NOVARTIS

Clinical Trial Results Website

Sponsor

Novartis Pharmaceuticals

Generic Drug Name

Secukinumab

Trial Indication(s)

Plaque Psoriasis

Protocol Number

CAIN457ADE06

Protocol Title

A randomized, controlled, multicenter, open-label study with blinded assessment of the efficacy of subcutaneous secukinumab compared to Fumaderm® in adults with moderate to severe plaque psoriasis.

Clinical Trial Phase

Phase 3

Phase of Drug Development

Phase 4

Study Start/End Dates

Study Start Date: April 2015 (Actual)
Primary Completion Date: June 2016 (Actual)
Study Completion Date: June 2016 (Actual)

Reason for Termination (If applicable)

Not applicable

Study Design/Methodology

This was a multicenter, open-label, randomized, controlled, parallel-group study over 24 weeks, in which the efficacy data on secukinumab 2 x 150 mg vs. Fumaric acid in the treatment of patients with moderate to severe plaque psoriasis were evaluated by a blinded assessor.

Centers

Germany(76)

Objectives:

Primary objective(s)

The primary study objective was to demonstrate the superiority of secukinumab compared to Fumaric Acid in patients with moderate to severe plaque psoriasis based on the proportion of Psoriasis Area Severity Index (PASI) 75 responders at week 24.

Secondary objectives

Secondary study objectives were:

• To compare the efficacy of secukinumab and Fumaric Acid on raw PASI and PASI 50/75/90/100 response rates at weeks 1, 2, 3, 4, 6, 8, 12, 16, 20, and 24.
• To compare efficacy of secukinumab and Fumaric Acid on Body Surface Area (BSA) at weeks 1, 2, 3, 4, 6, 8, 12, 16, 20, and 24.
• To compare the effect of secukinumab and Fumaric Acid on Nail Psoriasis Severity Index (NAPSI) response at weeks 1, 2, 3, 4, 6, 8, 12, 16, 20, and 24.
• To compare efficacy of secukinumab and Fumaric Acid on the 2011 modifiednInvestigator's Global Assessment (IGA mod 2011) and IGA mod 2011 0/1 response at weeks 1, 2, 3, 4, 6, 8, 12, 16, 20, and 24.
• To compare the effect of secukinumab and Fumaric Acid on Dermatology Quality of Life Index (DLQI) and DLQI 0/1 response at weeks 1, 2, 3, 4, 6, 8, 12, 16, 20, and 24.

• To compare the effect of secukinumab and Fumaric Acid on Short Form (SF)-36 response at weeks 4, 16 and 24.

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

Secukinumab 150 mg in 1 mL prefilled pens for subcutaneous injection. Patients in the secukinumab arm received a dose of 300 mg secukinumab, administered as 2 subcutaneous injections of 150 mg at weeks 0, 1, 2, 3, 4, 8, 12, 16, and 20.

Fumaric acid (initial and maintenance therapy) for oral administration. Patients in the Fumaric acid arm received daily doses of Fumaric acid (initial and maintenance therapy) according to the dose-titration scheme and the recommendations for dose adjustment provided in the local product information.

Statistical Methods

The primary efficacy analysis was performed in the FAS by calculating the Odds ratio (OR) for PASI 75 response rates at week 24 based on a logistic regression model with factor “treatment” and covariate “baseline value”. For the main analysis, patients with missing values for week 24 were considered responders, if they had met the response criterion already at the time of drop-out; otherwise, they were considered non-responders.

All secondary efficacy variables were analyzed descriptively.

Study Population: Key Inclusion/Exclusion Criteria

Inclusion Criteria:
- Men or women must be at least 18 years of age at the time of screening
- Chronic plaque-type psoriasis diagnosed for at least 6 months before randomization Patients with moderate to severe plaque psoriasis who are candidates for systemic therapy as defined at randomization by:
- PASI score of >10
- Affected body surface area (BSA) > 10%
- DLQI >10
- Inadequate response, intolerance or contraindication to topical psoriasis treatment as documented in the patient’s medical history or reported by the patient or determined by the investigator at screening.

Exclusion Criteria (abbreviated):

- Previous systemic treatment of plaque psoriasis or known contraindication for systemic therapy at baseline
- Ongoing use of other prohibited psoriasis and non-psoriasis treatment.
- Clinically important active infections or infestations, chronic, recurrent or latent infections or infestations
- Patients with severe liver diseases
- Patients with severe gastrointestinal diseases including but not limited to ventricular and duodenal ulcers
- Patients with severe kidney diseases or serum creatinine above 1 x ULN
- Patients with known hematological disease or lab abnormalities
- Pregnancy, breast feeding, or unwillingness/inability to use appropriate measures of contraception (if necessary)

Participant Flow Table

Overall Study

	Secukinumab	Fumaric acid (initial and maintenance therapy)
Started	105	97
Full analysis set (FAS)	105	95
Completed	99	43
Not Completed	6	54
Adverse Event	2	32
Withdrawal of informed consent	1	11
Lost to Follow-up	2	2
Dose tapering not achieved	0	4
Participant/guardian decision	1	2
Non-compliance with study treatment	0	2

Protocol deviation	0	1

Baseline Characteristics

	Secukinumab	Fumaric acid (initial and maintenance therapy)	Total
Number of Participants [units: participants]	105	97	202
Age Continuous (units: years) Mean ± Standard Deviation	43.2±14.2	42.4±13.2	42.8±13.7
Gender, Male/Female (units: Participants)			
Female	40	37	77
Male	65	60	125
Age Categorical (units: Participants)			
<=18 years	0	0	0
Between 18 and 65 years	98	90	188
>=65 years	7	7	14

Summary of Efficacy

Primary Outcome Result(s)

Percentage of participants achieving Psoriasis Area and Severity Index (PASI) 75 Response at week 24

	Secukinumab	Fumaric acid (initial and maintenance therapy)
Number of Participants Analyzed [units: participants]	105	95
Percentage of participants achieving Psoriasis Area and Severity Index (PASI) 75 Response at week 24 (units: Percentage of participants)	89.52	33.68

Statistical Analysis

Groups	Secukinumab, Fumaric acid (initial and maintenance therapy)
Non-Inferiority/Equivalence Test	No
P Value	<0.0001
Method	Regression, Logistic
Odds Ratio (OR)	16.61

95 % Confidence Interval 2-Sided	7.79 to 35.40

Secondary Outcome Result(s)

Percentage of participants achieving Psoriasis Area and Severity Index (PASI) 50 Response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

	Secukinumab	Fumaric acid (initial and maintenance therapy)
Number of Participants Analyzed [units: participants]	105	95
Percentage of participants achieving Psoriasis Area and Severity Index (PASI) 50 Response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24 (units: Percentage of participants)		
Week 1 (n = 105, 91)	9.5	1.1
Week 2 (n = 105, 95)	37.1	6.3
Week 3 (n= 105, 95)	63.8	10.5
Week 4 (n = 105, 95)	81.9	14.7

Week 6 (n = 105, 95)	93.3	28.4
Week 8 (n = 105, 95)	96.2	41.1
Week 12 (n = 105, 95)	97.1	56.8
Week 16 (n = 105, 95)	98.1	60.0
Week 20 (n = 105, 95)	98.1	61.1
Week 24 (n = 105, 95)	98.1	61.1

Percentage of participants achieving Psoriasis Area and Severity Index (PASI) 75 Response at week 1, 2, 3, 4, 6, 8, 12, 16 and 20

	Secukinumab	Fumaric acid (initial and maintenance therapy)
Number of Participants Analyzed [units: participants]	105	95
Percentage of participants achieving Psoriasis Area and Severity Index (PASI) 75 Response at week 1, 2, 3, 4, 6, 8, 12, 16 and 20 (units: Percentage of participants)		
Week 1 (n = 105, 91)	0	0
Week 2 (n = 105, 95)	5.7	0
Week 3 (n = 105, 95)	24.8	0
Week 4 (n = 105, 95)	47.6	1.1
Week 6 (n = 105, 95)	69.5	2.1
Week 8 (n = 105, 95)	80.0	8.4
Week 12 (n = 105, 95)	87.6	21.1
Week 16 (n = 105, 95)	88.6	27.4
Week 20 (n = 105, 95)	88.6	36.8

Percentage of participants achieving Psoriasis Area and Severity Index (PASI) 90 Response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

	Secukinumab	Fumaric acid (initial and maintenance therapy)
Number of Participants Analyzed [units: participants]	105	95
Percentage of participants achieving Psoriasis Area and Severity Index (PASI) 90 Response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24 (units: Percentage of participants)		
Week 1 (n = 105, 91)	0	0
Week 2 (n = 105, 95)	1.9	0
Week 3 (n = 105, 95)	2.9	0
Week 4 (n = 105, 95)	17.1	0
Week 6 (n = 105, 95)	32.4	0
Week 8 (n = 105, 95)	46.7	1.1
Week 12 (n = 105, 95)	63.8	2.1
Week 16 (n = 105, 95)	68.6	8.4
Week 20 (n = 105, 95)	75.2	14.7
Week 24 (n = 105, 95)	75.2	18.9

Percentage of participants achieving Psoriasis Area and Severity Index (PASI) 100 Response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

	Secukinumab	Fumaric acid (initial and maintenance

		therapy)
Number of Participants Analyzed [units: participants]	105	95
Percentage of participants achieving Psoriasis Area and Severity Index (PASI) 100 Response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24 (units: Percentage of participants)		
Week 1 (n = 105, 91)	0	0
Week 2 (n = 105, 95)	0	0
Week 3 (n = 105, 95)	0	0
Week 4 (n = 105, 95)	3.8	0
Week 6 (n = 105, 95)	7.6	0
Week 8 (n = 105, 95)	15.2	0
Week 12 (n = 105, 95)	28.6	0
Week 16 (n = 105, 95)	37.1	0
Week 20 (n = 105, 95)	41.0	0
Week 24 (n = 105, 95)	43.8	3.2

Body surface area (BSA) at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

	Secukinumab	Fumaric acid (initial and maintenance therapy)
Number of Participants Analyzed [units: participants]	105	95
Body surface area (BSA) at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24 (units: Percentage of area)		

Mean ± Standard Deviation		
Week 1 (n = 105, 94)	23.8 ± 12.82	23.2 ± 14.11
Week 2 (n = 105, 91)	20.1 ± 12.25	22.5 ± 14.37
Week 3 (n = 105, 89)	17.0 ± 11.95	22.1 ± 14.33
Week 4 (n = 103, 84)	13.0 ± 11.93	21.6 ± 14.12
Week 6 (n = 98, 82)	9.8 ± 11.12	19.7 ± 13.52
Week 8 (n = 102, 75)	7.6 ± 10.19	17.8 ± 12.65
Week 12 (n = 103, 67)	5.2 ± 9.12	13.7 ± 11.60
Week 16 (n = 99, 59)	3.7 ± 6.72	11.4 ± 11.52
Week 20 (n = 99, 50)	2.6 ± 5.77	9.2 ± 11.87
Week 24 (n = 99, 48)	2.9 ± 6.43	7.9 ± 9.92

Percentage of participants achieving Nail Psoriasis Severity Index (NAPSI) 50 response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

	Secukinumab	**Fumaric acid (initial and maintenance therapy)**
Number of Participants Analyzed [units: participants]	105	95
Percentage of participants achieving Nail Psoriasis Severity Index (NAPSI) 50 response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24 (units: Percentage of participants)		
Week 1 (n = 56, 49)	1.8	4.1
Week 2 (n = 56, 49)	3.6	8.2
Week 3 (n = 56, 49)	5.4	10.2
Week 4 (n = 56, 49)	7.1	12.2

Week 6 (n = 56, 49)	19.6	10.2
Week 8 (n = 56, 49)	23.2	8.2
Week 12 (n = 56, 49)	41.1	12.2
Week 16 (n = 56, 49)	51.8	10.2
Week 20 (n = 56, 49)	62.5	18.4
Week 24 (n = 56, 49)	67.9	18.4

Percentage of participants achieving Nail Psoriasis Severity Index (NAPSI) 75 response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

	Secukinumab	Fumaric acid (initial and maintenance therapy)
Number of Participants Analyzed [units: participants]	105	95
Percentage of participants achieving Nail Psoriasis Severity Index (NAPSI) 75 response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24 (units: Percentage of participants)		
Week 1 (n = 56, 49)	1.8	0
Week 2 (n = 56, 49)	1.8	2.0
Week 3 (n = 56, 49)	5.4	2.0
Week 4 (n = 56, 49)	7.1	2.0
Week 6 (n = 56, 49)	8.9	2.0
Week 8 (n = 56, 49)	17.9	2.0
Week 12 (n = 56, 49)	28.6	2.0
Week 16 (n = 56, 49)	30.4	2.0
Week 20 (n = 56, 49)	44.6	6.1

Week 24 (n = 56, 49)	53.6	4.1

Percentage of participants achieving Nail Psoriasis Severity Index (NAPSI) 90 response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

	Secukinumab	Fumaric acid (initial and maintenance therapy)
Number of Participants Analyzed [units: participants]	105	95
Percentage of participants achieving Nail Psoriasis Severity Index (NAPSI) 90 response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24 (units: Percentage of participants)		
Week 1 (n = 56, 49)	1.8	0
Week 2 (n = 56, 49)	1.8	0
Week 3 (n = 56, 49)	0	0
Week 4 (n = 56, 49)	3.6	0
Week 6 (n = 56, 49)	3.6	0
Week 8 (n = 56, 49)	7.1	2.0
Week 12 (n = 56, 49)	14.3	2.0
Week 16 (n = 56, 49)	21.4	2.0
Week 20 (n = 56, 49)	26.8	4.1
Week 24 (n = 56, 49)	35.7	4.1

Percentage of participants achieving Nail Psoriasis Severity Index (NAPSI) 100 response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

	Secukinumab	Fumaric acid (initial and maintenance therapy)
Number of Participants Analyzed [units: participants]	105	95
Percentage of participants achieving Nail Psoriasis Severity Index (NAPSI) 100 response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24 (units: Percentage of participants)		
Week 1 (n = 56, 49)	1.8	0
Week 2 (n = 56, 49)	0	0
Week 3 (n = 56, 49)	0	0
Week 4 (n =56, 49)	3.6	0
Week 6 (n = 56, 49)	3.6	0
Week 8 (n = 56, 49)	5.4	2.0
Week 12 (n = 56, 49)	10.7	2.0
Week 16 (n = 56, 49)	19.6	2.0
Week 20 (n = 56, 49)	19.6	2.0
Week 24 (n = 56, 49)	23.2	2.0

Number of participants with Investigator's global assessment (IGA mod 2011) at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

	Secukinumab	Fumaric acid (initial and maintenance therapy)
Number of Participants Analyzed [units: participants]	105	95

Number of participants with Investigator's global assessment (IGA mod 2011) at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24
(units: Participants)

Week 1 (n = 105, 94) : Clear	0	0
Week 1 (n = 105, 94) : Almost Clear	0	0
Week 1 (n = 105, 94) : Mild	18	8
Week 1 (n = 105, 94) : Moderate	65	58
Week 1 (n = 105, 94) : Severe	22	28
Week 2 (n = 105, 91) : Clear	0	0
Week 2 (n = 105, 91) : Almost Clear	6	0
Week 2 (n = 105, 91) : Mild	38	15
Week 2 (n = 105, 91) : Moderate	49	56
Week 2 (n = 105, 91) : Severe	12	20
Week 3 (n = 105, 89) : Clear	0	0
Week 3 (n = 105, 89) : Almost Clear	14	1
Week 3 (n = 105, 89) : Mild	51	18
Week 3 (n = 105, 89) : Moderate	35	51

Week 3 (n = 105, 89) : Severe	5	19
Week 4 (n = 103, 84) : Clear	4	0
Week 4 (n = 103, 84) : Almost Clear	31	1
Week 4 (n = 103, 84) : Mild	46	21
Week 4 (n = 103, 84) : Moderate	19	46
Week 4 (n = 103, 84) : Severe	3	16
Week 6 (n = 98, 82) : Clear	9	0
Week 6 (n = 98, 82) : Almost Clear	42	2
Week 6 (n = 98, 82) : Mild	39	26
Week 6 (n = 98, 82) : Moderate	7	44
Week 6 (n = 98, 82) : Severe	1	10
Week 8 (n = 102, 75) : Clear	17	0
Week 8 (n = 102, 75) : Almost Clear	52	4
Week 8 (n = 102, 75) : Mild	29	32
Week 8 (n = 102, 75) : Moderate	2	34
Week 8 (n = 102, 75) : Severe	2	5
Week 12 (n = 103, 67) :	31	0

Clear		
Week 12 (n = 103, 67) : Almost Clear	49	11
Week 12 (n = 103, 67) : Mild	19	35
Week 12 (n = 103, 67) : Moderate	4	19
Week 12 (n = 103, 67) : Severe	0	2
Week 16 (n = 99, 59) : Clear	38	0
Week 16 (n = 99, 59) : Almost Clear	42	12
Week 16 (n = 99, 59) : Mild	15	35
Week 16 (n = 99, 59) : Moderate	4	11
Week 16 (n = 99, 59) : Severe	0	1
Week 20 (n = 99, 50) : Clear	43	0
Week 20 (n = 99, 50) : Almost Clear	36	17
Week 20 (n = 99, 50) : Mild	18	24
Week 20 (n = 99, 50) : Moderate	2	8
Week 20 (n = 99, 50) : Severe	0	1
Week 24 (n = 99, 48) : Clear	45	4
Week 24 (n = 99, 48) :	36	21

Almost Clear		
Week 24 (n = 99, 48) : Mild	13	15
Week 24 (n = 99, 48) : Moderate	5	7
Week 24 (n = 99, 48) : Severe	0	1

Percentage of participants with IGA mod. 2011 0/1-response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

	Secukinumab	Fumaric acid (initial and maintenance therapy)
Number of Participants Analyzed [units: participants]	105	95
Percentage of participants with IGA mod. 2011 0/1-response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24 (units: Percentage of participants)		
Week 1	0	0
Week 2	5.7	0
Week 3	13.3	1.1
Week 4	34.3	1.1
Week 6	50.5	2.1
Week 8	66.7	4.2
Week 12	77.1	12.6
Week 16	80.0	14.7
Week 20	79.0	20.0
Week 24	81.0	28.4

Dermatology Life Quality Index (DLQI) at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

	Secukinumab	Fumaric acid (initial and maintenance therapy)
Number of Participants Analyzed [units: participants]	105	95
Dermatology Life Quality Index (DLQI) at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24 (units: Score on a scale) Mean ± Standard Deviation		
Week 1 (n = 105, 94)	13.9 ± 5.86	16.3 ± 6.44
Week 2 (n = 105, 91)	10.5 ± 6.22	15.3 ± 6.99
Week 3 (n = 105, 89)	8.4 ± 5.96	14.6 ± 7.01
Week 4 (n = 102, 84)	6.6 ± 5.13	13.8 ± 7.23
Week 6 (n = 98, 82)	5.3 ± 5.79	12.4 ± 7.24
Week 8 (n = 102, 77)	4.2 ± 4.75	11.0 ± 7.16
Week 12 (n = 103, 67)	3.1 ± 4.41	8.8 ± 7.10
Week 16 (n = 99, 59)	2.7 ± 3.95	6.8 ± 6.05
Week 20 (n = 98, 50)	2.5 ± 3.84	5.9 ± 5.67
Week 24 (n = 99, 48)	2.0 ± 3.58	5.4 ± 5.56

Percentage of participants with DLQI 0/1 response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24

	Secukinumab	Fumaric acid (initial and maintenance therapy)
Number of Participants Analyzed [units:	105	95

participants]		
Percentage of participants with DLQI 0/1 response at week 1, 2, 3, 4, 6, 8, 12, 16, 20 and 24 (units: Percentage of participants)		
Week 1	0	0
Week 2	3.8	1.1
Week 3	7.6	0
Week 4	19.0	2.1
Week 6	30.5	4.2
Week 8	40.0	6.3
Week 12	57.1	10.5
Week 16	59.0	14.7
Week 20	64.8	15.8
Week 24	71.4	25.3

Percentage of participants with Short Form 36 (SF-36) response at week 4, 16 and 24

	Secukinumab	Fumaric acid (initial and maintenance therapy)
Number of Participants Analyzed [units: participants]	105	95
Percentage of participants with Short Form 36 (SF-36) response at week 4, 16 and 24 (units: Percentage of participants)		
Physical Component Summary Week 4 (n= 97, 88)	38.1	26.1

Mental component summary Week 4 (n= 97, 88)	41.2	36.4
Physical functioning scale Week 4 (n= 102, 92)	24.5	19.6
Role physical scale Week 4 (n= 104, 93)	44.2	23.7
Bodily pain scale Week 4 (n= 105, 95)	53.3	31.6
General health scale Week 4 (n= 102, 95)	32.4	21.1
Vitality scale Week 4 (n= 104, 93)	31.7	20.4
Social functioning scale Week 4 (n= 102, 94)	39.2	27.7
Role emotional scale Week 4 (n= 104, 95)	41.3	34.7
Mental health scale Week 4 (n = 105, 95)	33.3	32.6
Physical Component Summary Week 16 (n= 97, 88)	52.6	39.8
Mental component summary Week 16 (n= 97, 88)	63.9	46.6
Physical functioning scale Week 16 (n= 102, 92)	36.3	31.5
Role physical scale Week 16 (n= 104, 93)	52.9	36.6
Bodily pain scale Week 16 (n= 105, 95)	63.8	45.3
General health scale Week 16 (n= 102, 95)	38.2	22.1

Vitality scale Week 16 (n= 104, 93)	45.2	23.7
Social functioning scale Week 16 (n= 102, 94)	57.8	41.5
Role emotional scale Week 16 (n= 104, 95)	56.7	43.2
Mental health scale Week 16 (n = 105, 95)	54.3	42.1
Physical Component Summary Week 24 (n= 97, 88)	57.7	43.2
Mental component summary Week 24 (n= 97, 88)	63.9	50.0
Physical functioning scale Week 24 (n= 102, 92)	38.2	31.5
Role physical scale Week 24 (n= 104, 93)	52.9	37.6
Bodily pain scale Week 24 (n= 105, 95)	64.8	49.5
General health scale Week 24 (n= 102, 95)	41.2	21.1
Vitality scale Week 24 (n= 104, 93)	48.1	29.0
Social functioning scale Week 24 (n= 102, 94)	63.7	45.7
Role emotional scale Week 24 (n= 104, 95)	54.8	41.1
Mental health scale Week 24 (n = 105, 95)	53.3	38.9

Summary of Safety

Safety Results

Serious Adverse Events by System Organ Class

Time Frame	Adverse Events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All Adverse events are reported in this record from First Patient First Treatment until Last Patient Last Visit.
Additional Description	The safety analysis set consisted of all patients who took at least one dose of study treatment during the treatment period.
Source Vocabulary for Table Default	MedDRA (19.0)
Assessment Type for Table Default	Systematic Assessment

	Secukinumab N = 105	Fumaric Acid (Initial and Maintenance Therapy) N = 95
Total participants affected	4 (3.81%)	4 (4.21%)
GASTROINTESTINAL DISORDERS		
ANAL HAEMORRHAGE	0 (0.00%)	1 (1.05%)
DIARRHOEA	0 (0.00%)	1 (1.05%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		
ASTHENIA	1 (0.95%)	0 (0.00%)
INFECTIONS AND INFESTATIONS		
PILONIDAL CYST	0 (0.00%)	1 (1.05%)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS		
CLAVICLE FRACTURE	1 (0.95%)	0 (0.00%)
METABOLISM AND NUTRITION DISORDERS		
DEHYDRATION	1 (0.95%)	0 (0.00%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)		
METASTASES TO CENTRAL NERVOUS SYSTEM	1 (0.95%)	0 (0.00%)
SMALL CELL LUNG	1 (0.95%)	0 (0.00%)

CANCER		
NERVOUS SYSTEM DISORDERS		
BRAIN OEDEMA	1 (0.95%)	0 (0.00%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		
PSORIASIS	0 (0.00%)	2 (2.11%)
VASCULAR DISORDERS		
THROMBOSIS	1 (0.95%)	0 (0.00%)

Other Adverse Events by System Organ Class

Time Frame	Adverse Events are collected from First Patient First Visit (FPFV) until Last Patient Last Visit (LPLV). All Adverse events are reported in this record from First Patient First Treatment until Last Patient Last Visit.
Additional Description	The safety analysis set consisted of all patients who took at least one dose of study treatment during the treatment period.
Source Vocabulary for Table Default	MedDRA (19.0)
Assessment Type for Table Default	Systematic Assessment
Frequent Event Reporting Threshold	5%

	Secukinumab N = 105	**Fumaric Acid (Initial and Maintenance Therapy) N = 95**
Total participants affected	75 (71.43%)	85 (89.47%)

BLOOD AND LYMPHATIC SYSTEM DISORDERS		
EOSINOPHILIA	1 (0.95%)	17 (17.89%)
LEUKOCYTOSIS	2 (1.90%)	5 (5.26%)
LEUKOPENIA	1 (0.95%)	5 (5.26%)
LYMPHOPENIA	2 (1.90%)	23 (24.21%)
GASTROINTESTINAL DISORDERS		
ABDOMINAL DISTENSION	1 (0.95%)	6 (6.32%)
ABDOMINAL PAIN	2 (1.90%)	11 (11.58%)
ABDOMINAL PAIN UPPER	3 (2.86%)	37 (38.95%)
DIARRHOEA	7 (6.67%)	48 (50.53%)
FLATULENCE	0 (0.00%)	5 (5.26%)
NAUSEA	3 (2.86%)	20 (21.05%)
VOMITING	2 (1.90%)	7 (7.37%)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS		
FATIGUE	4 (3.81%)	6 (6.32%)
INFECTIONS AND INFESTATIONS		
NASOPHARYNGITIS	54 (51.43%)	40 (42.11%)
URINARY TRACT INFECTION	6 (5.71%)	3 (3.16%)
INVESTIGATIONS		
BLOOD CREATININE	1 (0.95%)	6 (6.32%)

INCREASED		
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS		
ARTHRALGIA	6 (5.71%)	4 (4.21%)
NERVOUS SYSTEM DISORDERS		
HEADACHE	15 (14.29%)	15 (15.79%)
RENAL AND URINARY DISORDERS		
HAEMATURIA	6 (5.71%)	3 (3.16%)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS		
PRURITUS	7 (6.67%)	8 (8.42%)
VASCULAR DISORDERS		
FLUSHING	1 (0.95%)	34 (35.79%)
HOT FLUSH	1 (0.95%)	7 (7.37%)
HYPERTENSION	6 (5.71%)	1 (1.05%)

Other Relevant Findings

Not applicable

Conclusion:

Results from this study demonstrate superior efficacy, health-related quality of life and tolerability for secukinumab compared to Fumaric Acid in systemic treatment-naïve patients with moderate to severe plaque psoriasis.

Date of Clinical Trial Report

April 11, 2017