NOVARTIS

Clinical Trial Results Website

Sponsor

Novartis Pharmaceuticals

Generic Drug Name

Secukinumab

Trial Indication

Axial spondyloarthritis (axSpA)

Protocol Number

CAIN457H3301

Protocol Title

A 24-week, randomized, double-blind, placebo-controlled, multicenter study to evaluate the efficacy and safety of secukinumab in controlling spinal pain in patients with axial spondyloarthritis

Clinical Trial Phase

Phase 3

Phase of Drug Development

Phase IIIb

Study Start/End Dates

Study Start Date: June 2017
Primary Completion Date: February 2019
Study Completion Date: February 2019

Study Design/Methodology

This was a randomized, double-blind, placebo-controlled, multicenter study. At Baseline, patients whose eligibility was confirmed were randomized in a 3:1 ratio to receive double-blind treatment with either secukinumab 150 mg or placebo in Treatment Period 1 (Baseline to Week 8):

- Group A: secukinumab 150 mg
- Group B: placebo

During Treatment Period 1, patients were scheduled to receive 1 × 1.0 mL s.c. injection of either secukinumab 150 mg or placebo at Baseline and Week 1, 2, 3 and 4.

At Week 8, patients entered Treatment Period 2 (Week 8 to Week 24).

Patients randomized to Group A (secukinumab 150 mg) at Baseline were classified as responders (i.e. average spinal pain score < 4) or non-responders (i.e. average spinal pain score ≥ 4):

- Responders at Week 8 were re-assigned to the following treatment arm:
  Arm A1: secukinumab 150 mg + placebo
- Non-responders at Week 8 were re-randomized to the following treatment arms:
  Arm A2: secukinumab 150 mg + placebo
  Arm A3: secukinumab 300 mg

Patients randomized to Group B (placebo) at Baseline were re-randomized to receive secukinumab as follows:
Arm B1: secukinumab 150 mg + placebo
Arm B2: secukinumab 300 mg

During Treatment Period 2, patients were scheduled to receive either 1 × 1.0 mL s.c. injection of secukinumab 150 mg and 1 × 1.0 mL s.c. injection of placebo, or 2 × 1.0 mL s.c. injections of secukinumab 150 mg at Week 8, 12, 16 and 20.

Centers

70 centers in 17 countries: Spain (15), Czech Republic (3), Finland (2), Lithuania (2), Estonia (3), Latvia (3), Switzerland (3), Russia (5), Sweden (4), United Kingdom (5), Belgium (2), Ireland (2), Poland (7), Croatia (3), Bulgaria (5), Greece (5), Italy (1)

Objectives:

Primary Objective

The primary objective of this study was to assess the superiority of secukinumab 150 mg compared to placebo in achieving a spinal pain score of < 4 on a 0-10 numerical rating scale (NRS) at Week 8 (Treatment Period 1). The related endpoint was the proportion of patients with a spinal pain score of < 4 at Week 8 in Group A compared to Group B.

Secondary Objective

The secondary objective of this study was to assess the superiority of secukinumab 150 mg compared to placebo in achieving a Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) score of < 4 at Week 8 (Treatment Period 1). The related endpoint was the proportion of patients with a BASDAI score of < 4 at Week 8 in Group A compared to Group B.

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

1 × 1.0 mL s.c. injection of secukinumab 150 mg

Statistical Methods

The primary analysis was conducted via logistic regression model with treatment, country and the stratification factor of prior exposure to TNF inhibitors (i.e. according to whether patients were TNF-naïve compared to TNFα-IR) as covariates. The odds ratio (OR), its 95% confidence interval (CI), and p-values were presented comparing the secukinumab 150 mg treatment group to the placebo group at Week 8.

The secondary analysis was performed analogously to the primary analysis. The secondary endpoint was included in a confirmatory testing strategy and was tested hierarchically after the primary endpoint.

Study Population: Key Inclusion/Exclusion Criteria

Key Inclusion Criteria:

- Diagnosis of axial spondylarthritis (axSpA, either ankylosing spondylitis or non radiographic axial spondylarthritis) according to ASAS axSpA classification criteria
- Patients with back pain for at least 3 months and age of onset less than 45 years
- Active axSpA as assessed by total BASDAI score of at least 4 at Baseline.
- Spinal pain numeric rating scale score of more than 4 at Baseline.
- Inadequate response to or failure to respond to at least 2 different NSAIDs at the highest recommended dose for at least 4 weeks in total prior to randomization

Key Exclusion Criteria:

- Chest X-ray or MRI with evidence of ongoing infectious or malignant process
- Patients previously treated with any biological immunomodulating agents, except those targeting tumor necrosis factor alpha.
- Patients who have been exposed to more than one anti-tumor necrosis factor alpha agent.
- Active ongoing inflammatory diseases other than axial spondyloarthritis
- Other ongoing mechanical diseases affecting the spine.

Participant Flow Table

Treatment Period 1 (TP1)(Baseline-Wk 8)

	Secukinumab 150 mg (Group A)	Placebo (Group B)	Arm A1	Arm A2	Arm A3	Arm B1	Arm B2	Total
Arm/Group Description	Treatment Period 1: Secukinumab 150 mg (1 x 1.0 mL) s.c. administered at Baseline, Week 1, 2, 3 and 4	Treatment Period 1: Placebo (1 x 1.0 mL) s.c. administered at Baseline and Week 1, 2, 3 and 4	Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20	Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20	
Started	285	95	0	0	0	0	0	380
Completed	278	89	0	0	0	0	0	367
Not Completed	7	6	0	0	0	0	0	13
Adverse Event	3	2	0	0	0	0	0	5
Lost to Follow-up	1	1	0	0	0	0	0	2
Protocol Deviation	2	1	0	0	0	0	0	3
Subject/Guardian Decision	0	1	0	0	0	0	0	1
Withdrawal of Informed Consent	1	1	0	0	0	0	0	2

Treatment Period 2 (TP2) (Wk 8-Wk 24)

	Secukinumab 150 mg (Group A)	Placebo (Group B)	Arm A1	Arm A2	Arm A3	Arm B1	Arm B2	Total
Arm/Group Description	Treatment Period 1: Secukinumab	Treatment Period 1: Placebo (1 x	Treatment Period 2: Secukinumab	Treatment Period 2: Secukinumab	Treatment Period 2: Secukinumab	Treatment Period 2: Secukinumab	Treatment Period 2: Secukinumab	

	150 mg (1 x 1.0 mL) s.c. administered at Baseline, Week 1, 2, 3 and 4	1.0 mL) s.c. administered at Baseline and Week 1, 2, 3 and 4	150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20	150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20	
Started	0	0	90	94	94	45	44	367
Completed	0	0	88	93	92	45	43	361
Not Completed	0	0	2	1	2	0	1	6
Adverse Event	0	0	0	1	2	0	1	4
Lost to Follow-up	0	0	1	0	0	0	0	1
Withdrawal of Informed Consent	0	0	1	0	0	0	0	1

Baseline Characteristics

	Secukinumab 150 mg (Group A)	**Placebo (Group B)**	**Arm A1**	**Arm A2**	**Arm A3**	**Arm B1**	**Arm B2**	**Total**
Arm/Group Description	Treatment Period 1: Secukinumab 150 mg (1 x 1.0 mL) s.c. administered at Baseline, Week 1, 2, 3 and 4	Treatment Period 1: Placebo (1 x 1.0 mL) s.c. administered at Baseline and Week 1, 2, 3 and 4	Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20	Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20	
Number of Participants [units: participants]	285	95	0	0	0	0	0	380

Age Continuous[1] (units: Years) Mean ± Standard Deviation				
	42.3±11.88	40.9±12.20		42.0±11.96
Sex: Female, Male[2] (units: Participants) Count of Participants				
Female	106	39		145
Male	179	56		235
Race/Ethnicity, Customized[3] (units: Participants)				
Caucasian	267	93		360
Asian	2	1		3
Other	16	1		17

[1] Age continuous at Baseline Treatment Period 1
[2] Gender at Baseline Treatment Period 1
[3] Race at Baseline Treatment Period 1

Summary of Efficacy

Primary Outcome Result

Percentage of participants with an average spinal pain numerical rating scale (NRS) score below 4 out of 10 at Week 8 (Treatment Period 1) **- Average Spinal Pain Score**
(Time Frame: Week 8)

	Secukinumab 150 mg (Group A)	**Placebo (Group B)**

Arm/Group Description	Treatment Period 1: Secukinumab 150 mg (1 x 1.0 mL) s.c. administered at Baseline, Week 1, 2, 3 and 4	Treatment Period 1: Placebo (1 x 1.0 mL) s.c. administered at Baseline and Week 1, 2, 3 and 4
Number of Participants Analyzed [units: participants]	279	92
Percentage of participants with a spinal pain numerical rating scale (NRS) score below 4 at Week 8 - Average Spinal Pain Score (units: Percentage of Participants)		
Average Spinal Pain Score	31.9	20.0
Total Spinal Pain Score	27.0	17.9
Nocturnal Pain Score	32.3	16.8

Statistical Analysis

Groups	Secukinumab 150 mg (Group A), Placebo (Group B)	Average Spinal Pain Score <4 at Week 8
P Value	0.0264	
Method	Regression, Logistic	Logistic regression model: logit (proportion) = treatment + stratification factor of prior exposure to TNF inhibitors (i.e. TNF-naïve or TNFα-IR).
Odds Ratio (OR)	1.89	
95% Confidence Interval 2-Sided	1.08 to 3.33	

Statistical Analysis

Groups	Secukinumab 150 mg (Group A), Placebo (Group B)	Total Spinal Pain Score <4 at Week 8
P Value	0.0720	

Method	Regression, Logistic
Odds Ratio, log	1.72
95% Confidence Interval 2-Sided	0.95 to 3.10

Statistical Analysis

Groups	Secukinumab 150 mg (Group A), Placebo (Group B)	Nocturnal Pain Score <4 at Week 8
P Value	0.0043	
Method	Regression, Logistic	
Odds Ratio (OR)	2.38	
95% Confidence Interval 2-Sided	1.31 to 4.31	

Secondary Outcome Result

Percentage of participants with a Bath ankylosing spondylitis disease activity index score below 4 at Week 8

(Time Frame: Week 8)

	Secukinumab 150 mg (Group A)	Placebo (Group B)
Arm/Group Description	Treatment Period 1: Secukinumab 150 mg (1 x 1.0 mL) s.c. administered at Baseline, Week 1, 2, 3 and 4	Treatment Period 1: Placebo (1 x 1.0 mL) s.c. administered at Baseline and Week 1, 2, 3 and 4
Number of Participants Analyzed [units: participants]	280	92

Percentage of participants with a Bath ankylosing spondylitis disease activity index score below 4 at Week 8 (units: Percentaghe of Participants)		
	33.3	23.2

Statistical Analysis

Groups	Secukinumab 150 mg (Group A), Placebo (Group B)	BASDAI Score <4 at Week 8
P Value	0.0466	
Method	Regression, Logistic	Logistic regression model: logit (proportion) = treatment + stratification factor of prior exposure to TNF inhibitors (i.e. TNF-naïve or TNFα-IR).
Odds Ratio (OR)	1.75	
95% Confidence Interval 2-Sided	1.01 to 3.04	

Summary of Safety

Safety Results

All-Cause Mortality

Secukinumab 150 mg (Group A) N = 285	**Placebo (Group B) N = 95**	**Arm A1 N = 90**	**Arm A2 N = 94**	**Arm A3 N = 94**	**Arm B1 N = 45**	**Arm B2 N = 44**

Arm/Group Description	Treatment Period 1: Secukinumab 150 mg (1 x 1.0 mL) s.c. administered at Baseline, Week 1, 2, 3 and 4	Treatment Period 1: Placebo (1 x 1.0 mL) s.c. administered at Baseline and Week 1, 2, 3 and 4	Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20	Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20
Total participants affected	0 (0.00%)	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	Treatment emergent adverse events were collected from first dose of study treatment until end of study treatment plus 12 weeks, up to a maximum duration of 32 weeks.
Additional Description	Any sign or symptom that occurs after written informed consent provided. Treatment emergent adverse events were reported until end of study treatment plus 12 weeks post treatment. Treatment emergent adverse events occurring during Treatment Period 1 are recorded in Group A and B arms. Treatment emergent adverse events occurring during Treatment Period 2 are recorded in Arm A1 to Arm B2.
Source Vocabulary for Table Default	MedDRA (21.0)
Assessment Type for Table Default	Systematic Assessment

	Secukinumab 150 mg (Group A) N = 285	**Placebo (Group B) N = 95**	**Arm A1 N = 90**	**Arm A2 N = 94**	**Arm A3 N = 94**	**Arm B1 N = 45**	**Arm B2 N = 44**
Arm/Group Description	Treatment Period 1: Secukinumab 150 mg (1 x 1.0 mL) s.c. administered	Treatment Period 1: Placebo (1 x 1.0 mL) s.c. administered at Baseline	Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x	Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x	Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered	Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x	Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered

	at Baseline, Week 1, 2, 3 and 4	and Week 1, 2, 3 and 4	1.0 mL) administered at Week 8, 12, 16 and 20	1.0 mL) administered at Week 8, 12, 16 and 20	at Week 8, 12, 16, and 20	1.0 mL) administered at Week 8, 12, 16 and 20	at Week 8, 12, 16, and 20
Total participants affected	4 (1.40%)	0 (0.00%)	3 (3.33%)	1 (1.06%)	1 (1.06%)	0 (0.00%)	0 (0.00%)
Cardiac disorders							
Acute myocardial infarction	1 (0.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Myocardial infarction	1 (0.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Gastrointestinal disorders							
Colitis ulcerative	0 (0.00%)	0 (0.00%)	1 (1.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Pancreatitis	0 (0.00%)	0 (0.00%)	1 (1.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Infections and infestations							
Anal abscess	1 (0.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injury, poisoning and procedural complications							
Facial bones fracture	1 (0.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)							
Malignant melanoma	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.06%)	0 (0.00%)	0 (0.00%)
Nervous system disorders							
Hemiparesis	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal and urinary disorders							

Renal impairment	0 (0.00%)	0 (0.00%)	1 (1.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal mass	1 (0.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)

Other Adverse Events by System Organ Class

Time Frame	Treatment emergent adverse events were collected from first dose of study treatment until end of study treatment plus 12 weeks, up to a maximum duration of 32 weeks.
Additional Description	Any sign or symptom that occurs after written informed consent provided. Treatment emergent adverse events were reported until end of study treatment plus 12 weeks post treatment. Treatment emergent adverse events occurring during Treatment Period 1 are recorded in Group A and B arms. Treatment emergent adverse events occurring during Treatment Period 2 are recorded in Arm A1 to Arm B2.
Source Vocabulary for Table Default	MedDRA (21.0)
Assessment Type for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	2%

	Secukinumab 150 mg (Group A) N = 285	**Placebo (Group B) N = 95**	**Arm A1 N = 90**	**Arm A2 N = 94**	**Arm A3 N = 94**	**Arm B1 N = 45**	**Arm B2 N = 44**
Arm/Group Description	Treatment Period 1: Secukinumab 150 mg (1 x 1.0 mL) s.c. administered at Baseline, Week 1, 2, 3 and 4	Treatment Period 1: Placebo (1 x 1.0 mL) s.c. administered at Baseline and Week 1, 2, 3 and 4	Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20	Treatment Period 2: Secukinumab 150 mg (1 x 1.0 mL) plus placebo (1 x 1.0 mL) administered at Week 8, 12, 16 and 20	Treatment Period 2: Secukinumab 300 mg (2 x 1.0 mL) administered at Week 8, 12, 16, and 20
Total participants affected	59 (20.70%)	23 (24.21%)	21 (23.33%)	24 (25.53%)	23 (24.47%)	9 (20.00%)	13 (29.55%)

Blood and lymphatic system disorders							
Neutropenia	1 (0.35%)	1 (1.05%)	1 (1.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Ear and labyrinth disorders							
Deafness	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.22%)	0 (0.00%)
Eye disorders							
Blepharitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (2.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Iritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.22%)	0 (0.00%)
Vitreous haemorrhage	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Gastrointestinal disorders							
Abdominal pain	3 (1.05%)	1 (1.05%)	0 (0.00%)	1 (1.06%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Diarrhoea	6 (2.11%)	1 (1.05%)	0 (0.00%)	0 (0.00%)	1 (1.06%)	0 (0.00%)	0 (0.00%)
Frequent bowel movements	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Toothache	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (2.13%)	1 (1.06%)	0 (0.00%)	0 (0.00%)
General disorders and administration site conditions							
Fatigue	6 (2.11%)	0 (0.00%)	1 (1.11%)	1 (1.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Injection site pain	2 (0.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	3 (3.19%)	0 (0.00%)	0 (0.00%)
Hepatobiliary disorders							
Hypertransaminasaemia	1 (0.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.06%)	1 (2.22%)	0 (0.00%)
Infections and infestations							
Bronchitis	0 (0.00%)	1 (1.05%)	1 (1.11%)	1 (1.06%)	0 (0.00%)	1 (2.22%)	0 (0.00%)

Conjunctivitis	0 (0.00%)	0 (0.00%)	2 (2.22%)	2 (2.13%)	1 (1.06%)	0 (0.00%)	0 (0.00%)
Herpes simplex	1 (0.35%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Nasopharyngitis	6 (2.11%)	1 (1.05%)	1 (1.11%)	3 (3.19%)	4 (4.26%)	2 (4.44%)	2 (4.55%)
Otitis externa	1 (0.35%)	0 (0.00%)	1 (1.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Pharyngitis	3 (1.05%)	0 (0.00%)	2 (2.22%)	2 (2.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinitis	1 (0.35%)	0 (0.00%)	2 (2.22%)	2 (2.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Tooth infection	0 (0.00%)	2 (2.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Upper respiratory tract infection	4 (1.40%)	5 (5.26%)	1 (1.11%)	0 (0.00%)	3 (3.19%)	0 (0.00%)	0 (0.00%)
Viral pharyngitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Viral upper respiratory tract infection	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (1.06%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Injury, poisoning and procedural complications							
Arthropod bite	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Foot fracture	0 (0.00%)	1 (1.05%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.22%)	0 (0.00%)
Limb injury	1 (0.35%)	0 (0.00%)	2 (2.22%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Investigations							
Alanine aminotransferase increased	1 (0.35%)	1 (1.05%)	0 (0.00%)	1 (1.06%)	2 (2.13%)	1 (2.22%)	0 (0.00%)
Blood creatinine increased	4 (1.40%)	0 (0.00%)	3 (3.33%)	1 (1.06%)	0 (0.00%)	0 (0.00%)	2 (4.55%)
Metabolism and nutrition disorders							
Hypercholesterolaemia	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Lactose intolerance	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)

Musculoskeletal and connective tissue disorders							
Ankylosing spondylitis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.22%)	0 (0.00%)
Arthralgia	4 (1.40%)	2 (2.11%)	0 (0.00%)	3 (3.19%)	1 (1.06%)	0 (0.00%)	0 (0.00%)
Back pain	1 (0.35%)	3 (3.16%)	0 (0.00%)	2 (2.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Bursitis	1 (0.35%)	0 (0.00%)	1 (1.11%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Foot deformity	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Muscle contracture	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Osteoarthritis	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Pain in extremity	6 (2.11%)	0 (0.00%)	1 (1.11%)	1 (1.06%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Nervous system disorders							
Headache	10 (3.51%)	1 (1.05%)	2 (2.22%)	2 (2.13%)	3 (3.19%)	0 (0.00%)	1 (2.27%)
Psychiatric disorders							
Insomnia	0 (0.00%)	0 (0.00%)	0 (0.00%)	2 (2.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Renal and urinary disorders							
Haematuria	1 (0.35%)	0 (0.00%)	1 (1.11%)	0 (0.00%)	3 (3.19%)	1 (2.22%)	0 (0.00%)
Proteinuria	3 (1.05%)	1 (1.05%)	0 (0.00%)	2 (2.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Reproductive system and breast disorders							
Vulvovaginal pruritus	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Respiratory, thoracic and mediastinal disorders							
Bronchospasm	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)
Cough	2 (0.70%)	0 (0.00%)	3 (3.33%)	1 (1.06%)	1 (1.06%)	0 (0.00%)	0 (0.00%)

Oropharyngeal pain	8 (2.81%)	1 (1.05%)	4 (4.44%)	2 (2.13%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Rhinorrhoea	1 (0.35%)	1 (1.05%)	0 (0.00%)	0 (0.00%)	2 (2.13%)	0 (0.00%)	0 (0.00%)
Skin and subcutaneous tissue disorders							
Pruritus	2 (0.70%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.22%)	0 (0.00%)
Vascular disorders							
Hypertension	3 (1.05%)	1 (1.05%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	0 (0.00%)	1 (2.27%)

Conclusion:

The primary efficacy endpoint was met for this study; secukinumab 150 mg was superior to placebo (31.9% vs. 20.0%, OR = 1.89, p = 0.0264) in achieving an average spinal pain score of < 4 following 8 weeks of treatment in patients with axSpA. Analysis of the mean average spinal pain score at Week 8, using repeated measure ANCOVA model, supported the primary analysis findings showing a significant difference between secukinumab 150 mg and placebo (p = 0.0004).

The secondary efficacy endpoint was also met for this study; secukinumab 150 mg was superior to placebo (33.3% vs. 23.2%, OR = 1.75, p = 0.0466) in achieving a BASDAI score of < 4 following 8 weeks of treatment in patients with axSpA. Analysis of the mean BASDAI score at Week 8, using repeated measure ANCOVA model, supported the secondary analysis findings showing a significant treatment difference between secukinumab 150 mg and placebo (p = 0.0001).

The adverse events participants had during this trial were consistent with those other participants had during past trials of secukinumab.

Date of Clinical Trial Report

22 October 2019