs
- Inadequate control of symptoms with a conventional DMARD.

Key Exclusion Criteria:
- Pregnant or nursing women
- Evidence of ongoing infectious or malignant process
- Previous exposure to any biologic drug for Psoriatic Arthritis or Psoriasis
- Subjects taking high potency opioid analgesics
- Ongoing use of prohibited psoriasis treatments/medications
- Previous treatment with any cell-depleting therapies including but not limited to anti-CD20 investigational agents.

Participant Flow Table

Overall Study

	Secukinumab 300 mg s.c.	Adalimumab 40 mg s.c.	Total
Arm/Group Description	Secukinumab 300 mg administered at Baseline, Weeks 1, 2, 3 and 4, followed by dosing every 4 weeks until Week 48.	Adalimumab 40 mg administered at Baseline followed by dosing every 2 weeks until Week 50.	
Started	426	427	853
Completed	371	338	709
Not Completed	55	89	144
Adverse Event	13	21	34
Lack of Efficacy	11	23	34
Lost to Follow-up	3	3	6
Physician Decision	3	0	3
Protocol Violation	3	1	4
Withdrawal by Subject	22	41	63

Baseline Characteristics

	Secukinumab 300 mg s.c.	Adalimumab 40 mg s.c.	Total
Arm/Group Description	Secukinumab 300 mg administered at Baseline, Weeks 1, 2, 3 and 4, followed by dosing every 4 weeks until Week 48.	Adalimumab 40 mg administered at Baseline followed by dosing every 2 weeks until Week 50.	
Number of Participants [units: participants]	426	427	853
Age Continuous (units: Years) Mean ± Standard Deviation			
	48.5±12.38	49.5±12.44	49.0±12.41
Sex: Female, Male (units: Participants) Count of Participants (Not Applicable)			
Female	218	198	416
Male	208	229	437
Race/Ethnicity, Customized (units: Participants)			
Asian	16	20	36
American Indian or Alaska Native	0	1	1
Black or African American	3	2	5
White	402	391	793
Unknown	1	5	6
Other	4	8	12

Primary Outcome Result(s)

Percentage of Participants Who Achieved an American College of Rheumatology 20% (ACR20) Response at Week 52

(Time Frame: Week 52)

	Secukinumab 300 mg s.c.	Adalimumab 40 mg s.c.
Arm/Group Description	Secukinumab 300 mg administered at Baseline, Weeks 1, 2, 3 and 4, followed by dosing every 4 weeks until Week 48.	Adalimumab 40 mg administered at Baseline followed by dosing every 2 weeks until Week 50.
Number of Participants Analyzed [units: participants]	426	427
Percentage of Participants Who Achieved an American College of Rheumatology 20% (ACR20) Response at Week 52 (units: Percentage of Participants) Number (95% Confidence Interval)		
	67.4 (62.8 to 71.7)	61.5 (56.8 to 66.0)

Statistical Analysis

Groups	Secukinumab 300 mg s.c., Adalimumab 40 mg s.c.	
P Value	0.0719	
Method	Regression, Logistic	
Odds Ratio (OR)	1.30	Odds ratio, 95% confidence interval, and p-

		value are from a logistic regression model with treatment as a factor and baseline weight as a covariate
95 % Confidence Interval 2-Sided	0.98 to 1.72	

Secondary Outcome Result(s)

Percentage of Participants Who Achieved a PASI90 Response at Week 52

(Time Frame: Week 52)

	Secukinumab 300 mg s.c.	**Adalimumab 40 mg s.c.**
Arm/Group Description	Secukinumab 300 mg administered at Baseline, Weeks 1, 2, 3 and 4, followed by dosing every 4 weeks until Week 48.	Adalimumab 40 mg administered at Baseline followed by dosing every 2 weeks until Week 50.
Number of Participants Analyzed [units: participants]	215	202
Percentage of Participants Who Achieved a PASI90 Response at Week 52 (units: Percentage of Participants) Number (95% Confidence Interval)		
	65.4 (58.8 to 71.5)	43.2 (36.5 to 50.2)

Statistical Analysis

Groups	Secukinumab 300 mg s.c., Adalimumab 40 mg s.c.	
P Value	<0.0001	
Method	Regression, Logistic	
Odds Ratio (OR)	2.49	Odds ratio, 95% confidence interval, and p-value are from a logistic regression model with treatment as a factor and baseline weight as a covariate
95 % Confidence Interval 2-Sided	1.67 to 3.71	

Percentage of Participants Who Achieved an American College of Rheumatology 50% (ACR50) Response at Week 52

(Time Frame: Week 52)

	Secukinumab 300 mg s.c.	**Adalimumab 40 mg s.c.**
Arm/Group Description	Secukinumab 300 mg administered at Baseline, Weeks 1, 2, 3 and 4, followed by dosing every 4 weeks until Week 48.	Adalimumab 40 mg administered at Baseline followed by dosing every 2 weeks until Week 50.
Number of Participants Analyzed [units: participants]	426	427
Percentage of Participants Who Achieved an American College of Rheumatology 50% (ACR50) Response at Week 52 (units: Percentage of Participants) Number (95% Confidence Interval)		

49.0 (44.3 to 53.7)	44.8 (40.1 to 49.5)

Statistical Analysis

Groups	Secukinumab 300 mg s.c., Adalimumab 40 mg s.c.	
P Value	0.2251	
Method	Regression, Logistic	
Odds Ratio (OR)	1.18	Odds ratio, 95% confidence interval, and p-value are from a logistic regression model with treatment as a factor and baseline weight as a covariate
95 % Confidence Interval 2-Sided	0.90 to 1.55	

Change from Baseline in Health Assessment Questionnaire – Disability Index (HAQ-DI score) at Week 52

(Time Frame: Week 52)

	Secukinumab 300 mg s.c.	**Adalimumab 40 mg s.c.**
Arm/Group Description	Secukinumab 300 mg administered at Baseline, Weeks 1, 2, 3 and 4, followed by dosing every 4 weeks until Week 48.	Adalimumab 40 mg administered at Baseline followed by dosing every 2 weeks until Week 50.
Number of Participants Analyzed [units: participants]	426	427
Change from Baseline in Health Assessment Questionnaire – Disability Index (HAQ-DI score) at Week 52		

(units: Unit on a scale) Least Squares Mean ± Standard Error		
	-0.58 ± 0.027	-0.56 ± 0.027

Statistical Analysis

Groups	Secukinumab 300 mg s.c., Adalimumab 40 mg s.c.	
P Value	0.5465	
Method	Mixed Models Analysis	
Other least squares (LS) mean change	-0.02	Mixed model repeated measures (MMRM) with treatment group, analysis visit as factors, weight/baseline score as covariates, treatment by analysis visit, baseline score by analysis visit as interation terms and unstructured covariance structure
Standard Error of the mean	0.038	
95 % Confidence Interval 2-Sided	-0.10 to 0.05	

Percentage of Participants Who Achieved Resolution of enthesitis at Week 52

(Time Frame: Week 52)

	Secukinumab 300 mg s.c.	**Adalimumab 40 mg s.c.**

Arm/Group Description	Secukinumab 300 mg administered at Baseline, Weeks 1, 2, 3 and 4, followed by dosing every 4 weeks until Week 48.	Adalimumab 40 mg administered at Baseline followed by dosing every 2 weeks until Week 50.
Number of Participants Analyzed [units: participants]	234	264
Percentage of Participants Who Achieved Resolution of enthesitis at Week 52 (units: Percentage of Participants) Number (95% Confidence Interval)		
	60.5 (54.1 to 66.6)	54.2 (48.2 to 60.2)

Statistical Analysis

Groups	Secukinumab 300 mg s.c., Adalimumab 40 mg s.c.	
P Value	0.1498	
Method	Regression, Logistic	
Odds Ratio (OR)	1.30	Odds ratio, 95% confidence interval, and p-value are from a logistic regression model with treatment as a factor and baseline weight as a covariate
95 % Confidence Interval 2-Sided	0.91 to 1.87	

Safety Results

All-Cause Mortality

	AIN457 300 mg N = 426	Adalimumab 40 mg N = 427	Total N = 853
Arm/Group Description	Secukinumab 300 mg administered at Baseline, Weeks 1, 2, 3 and 4, followed by dosing every 4 weeks until Week 48.	Adalimumab 40 mg administered at Baseline followed by dosing every 2 weeks until Week 50.	Total
Total participants affected	1 (0.23%)	0 (0.00%)	1 (0.12%)

Serious Adverse Events by System Organ Class

Time Frame	Treatment emergent adverse events were collected from first dose of study treatment until 12 Weeks (84 days) following the last administration of study treatment, an average of 68 weeks.
Additional Description	Any sign or symptom that occurs during the study treatment plus the 30 days post-treatment.
Source Vocabulary for Table Default	MedDRA (22.1)
Assessment Type for Table Default	Systematic Assessment

	AIN457 300 mg N = 426	Adalimumab 40 mg N = 427	Total N = 853
Arm/Group Description	Secukinumab 300 mg administered at Baseline, Weeks 1, 2, 3 and 4, followed by dosing every 4 weeks until Week 48.	Adalimumab 40 mg administered at Baseline followed by dosing every 2 weeks until Week 50.	Total

Total participants affected	37 (8.69%)	36 (8.43%)	73 (8.56%)
Blood and lymphatic system disorders			
Anaemia	1 (0.23%)	0 (0.00%)	1 (0.12%)
Lymphadenopathy	1 (0.23%)	0 (0.00%)	1 (0.12%)
Cardiac disorders			
Acute myocardial infarction	2 (0.47%)	0 (0.00%)	2 (0.23%)
Angina pectoris	0 (0.00%)	1 (0.23%)	1 (0.12%)
Cardiac failure acute	0 (0.00%)	1 (0.23%)	1 (0.12%)
Myocardial infarction	1 (0.23%)	0 (0.00%)	1 (0.12%)
Pericarditis	1 (0.23%)	0 (0.00%)	1 (0.12%)
Gastrointestinal disorders			
Abdominal pain	1 (0.23%)	0 (0.00%)	1 (0.12%)
Abdominal pain upper	1 (0.23%)	0 (0.00%)	1 (0.12%)
Abdominal wall haematoma	0 (0.00%)	1 (0.23%)	1 (0.12%)
Colitis ulcerative	1 (0.23%)	0 (0.00%)	1 (0.12%)
Diarrhoea	1 (0.23%)	0 (0.00%)	1 (0.12%)
Intestinal perforation	1 (0.23%)	0 (0.00%)	1 (0.12%)
Splenic artery aneurysm	0 (0.00%)	1 (0.23%)	1 (0.12%)
Umbilical hernia	0 (0.00%)	1 (0.23%)	1 (0.12%)
General disorders and administration site conditions			
Chest pain	1 (0.23%)	0 (0.00%)	1 (0.12%)

Hepatobiliary disorders			
Cholecystitis	1 (0.23%)	0 (0.00%)	1 (0.12%)
Infections and infestations			
Anal abscess	0 (0.00%)	1 (0.23%)	1 (0.12%)
Appendicitis	1 (0.23%)	0 (0.00%)	1 (0.12%)
Bursitis infective	0 (0.00%)	1 (0.23%)	1 (0.12%)
Chronic sinusitis	1 (0.23%)	0 (0.00%)	1 (0.12%)
Diverticulitis	0 (0.00%)	1 (0.23%)	1 (0.12%)
Gastroenteritis salmonella	1 (0.23%)	0 (0.00%)	1 (0.12%)
Groin abscess	0 (0.00%)	1 (0.23%)	1 (0.12%)
Influenza	1 (0.23%)	0 (0.00%)	1 (0.12%)
Labyrinthitis	0 (0.00%)	1 (0.23%)	1 (0.12%)
Lower respiratory tract infection fungal	1 (0.23%)	0 (0.00%)	1 (0.12%)
Measles	0 (0.00%)	1 (0.23%)	1 (0.12%)
Mycobacterial infection	0 (0.00%)	1 (0.23%)	1 (0.12%)
Pilonidal cyst	1 (0.23%)	0 (0.00%)	1 (0.12%)
Pneumonia	0 (0.00%)	3 (0.70%)	3 (0.35%)
Puncture site abscess	1 (0.23%)	0 (0.00%)	1 (0.12%)
Tonsillitis	1 (0.23%)	0 (0.00%)	1 (0.12%)
Varicella	1 (0.23%)	0 (0.00%)	1 (0.12%)
Injury, poisoning and procedural complications			
Burns second degree	1 (0.23%)	0 (0.00%)	1 (0.12%)

Concussion	1 (0.23%)	0 (0.00%)	1 (0.12%)
Epicondylitis	0 (0.00%)	1 (0.23%)	1 (0.12%)
Foot fracture	1 (0.23%)	0 (0.00%)	1 (0.12%)
Forearm fracture	0 (0.00%)	1 (0.23%)	1 (0.12%)
Hand fracture	0 (0.00%)	1 (0.23%)	1 (0.12%)
Joint dislocation	1 (0.23%)	0 (0.00%)	1 (0.12%)
Post procedural haematoma	1 (0.23%)	0 (0.00%)	1 (0.12%)
Post-traumatic neck syndrome	1 (0.23%)	0 (0.00%)	1 (0.12%)
Skin laceration	1 (0.23%)	0 (0.00%)	1 (0.12%)
Tibia fracture	0 (0.00%)	1 (0.23%)	1 (0.12%)
VIIIth nerve injury	0 (0.00%)	1 (0.23%)	1 (0.12%)
Wound	1 (0.23%)	0 (0.00%)	1 (0.12%)
Musculoskeletal and connective tissue disorders			
Arthritis	1 (0.23%)	0 (0.00%)	1 (0.12%)
Cervical spinal stenosis	1 (0.23%)	0 (0.00%)	1 (0.12%)
Foot deformity	0 (0.00%)	1 (0.23%)	1 (0.12%)
Intervertebral disc protrusion	1 (0.23%)	0 (0.00%)	1 (0.12%)
Osteoarthritis	1 (0.23%)	1 (0.23%)	2 (0.23%)
Psoriatic arthropathy	0 (0.00%)	1 (0.23%)	1 (0.12%)
Synovitis	1 (0.23%)	0 (0.00%)	1 (0.12%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			

Colon cancer	1 (0.23%)	0 (0.00%)	1 (0.12%)
Leiomyoma	0 (0.00%)	1 (0.23%)	1 (0.12%)
Non-Hodgkin's lymphoma	0 (0.00%)	1 (0.23%)	1 (0.12%)
Pancreatic carcinoma	0 (0.00%)	1 (0.23%)	1 (0.12%)
Plasma cell myeloma	1 (0.23%)	0 (0.00%)	1 (0.12%)
Synovial sarcoma	0 (0.00%)	1 (0.23%)	1 (0.12%)
Uterine leiomyoma	1 (0.23%)	0 (0.00%)	1 (0.12%)
Nervous system disorders			
Horner's syndrome	0 (0.00%)	1 (0.23%)	1 (0.12%)
Intracranial aneurysm	1 (0.23%)	0 (0.00%)	1 (0.12%)
Ischaemic stroke	0 (0.00%)	1 (0.23%)	1 (0.12%)
Paraesthesia	0 (0.00%)	1 (0.23%)	1 (0.12%)
Radiculopathy	0 (0.00%)	1 (0.23%)	1 (0.12%)
Syncope	2 (0.47%)	0 (0.00%)	2 (0.23%)
Transient ischaemic attack	0 (0.00%)	1 (0.23%)	1 (0.12%)
Psychiatric disorders			
Alcohol abuse	0 (0.00%)	1 (0.23%)	1 (0.12%)
Depression	0 (0.00%)	1 (0.23%)	1 (0.12%)
Reproductive system and breast disorders			
Endometrial hypertrophy	1 (0.23%)	0 (0.00%)	1 (0.12%)
Ovarian cyst	1 (0.23%)	1 (0.23%)	2 (0.23%)
Prostatitis	0 (0.00%)	2 (0.47%)	2 (0.23%)
Uterine polyp	0 (0.00%)	1 (0.23%)	1 (0.12%)

Respiratory, thoracic and mediastinal disorders			
Alveolitis	0 (0.00%)	1 (0.23%)	1 (0.12%)
Dyspnoea	1 (0.23%)	0 (0.00%)	1 (0.12%)
Epistaxis	1 (0.23%)	0 (0.00%)	1 (0.12%)
Haemoptysis	0 (0.00%)	1 (0.23%)	1 (0.12%)
Pulmonary embolism	1 (0.23%)	1 (0.23%)	2 (0.23%)
Sleep apnoea syndrome	1 (0.23%)	0 (0.00%)	1 (0.12%)
Skin and subcutaneous tissue disorders			
Drug reaction with eosinophilia and systemic symptoms	1 (0.23%)	0 (0.00%)	1 (0.12%)
Perioral dermatitis	0 (0.00%)	1 (0.23%)	1 (0.12%)
Skin ulcer	1 (0.23%)	0 (0.00%)	1 (0.12%)
Vascular disorders			
Aortic aneurysm	0 (0.00%)	1 (0.23%)	1 (0.12%)
Peripheral arterial occlusive disease	1 (0.23%)	0 (0.00%)	1 (0.12%)

Other Adverse Events by System Organ Class

Time Frame	Treatment emergent adverse events were collected from first dose of study treatment until 12 Weeks (84 days) following the last administration of study treatment, an average of 68 weeks.
Additional Description	Any sign or symptom that occurs during the study treatment plus the 30 days post-treatment.
Source Vocabulary for Table Default	MedDRA (22.1)

Assessment Type for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	5%

	AIN457 300 mg N = 426	**Adalimumab 40 mg N = 427**	**Total N = 853**
Arm/Group Description	Secukinumab 300 mg administered at Baseline, Weeks 1, 2, 3 and 4, followed by dosing every 4 weeks until Week 48.	Adalimumab 40 mg administered at Baseline followed by dosing every 2 weeks until Week 50.	Total
Total participants affected	226 (53.05%)	236 (55.27%)	462 (54.16%)
Gastrointestinal disorders			
Diarrhoea	32 (7.51%)	37 (8.67%)	69 (8.09%)
General disorders and administration site conditions			
Injection site reaction	4 (0.94%)	28 (6.56%)	32 (3.75%)
Infections and infestations			
Bronchitis	16 (3.76%)	27 (6.32%)	43 (5.04%)
Nasopharyngitis	88 (20.66%)	84 (19.67%)	172 (20.16%)
Upper respiratory tract infection	42 (9.86%)	54 (12.65%)	96 (11.25%)
Musculoskeletal and connective tissue disorders			
Arthralgia	29 (6.81%)	31 (7.26%)	60 (7.03%)
Back pain	17 (3.99%)	31 (7.26%)	48 (5.63%)
Psoriatic arthropathy	34 (7.98%)	38 (8.90%)	72 (8.44%)

Nervous system disorders			
Headache	36 (8.45%)	33 (7.73%)	69 (8.09%)
Respiratory, thoracic and mediastinal disorders			
Cough	24 (5.63%)	14 (3.28%)	38 (4.45%)
Oropharyngeal pain	25 (5.87%)	15 (3.51%)	40 (4.69%)
Skin and subcutaneous tissue disorders			
Psoriasis	33 (7.75%)	34 (7.96%)	67 (7.85%)
Vascular disorders			
Hypertension	27 (6.34%)	24 (5.62%)	51 (5.98%)

Other Relevant Findings

None

Conclusion:

Secukinumab narrowly missed statistical significance for superiority versus adalimumab in the primary endpoint of ACR20 response at Week 52. Secukinumab was associated with a higher treatment retention rate than adalimumab and provided numerically higher clinical responses across musculoskeletal, skin endpoints, and composite indices at Week 52. The safety profile of secukinumab showed no new or unexpected safety signals.

Date of Clinical Trial Report

29-Jul-2020