NovartisClinicalTrialResults:

Sponsor

Novartis

Generic Drug Name

Secukinumab

Therapeutic Area of Trial

Moderate to severe plaque psoriasis

Approved Indication

Investigational

Protocol Number

CAIN457A2303

Protocol Title

A randomized, double-blind, double-dummy, placebo controlled, multicenter study of subcutaneous secukinumab to demonstrate efficacy after twelve weeks of treatment, compared to placebo and etanercept, and to assess the safety, tolerability and long-term efficacy up to one year in subjects with moderate to severe chronic plaque-type psoriasis.

FIXTURE (Full year Investigative eXamination of secukinumab vs. eTanercept Using 2 dosing Regimens to determine Efficacy in psoriasis)

Study Phase

Phase III

Study Start / End Dates

First patient enrolled: 14-Jun-2011

Last patient completed: 07-Jul-2013

Study Design / Methodology

This was a multicenter, double-blind, double-dummy, randomized, parallel-group, active and placebo-controlled study in approximately 1264 patients with moderate to severe chronic plaque-type psoriasis.

Patients were randomized in a 1:1:1:1 ratio (stratified by geographical region and body weight) to any of the following 4 treatment groups: Etanercept active comparator group, secukinumab 150 mg regimen group, secukinumab 300 mg regimen group, or placebo group. Patients in the placebo group were assigned to the following treatment groups based on their PASI 75 response status at Week 12: PASI 75 responders continued on placebo, whereas PASI 75 non-responders were re-randomized 1:1 to receive 150 mg or 300 mg secukinumab.

Centers

All Centers

231 centers in 26 countries (Argentina 7 centers, Australia 4 centers, Belgium 6 centers, Brazil 6 centers, Canada 15 centers, Colombia 6 centers, Egypt 1 center, Finland 2 centers, France 8 centers, Germany 42 centers, Guatemala 5 centers, Hungary 9 centers, Iceland 1 center, India 13 centers, Italy 8 centers, Philippines 2 centers, Poland 4 centers, Republic of Korea 12 centers, Romania 5 centers, Russian Federation 11 centers, Singapore 2 centers, Spain 7 centers, Sweden 4 centers, Turkey 5 centers, United Kingdom [UK] 9 centers, United States [US] 37 centers).

Randomized Patient Centers

154 centers in 23 countries have randomized patients in the study (Argentina 7 centers, Australia 4 centers, Belgium 4 centers, Canada 8 centers, Colombia 3 centers, Egypt 1 center, Finland 2 centers, France 7 centers, Germany 36 centers, Guatemala 5 centers, Hungary 7 centers, Iceland 1 center, India 12 centers, Italy 5 centers, Philippines 2 centers, Poland 4 centers, Republic of Korea 10 centers, Romania 4 centers, Singapore 1 center, Spain 6 centers, Sweden 4 centers, United Kingdom [UK] 7 centers, United States [US] 14 centers)

Publication

Langley,G, Elewski, B et al (2014) Secukinumab in plaque psoriasis-Results of two phase three trials. N Engl J Med. Jul 24; 371(4): 326-38

Objectives:

The primary objective of this study was to demonstrate the superiority of secukinumab in subjects with moderate to severe chronic 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 endpoints) at Week 12, compared to placebo.

The key secondary objectives of this study were to demonstrate:

- The superiority of secukinumab in subjects with moderate to severe chronic plaque-type psoriasis with respect to PASI 90 response at Week 12, compared to placebo.
- The non-inferiority of secukinumab in subjects with moderate to severe chronic plaque-type psoriasis with respect to PASI 75 response at Week 12, compared to etanercept.
- The superiority of secukinumab in subjects with moderate to severe chronic plaque-type psoriasis with respect to PASI 75 response and IGA mod 2011 0 or 1 response at Week 12, compared to etanercept.
- The superiority of secukinumab in maintaining PASI 75 response at Week 52 for subjects who were PASI 75 responders at Week 12, compared to etanercept.
- The superiority of secukinumab in maintaining IGA mod 2011 0 or 1 response at Week 52 for subjects who were IGA mod 2011 0 or 1 responders at Week 12, compared to etanercept.
- Superiority of secukinumab in subjects with moderate to severe chronic plaque-type psoriasis with respect to psoriasis-related itching, pain and scaling as measured by the Psoriasis Diary at Week 12, compared to placebo.

Other secondary objectives included additional assessments of PASI and IGA mod 2011 0 or 1 responses up to Week 12 (vs. placebo and etanercept) and up to Week 52 (vs. etanercept), psoriasis-related itching, pain, and scaling measured by the Psoriasis Diary at Week 12 (vs. etanercept), EuroQOL 5-Dimension Health Status Questionnaire (EQ-5D) score at Week 12 (vs. placebo and etanercept) and Week 52 (vs. etanercept), Dermatology Life Quality Index (DLQI) at Week 12 (vs. placebo and etanercept) and over time up to Week 52 (vs. etanercept), DLQI 0 or 1 achievement at Week 12 (vs. placebo and etanercept) and over time up to Week 52 (vs. etanercept), the clinical safety and tolerability of secukinumab as assessed by vital signs, clinical laboratory variables, electrocardiograms (ECGs), and adverse event (AE) monitoring, the development of immunogenicity against secukinumab, and the relationship between response to secukinumab treatment and having failed to respond to previous biologic psoriasis therapy.

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

The investigational treatment was secukinumab (AIN457) 150 mg, provided in glass vials each containing powder for solution for injection. The 150 mg powder for solution was used to prepare both the 150 mg dose (1 vial for 1 s.c. injection) and the 300 mg dose (2 vials for 2 s.c. injections).

Statistical Methods

Statistical analyses of efficacy variables were performed on an intent-to-treat basis, involving all randomized patients who were assigned to study treatment (Full analysis set, FAS). Baseline characteristics were analyzed for all randomized patients. Safety analyses were performed for all randomized patients who received at least 1 dose of study treatment (Safety set).

A sequentially rejective testing strategy was used to evaluate the study hypotheses for co-primary and key secondary variables while retaining a family-wise type I error of 5%.

The statistical hypothesis for the co-primary efficacy variable (PASI 75 response at Week 12 and IGA mod 2011 0 or 1 response at Week 12) being tested was that there was no difference in the proportion of patients with PASI 75 response and IGA mod 2011 0 or 1 response at Week 12 in any of the secukinumab groups vs. placebo.

For the key secondary efficacy variables, the hypotheses were included in the testing strategy. These were:

- Secukinumab150 mg and secukinumab 300 mg are not different to placebo with respect to PASI 90 response at Week 12.
- Secukinumab150 mg and secukinumab 300 mg are not non-inferior to etanercept with respect to PASI 75 response at Week 12.
- Secukinumab150 mg and secukinumab 300 mg are not superior to etanercept with respect to PASI 75 response at Week 12.
- Secukinumab150 mg and secukinumab 300 mg are not superior to etanercept with respect to IGA mod 2011 0 or 1 response at Week 12.
- Secukinumab150 mg and secukinumab 300 mg are not superior to etanercept in maintaining PASI 75 response at Week 52 for subjects who were PASI 75 responders at Week 12.
- Secukinumab150 mg and secukinumab 300 mg are not superior to etanercept in maintaining IGA mod 2011 0 or 1 response at Week 52 for subjects who were IGA mod 2011 0 or 1 responders at Week 12.
- Secukinumab150 mg and secukinumab 300 mg are not different to placebo with respect to absolute changes from baseline in Psoriasis Diary items pain, itching, and scaling at Week 12.

For response efficacy variables, the Cochran-Mantel-Haenszel (CMH)-test was performed for pairwise comparisons of secukinumab dose regimens vs. placebo or etanercept.

For the non-inferiority comparison with regards to PASI 75 response at Week 12, the stratified Mantel-Haenszel risk difference for each secukinumab dose minus etanercept and the associated confidence interval (CI) was calculated and compared to the pre-set non-inferiority margin Δ of 10%.

The tests were stratified by geographical region and body weight stratum.

Between-treatment differences for maintenance of PASI 75 response and IGA mod 2011 0 or 1 response after 52 weeks of treatment for patients who were responders after 12 weeks of treatment were evaluated for loss of response using a log-rank test, stratified by geographical region and body weight stratum.

Missing values for the response variables were imputed with non-response, regardless of the reason of missing data.

The absolute changes from baseline to the Week 12 for the Psoriasis Diary items pain, itching, and scaling were analyzed in separate analyses of covariance (ANCOVAs) with treatment, geographical region and body weight stratum as explanatory variables and baseline value as covariate.

Treatment-emergent AEs were coded using Medical Dictionary for Regulatory Activities (MedDRA) version 16.0 and summarized by presenting the number and percentage of patients having any AE, having an AE in each primary system organ class (SOC), and having each individual AE. AEs were also summarized by standardized MedDRA query using a narrow search.

Descriptive summary statistics for the change from baseline to each study visit were presented by laboratory test and treatment group. In addition, laboratory parameters were analyzed with respect to Common Terminology Criteria for Adverse Events (CTCAE) grades.

No interim analysis was planned.

Study Population: Key Inclusion/Exclusion Criteria

The study population consisted of a representative group of male and female out-patients (≥18 years old) with moderate to severe chronic plaque-type psoriasis that was poorly controlled by topical treatments and/or phototherapy and/or previous systemic therapy. Chronic plaque-type psoriasis had to be diagnosed for at least 6 months before randomization. At randomization, psoriasis had to be moderate to severe, with a PASI score of ≥12, IGA mod 2011 score of ≥3 (based on a scale of 0 – 4), and a body surface area (BSA) affected by plaque-type psoriasis of ≥10%.

Additional important exclusion criteria included ongoing inflammatory diseases other than psoriasis, underlying immune-compromising conditions, significant medical problems (such as uncontrolled hypertension [systolic blood pressure (BP) ≥160 mmHg and/or diastolic BP ≥95 mmHg] or congestive heart failure [New York Heart Association status of class III or IV]), active systemic infections during the last 2 weeks (exception: common cold) prior to randomization and any infections that reoccurred on a regular basis, and history of ongoing, chronic or recurrent infectious disease (e.g. tuberculosis, human immunodeficiency virus [HIV], hepatitis B or hepatitis C, lymphoproliferative disease/known malignancy or history of malignancy). Patients with a serum creatinine level exceeding 176.8 µmol/L (2.0 mg/dL) and patients with a total white blood cell count (WBC) <2500/µL, platelets <100,000/µL, neutrophils <1500/µL, or hemoglobin <8.5 g/dL at screening were also excluded from the study.

Participant Flow Table

Induction period subject disposition
Randomized set

Disposition /Reason	AIN457 150 mg N=327 n (%)	AIN457 300 mg N=327 n (%)	Placebo N=326 n (%)	Etanercept N=326 n (%)	Total N=1306 n (%)
Randomized	327	327	326	326	1306 (100.00)
Completed Induction	315 (96.3)	312 (95.4)	301 (92.3)	305 (93.6)	1233 (94.41)
Discontinued Induction	12 (3.7)	15 (4.6)	25 (7.7)	21 (6.4)	73 (5.59)
Adverse event	2 (0.6)	4 (1.2)	2 (0.6)	6 (1.8)	14 (1.07)
Lack of efficacy	0 (0.0)	0 (0.0)	9 (2.8)	1 (0.3)	10 (0.77)
Lost to follow-up	0 (0.0)	0 (0.0)	1 (0.3)	4 (1.2)	5 (0.38)
Non-compliance with study treatment	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.00)
Physician decision	2 (0.6)	1 (0.3)	2 (0.6)	0 (0.0)	5 (0.38)
Pregnancy	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.00)
Protocol deviation	3 (0.9)	5 (1.5)	0 (0.0)	3 (0.9)	11 (0.84)

Disposition /Reason	AIN457 150 mg N=327 n (%)	AIN457 300 mg N=327 n (%)	Placebo N=326 n (%)	Etanercept N=326 n (%)	Total N=1306 n (%)
No longer requires treatment	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.00)
Study terminated by sponsor	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.00)
Technical problems	0 (0.0)	0 (0.0)	1 (0.3)	1 (0.3)	2 (0.15)
Subject/guardian decision	5 (1.5)	5 (1.5)	10 (3.1)	6 (1.8)	26 (1.99)
Death	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.00)

Maintenance period subject disposition
Randomized set

Disposition /Reason	AIN457 150 mg N=327 n (%)	AIN457 300 mg N=327 n (%)	Placebo - AIN457 150 mg N=142 n (%)	Placebo - AIN457 300 mg N=142 n (%)
Randomized	327	327	142	142

Entered Maintenance	315 (96.3)	312 (95.4)	142 (100.0)	142 (100.0)
Completed Maintenance	276 (84.4)	290 (88.7)	125 (88.0)	131 (92.3)
Discontinued Maintenance	39 (11.9)	22 (6.7)	17 (12.0)	11 (7.7)
Adverse event	2 (0.6)	7 (2.1)	4 (2.8)	3 (2.1)
Lack of efficacy	10 (3.1)	2 (0.6)	3 (2.1)	0 (0.0)
Lost to follow-up	4 (1.2)	0 (0.0)	1 (0.7)	1 (0.7)
Non-compliance with study treatment	3 (0.9)	1 (0.3)	1 (0.7)	2 (1.4)
Physician decision	0 (0.0)	1 (0.3)	0 (0.0)	0 (0.0)
Pregnancy	1 (0.3)	0 (0.0)	0 (0.0)	0 (0.0)
Protocol deviation	7 (2.1)	4 (1.2)	2 (1.4)	2 (1.4)
No longer requires treatment	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Study terminated by sponsor	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Technical problems	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Subject/guardian decision	12 (3.7)	7 (2.1)	6 (4.2)	3 (2.1)

Death	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Maintenance period subject disposition
Randomized set

Disposition /Reason	Placebo N=17 n (%)	Etanercept N=326 n (%)	Total N=1281 n (%)
Randomized	17	326	1281
Entered Maintenance	17 (100.0)	305 (93.6)	1233 (96.25)
Completed Maintenance	15 (88.2)	263 (80.7)	1100 (85.87)
Discontinued Maintenance	2 (11.8)	42 (12.9)	133 (10.38)
Adverse event	0 (0.0)	6 (1.8)	22 (1.72)
Lack of efficacy	0 (0.0)	11 (3.4)	26 (2.03)
Lost to follow-up	0 (0.0)	5 (1.5)	11 (0.86)
Non-compliance with study treatment	0 (0.0)	2 (0.6)	9 (0.70)
Physician decision	0 (0.0)	1 (0.3)	2 (0.16)

Disposition /Reason	Placebo N=17 n (%)	Etanercept N=326 n (%)	Total N=1281 n (%)
Pregnancy	0 (0.0)	0 (0.0)	1 (0.08)
Protocol deviation	0 (0.0)	2 (0.6)	17 (1.33)
No longer requires treatment	0 (0.0)	0 (0.0)	0 (0.00)
Study terminated by sponsor	0 (0.0)	0 (0.0)	0 (0.00)
Technical problems	0 (0.0)	0 (0.0)	0 (0.00)
Subject/guardian decision	2 (11.8)	15 (4.6)	45 (3.51)
Death	0 (0.0)	0 (0.0)	0 (0.00)

Follow-up period subject disposition
(Randomized set - Subjects of follow-up period)

Disposition/Reason	Any AIN457 150 mg N=148 n (%)	Any AIN457 300 mg N=125 n (%)	Any AIN457 dose N=273 n (%)	Placebo N=26 n (%)	Etanercept N=279 n (%)	Total N=578 n (%)
Entered Follow-up[a]	148	125	273	26	279	578
Completed Maintenance	111 (75.0)	100 (80.0)	211 (77.3)	13 (50.0)	246 (88.2)	470 (81.3)
Completed Follow up	138 (93.2)	119 (95.2)	257 (94.1)	21 (80.8)	260 (93.2)	538 (93.1)
Discontinued Follow up	10 (6.8)	6 (4.8)	16 (5.9)	5 (19.2)	19 (6.8)	40 (6.9)
Adverse event[b]	1 (0.7)	1 (0.8)	2 (0.7)	0 (0.0)	0 (0.0)	2 (0.3)
Lack of efficacy	3 (2.0)	0 (0.0)	3 (1.1)	4 (15.4)	1 (0.4)	8 (1.4)
Lost to follow-up	0 (0.0)	1 (0.8)	1 (0.4)	0 (0.0)	4 (1.4)	5 (0.9)
Non-compliance with study treatment[c]	1 (0.7)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.2)
Physician decision	1 (0.7)	1 (0.8)	2 (0.7)	0 (0.0)	2 (0.7)	4 (0.7)
Pregnancy	1 (0.7)	0 (0.0)	1 (0.4)	0 (0.0)	0 (0.0)	1 (0.2)
Patient/guardian decision	3 (2.0)	3 (2.4)	6 (2.2)	1 (3.8)	12 (4.3)	19 (3.3)

Baseline Characteristics

Demographics and background characteristics
induction treatment groups
Randomized set

Demographic variable	AIN457 150 mg N=327	AIN457 300 mg N=327	Placebo N=326	Etanercept N=326	Total N=1306
Age group in years, n(%)					

< 65	304 (93.0)	305 (93.3)	311 (95.4)	308 (94.5)	1228 (94.03)
>= 65	23 (7.0)	22 (6.7)	15 (4.6)	18 (5.5)	78 (5.97)
>= 75	5 (1.5)	3 (0.9)	5 (1.5)	3 (0.9)	16 (1.23)
Age (Years)					
n	327	327	326	326	1306
Mean	45.4	44.5	44.1	43.8	44.4
SD	12.92	13.19	12.64	12.95	12.93
Median	45.0	45.0	44.0	44.0	45.0
Min - Max	18 - 79	20 - 79	18 - 82	18 - 79	18 - 82
Gender, n(%)					
Female	91 (27.8)	103 (31.5)	89 (27.3)	94 (28.8)	377 (28.87)
Male	236 (72.2)	224 (68.5)	237 (72.7)	232 (71.2)	929 (71.13)
Race, n(%)					
Caucasian	219 (67.0)	224 (68.5)	218 (66.9)	219 (67.2)	880 (67.38)
Black	3 (0.9)	2 (0.6)	3 (0.9)	0 (0.0)	8 (0.61)
Asian	72 (22.0)	73 (22.3)	72 (22.1)	74 (22.7)	291 (22.28)
Native American	28 (8.6)	22 (6.7)	25 (7.7)	27 (8.3)	102 (7.81)
Pacific Islander	0 (0.0)	1 (0.3)	1 (0.3)	1 (0.3)	3 (0.23)
Unknown	0 (0.0)	0 (0.0)	2 (0.6)	1 (0.3)	3 (0.23)

Other	5 (1.5)	5 (1.5)	5 (1.5)	4 (1.2)	19 (1.45)
Ethnicity, n(%)					
Hispanic or Latino	46 (14.1)	42 (12.8)	47 (14.4)	51 (15.6)	186 (14.24)
East Asian	16 (4.9)	15 (4.6)	18 (5.5)	25 (7.7)	74 (5.67)
Southeast Asian	19 (5.8)	13 (4.0)	7 (2.1)	14 (4.3)	53 (4.06)
South Asian	36 (11.0)	40 (12.2)	45 (13.8)	32 (9.8)	153 (11.72)
West Asian	0 (0.0)	3 (0.9)	0 (0.0)	1 (0.3)	4 (0.31)
Russian	1 (0.3)	3 (0.9)	2 (0.6)	2 (0.6)	8 (0.61)
Mixed ethnicity	5 (1.5)	9 (2.8)	6 (1.8)	4 (1.2)	24 (1.84)
Other	174 (53.2)	167 (51.1)	163 (50.0)	171 (52.5)	675 (51.68)
Unknown	13 (4.0)	18 (5.5)	21 (6.4)	17 (5.2)	69 (5.28)
Not reported	17 (5.2)	17 (5.2)	17 (5.2)	9 (2.8)	60 (4.59)
Height (cm)					
n	327	325	326	324	1302
Mean	171.09	170.50	171.08	171.15	170.96
SD	10.389	9.826	10.439	10.579	10.304
Median	171.00	170.00	172.00	172.00	171.00
Min - Max	145.0 - 196.0	145.0 - 198.5	141.0 - 200.6	144.0 - 198.0	141.0 - 200.6

Weight (kg)					
n	327	327	326	326	1306
Mean	83.61	82.96	82.04	84.55	83.29
SD	20.803	21.591	20.394	20.512	20.827
Median	82.00	80.90	80.00	81.67	81.00
Min - Max	43.1 - 162.9	45.0 - 219.1	42.0 - 147.7	42.0 - 175.6	42.0 - 219.1
BMI (kg/m**2)					
n	327	325	326	324	1302
Mean	28.40	28.39	27.89	28.71	28.34
SD	5.898	6.444	6.077	5.921	6.089
Median	27.40	27.61	26.98	27.63	27.46
Min - Max	17.9 - 50.4	17.4 - 67.4	17.2 - 59.6	15.4 - 58.3	15.4 - 67.4
Current smoker at baseline, n (%)					
No	215 (65.7)	205 (62.7)	218 (66.9)	216 (66.3)	854 (65.39)
Yes	112 (34.3)	122 (37.3)	108 (33.1)	110 (33.7)	452 (34.61)

Demographics and background characteristics
maintenance treatment groups
Randomized set

Demographic variable	AIN457 150 mg N=327	AIN457 300 mg N=327	Placebo - AIN457 150 mg N=142	Placebo - AIN457 300 mg N=142	Placebo N=17	Etanercept N=326	Total N=1281
Age group in years, n(%)							
< 65	304 (93.0)	305 (93.3)	137 (96.5)	133 (93.7)	17 (100.0)	308 (94.5)	1204 (93.99)
>= 65	23 (7.0)	22 (6.7)	5 (3.5)	9 (6.3)	0 (0.0)	18 (5.5)	77 (6.01)
>= 75	5 (1.5)	3 (0.9)	2 (1.4)	3 (2.1)	0 (0.0)	3 (0.9)	16 (1.25)
Age (Years)							
n	327	327	142	142	17	326	1281
Mean	45.4	44.5	43.5	45.0	46.1	43.8	44.5
SD	12.92	13.19	12.31	13.15	13.03	12.95	12.96
Median	45.0	45.0	43.5	45.0	51.0	44.0	45.0
Min - Max	18 - 79	20 - 79	18 - 82	19 - 82	20 - 64	18 - 79	18 - 82

Gender, n(%)							
Female	91 (27.8)	103 (31.5)	32 (22.5)	43 (30.3)	5 (29.4)	94 (28.8)	368 (28.73)
Male	236 (72.2)	224 (68.5)	110 (77.5)	99 (69.7)	12 (70.6)	232 (71.2)	913 (71.27)
Race, n(%)							
Caucasian	219 (67.0)	224 (68.5)	98 (69.0)	96 (67.6)	7 (41.2)	219 (67.2)	863 (67.37)
Black	3 (0.9)	2 (0.6)	2 (1.4)	1 (0.7)	0 (0.0)	0 (0.0)	8 (0.62)
Asian	72 (22.0)	73 (22.3)	29 (20.4)	29 (20.4)	8 (47.1)	74 (22.7)	285 (22.25)
Native American	28 (8.6)	22 (6.7)	11 (7.7)	12 (8.5)	2 (11.8)	27 (8.3)	102 (7.96)
Pacific Islander	0 (0.0)	1 (0.3)	1 (0.7)	0 (0.0)	0 (0.0)	1 (0.3)	3 (0.23)
Unknown	0 (0.0)	0 (0.0)	1 (0.7)	1 (0.7)	0 (0.0)	1 (0.3)	3 (0.23)
Other	5 (1.5)	5 (1.5)	0 (0.0)	3 (2.1)	0 (0.0)	4 (1.2)	17 (1.33)
Ethnicity, n(%)							

Hispanic or Latino	46 (14.1)	42 (12.8)	19 (13.4)	22 (15.5)	3 (17.6)	51 (15.6)	183 (14.29)
East Asian	16 (4.9)	15 (4.6)	8 (5.6)	7 (4.9)	1 (5.9)	25 (7.7)	72 (5.62)
Southeast Asian	19 (5.8)	13 (4.0)	4 (2.8)	2 (1.4)	0 (0.0)	14 (4.3)	52 (4.06)
South Asian	36 (11.0)	40 (12.2)	16 (11.3)	20 (14.1)	6 (35.3)	32 (9.8)	150 (11.71)
West Asian	0 (0.0)	3 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.3)	4 (0.31)
Russian	1 (0.3)	3 (0.9)	0 (0.0)	1 (0.7)	0 (0.0)	2 (0.6)	7 (0.55)
Mixed ethnicity	5 (1.5)	9 (2.8)	4 (2.8)	2 (1.4)	0 (0.0)	4 (1.2)	24 (1.87)
Other	174 (53.2)	167 (51.1)	79 (55.6)	67 (47.2)	4 (23.5)	171 (52.5)	662 (51.68)
Unknown	13 (4.0)	18 (5.5)	3 (2.1)	13 (9.2)	3 (17.6)	17 (5.2)	67 (5.23)
Not reported	17 (5.2)	17 (5.2)	9 (6.3)	8 (5.6)	0 (0.0)	9 (2.8)	60 (4.68)
Height (cm)							
n	327	325	142	142	17	324	1277
Mean	171.09	170.50	171.77	171.21	167.94	171.15	171.00

SD	10.389	9.826	10.441	9.793	11.925	10.579	10.253
Median	171.00	170.00	173.00	172.00	167.00	172.00	171.00
Min - Max	145.0 - 196.0	145.0 - 198.5	147.0 - 198.0	141.0 - 193.0	149.9 - 193.0	144.0 - 198.0	141.0 - 198.5

Weight (kg)

n	327	327	142	142	17	326	1281
Mean	83.61	82.96	84.73	80.72	78.06	84.55	83.41
SD	20.803	21.591	20.751	20.477	16.355	20.512	20.845
Median	82.00	80.90	82.00	79.20	76.80	81.67	81.00
Min - Max	43.1 - 162.9	45.0 - 219.1	43.0 - 147.7	47.0 - 147.4	57.2 - 124.7	42.0 - 175.6	42.0 - 219.1

BMI (kg/m**2)

n	327	325	142	142	17	324	1277
Mean	28.40	28.39	28.55	27.46	27.41	28.71	28.37
SD	5.898	6.444	5.889	6.583	2.554	5.921	6.095
Median	27.40	27.61	27.31	26.66	26.57	27.63	27.47
Min - Max	17.9 - 50.4	17.4 - 67.4	19.0 - 48.8	17.5 - 59.6	23.5 - 33.5	15.4 - 58.3	15.4 - 67.4

Current smoker at baseline, n (%)

No	215 (65.7)	205 (62.7)	95 (66.9)	98 (69.0)	9 (52.9)	216 (66.3)	838 (65.42)
Yes	112 (34.3)	122 (37.3)	47 (33.1)	44 (31.0)	8 (47.1)	110 (33.7)	443 (34.58)

Summary of Efficacy

Primary Outcome Result(s)

Statistical analysis (Cochran-Mantel-Haenszel test) of IGA mod 2011 0 or 1 and PASI 75 response at Week 12 for secukinumab vs. placebo (non-responder imputation) (Full analysis set)

Response criterion	Treatment comparison "test" vs. "control"	"Test" n/m (%)	"Control" n/m (%)	Odds ratio estimate (95%CI)	p-value
IGA mod 2011 0 or 1	AIN457 150 mg vs. placebo	167/327 (51.1)	9/324 (2.8)	40.62 (19.80, 83.35)	<0.0001
	AIN457 300 mg vs. placebo	202/323 (62.5)	9/324 (2.8)	79.13 (35.97, 174.09)	<0.0001
PASI 75	AIN457 150 mg vs. placebo	219/327 (67.0)	16/324 (4.9)	42.76 (23.57, 77.60)	<0.0001
	AIN457 300 mg vs. placebo	249/323 (77.1)	16/324 (4.9)	65.95 (36.07, 20.59)	<0.0001

IGA mod 2011 = Investigator's global assessment modified 2011, m=number of evaluable subjects, n=number of subjects with response, PASI = psoriasis area and severity index.

Secondary Outcome Result(s):

Non-inferiority analysis (Mantel-Haenszel risk difference) of PASI 75 response at Week 12 (non-responder imputation) (Full analysis set)

Response criterion	Comparison "test" vs. "control"	"Test" n/m (%)	"Control" n/m (%)	Mantel-Haenszel risk difference		
				Estimate (%)	Confidence level (1-sided)	CI
PASI 75	AIN457 150 mg vs. Etanercept	219/327 (67.0)	142/323 (44.0)	23.12	initial 99.375% adjusted 99.375%	(14.06, 32.19)
	AIN457 300 mg vs. Etanercept	249/323 (77.1)	142/323 (44.0)	32.80	initial 99.375% adjusted 99.375%	(24.06, 41.53)

CI = confidence interval, m=number of subjects evaluable, n=number of subjects with response, PASI = psoriasis area and severity index.
Non-inferiority margin is 10%.

Statistical analysis (Cochran-Mantel-Haenszel test) of PASI 90 response at Week 12 (non-responder imputation) (Full analysis set)

Response criterion	Treatment comparison "test" vs. "control"	"Test" n/m (%)	"Control" n/m (%)	Odds ratio estimate (95%CI)	p-value
PASI 90	AIN457 150 mg vs. placebo	137/327 (41.9)	5/324 (1.5)	56.10 (21.41, 147.03)	<0.0001
	AIN457 300 mg vs. placebo	175/323 (54.2)	5/324 (1.5)	118.48 (41.34, 339.58)	<0.0001
	AIN457 150 mg vs. etanercept	137/327 (41.9)	67/323 (20.7)	2.86 (2.01, 4.07)	<0.0001
	AIN457 300 mg vs. etanercept	175/323 (54.2)	67/323 (20.7)	4.67 (3.28, 6.66)	<0.0001

m=number of evaluable subjects, n=number of subjects with response, PASI = psoriasis area and severity index.

Statistical analysis (Cochran-Mantel-Haenszel test) of IGA mod 2011 0 or 1 and PASI 75 response at Week 12 for secukinumab vs. etanercept (non-responder imputation) (Full analysis set)

Response criterion	Treatment comparison "test" vs. "control"	"Test" n/m (%)	"Control" n/m (%)	Odds ratio estimate (95%CI)	p-value
IGA mod 2011 0 or 1	AIN457 150 mg vs. etanercept	167/327 (51.1)	88/323 (27.2)	2.96 (2.11, 4.15)	<0.0001
	AIN457 300 mg vs. etanercept	202/323 (62.5)	88/323 (27.2)	4.91 (3.46, 6.97)	<0.0001
PASI 75	AIN457 150 mg vs. etanercept	219/327 (67.0)	142/323 (44.0)	2.73 (1.96, 3.79)	<0.0001
	AIN457 300 mg vs. etanercept	249/323 (77.1)	142/323 (44.0)	4.69 (3.28, 6.70)	<0.0001

IGA mod 2011 = Investigator's global assessment modified 2011, m=number of evaluable subjects, n=number of subjects with response, PASI = psoriasis area and severity index.

Maintenance of PASI 75 response at Week 52 for subjects who were PASI 75 responders at Week 12 (non-responder imputation) Full analysis set

	Statistic	AIN457 150 mg (N=327)	AIN457 300 mg (N=327)	Etanercept (N=326)
PASI 75 response at Week 12	n	219	249	142
Maintained PASI 75 response at Week 52	n evaluable	219	249	142
	n (%)	180 (82.2)	210 (84.3)	103 (72.5)
	95 % CI	(76.3, 86.9)	(79.1, 88.5)	(64.3, 79.5)
Loss of PASI 75 response	Hazard Ratio AIN vs Etanercept (COX PH)(95%CI)	0.568 (0.380, 0.848)	0.301 (0.191, 0.474)	
	p-value (Log-Rank test)	0.0088	<.0001	
	p-value (Wilcoxon test)	0.0321	<.0001	
	cumulative rate (95% CI)	22.5 (17.5, 28.7)	11.9 (8.4, 16.8)	33.8 (26.6, 42.5)
	lower quartile time (95% CI)(days)	310 (196, -)	- (-, -)	141 (60, 225)
	median time (95% CI)(days)	310 (310, -)	- (-, -)	- (290, -)
	upper quartile time (95% CI)(days)	- (310, -)	- (-, -)	- (-, -)

Maintenance of IGA mod 2011 0 or 1 response at Week 52 for subjects who were IGA mod 2011 0 or 1 responders at Week 12 (non-responder imputation)

	Statistic	AIN457 150 mg (N=327)	AIN457 300 mg (N=327)	Etanercept (N=326)
IGA mod 2011 0 or 1 response at Week	n	167	202	88
Maintained IGA mod 2011 0 or 1 response at Week 52	n evaluable	167	202	88
	n (%)	113 (67.7)	161 (79.7)	50 (56.8)
	95 % CI	(59.9, 74.6)	(73.4, 84.9)	(45.8, 67.2)
Loss of IGA mod 2011 0 or 1 response	Hazard ratio AIN457 vs. etanercept (95% CI)	0.55 (0.38, 0.80)	0.33 (0.22, 0.49)	-
	p-value (Log-rank test)	0.0022	<0.0001	-
	p-value (Wilcoxon test)	0.0103	<0.0001	-
	Cumulative rate (95% CI)	37.6 (30.6, 45.6)	23.5 (18.1, 30.1)	56.9 (46.4, 67.8)

Analysis of covariance for absolute change from baseline to Week 12 in Psoriasis Diary items itching, pain and scaling
Full analysis set

Item	Treatment comparison "test" vs. "control"	"test" n mean change (SE)	"control" n mean change (SE)	Treatment contrast in LS mean estimate (SE) (95% CI)	p-value
itching	AIN457 150 mg vs. Placebo	n=117 -4.92 (0.249)	n=109 -0.54 (0.201)	-4.00 (0.283) (-4.56,-3.45)	<0.0001
	AIN457 300 mg vs. Placebo	n=117 -4.93 (0.247)	n=109 -0.54 (0.201)	-4.21 (0.282) (-4.76,-3.65)	<0.0001
	AIN457 150 mg vs. Etanercept	n=117 -4.92 (0.249)	n=116 -3.80 (0.257)	-0.94 (0.277) (-1.48,-0.40)	0.0008
	AIN457 300 mg vs. Etanercept	n=117 -4.93 (0.247)	n=116 -3.80 (0.257)	-1.14 (0.278) (-1.69,-0.60)	<0.0001
pain	AIN457 150 mg vs. Placebo	n=117 -4.10 (0.277)	n=109 -0.33 (0.216)	-3.30 (0.275) (-3.84,-2.76)	<0.0001

Item	Treatment comparison "test" vs. "control"	"test" n mean change (SE)	"control" n mean change (SE)	Treatment contrast in LS mean estimate (SE) (95% CI)	p-value
	AIN457 300 mg vs. Placebo	n=117 -4.48 (0.278)	n=109 -0.33 (0.216)	-3.76 (0.275) (-4.30,-3.22)	<0.0001
	AIN457 150 mg vs. Etanercept	n=117 -4.10 (0.277)	n=116 -3.48 (0.251)	-0.54 (0.268) (-1.06,-0.01)	0.0467
	AIN457 300 mg vs. Etanercept	n=117 -4.48 (0.278)	n=116 -3.48 (0.251)	-0.99 (0.269) (-1.52,-0.47)	0.0002
scaling	AIN457 150 mg vs. Placebo	n=117 -4.89 (0.241)	n=109 -0.42 (0.217)	-4.10 (0.279) (-4.65,-3.55)	<0.0001
	AIN457 300 mg vs. Placebo	n=117 -4.93 (0.258)	n=109 -0.42 (0.217)	-4.47 (0.278) (-5.01,-3.92)	<0.0001

Item	Treatment comparison "test" vs. "control"	"test" n mean change (SE)	"control" n mean change (SE)	Treatment contrast in LS mean estimate (SE) (95% CI)	p-value
	AIN457 150 mg vs. Etanercept	n=117 -4.89 (0.241)	n=116 -3.74 (0.260)	-0.99 (0.273) (-1.52,-0.45)	0.0003
	AIN457 300 mg vs. Etanercept	n=117 -4.93 (0.258)	n=116 -3.74 (0.260)	-1.36 (0.274) (-1.89,-0.82)	<0.0001

Number (%) of subjects with PASI 50, PASI 75, PASI 90, PASI 100 and IGA mod 2011 0 or 1 response by visit (non-responder imputation) induction period

Visit	Criterion	AIN457 150 mg N=327 n/m (%)	AIN457 300 mg N=327 n/m (%)	Placebo N=325 n/m (%)	Etanercept N=326 n/m (%)
Week 1	IGA mod 2011 0 or 1	1/327 (0.3)	3/323 (0.9)	0/324 (0.0)	1/323 (0.3)
	PASI 75	2/327 (0.6)	2/323 (0.6)	0/324 (0.0)	2/323 (0.6)
	PASI 50	10/327 (3.1)	13/323 (4.0)	3/324 (0.9)	9/323 (2.8)
	PASI 90	1/327 (0.3)	0/323 (0.0)	0/324 (0.0)	1/323 (0.3)
	PASI 100	0/327 (0.0)	0/323 (0.0)	0/324 (0.0)	0/323 (0.0)
Week 2	IGA mod 2011 0 or 1	6/327 (1.8)	11/323 (3.4)	3/324 (0.9)	1/323 (0.3)
	PASI 75	11/327 (3.4)	11/323 (3.4)	1/324 (0.3)	4/323 (1.2)
	PASI 50	51/327 (15.6)	75/323 (23.2)	14/324 (4.3)	34/323 (10.5)
	PASI 90	2/327 (0.6)	2/323 (0.6)	0/324 (0.0)	2/323 (0.6)
	PASI 100	0/327 (0.0)	0/323 (0.0)	0/324 (0.0)	1/323 (0.3)

Visit	Criterion	AIN457 150 mg N=327 n/m (%)	AIN457 300 mg N=327 n/m (%)	Placebo N=325 n/m (%)	Etanercept N=326 n/m (%)
Week 3	IGA mod 2011 0 or 1	19/327 (5.8)	34/323 (10.5)	2/324 (0.6)	5/323 (1.5)
	PASI 75	26/327 (8.0)	53/323 (16.4)	3/324 (0.9)	12/323 (3.7)
	PASI 50	108/327 (33.0)	169/323 (52.3)	21/324 (6.5)	66/323 (20.4)
	PASI 90	6/327 (1.8)	12/323 (3.7)	0/324 (0.0)	1/323 (0.3)
	PASI 100	2/327 (0.6)	3/323 (0.9)	0/324 (0.0)	0/323 (0.0)
Week 4	IGA mod 2011 0 or 1	42/327 (12.8)	79/323 (24.5)	2/324 (0.6)	15/323 (4.6)
	PASI 75	70/327 (21.4)	110/323 (34.1)	6/324 (1.9)	22/323 (6.8)
	PASI 50	183/327 (56.0)	237/323 (73.4)	26/324 (8.0)	113/323 (35.0)
	PASI 90	15/327 (4.6)	38/323 (11.8)	0/324 (0.0)	5/323 (1.5)
	PASI 100	5/327 (1.5)	11/323 (3.4)	0/324 (0.0)	0/323 (0.0)
Week 8	IGA mod 2011 0 or 1	118/327 (36.1)	164/323 (50.8)	2/324 (0.6)	51/323 (15.8)
	PASI 75	183/327 (56.0)	219/323 (67.8)	10/324 (3.1)	87/323 (26.9)
	PASI 50	261/327 (79.8)	284/323 (87.9)	44/324 (13.6)	199/323 (61.6)
	PASI 90	85/327 (26.0)	122/323 (37.8)	4/324 (1.2)	28/323 (8.7)
	PASI 100	28/327 (8.6)	46/323 (14.2)	2/324 (0.6)	5/323 (1.5)
Week 12	IGA mod 2011 0 or 1	167/327 (51.1)	202/323 (62.5)	9/324 (2.8)	88/323 (27.2)
	PASI 75	219/327 (67.0)	249/323 (77.1)	16/324 (4.9)	142/323 (44.0)
	PASI 50	266/327 (81.3)	296/323 (91.6)	49/324 (15.1)	226/323 (70.0)
	PASI 90	137/327 (41.9)	175/323 (54.2)	5/324 (1.5)	67/323 (20.7)
	PASI 100	47/327 (14.4)	78/323 (24.1)	0/324 (0.0)	14/323 (4.3)

Number (%) of subjects with PASI 50, PASI 75, PASI 90, PASI 100 and IGA mod 2011 0 or 1 response by visit (non-responder imputation) maintenance period

	AIN457 150 mg	AIN457 300 mg	Placebo - AIN457 150 mg	Placebo - AIN457 300 mg	Placebo	Etanercept

		N=327		N=327		N=142		N=141		N=17		N=326	
Visit	**Criterion**	**n/m**	**(%)**	**n/m**	**(%)**	**n/m**	**(%)**	**n/m**	**(%)**	**n/m**	**(%)**	**n/m**	**(%)**
Week 12	IGA mod 2011 0 or 1	167/327	(51.1)	202/323	(62.5)	0/142	(0.0)	1/141	(0.7)	7/ 17	(41.2)	88/323	(27.2)
	PASI 75	219/327	(67.0)	249/323	(77.1)	0/142	(0.0)	1/141	(0.7)	12/ 17	(70.6)	142/323	(44.0)
	PASI 50	266/327	(81.3)	296/323	(91.6)	14/142	(9.9)	15/141	(10.6)	16/ 17	(94.1)	226/323	(70.0)
	PASI 90	137/327	(41.9)	175/323	(54.2)	0/142	(0.0)	0/141	(0.0)	4/ 17	(23.5)	67/323	(20.7)
	PASI 100	47/327	(14.4)	78/323	(24.1)	0/142	(0.0)	0/141	(0.0)	0/ 17	(0.0)	14/323	(4.3)
Week 13	IGA mod 2011 0 or 1	175/327	(53.5)	204/323	(63.2)	1/142	(0.7)	5/141	(3.5)	8/ 17	(47.1)	89/323	(27.6)
	PASI 75	221/327	(67.6)	252/323	(78.0)	7/142	(4.9)	7/141	(5.0)	10/ 17	(58.8)	156/323	(48.3)
	PASI 50	266/327	(81.3)	283/323	(87.6)	22/142	(15.5)	40/141	(28.4)	15/ 17	(88.2)	223/323	(69.0)
	PASI 90	149/327	(45.6)	187/323	(57.9)	0/142	(0.0)	0/141	(0.0)	4/ 17	(23.5)	68/323	(21.1)
	PASI 100	62/327	(19.0)	92/323	(28.5)	0/142	(0.0)	0/141	(0.0)	0/ 17	(0.0)	16/323	(5.0)
Week 14	IGA mod 2011 0 or 1	193/327	(59.0)	224/323	(69.3)	9/142	(6.3)	12/141	(8.5)	8/ 17	(47.1)	108/323	(33.4)
	PASI 75	241/327	(73.7)	265/323	(82.0)	11/142	(7.7)	21/141	(14.9)	12/ 17	(70.6)	167/323	(51.7)
	PASI 50	279/327	(85.3)	288/323	(89.2)	58/142	(40.8)	72/141	(51.1)	14/ 17	(82.4)	242/323	(74.9)
	PASI 90	166/327	(50.8)	199/323	(61.6)	1/142	(0.7)	4/141	(2.8)	8/ 17	(47.1)	82/323	(25.4)
	PASI 100	70/327	(21.4)	99/323	(30.7)	0/142	(0.0)	0/141	(0.0)	1/ 17	(5.9)	22/323	(6.8)
Week 15	IGA mod 2011 0 or 1	191/327	(58.4)	235/323	(72.8)	20/142	(14.1)	26/141	(18.4)	7/ 17	(41.2)	115/323	(35.6)
	PASI 75	240/327	(73.4)	267/323	(82.7)	32/142	(22.5)	49/141	(34.8)	12/ 17	(70.6)	180/323	(55.7)
	PASI 50	281/327	(85.9)	289/323	(89.5)	84/142	(59.2)	101/141	(71.6)	14/ 17	(82.4)	250/323	(77.4)

	PASI 90	165/327	(50.5)	213/323	(65.9)	6/142	(4.2)	11/141	(7.8)	8/ 17	(47.1)	94/323	(29.1)
	PASI 100	82/327	(25.1)	110/323	(34.1)	0/142	(0.0)	2/141	(1.4)	1/ 17	(5.9)	25/323	(7.7)
Week 16	IGA mod 2011 0 or 1	200/327	(61.2)	244/323	(75.5)	34/142	(23.9)	55/141	(39.0)	8/ 17	(47.1)	127/323	(39.3)
	PASI 75	247/327	(75.5)	280/323	(86.7)	54/142	(38.0)	82/141	(58.2)	12/ 17	(70.6)	189/323	(58.5)
	PASI 50	290/327	(88.7)	302/323	(93.5)	109/142	(76.8)	122/141	(86.5)	14/ 17	(82.4)	257/323	(79.6)
	PASI 90	176/327	(53.8)	234/323	(72.4)	19/142	(13.4)	28/141	(19.9)	8/ 17	(47.1)	101/323	(31.3)
	PASI 100	84/327	(25.7)	119/323	(36.8)	2/142	(1.4)	7/141	(5.0)	3/ 17	(17.6)	24/323	(7.4)
Week 20	IGA mod 2011 0 or 1	206/327	(63.0)	241/323	(74.6)	81/142	(57.0)	90/141	(63.8)	10/ 17	(58.8)	139/323	(43.0)
	PASI 75	257/327	(78.6)	281/323	(87.0)	103/142	(72.5)	117/141	(83.0)	11/ 17	(64.7)	194/323	(60.1)
	PASI 50	290/327	(88.7)	300/323	(92.9)	133/142	(93.7)	136/141	(96.5)	14/ 17	(82.4)	260/323	(80.5)
	PASI 90	189/327	(57.8)	227/323	(70.3)	60/142	(42.3)	76/141	(53.9)	9/ 17	(52.9)	109/323	(33.7)
	PASI 100	79/327	(24.2)	111/323	(34.4)	20/142	(14.1)	32/141	(22.7)	2/ 17	(11.8)	33/323	(10.2)
Week 24	IGA mod 2011 0 or 1	202/327	(61.8)	244/323	(75.5)	100/142	(70.4)	106/141	(75.2)	9/ 17	(52.9)	149/323	(46.1)
	PASI 75	253/327	(77.4)	279/323	(86.4)	122/142	(85.9)	128/141	(90.8)	10/ 17	(58.8)	198/323	(61.3)
	PASI 50	289/327	(88.4)	302/323	(93.5)	136/142	(95.8)	136/141	(96.5)	13/ 17	(76.5)	269/323	(83.3)
	PASI 90	187/327	(57.2)	229/323	(70.9)	86/142	(60.6)	99/141	(70.2)	6/ 17	(35.3)	122/323	(37.8)
	PASI 100	81/327	(24.8)	129/323	(39.9)	39/142	(27.5)	52/141	(36.9)	1/ 17	(5.9)	36/323	(11.1)
Week 28	IGA mod 2011 0 or 1	199/327	(60.9)	239/323	(74.0)	96/142	(67.6)	118/141	(83.7)	7/ 17	(41.2)	150/323	(46.4)
	PASI 75	248/327	(75.8)	274/323	(84.8)	122/142	(85.9)	134/141	(95.0)	10/ 17	(58.8)	207/323	(64.1)
	PASI 50	284/327	(86.9)	296/323	(91.6)	134/142	(94.4)	138/141	(97.9)	13/ 17	(76.5)	268/323	(83.0)

	PASI 90	182/327	(55.7)	235/323	(72.8)	88/142	(62.0)	110/141	(78.0)	7/ 17	(41.2)	128/323	(39.6)
	PASI 100	77/327	(23.5)	129/323	(39.9)	41/142	(28.9)	65/141	(46.1)	1/ 17	(5.9)	39/323	(12.1)
Week 32	IGA mod 2011 0 or 1	193/327	(59.0)	235/323	(72.8)	99/142	(69.7)	116/141	(82.3)	7/ 17	(41.2)	146/323	(45.2)
	PASI 75	240/327	(73.4)	271/323	(83.9)	117/142	(82.4)	128/141	(90.8)	12/ 17	(70.6)	198/323	(61.3)
	PASI 50	284/327	(86.9)	290/323	(89.8)	132/142	(93.0)	134/141	(95.0)	14/ 17	(82.4)	261/323	(80.8)
	PASI 90	175/327	(53.5)	232/323	(71.8)	92/142	(64.8)	113/141	(80.1)	7/ 17	(41.2)	134/323	(41.5)
	PASI 100	78/327	(23.9)	131/323	(40.6)	44/142	(31.0)	66/141	(46.8)	2/ 17	(11.8)	42/323	(13.0)
Week 36	IGA mod 2011 0 or 1	180/327	(55.0)	231/323	(71.5)	93/142	(65.5)	119/141	(84.4)	9/ 17	(52.9)	140/323	(43.3)
	PASI 75	226/327	(69.1)	268/323	(83.0)	116/142	(81.7)	129/141	(91.5)	10/ 17	(58.8)	203/323	(62.8)
	PASI 50	270/327	(82.6)	288/323	(89.2)	126/142	(88.7)	134/141	(95.0)	13/ 17	(76.5)	256/323	(79.3)
	PASI 90	166/327	(50.8)	225/323	(69.7)	93/142	(65.5)	112/141	(79.4)	8/ 17	(47.1)	122/323	(37.8)
	PASI 100	77/327	(23.5)	124/323	(38.4)	46/142	(32.4)	68/141	(48.2)	2/ 17	(11.8)	41/323	(12.7)
Week 40	IGA mod 2011 0 or 1	183/327	(56.0)	224/323	(69.3)	92/142	(64.8)	112/141	(79.4)	7/ 17	(41.2)	139/323	(43.0)
	PASI 75	225/327	(68.8)	265/323	(82.0)	111/142	(78.2)	127/141	(90.1)	11/ 17	(64.7)	199/323	(61.6)
	PASI 50	266/327	(81.3)	285/323	(88.2)	127/142	(89.4)	132/141	(93.6)	12/ 17	(70.6)	256/323	(79.3)
	PASI 90	169/327	(51.7)	217/323	(67.2)	91/142	(64.1)	111/141	(78.7)	7/ 17	(41.2)	128/323	(39.6)
	PASI 100	79/327	(24.2)	126/323	(39.0)	44/142	(31.0)	72/141	(51.1)	2/ 17	(11.8)	38/323	(11.8)
Week 44	IGA mod 2011 0 or 1	175/327	(53.5)	220/323	(68.1)	89/142	(62.7)	110/141	(78.0)	7/ 17	(41.2)	140/323	(43.3)
	PASI 75	228/327	(69.7)	266/323	(82.4)	109/142	(76.8)	126/141	(89.4)	10/ 17	(58.8)	199/323	(61.6)
	PASI 50	266/327	(81.3)	283/323	(87.6)	123/142	(86.6)	132/141	(93.6)	12/ 17	(70.6)	252/323	(78.0)

	PASI 90	170/327	(52.0)	211/323	(65.3)	89/142	(62.7)	115/141	(81.6)	7/ 17	(41.2)	123/323	(38.1)
	PASI 100	81/327	(24.8)	119/323	(36.8)	40/142	(28.2)	68/141	(48.2)	3/ 17	(17.6)	36/323	(11.1)
Week 48	IGA mod 2011 0 or 1	167/327	(51.1)	219/323	(67.8)	82/142	(57.7)	108/141	(76.6)	6/ 17	(35.3)	136/323	(42.1)
	PASI 75	217/327	(66.4)	264/323	(81.7)	103/142	(72.5)	124/141	(87.9)	11/ 17	(64.7)	197/323	(61.0)
	PASI 50	261/327	(79.8)	280/323	(86.7)	120/142	(84.5)	129/141	(91.5)	12/ 17	(70.6)	251/323	(77.7)
	PASI 90	157/327	(48.0)	214/323	(66.3)	74/142	(52.1)	112/141	(79.4)	7/ 17	(41.2)	119/323	(36.8)
	PASI 100	80/327	(24.5)	117/323	(36.2)	37/142	(26.1)	64/141	(45.4)	2/ 17	(11.8)	40/323	(12.4)
Week 52	IGA mod 2011 0 or 1	168/327	(51.4)	219/323	(67.8)	80/142	(56.3)	104/141	(73.8)	5/ 17	(29.4)	120/323	(37.2)
	PASI 75	215/327	(65.7)	254/323	(78.6)	103/142	(72.5)	117/141	(83.0)	10/ 17	(58.8)	179/323	(55.4)
	PASI 50	249/327	(76.1)	274/323	(84.8)	116/142	(81.7)	125/141	(88.7)	14/ 17	(82.4)	234/323	(72.4)
	PASI 90	147/327	(45.0)	210/323	(65.0)	78/142	(54.9)	105/141	(74.5)	6/ 17	(35.3)	108/323	(33.4)
	PASI 100	65/327	(19.9)	117/323	(36.2)	36/142	(25.4)	71/141	(50.4)	2/ 17	(11.8)	32/323	(9.9)
At any time up to Week 52	IGA mod 2011 0 or 1	251/327	(76.8)	280/323	(86.7)	117/142	(82.4)	133/141	(94.3)	14/ 17	(82.4)	218/323	(67.5)
	PASI 75	280/327	(85.6)	306/323	(94.7)	131/142	(92.3)	139/141	(98.6)	17/ 17	(100.0)	259/323	(80.2)
	PASI 50	306/327	(93.6)	309/323	(95.7)	140/142	(98.6)	140/141	(99.3)	17/ 17	(100.0)	291/323	(90.1)
	PASI 90	239/327	(73.1)	282/323	(87.3)	112/142	(78.9)	129/141	(91.5)	12/ 17	(70.6)	188/323	(58.2)
	PASI 100	138/327	(42.2)	202/323	(62.5)	72/142	(50.7)	95/141	(67.4)	6/ 17	(35.3)	80/323	(24.8)

Summary statistics for PASI score by visit (LOCF) Induction period.

		AIN457 150 mg N=327		AIN457 300 mg N=327		Placebo N=325		Etanercept N=326	
Visit	Statistic	Base	Post	Base	Post	Base	Post	Base	Post
Week 1	n	321	321	320	320	318	318	319	319
	Mean	23.75	20.93	23.98	19.85	23.86	22.72	23.19	21.28
	SD	10.501	10.117	9.998	9.271	10.242	9.826	9.784	9.141
	Min	12	0.6	12	3.8	12	6.4	12	1.2
	Q1	15.9	13.8	16.2	13.3	16.2	15.8	15.7	14.9
	Median	20.4	18.1	21.55	17.6	20.5	20	20.2	18.3
	Q3	28.8	25.2	28.9	24.1	29.7	27	28.4	25.9
	Max	69.6	67	64.2	54.6	61.8	68.4	54.5	53.9
Week 2	n	326	326	323	323	323	323	322	322
	Mean	23.62	17.48	23.89	15.64	23.82	21.71	23.17	18.3
	SD	10.478	9.586	9.993	8.647	10.182	10.402	9.763	9.291
	Min	12	0.4	12	0.1	12	4.9	12	0
	Q1	15.8	10.4	16.2	9.6	16.2	15.2	15.8	12
	Median	20.25	15.5	21.5	13.7	20.6	19	20	15.85
	Q3	28.7	22.1	28.8	19.8	29.5	26	28.4	22.1
	Max	69.6	54.7	64.2	51.2	61.8	68.4	54.5	54
Week 3	n	327	327	323	323	324	324	322	322
	Mean	23.67	14.58	23.89	11.9	23.95	21.5	23.17	15.81

	SD	10.499	9.598	9.993	8.184	10.413	11.268	9.763	8.764
	Min	12	0	12	0	12	2.7	12	2.2
	Q1	15.8	8.1	16.2	6.4	16.2	14.1	15.8	10
	Median	20.3	12.2	21.5	9.6	20.65	18.4	20	13.4
	Q3	28.8	18.8	28.8	15.4	29.6	25.8	28.4	19.2
	Max	69.6	68.3	64.2	42.4	64.4	66.6	54.5	55.8
Week 4	n	327	327	323	323	324	324	322	322
	Mean	23.67	11.61	23.89	9.09	23.95	20.93	23.17	14.21
	SD	10.499	8.881	9.993	7.7	10.413	11.145	9.763	9.117
	Min	12	0	12	0	12	3.2	12	0.4
	Q1	15.8	5.6	16.2	3.9	16.2	13.4	15.8	8.5
	Median	20.3	9	21.5	6.7	20.65	18.4	20	11.95
	Q3	28.8	14.8	28.8	12.4	29.6	25.4	28.4	17
	Max	69.6	54.7	64.2	40.2	64.4	65.1	54.5	57
Week 8	n	327	327	323	323	324	324	323	323
	Mean	23.67	7.09	23.89	5.27	23.95	20.67	23.19	10.35
	SD	10.499	7.696	9.993	6.802	10.413	12.231	9.75	8.777
	Min	12	0	12	0	12	0	12	0
	Q1	15.8	2	16.2	1.1	16.2	13.3	15.8	4.6
	Median	20.3	4.2	21.5	3.1	20.65	17.2	20.2	7.8
	Q3	28.8	9.8	28.8	6.3	29.6	25.4	28.4	13.8
	Max	69.6	45.6	64.2	39.1	64.4	67.5	54.5	60
Week 12	n	327	327	323	323	324	324	323	323
	Mean	23.67	5.31	23.89	3.43	23.95	20.61	23.19	8.03
	SD	10.499	7.83	9.993	5.454	10.413	13.027	9.75	8.643
	Min	12	0	12	0	12	0	12	0

	Q1	15.8	0.9	16.2	0	16.2	12.4	15.8	2.7
	Median	20.3	2.6	21.5	1.8	20.65	17	20.2	5.8
	Q3	28.8	6.2	28.8	4.4	29.6	26	28.4	10.9
	Max	69.6	57	64.2	39.4	64.4	67.5	54.5	64.8

Summary statistics for PASI score by visit (LOCF) maintenance period.

		AIN457 150 mg N=327		AIN457 300 mg N=327		Placebo - AIN457 150 mg N=142		Placebo - AIN457 300 mg N=141		Placebo N=17		Etanercept N=326	
Visit	**Statistic**	**Base**	**Post**	**Base**	**Post**	**Base**	**Post**	**Base**	**Post**	**Base**	**Post**	**Base**	**Post**
Week 12	n	327	327	323	323	142	142	141	141	17	17	323	323
	Mean	23.67	5.31	23.89	3.43	23.89	22.02	23.13	20.79	29.64	5.12	23.19	8.03
	SD	10.499	7.83	9.993	5.454	10.714	12.985	9.758	12.319	11.88	4.438	9.75	8.643
	Min	12	0	12	0	12	4.2	12	3.2	13.6	0	12	0
	Q1	15.8	0.9	16.2	0	15.2	13.2	16.4	12.8	18.5	1.9	15.8	2.7
	Median	20.3	2.6	21.5	1.8	20.95	18.05	20	17	30	3.8	20.2	5.8
	Q3	28.8	6.2	28.8	4.4	30.6	26.2	27.2	25.9	34.6	6.7	28.4	10.9
	Max	69.6	57	64.2	39.4	64.4	63.3	57.6	67.5	61.8	16.4	54.5	64.8
Week 13	n	327	327	323	323	135	135	133	133	17	17	323	323
	Mean	23.67	4.67	23.89	2.97	23.99	17.94	23.59	16.92	29.64	5.65	23.19	7.1
	SD	10.499	7.379	9.993	5.342	10.82	10.456	9.833	10.871	11.88	5.987	9.75	7.559
	Min	12	0	12	0	12	3.1	12.5	2.2	13.6	0	12	0
	Q1	15.8	0.6	16.2	0	15.3	11.3	16.6	9.7	18.5	1.8	15.8	2.2
	Median	20.3	2	21.5	1.2	21.2	15	20.1	14	30	3	20.2	4.8
	Q3	28.8	5.3	28.8	3.6	30.6	21.3	27.4	21.5	34.6	8.4	28.4	9.4
	Max	69.6	48.6	64.2	39.4	64.4	61.2	57.6	63	61.8	22.2	54.5	46.3

Week 14	n	327	327	323	323	141	141	140	140	17	17	323	323
	Mean	23.67	4.3	23.89	2.71	23.82	13.93	23.2	12.5	29.64	4.79	23.19	6.43
	SD	10.499	7.105	9.993	5.004	10.72	8.345	9.756	9.318	11.88	6.005	9.75	7.093
	Min	12	0	12	0	12	1.2	12	0.9	13.6	0	12	0
	Q1	15.8	0.4	16.2	0	15.2	8.3	16.4	6.1	18.5	1.2	15.8	1.9
	Median	20.3	2	21.5	1.2	20.7	12.2	20.05	10.15	30	2.6	20.2	4.1
	Q3	28.8	4.7	28.8	3.4	30.3	17.3	27.3	15.2	34.6	4	28.4	8.6
	Max	69.6	50.6	64.2	39.5	64.4	55.6	57.6	47.1	61.8	23.1	54.5	55.3
Week 15	n	327	327	323	323	141	141	141	141	17	17	323	323
	Mean	23.67	3.97	23.89	2.34	23.82	10.48	23.13	8.76	29.64	4.94	23.19	5.87
	SD	10.499	6.712	9.993	4.458	10.72	7.42	9.758	7.284	11.88	6.254	9.75	6.414
	Min	12	0	12	0	12	0.4	12	0	13.6	0	12	0
	Q1	15.8	0	16.2	0	15.2	5.4	16.4	4	18.5	1.3	15.8	1.6
	Median	20.3	1.8	21.5	1.1	20.7	9.5	20	6.4	30	2.1	20.2	3.9
	Q3	28.8	5	28.8	2.7	30.3	13.2	27.2	10.9	34.6	4.5	28.4	8.4
	Max	69.6	45.6	64.2	47.5	64.4	57.8	57.6	38.8	61.8	23.1	54.5	44.8
Week 16	n	327	327	323	323	141	141	141	141	17	17	323	323
	Mean	23.67	3.86	23.89	2.22	23.82	7.89	23.13	6.2	29.64	4.49	23.19	5.56
	SD	10.499	6.578	9.993	4.391	10.72	6.627	9.758	5.766	11.88	6.368	9.75	6.212
	Min	12	0	12	0	12	0	12	0	13.6	0	12	0
	Q1	15.8	0	16.2	0	15.2	3.1	16.4	2.4	18.5	0.3	15.8	1.5
	Median	20.3	1.6	21.5	0.8	20.7	7	20	4.5	30	1.8	20.2	3.6
	Q3	28.8	4.4	28.8	2.8	30.3	10.2	27.2	8.4	34.6	4.7	28.4	7.4
	Max	69.6	45.6	64.2	43.7	64.4	49.4	57.6	36	61.8	20.7	54.5	43.3

Week 20	n	327	327	323	323	142	142	141	141	17	17	323	323
	Mean	23.67	3.81	23.89	2.15	23.89	4.42	23.13	2.96	29.64	4.84	23.19	5.3
	SD	10.499	6.581	9.993	4.113	10.714	5.743	9.758	3.52	11.88	6.653	9.75	6.11
	Min	12	0	12	0	12	0	12	0	13.6	0	12	0
	Q1	15.8	0.1	16.2	0	15.2	1	16.4	0.3	18.5	0.9	15.8	1.4
	Median	20.3	1.5	21.5	0.8	20.95	2.6	20	1.8	30	1.7	20.2	3.2
	Q3	28.8	4.3	28.8	2.4	30.6	6	27.2	4.6	34.6	6.9	28.4	7.3
	Max	69.6	45.6	64.2	38.8	64.4	49	57.6	20.7	61.8	20.7	54.5	46.3
Week 24	n	327	327	323	323	142	142	141	141	17	17	323	323
	Mean	23.67	3.78	23.89	2.06	23.89	3.18	23.13	1.62	29.64	4.12	23.19	4.94
	SD	10.499	6.647	9.993	4.622	10.714	5.491	9.758	2.163	11.88	5.667	9.75	6.169
	Min	12	0	12	0	12	0	12	0	13.6	0	12	0
	Q1	15.8	0	16.2	0	15.2	0	16.4	0	18.5	0.7	15.8	1.2
	Median	20.3	1.2	21.5	0.6	20.95	1.4	20	0.8	30	1.7	20.2	3
	Q3	28.8	3.9	28.8	2.4	30.6	4	27.2	2.4	34.6	3.3	28.4	6.8
	Max	69.6	45.6	64.2	56.7	64.4	46.3	57.6	11.7	61.8	19	54.5	47.3
Week 28	n	327	327	323	323	142	142	141	141	17	17	323	323
	Mean	23.67	4.06	23.89	2.16	23.89	2.88	23.13	1.22	29.64	4.51	23.19	4.72
	SD	10.499	6.941	9.993	4.39	10.714	4.846	9.758	1.816	11.88	5.498	9.75	5.782
	Min	12	0	12	0	12	0	12	0	13.6	0	12	0
	Q1	15.8	0.2	16.2	0	15.2	0	16.4	0	18.5	0.6	15.8	1.2
	Median	20.3	1.4	21.5	0.6	20.95	1.3	20	0.4	30	1.7	20.2	3
	Q3	28.8	4.4	28.8	2	30.6	3.5	27.2	2	34.6	6	28.4	6.5
	Max	69.6	45.6	64.2	38.6	64.4	38.4	57.6	11.7	61.8	16.6	54.5	45.9

Week 32	n	327	327	323	323	142	142	141	141	17	17	323	323
	Mean	23.67	4.15	23.89	2.09	23.89	2.78	23.13	1.12	29.64	3.71	23.19	4.7
	SD	10.499	6.786	9.993	4.114	10.714	4.244	9.758	1.847	11.88	4.381	9.75	5.893
	Min	12	0	12	0	12	0	12	0	13.6	0	12	0
	Q1	15.8	0.2	16.2	0	15.2	0	16.4	0	18.5	0.6	15.8	1
	Median	20.3	1.8	21.5	0.4	20.95	1.2	20	0.2	30	2	20.2	2.7
	Q3	28.8	4.8	28.8	2	30.6	3.6	27.2	1.8	34.6	5.4	28.4	6.4
	Max	69.6	45.6	64.2	36.9	64.4	23.6	57.6	11.7	61.8	16.6	54.5	45.1
Week 36	n	327	327	323	323	142	142	141	141	17	17	323	323
	Mean	23.67	4.38	23.89	2.28	23.89	2.88	23.13	1.16	29.64	4.4	23.19	4.77
	SD	10.499	7.042	9.993	4.765	10.714	5.008	9.758	1.955	11.88	5.207	9.75	6.18
	Min	12	0	12	0	12	0	12	0	13.6	0	12	0
	Q1	15.8	0.1	16.2	0	15.2	0	16.4	0	18.5	0.8	15.8	1.2
	Median	20.3	1.6	21.5	0.4	20.95	1.2	20	0.2	30	2.4	20.2	3
	Q3	28.8	5.4	28.8	2.4	30.6	3.2	27.2	1.5	34.6	6	28.4	6.3
	Max	69.6	45.6	64.2	41	64.4	39.8	57.6	11.7	61.8	19	54.5	47.5
Week 40	n	327	327	323	323	142	142	141	141	17	17	323	323
	Mean	23.67	4.38	23.89	2.16	23.89	2.96	23.13	1.15	29.64	5.46	23.19	4.83
	SD	10.499	7.035	9.993	4.315	10.714	4.609	9.758	2.064	11.88	7.444	9.75	6.133
	Min	12	0	12	0	12	0	12	0	13.6	0	12	0
	Q1	15.8	0	16.2	0	15.2	0	16.4	0	18.5	0.8	15.8	1
	Median	20.3	1.6	21.5	0.4	20.95	1.1	20	0	30	2.2	20.2	2.9
	Q3	28.8	5.1	28.8	2.4	30.6	3.2	27.2	1.5	34.6	6	28.4	6.3
	Max	69.6	45.6	64.2	41.9	64.4	24.2	57.6	11.7	61.8	22.1	54.5	47.5

Week 44	n	327	327	323	323	142	142	141	141	17	17	323	323
	Mean	23.67	4.33	23.89	2.35	23.89	3.28	23.13	1.21	29.64	5.65	23.19	4.79
	SD	10.499	6.755	9.993	4.999	10.714	5.788	9.758	2.283	11.88	7.616	9.75	5.983
	Min	12	0	12	0	12	0	12	0	13.6	0	12	0
	Q1	15.8	0	16.2	0	15.2	0	16.4	0	18.5	0.3	15.8	1.2
	Median	20.3	1.8	21.5	0.6	20.95	1.2	20	0	30	1.7	20.2	2.9
	Q3	28.8	5.7	28.8	2.4	30.6	3.9	27.2	1.6	34.6	6.8	28.4	6.6
	Max	69.6	45.6	64.2	50.4	64.4	48.3	57.6	15.6	61.8	23.1	54.5	47.5
Week 48	n	327	327	323	323	142	142	141	141	17	17	323	323
	Mean	23.67	4.48	23.89	2.37	23.89	3.42	23.13	1.39	29.64	5.76	23.19	4.88
	SD	10.499	6.936	9.993	4.954	10.714	4.797	9.758	2.807	11.88	7.184	9.75	6.158
	Min	12	0	12	0	12	0	12	0	13.6	0	12	0
	Q1	15.8	0	16.2	0	15.2	0	16.4	0	18.5	0.6	15.8	1.2
	Median	20.3	1.9	21.5	0.7	20.95	1.6	20	0.2	30	1.7	20.2	3
	Q3	28.8	5.6	28.8	2.4	30.6	4.8	27.2	1.6	34.6	8.4	28.4	6.9
	Max	69.6	45.6	64.2	50.4	64.4	22.4	57.6	18	61.8	20.7	54.5	47.5
Week 52	n	327	327	323	323	142	142	141	141	17	17	323	323
	Mean	23.67	4.81	23.89	2.53	23.89	3.38	23.13	1.36	29.64	4.63	23.19	5.05
	SD	10.499	7.203	9.993	5.411	10.714	4.46	9.758	2.658	11.88	4.852	9.75	6.235
	Min	12	0	12	0	12	0	12	0	13.6	0	12	0
	Q1	15.8	0.3	16.2	0	15.2	0	16.4	0	18.5	0.8	15.8	1.2
	Median	20.3	2.1	21.5	0.7	20.95	1.6	20	0	30	3.6	20.2	3
	Q3	28.8	6	28.8	2.6	30.6	4.9	27.2	1.6	34.6	7.4	28.4	7.2
	Max	69.6	45.6	64.2	50.4	64.4	21	57.6	18	61.8	15.6	54.5	47.5

Time to PASI 75 response up to Week 12: life-table summary including cumulative probabilities (Kaplan-Meier estimates) and Cox regression analysis

	AIN457 150 mg N=327					
Time (weeks)	subj. at risk	subj. with event	subj. with event/ at risk	cum. subj. with event	cum. event prob. (%)	95% confidence interval
0 to <=4	327	36	0.1101	36	11.1	(8.2, 15.1)
>4 to <=8	287	72	0.2509	108	33.6	(28.7, 39.1)
>8 to <=12	211	94	0.4455	202	63.3	(58.1, 68.6)
>12	98	41	0.4184	243	85.6	(77.1, 92.2)

Hazard ratio (COX PH) (95% CI) 22.52 (14.38,35.27)

p-value (Log-rank test) = <0.0001

p-value (Wilcoxon test) = <0.0001

Placebo
N=325

Time (weeks)	subj. at risk	subj. with event	subj. with event/ at risk	cum. subj. with event	cum. event prob. (%)	95% confidence interval
0 to <=4	324	3	0.0093	3	0.9	(0.3, 2.9)
>4 to <=8	316	4	0.0127	7	2.2	(1.0, 4.5)
>8 to <=12	306	9	0.0294	16	5.2	(3.2, 8.3)
>12	228	5	0.0219	21	7.3	(4.8, 11.0)

Hazard ratio (COX PH) (95% CI) 22.52 (14.38,35.27)

p-value (Log-rank test) = <0.0001

p-value (Wilcoxon test) = <0.0001

AIN457 300 mg
N=327

Time (weeks)	subj. at risk	subj. with event	subj. with event/ at risk	cum. subj. with event	cum. event prob. (%)	95% confidence interval
0 to <=4	323	62	0.1920	62	19.3	(15.4, 24.0)

AIN457 300 mg
N=327

Time (weeks)	subj. at risk	subj. with event	subj. with event/ at risk	cum. subj. with event	cum. event prob. (%)	95% confidence interval
>4 to <=8	260	74	0.2846	136	42.3	(37.2, 47.9)
>8 to <=12	183	95	0.5191	231	72.3	(67.3, 77.1)
>12	78	36	0.4615	267	92.3	(85.7, 96.6)

Hazard ratio (COX PH) (95% CI) 27.92 (17.85,43.67)

p-value (Log-rank test) = <0.0001

p-value (Wilcoxon test) = <0.0001

Placebo
N=325

Time (weeks)	subj. at risk	subj. with event	subj. with event/ at risk	cum. subj. with event	cum. event prob. (%)	95% confidence interval
0 to <=4	324	3	0.0093	3	0.9	(0.3, 2.9)
>4 to <=8	316	4	0.0127	7	2.2	(1.0, 4.5)

Placebo
N=325

Time (weeks)	subj. at risk	subj. with event	subj. with event/ at risk	cum. subj. with event	cum. event prob. (%)	95% confidence interval
>8 to <=12	306	9	0.0294	16	5.2	(3.2, 8.3)
>12	228	5	0.0219	21	7.3	(4.8, 11.0)

Hazard ratio (COX PH) (95% CI) 27.92 (17.85,43.67)

p-value (Log-rank test) = <0.0001

p-value (Wilcoxon test) = <0.0001

AIN457 150 mg
N=327

Time (weeks)	subj. at risk	subj. with event	subj. with event/ at risk	cum. subj. with event	cum. event prob. (%)	95% confidence interval
0 to <=4	327	36	0.1101	36	11.1	(8.2, 15.1)
>4 to <=8	287	72	0.2509	108	33.6	(28.7, 39.1)
>8 to <=12	211	94	0.4455	202	63.3	(58.1, 68.6)

AIN457 150 mg N=327						
Time (weeks)	**subj. at risk**	**subj. with event**	**subj. with event/ at risk**	**cum. subj. with event**	**cum. event prob. (%)**	**95% confidence interval**
>12	98	41	0.4184	243	85.6	(77.1, 92.2)

Hazard ratio (COX PH) (95% CI) 2.46 (2.00,3.02)

p-value (Log-rank test) = <0.0001

p-value (Wilcoxon test) = <0.0001

Etanercept N=326						
Time (weeks)	**subj. at risk**	**subj. with event**	**subj. with event/ at risk**	**cum. subj. with event**	**cum. event prob. (%)**	**95% confidence interval**
0 to <=4	323	14	0.0433	14	4.4	(2.6, 7.3)
>4 to <=8	306	22	0.0719	36	11.3	(8.3, 15.3)
>8 to <=12	279	63	0.2258	99	31.6	(26.7, 37.0)

Etanercept
N=326

Time (weeks)	subj. at risk	subj. with event	subj. with event/ at risk	cum. subj. with event	cum. event prob. (%)	95% confidence interval
>12	179	54	0.3017	153	65.4	(54.8, 75.8)

Hazard ratio (COX PH) (95% CI) 2.46 (2.00,3.02)

p-value (Log-rank test) = <0.0001

p-value (Wilcoxon test) = <0.0001

AIN457 300 mg
N=327

Time (weeks)	subj. at risk	subj. with event	subj. with event/ at risk	cum. subj. with event	cum. event prob. (%)	95% confidence interval
0 to <=4	323	62	0.1920	62	19.3	(15.4, 24.0)
>4 to <=8	260	74	0.2846	136	42.3	(37.2, 47.9)
>8 to <=12	183	95	0.5191	231	72.3	(67.3, 77.1)

AIN457 300 mg
N=327

Time (weeks)	subj. at risk	subj. with event	subj. with event/ at risk	cum. subj. with event	cum. event prob. (%)	95% confidence interval
>12	78	36	0.4615	267	92.3	(85.7, 96.6)

Hazard ratio (COX PH) (95% CI) 3.04 (2.49,3.73)

p-value (Log-rank test) = <0.0001

p-value (Wilcoxon test) = <0.0001

Etanercept
N=326

Time (weeks)	subj. at risk	subj. with event	subj. with event/ at risk	cum. subj. with event	cum. event prob. (%)	95% confidence interval
0 to <=4	323	14	0.0433	14	4.4	(2.6, 7.3)
>4 to <=8	306	22	0.0719	36	11.3	(8.3, 15.3)
>8 to <=12	279	63	0.2258	99	31.6	(26.7, 37.0)

		Etanercept N=326				
Time (weeks)	subj. at risk	subj. with event	subj. with event/ at risk	cum. subj. with event	cum. event prob. (%)	95% confidence interval
>12	179	54	0.3017	153	65.4	(54.8, 75.8)

Hazard ratio (COX PH) (95% CI) 3.04 (2.49,3.73)

p-value (Log-rank test) = <0.0001

p-value (Wilcoxon test) = <0.0001

Number (%) of subjects with PASI 75, PASI 90 and PASI 100 response by visit for subjects with partial PASI response at Week 12 (non-responder imputation)

		AIN457 150 mg N=47		AIN457 300 mg N=47		Etanercept N=84	
Visit	Criterion	n/m	(%)	n/m	(%)	n/m	(%)
Week 13	PASI 75	14/ 47	(29.8)	17/ 47	(36.2)	29/ 84	(34.5)
	PASI 90	0/ 47	(0.0)	1/ 47	(2.1)	1/ 84	(1.2)
	PASI 100	0/ 47	(0.0)	0/ 47	(0.0)	0/ 84	(0.0)
Week 14	PASI 75	25/ 47	(53.2)	28/ 47	(59.6)	35/ 84	(41.7)
	PASI 90	3/ 47	(6.4)	7/ 47	(14.9)	6/ 84	(7.1)
	PASI 100	0/ 47	(0.0)	1/ 47	(2.1)	1/ 84	(1.2)

Week 15	PASI 75	23/ 47	(48.9)	31/ 47	(66.0)	43/ 84	(51.2)
	PASI 90	3/ 47	(6.4)	13/ 47	(27.7)	11/ 84	(13.1)
	PASI 100	0/ 47	(0.0)	1/ 47	(2.1)	2/ 84	(2.4)
Week 16	PASI 75	24/ 47	(51.1)	34/ 47	(72.3)	46/ 84	(54.8)
	PASI 90	7/ 47	(14.9)	18/ 47	(38.3)	15/ 84	(17.9)
	PASI 100	0/ 47	(0.0)	1/ 47	(2.1)	0/ 84	(0.0)
Week 20	PASI 75	27/ 47	(57.4)	35/ 47	(74.5)	50/ 84	(59.5)
	PASI 90	13/ 47	(27.7)	22/ 47	(46.8)	16/ 84	(19.0)
	PASI 100	1/ 47	(2.1)	4/ 47	(8.5)	1/ 84	(1.2)
Week 24	PASI 75	28/ 47	(59.6)	34/ 47	(72.3)	50/ 84	(59.5)
	PASI 90	15/ 47	(31.9)	19/ 47	(40.4)	25/ 84	(29.8)
	PASI 100	2/ 47	(4.3)	5/ 47	(10.6)	3/ 84	(3.6)
Week 28	PASI 75	26/ 47	(55.3)	37/ 47	(78.7)	50/ 84	(59.5)
	PASI 90	15/ 47	(31.9)	22/ 47	(46.8)	30/ 84	(35.7)
	PASI 100	1/ 47	(2.1)	6/ 47	(12.8)	5/ 84	(6.0)
Week 32	PASI 75	24/ 47	(51.1)	37/ 47	(78.7)	48/ 84	(57.1)
	PASI 90	12/ 47	(25.5)	26/ 47	(55.3)	31/ 84	(36.9)
	PASI 100	0/ 47	(0.0)	10/ 47	(21.3)	7/ 84	(8.3)
Week 36	PASI 75	21/ 47	(44.7)	35/ 47	(74.5)	52/ 84	(61.9)
	PASI 90	10/ 47	(21.3)	25/ 47	(53.2)	32/ 84	(38.1)
	PASI 100	2/ 47	(4.3)	7/ 47	(14.9)	8/ 84	(9.5)
Week 40	PASI 75	23/ 47	(48.9)	36/ 47	(76.6)	51/ 84	(60.7)
	PASI 90	11/ 47	(23.4)	24/ 47	(51.1)	28/ 84	(33.3)

	PASI 100	2/ 47	(4.3)	7/ 47	(14.9)	7/ 84	(8.3)
Week 44	PASI 75	20/ 47	(42.6)	37/ 47	(78.7)	54/ 84	(64.3)
	PASI 90	12/ 47	(25.5)	25/ 47	(53.2)	31/ 84	(36.9)
	PASI 100	3/ 47	(6.4)	8/ 47	(17.0)	7/ 84	(8.3)
Week 48	PASI 75	19/ 47	(40.4)	37/ 47	(78.7)	54/ 84	(64.3)
	PASI 90	11/ 47	(23.4)	27/ 47	(57.4)	32/ 84	(38.1)
	PASI 100	3/ 47	(6.4)	7/ 47	(14.9)	9/ 84	(10.7)
Week 52	PASI 75	19/ 47	(40.4)	35/ 47	(74.5)	49/ 84	(58.3)
	PASI 90	10/ 47	(21.3)	25/ 47	(53.2)	29/ 84	(34.5)
	PASI 100	2/ 47	(4.3)	8/ 47	(17.0)	8/ 84	(9.5)
at any time	PASI 75	38/ 47	(80.9)	45/ 47	(95.7)	69/ 84	(82.1)
up to Week 52	PASI 90	21/ 47	(44.7)	37/ 47	(78.7)	43/ 84	(51.2)
	PASI 100	4/ 47	(8.5)	14/ 47	(29.8)	13/ 84	(15.5)

Summary statistics of the EQ-5D health state assessment (from 0 to 100) and change from baseline by visit (LOCF) induction period
Full analysis set

		AIN457 150 mg N=327			AIN457 300 mg N=327			Placebo N=325			Etanercept N=326		
Visit	Statistic	Base	Post	Abs. change	Base	Post	Abs. change	Base	Post	Abs. change	Base	Post	Abs. change
Baseline	n	319			316			310			319		
	Mean	60			59.6			60.1			62.6		
	SD	23.69			23.21			23.4			22.09		
	Min	0			0			0			0		
	Q1	41			41			42			50		
	Median	61			61.5			61			69		
	Q3	80			79			80			80		
	Max	100			99			100			100		
Week 4	n	310	310	310	308	308	308	306	306	306	309	309	309
	Mean	60.1	71.7	11.6	59.7	71.4	11.8	60.3	61.6	1.2	62.6	70.5	7.9
	SD	23.75	19.51	19.74	23.29	19.68	20.08	23.29	22.73	16.21	22.01	19.06	16.2
	Min	0	5	-40	0	0	-61	0	0	-58	0	1	-58
	Q1	41	60	0	41	60	0	43	44	-9	50	60	0
	Median	61	76	9	62.5	75.5	8	61	65	1	69	75	5
	Q3	80	89	20	79	87	20	80	80	10	80	85	15
	Max	100	100	92	99	100	89	100	100	52	100	100	61
Week 8	n	317	317	317	313	313	313	308	308	308	315	315	315
	Mean	60.2	76.5	16.3	59.7	78.9	19.1	60.1	62.4	2.2	62.5	74.5	11.9
	SD	23.66	19.21	22.47	23.26	17.19	21.86	23.45	22.75	17.15	21.96	19.09	19.49

	Min	0	5	-60	0	0	-50	0	0	-54	0	0	-52
	Q1	41	70	4	41	70	5	43	48	-8	50	64	0
	Median	61	81	10	62	81	14	61	66.5	1	69	80	10
	Q3	80	90	26	79	91	31	80	80	10	80	89	20
	Max	100	100	94	99	100	89	100	100	80	100	100	80
Week 12	n	317	317	317	313	313	313	309	309	309	315	315	315
	Mean	60.2	79.9	19.7	59.7	82.1	22.3	60.2	62.3	2.2	62.5	76.9	14.4
	SD	23.66	18.44	22.87	23.26	16.31	23.17	23.41	23.77	19.65	21.96	18.25	20.17
	Min	0	5	-60	0	0	-50	0	0	-79	0	0	-52
	Q1	41	71	5	41	76	6	43	46	-9	50	70	2
	Median	61	85	15	62	86	18	61	68	1	69	80	10
	Q3	80	93	30	79	94	36	80	81	10	80	90	23
	Max	100	100	95	99	100	99	100	100	80	100	100	90

Summary statistics of the EQ-5D health state assessment (from 0 to 100) and change from baseline by visit (LOCF) maintenance period
Full analysis set

		AIN457 150 mg N=327			AIN457 300 mg N=327			Placebo - AIN457 150 mg N=142			Placebo - AIN457 300 mg N=141			Etanercept N=326		
Visit	**Statistic**	**Base**	**Post**	**Abs. change**	**Base**	**Post**	**Abs. change**	**Base**	**Post**	**Abs. change**	**Base**	**Post**	**Abs. change**	**Base**	**Post**	**Abs. change**
Week 12	n	317	317	317	313	313	313	137	137	137	133	133	133	315	315	315
	Mean	60.2	79.9	19.7	59.7	82.1	22.3	60.4	63.8	3.3	62	62.1	0.1	62.5	76.9	14.4
	SD	23.66	18.44	22.87	23.26	16.31	23.17	24.5	23.21	20.44	21.66	22.87	16.84	21.96	18.25	20.17
	Min	0	5	-60	0	0	-50	0	3	-79	0	0	-61	0	0	-52
	Q1	41	71	5	41	76	6	41	50	-8	50	49	-9	50	70	2
	Median	61	85	15	62	86	18	61	69	1	65	66	0	69	80	10
	Q3	80	93	30	79	94	36	80	84	11	80	80	10	80	90	23
	Max	100	100	95	99	100	99	100	100	80	100	100	48	100	100	90

Week 24	n	317	317	317	313	313	313	137	137	137	127	127	127	315	315	315
	Mean	60.2	81.5	21.3	59.7	84.4	24.7	60.4	80.1	19.6	62.3	83.9	21.6	62.5	78.9	16.4
	SD	23.66	17.01	23.43	23.26	15.4	24.13	24.5	17.15	22.68	21.04	14.41	22.45	21.96	17.99	20.11
	Min	0	6	-30	0	0	-50	0	20	-45	0	10	-59	0	0	-50
	Q1	41	75	5	41	80	6	41	72	6	50	79	6	50	71	3
	Median	61	87	16	62	89	20	61	85	15	65	88	15	69	84	14
	Q3	80	94	36	79	95	40	80	91	30	80	95	35	80	91	29
	Max	100	100	95	99	100	98	100	100	100	100	100	95	100	100	82
Week 36	n	317	317	317	313	313	313	137	137	137	131	131	131	315	315	315
	Mean	60.2	80.1	19.9	59.7	85	25.3	60.4	81.6	21.2	61.9	85.8	23.9	62.5	79	16.4
	SD	23.66	19.39	24.02	23.26	16.3	25.42	24.5	14.46	24.49	21.56	13.25	24.17	21.96	18.03	21.14
	Min	0	5	-36	0	1	-50	0	38	-45	0	10	-59	0	0	-61
	Q1	41	74	3	41	80	7	41	74	5	50	80	8	50	71	0
	Median	61	87	16	62	90	20	61	85	16	65	90	20	69	84	15
	Q3	80	93	35	79	96	41	80	91	40	80	95	40	80	91	28
	Max	100	100	95	99	100	100	100	100	99	100	100	91	100	100	80
Week 52	n	317	317	317	313	313	313	137	137	137	132	132	132	315	315	315
	Mean	60.2	79.5	19.3	59.7	84.9	25.1	60.4	83.5	23.1	62.2	85.8	23.6	62.5	79.3	16.8
	SD	23.66	20.36	25.33	23.26	17.13	26.04	24.5	15.69	25.67	21.67	14.45	23.36	21.96	18.7	21.52
	Min	0	4	-54	0	1	-50	0	9	-39	0	10	-59	0	0	-50
	Q1	41	70	3	41	80	5	41	80	5	50	80	7	50	71	1
	Median	61	88	15	62	90	20	61	88	17	65	90	21	69	85	14
	Q3	80	94	35	79	97	44	80	95	40	80	96	39	80	92	30
	Max	100	100	95	99	100	99	100	100	100	100	100	89	100	100	84

Summary statistics for Dermatology Life Quality Index, including change from baseline by score and visit (LOCF) induction period

Score: DLQI total score

		AIN457 150 mg N=327			AIN457 300 mg N=327			Placebo N=325			Etanercept N=326		
Visit	Statistic	Base	Post	Abs. change	Base	Post	Abs. change	Base	Post	Abs. change	Base	Post	Abs. change
Baseline	n	319			317			309			318		
	Mean	13.4			13.3			13.4			13.4		
	SD	7.04			6.99			6.57			7.29		
	Min	0			0			0			0		
	Q1	8			8			9			7		
	Median	13			13			13			13		
	Q3	18			18			18			19		
	Max	30			29			30			30		
Week 4	n	309	309	309	308	308	308	304	304	304	308	308	308
	Mean	13.4	6.7	-6.7	13.3	6.3	-7	13.3	11.6	-1.8	13.5	8.3	-5.1
	SD	7.06	5.81	6.01	6.98	5.7	5.58	6.58	7.06	5.14	7.31	6.25	5.66
	Min	0	0	-26	0	0	-27	0	0	-22	0	0	-22
	Q1	8	3	-10	8	2	-10	9	6.5	-5	7.5	3	-9
	Median	13	5	-6	13	5	-6	12	10.5	-1	13	7	-4
	Q3	18	10	-2	19	9	-3	18	16	1	19	12	-1
	Max	30	30	8	29	29	8	30	30	13	30	30	13
Week 8	n	317	317	317	314	314	314	308	308	308	313	313	313
	Mean	13.4	4.6	-8.8	13.3	3.8	-9.5	13.4	11.2	-2.2	13.4	6.3	-7.1
	SD	7.05	5.58	6.65	6.96	4.8	6.44	6.57	7.26	6.04	7.3	6.25	6.98
	Min	0	0	-29	0	0	-27	0	0	-24	0	0	-30
	Q1	8	1	-13	8	0	-14	9	5	-6	7	1	-11
	Median	13	3	-8	13	2	-9	13	10	-2	13	4	-6

	Q3	18	7	-4	18	6	-5	18	16	1	19	10	-2
	Max	30	30	12	29	29	9	30	30	18	30	28	16
Week 12	n	317	317	317	314	314	314	308	308	308	313	313	313
	Mean	13.4	3.7	-9.7	13.3	2.9	-10.4	13.4	11.5	-1.9	13.4	5.5	-7.9
	SD	7.05	5.39	6.98	6.96	4.57	6.77	6.57	7.64	7.01	7.3	6.27	7.35
	Min	0	0	-30	0	0	-29	0	0	-24	0	0	-30
	Q1	8	0	-14	8	0	-15	9	5	-6	7	1	-13
	Median	13	1	-10	13	1	-10	13	10	-2	13	3	-7
	Q3	18	5	-4	18	4	-6	18	16.5	2	19	8	-3
	Max	30	30	12	29	29	9	30	30	23	30	29	19

Summary statistics for Dermatology Life Quality Index, including change from baseline by score and visit (LOCF) maintenance period

Score: DLQI total score

		AIN457 150 mg N=327			AIN457 300 mg N=327			Placebo - AIN457 150 mg N=142			Placebo - AIN457 300 mg N=141			Etanercept N=326		
Visit	**Statistic**	**Base**	**Post**	**Abs. change**	**Base**	**Post**	**Abs. change**	**Base**	**Post**	**Abs. change**	**Base**	**Post**	**Abs. change**	**Base**	**Post**	**Abs. change**
Week 12	n	317	317	317	314	314	314	136	136	136	133	133	133	313	313	313
	Mean	13.4	3.7	-9.7	13.3	2.9	-10.4	13.2	11.7	-1.5	12.8	10.8	-2	13.4	5.5	-7.9
	SD	7.05	5.39	6.98	6.96	4.57	6.77	6.79	7.83	6.93	5.92	7.03	6.02	7.3	6.27	7.35
	Min	0	0	-30	0	0	-29	1	0	-22	0	0	-19	0	0	-30
	Q1	8	0	-14	8	0	-15	8	5.5	-6	9	6	-5	7	1	-13
	Median	13	1	-10	13	1	-10	13	10	-1	12	9	-2	13	3	-7
	Q3	18	5	-4	18	4	-6	18	17	2.5	17	15	1	19	8	-3
	Max	30	30	12	29	29	9	30	30	21	30	29	23	30	29	19
Week 24	n	317	317	317	314	314	314	136	136	136	127	127	127	313	313	313
	Mean	13.4	3.3	-10.1	13.3	2.4	-10.9	13.2	3.1	-10.1	12.8	1.8	-11	13.4	4.6	-8.8
	SD	7.05	5.52	7.08	6.96	4.79	7.17	6.79	4.58	7.06	5.99	3.66	6.48	7.3	6.3	7.95
	Min	0	0	-30	0	0	-29	1	0	-28	0	0	-30	0	0	-30

	Q1	8	0	-14	8	0	-16	8	0	-14	9	0	-15	7	0	-14
	Median	13	1	-10	13	0	-10	13	1	-9	12	0	-11	13	2	-9
	Q3	18	4	-5	18	3	-6	18	4	-6	17	2	-7	19	6	-3
	Max	30	30	14	29	29	18	30	25	8	30	27	18	30	30	19
Week 36	n	317	317	317	314	314	314	136	136	136	131	131	131	313	313	313
	Mean	13.4	3.8	-9.6	13.3	2.5	-10.8	13.2	3.3	-10	12.9	1.5	-11.4	13.4	4.4	-9
	SD	7.05	6.14	7.45	6.96	4.92	7.08	6.79	5.08	7.06	5.93	3.33	6.6	7.3	6.32	8.24
	Min	0	0	-29	0	0	-29	1	0	-27	0	0	-27	0	0	-30
	Q1	8	0	-14	8	0	-16	8	0	-14	9	0	-16	7	0	-14
	Median	13	1	-9	13	0	-10	13	1	-9	12	0	-11	13	2	-9
	Q3	18	5	-4	18	3	-6	18	5	-5.5	17	1	-8	19	6	-3
	Max	30	30	14	29	29	9	30	21	8	30	27	18	30	29	19
Week 52	n	317	317	317	314	314	314	136	136	136	132	132	132	313	313	313
	Mean	13.4	4.2	-9.2	13.3	2.4	-10.8	13.2	3.4	-9.8	12.8	1.5	-11.3	13.4	4.6	-8.7
	SD	7.05	6.5	7.5	6.96	5.11	7.16	6.79	5.28	7.5	5.94	3.35	6.44	7.3	6.54	8.18
	Min	0	0	-29	0	0	-29	1	0	-27	0	0	-27	0	0	-30
	Q1	8	0	-14	8	0	-16	8	0	-14.5	9	0	-15.5	7	0	-14
	Median	13	1	-9	13	0	-10	13	1	-9	12	0	-11	13	2	-8
	Q3	18	6	-4	18	2	-6	18	4	-5	17	1	-7.5	19	6	-3
	Max	30	30	14	29	29	10	30	26	12	30	27	18	30	29	21

Number (%) of subjects with Dermatology Life Quality Index response (DLQI 0 or 1) by visit (LOCF) induction period

Visit	Treatment	n/m (%)
Week 4	AIN457 150 mg	58/316 (18.4)
	AIN457 300 mg	60/316 (19.0)
	Placebo	18/316 (5.7)
	Etanercept	41/314 (13.1)

Visit	Treatment	n/m (%)
Week 8	AIN457 150 mg	132/324 (40.7)
	AIN457 300 mg	144/322 (44.7)
	Placebo	22/320 (6.9)
	Etanercept	87/319 (27.3)
Week 12	AIN457 150 mg	164/324 (50.6)
	AIN457 300 mg	183/323 (56.7)
	Placebo	21/320 (6.6)
	Etanercept	110/319 (34.5)

Number (%) of subjects with Dermatology Life Quality Index response (DLQI 0 or 1) by visit (LOCF) maintenance period

Visit	Treatment	n/m (%)
Week 12	AIN457 150 mg	164/324 (50.6)
	AIN457 300 mg	183/323 (56.7)
	Placebo - AIN457 150 mg	11/142 (7.7)
	Placebo - AIN457 300 mg	8/139 (5.8)
	Placebo	2/ 17 (11.8)
	Etanercept	110/319 (34.5)

Week 24	AIN457 150 mg	184/324 (56.8)
	AIN457 300 mg	225/323 (69.7)
	Placebo - AIN457 150 mg	85/142 (59.9)
	Placebo - AIN457 300 mg	90/134 (67.2)
	Placebo	4/ 17 (23.5)
	Etanercept	137/320 (42.8)
Week 36	AIN457 150 mg	188/324 (58.0)
	AIN457 300 mg	215/323 (66.6)
	Placebo - AIN457 150 mg	81/142 (57.0)
	Placebo - AIN457 300 mg	104/139 (74.8)
	Placebo	6/ 17 (35.3)
	Etanercept	152/320 (47.5)
Week 52	AIN457 150 mg	182/324 (56.2)
	AIN457 300 mg	225/323 (69.7)
	Placebo - AIN457 150 mg	78/142 (54.9)
	Placebo - AIN457 300 mg	107/140 (76.4)
	Placebo	7/ 17 (41.2)
	Etanercept	150/320 (46.9)

Number (%) of subjects with PASI 50, PASI 75, PASI 90, PASI 100 and IGA mod 2011 0 or 1 response at week 12 by previous biologic therapy induction period

Previous biologic therapy : Yes, Failure : Yes

Visit	Criterion	AIN457 150 mg N=15 n/m (%)	AIN457 300 mg N=16 n/m (%)	Placebo N=12 n/m (%)	Etanercept N=16 n/m (%)
Week 12	IGA 0/1	3/15 (20.0)	6/16 (37.5)	0/12 (0.0)	4/16 (25.0)
	PASI 50	10/15 (66.7)	13/16 (81.3)	1/12 (8.3)	9/16 (56.3)
	PASI 75	7/15 (46.7)	11/16 (68.8)	0/12 (0.0)	6/16 (37.5)
	PASI 90	3/15 (20.0)	7/16 (43.8)	0/12 (0.0)	2/16 (12.5)
	PASI 100	1/15 (6.7)	3/16 (18.8)	0/12 (0.0)	1/16 (6.3)

Summary of Safety

Safety Results

Adverse Events by System Organ Class

Treatment emergent adverse events, by primary system organ class - induction period (Safety set)

Primary system organ class	AIN457 150 mg N=327 n (%)	AIN457 300 mg N=326 n (%)	Any AIN457 dose N=653 n (%)	Placebo N=327 n (%)	Etanercept N=323 n (%)
- Any primary system organ class	190 (58.1)	181 (55.5)	371 (56.8)	163 (49.8)	187 (57.9)

Primary system organ class	AIN457 150 mg N=327 n (%)	AIN457 300 mg N=326 n (%)	Any AIN457 dose N=653 n (%)	Placebo N=327 n (%)	Etanercept N=323 n (%)
INFECTIONS AND INFESTATIONS	101 (30.9)	87 (26.7)	188 (28.8)	63 (19.3)	80 (24.8)
GASTROINTESTINAL DISORDERS	38 (11.6)	48 (14.7)	86 (13.2)	35 (10.7)	32 (9.9)
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	44 (13.5)	35 (10.7)	79 (12.1)	29 (8.9)	35 (10.8)
NERVOUS SYSTEM DISORDERS	30 (9.2)	40 (12.3)	70 (10.7)	31 (9.5)	29 (9.0)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	41 (12.5)	28 (8.6)	69 (10.6)	26 (8.0)	27 (8.4)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	18 (5.5)	28 (8.6)	46 (7.0)	18 (5.5)	16 (5.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	24 (7.3)	20 (6.1)	44 (6.7)	19 (5.8)	58 (18.0)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	17 (5.2)	16 (4.9)	33 (5.1)	16 (4.9)	14 (4.3)

Primary system organ class	AIN457 150 mg N=327 n (%)	AIN457 300 mg N=326 n (%)	Any AIN457 dose N=653 n (%)	Placebo N=327 n (%)	Etanercept N=323 n (%)
METABOLISM AND NUTRITION DISORDERS	16 (4.9)	7 (2.1)	23 (3.5)	14 (4.3)	12 (3.7)
INVESTIGATIONS	11 (3.4)	8 (2.5)	19 (2.9)	7 (2.1)	12 (3.7)
VASCULAR DISORDERS	12 (3.7)	6 (1.8)	18 (2.8)	7 (2.1)	7 (2.2)
EYE DISORDERS	5 (1.5)	11 (3.4)	16 (2.5)	5 (1.5)	1 (0.3)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	5 (1.5)	8 (2.5)	13 (2.0)	5 (1.5)	8 (2.5)
PSYCHIATRIC DISORDERS	4 (1.2)	7 (2.1)	11 (1.7)	10 (3.1)	6 (1.9)
RENAL AND URINARY DISORDERS	5 (1.5)	4 (1.2)	9 (1.4)	1 (0.3)	5 (1.5)
EAR AND LABYRINTH DISORDERS	4 (1.2)	4 (1.2)	8 (1.2)	3 (0.9)	2 (0.6)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	2 (0.6)	5 (1.5)	7 (1.1)	2 (0.6)	2 (0.6)
CARDIAC DISORDERS	4 (1.2)	2 (0.6)	6 (0.9)	6 (1.8)	7 (2.2)
IMMUNE SYSTEM DISORDERS	4 (1.2)	1 (0.3)	5 (0.8)	1 (0.3)	4 (1.2)
HEPATOBILIARY DISORDERS	2 (0.6)	1 (0.3)	3 (0.5)	0 (0.0)	2 (0.6)

Primary system organ class	AIN457 150 mg N=327 n (%)	AIN457 300 mg N=326 n (%)	Any AIN457 dose N=653 n (%)	Placebo N=327 n (%)	Etanercept N=323 n (%)
NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	2 (0.6)	1 (0.3)	3 (0.5)	3 (0.9)	4 (1.2)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0 (0.0)	1 (0.3)	1 (0.2)	0 (0.0)	0 (0.0)
SOCIAL CIRCUMSTANCES	1 (0.3)	0 (0.0)	1 (0.2)	2 (0.6)	0 (0.0)

Treatment emergent adverse events, by primary system organ class – entire Treatment Period (Safety Set)

	Any AIN457 150 mg N=469	Any AIN457 300 mg N=467	Any AIN457 dose N=936	Placebo N=327	Etanercept N=323
Primary system organ class	**n (%)**	**n (%)**	**n (%)**	**n (%)**	**n (%)**
-Any primary system organ class	367 (78.3)	376 (80.5)	743 (79.4)	168 (51.4)	255 (78.9)
INFECTIONS AND INFESTATIONS	241 (51.4)	269 (57.6)	510 (54.5)	65 (19.9)	171 (52.9)
GASTROINTESTINAL DISORDERS	113 (24.1)	108 (23.1)	221 (23.6)	37 (11.3)	68 (21.1)

SKIN AND SUBCUTANEOUS TISSUE DISORDERS	103 (22.0)	97 (20.8)	200 (21.4)	30 (9.2)	62 (19.2)
MUSCULOSKELETAL AND CONNECTIVE TISSUE DISORDERS	101 (21.5)	97 (20.8)	198 (21.2)	26 (8.0)	69 (21.4)
NERVOUS SYSTEM DISORDERS	73 (15.6)	83 (17.8)	156 (16.7)	33 (10.1)	55 (17.0)
GENERAL DISORDERS AND ADMINISTRATION SITE CONDITIONS	60 (12.8)	69 (14.8)	129 (13.8)	19 (5.8)	79 (24.5)
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	55 (11.7)	74 (15.8)	129 (13.8)	19 (5.8)	35 (10.8)
INJURY, POISONING AND PROCEDURAL COMPLICATIONS	64 (13.6)	56 (12.0)	120 (12.8)	17 (5.2)	38 (11.8)
METABOLISM AND NUTRITION DISORDERS	49 (10.4)	33 (7.1)	82 (8.8)	15 (4.6)	25 (7.7)
INVESTIGATIONS	34 (7.2)	30 (6.4)	64 (6.8)	7 (2.1)	24 (7.4)
VASCULAR DISORDERS	31 (6.6)	28 (6.0)	59 (6.3)	8 (2.4)	17 (5.3)
EYE DISORDERS	17 (3.6)	24 (5.1)	41 (4.4)	5 (1.5)	10 (3.1)
PSYCHIATRIC DISORDERS	19 (4.1)	21 (4.5)	40 (4.3)	10 (3.1)	16 (5.0)
BLOOD AND LYMPHATIC SYSTEM DISORDERS	14 (3.0)	25 (5.4)	39 (4.2)	5 (1.5)	16 (5.0)

NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)	15 (3.2)	20 (4.3)	35 (3.7)	3 (0.9)	10 (3.1)
CARDIAC DISORDERS	17 (3.6)	13 (2.8)	30 (3.2)	6 (1.8)	15 (4.6)
RENAL AND URINARY DISORDERS	18 (3.8)	12 (2.6)	30 (3.2)	2 (0.6)	9 (2.8)
REPRODUCTIVE SYSTEM AND BREAST DISORDERS	15 (3.2)	13 (2.8)	28 (3.0)	2 (0.6)	4 (1.2)
EAR AND LABYRINTH DISORDERS	9 (1.9)	14 (3.0)	23 (2.5)	3 (0.9)	3 (0.9)
IMMUNE SYSTEM DISORDERS	8 (1.7)	4 (0.9)	12 (1.3)	1 (0.3)	8 (2.5)
HEPATOBILIARY DISORDERS	7 (1.5)	4 (0.9)	11 (1.2)	1 (0.3)	5 (1.5)
ENDOCRINE DISORDERS	3 (0.6)	4 (0.9)	7 (0.7)	0 (0.0)	1 (0.3)
SOCIAL CIRCUMSTANCES	2 (0.4)	1 (0.2)	3 (0.3)	2 (0.6)	0 (0.0)
CONGENITAL, FAMILIAL AND GENETIC DISORDERS	0 (0.0)	2 (0.4)	2 (0.2)	0 (0.0)	0 (0.0)

AEs by primary system organ class – Follow-up period (Safety set, patients of the follow-up period)

Primary system organ class	Any AIN457 150 mg N=148 n (%)	Any AIN457 300 mg N=125 n (%)	Any AIN457 dose N=273 n (%)	Placebo N=27 n (%)	Etanercept N=278 n (%)
Any primary system organ class	**32 (21.6)**	**21 (16.8)**	**53 (19.4)**	**7 (25.9)**	**90 (32.4)**
Infections and infestations	11 (7.4)	4 (3.2)	15 (5.5)	5 (18.5)	30 (10.8)
Skin and subcutaneous tissue disorders	9 (6.1)	6 (4.8)	15 (5.5)	0 (0)	23 (8.3)
Musculoskeletal and connective tissue disorders	7 (4.7)	2 (1.6)	9 (3.3)	0 (0)	16 (5.8)
Nervous system disorders	5 (3.4)	2 (1.6)	7 (2.6)	0 (0)	3 (1.1)
General disorders and administration site conditions	4 (2.7)	2 (1.6)	6 (2.2)	1 (3.7)	8 (2.9)
Metabolism and nutrition disorders	4 (2.7)	2 (1.6)	6 (2.2)	0 (0)	3 (1.1)
Gastrointestinal disorders	4 (2.7)	1 (0.8)	5 (1.8)	0 (0)	8 (2.9)
Injury, poisoning and procedural complications	2 (1.4)	3 (2.4)	5 (1.8)	1 (3.7)	4 (1.4)
Respiratory, thoracic and mediastinal disorders	2 (1.4)	2 (1.6)	4 (1.5)	0 (0)	4 (1.4)
Endocrine disorders	1 (0.7)	1 (0.8)	2 (0.7)	0 (0)	0 (0)
Investigations	1 (0.7)	0 (0)	1 (0.4)	0 (0)	4 (1.4)
Vascular disorders	0 (0)	1 (0.8)	1 (0.4)	0 (0)	3 (1.1)
Blood and lymphatic system disorders	1 (0.7)	0 (0)	1 (0.4)	0 (0)	3 (1.1)
Ear and labyrinth disorders	0 (0)	1 (0.8)	1 (0.4)	0 (0)	2 (0.7)
Cardiac disorders	0 (0)	1 (0.8)	1 (0.4)	0 (0)	2 (0.7)
Eye disorders	0 (0)	1 (0.8)	1 (0.4)	0 (0)	1 (0.4)
Immune system disorders	1 (0.7)	0 (0)	1 (0.4)	0 (0)	0 (0)
Psychiatric disorders	0 (0)	0 (0)	0 (0)	0 (0)	2 (0.7)
Renal and urinary disorders	0 (0)	0 (0)	0 (0)	1 (3.7)	1 (0.4)
Hepatobiliary disorders	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.4)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	0 (0)	0 (0)	0 (0)	0 (0)	1 (0.4)

Primary system organ class	Any AIN457 150 mg N=148 n (%)	Any AIN457 300 mg N=125 n (%)	Any AIN457 dose N=273 n (%)	Placebo N=27 n (%)	Etanercept N=278 n (%)

Primary system organ classes are sorted in descending order of frequency in the “Any AIN457 dose” group.

Most frequent (>=2% in any treatment group) treatment emergent adverse events, by preferred term
induction period
Safety set

Preferred term	AIN457 150 mg N=327 n (%)	AIN457 300 mg N=326 n (%)	Any AIN457 dose N=653 n (%)	Placebo N=327 n (%)	Etanercept N=323 n (%)
-Any preferred term	190 (58.1)	181 (55.5)	371 (56.8)	163 (49.8)	187 (57.9)
NASOPHARYNGITIS	44 (13.5)	35 (10.7)	79 (12.1)	26 (8.0)	37 (11.5)
HEADACHE	16 (4.9)	30 (9.2)	46 (7.0)	23 (7.0)	23 (7.1)
DIARRHOEA	12 (3.7)	17 (5.2)	29 (4.4)	6 (1.8)	11 (3.4)
PRURITUS	12 (3.7)	8 (2.5)	20 (3.1)	11 (3.4)	9 (2.8)
ARTHRALGIA	14 (4.3)	5 (1.5)	19 (2.9)	10 (3.1)	12 (3.7)
COUGH	6 (1.8)	11 (3.4)	17 (2.6)	4 (1.2)	4 (1.2)

Preferred term	AIN457 150 mg N=327 n (%)	AIN457 300 mg N=326 n (%)	Any AIN457 dose N=653 n (%)	Placebo N=327 n (%)	Etanercept N=323 n (%)
UPPER RESPIRATORY TRACT INFECTION	10 (3.1)	7 (2.1)	17 (2.6)	3 (0.9)	7 (2.2)
BACK PAIN	8 (2.4)	8 (2.5)	16 (2.5)	6 (1.8)	10 (3.1)
HYPERTENSION	10 (3.1)	5 (1.5)	15 (2.3)	4 (1.2)	5 (1.5)
NAUSEA	6 (1.8)	8 (2.5)	14 (2.1)	7 (2.1)	4 (1.2)
OROPHARYNGEAL PAIN	5 (1.5)	9 (2.8)	14 (2.1)	7 (2.1)	4 (1.2)
FATIGUE	5 (1.5)	7 (2.1)	12 (1.8)	3 (0.9)	5 (1.5)
RHINITIS	4 (1.2)	7 (2.1)	11 (1.7)	4 (1.2)	3 (0.9)
RHINORRHOEA	1 (0.3)	7 (2.1)	8 (1.2)	1 (0.3)	2 (0.6)
PYREXIA	2 (0.6)	5 (1.5)	7 (1.1)	3 (0.9)	7 (2.2)
PSORIASIS	5 (1.5)	1 (0.3)	6 (0.9)	8 (2.4)	2 (0.6)
INJECTION SITE ERYTHEMA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	16 (5.0)

Most frequent (>=2% in any treatment group) treatment emergent adverse events, by preferred term
entire treatment period
Safety set

Preferred term	Any AIN457 150 mg N=469 n (%)	Any AIN457 300 mg N=467 n (%)	Any AIN457 dose N=936 n (%)	Placebo N=327 n (%)	Etanercept N=323 n (%)
-Any preferred term	367 (78.3)	376 (80.5)	743 (79.4)	168 (51.4)	255 (78.9)
NASOPHARYNGITIS	107 (22.8)	122 (26.1)	229 (24.5)	26 (8.0)	87 (26.9)
HEADACHE	47 (10.0)	59 (12.6)	106 (11.3)	24 (7.3)	40 (12.4)
DIARRHOEA	36 (7.7)	38 (8.1)	74 (7.9)	7 (2.1)	22 (6.8)
ARTHRALGIA	32 (6.8)	24 (5.1)	56 (6.0)	10 (3.1)	23 (7.1)
UPPER RESPIRATORY TRACT INFECTION	26 (5.5)	26 (5.6)	52 (5.6)	3 (0.9)	18 (5.6)
BACK PAIN	20 (4.3)	31 (6.6)	51 (5.4)	6 (1.8)	27 (8.4)
COUGH	16 (3.4)	30 (6.4)	46 (4.9)	4 (1.2)	12 (3.7)
OROPHARYNGEAL PAIN	20 (4.3)	26 (5.6)	46 (4.9)	7 (2.1)	10 (3.1)

HYPERTENSION	22 (4.7)	20 (4.3)	42 (4.5)	4 (1.2)	14 (4.3)
PRURITUS	21 (4.5)	17 (3.6)	38 (4.1)	11 (3.4)	16 (5.0)
INFLUENZA	12 (2.6)	22 (4.7)	34 (3.6)	3 (0.9)	11 (3.4)
PYREXIA	14 (3.0)	19 (4.1)	33 (3.5)	3 (0.9)	15 (4.6)
BRONCHITIS	14 (3.0)	17 (3.6)	31 (3.3)	2 (0.6)	9 (2.8)
GASTROENTERITIS	12 (2.6)	18 (3.9)	30 (3.2)	3 (0.9)	8 (2.5)
FATIGUE	12 (2.6)	16 (3.4)	28 (3.0)	3 (0.9)	6 (1.9)
FOLLICULITIS	14 (3.0)	13 (2.8)	27 (2.9)	1 (0.3)	8 (2.5)
ABDOMINAL PAIN UPPER	12 (2.6)	14 (3.0)	26 (2.8)	4 (1.2)	3 (0.9)
TOOTHACHE	12 (2.6)	13 (2.8)	25 (2.7)	6 (1.8)	7 (2.2)
PHARYNGITIS	10 (2.1)	13 (2.8)	23 (2.5)	0 (0.0)	6 (1.9)
RHINITIS	8 (1.7)	14 (3.0)	22 (2.4)	4 (1.2)	6 (1.9)
TONSILLITIS	10 (2.1)	12 (2.6)	22 (2.4)	2 (0.6)	3 (0.9)
ECZEMA	10 (2.1)	11 (2.4)	21 (2.2)	0 (0.0)	2 (0.6)
NAUSEA	10 (2.1)	11 (2.4)	21 (2.2)	7 (2.1)	7 (2.2)
PAIN IN EXTREMITY	8 (1.7)	13 (2.8)	21 (2.2)	4 (1.2)	4 (1.2)
URINARY TRACT INFECTION	8 (1.7)	13 (2.8)	21 (2.2)	3 (0.9)	10 (3.1)
SINUSITIS	11 (2.3)	9 (1.9)	20 (2.1)	1 (0.3)	5 (1.5)
MYALGIA	9 (1.9)	10 (2.1)	19 (2.0)	4 (1.2)	9 (2.8)
PSORIASIS	11 (2.3)	8 (1.7)	19 (2.0)	8 (2.4)	7 (2.2)

VIRAL UPPER RESPIRATORY TRACT INFECTION	8 (1.7)	11 (2.4)	19 (2.0)	1 (0.3)	1 (0.3)
ORAL CANDIDIASIS	6 (1.3)	12 (2.6)	18 (1.9)	0 (0.0)	0 (0.0)
ABDOMINAL PAIN	11 (2.3)	6 (1.3)	17 (1.8)	4 (1.2)	8 (2.5)
TINEA PEDIS	7 (1.5)	10 (2.1)	17 (1.8)	0 (0.0)	4 (1.2)
HYPERCHOLESTEROLAEMIA	10 (2.1)	6 (1.3)	16 (1.7)	5 (1.5)	7 (2.2)
INFLUENZA LIKE ILLNESS	7 (1.5)	8 (1.7)	15 (1.6)	1 (0.3)	9 (2.8)
MUSCULOSKELETAL PAIN	10 (2.1)	4 (0.9)	14 (1.5)	1 (0.3)	1 (0.3)
OEDEMA PERIPHERAL	10 (2.1)	4 (0.9)	14 (1.5)	4 (1.2)	5 (1.5)
ORAL HERPES	4 (0.9)	10 (2.1)	14 (1.5)	0 (0.0)	9 (2.8)
VOMITING	4 (0.9)	10 (2.1)	14 (1.5)	1 (0.3)	9 (2.8)
CONJUNCTIVITIS	3 (0.6)	10 (2.1)	13 (1.4)	1 (0.3)	3 (0.9)
RHINORRHOEA	3 (0.6)	10 (2.1)	13 (1.4)	1 (0.3)	2 (0.6)
INJECTION SITE ERYTHEMA	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	17 (5.3)

AEs by preferred term (at least 1% incidence in any treatment group) – Follow-up period (Safety set, patients of the follow-up period)

Preferred term	Any AIN457 150 mg N=148 n (%)	Any AIN457 300 mg N=125 n (%)	Any AIN457 dose N=273 n (%)	Placebo N=27 n (%)	Etanercept N=278 n (%)
Erythrodermic psoriasis	3 (2.0)	5 (4.0)	8 (2.9)	0 (0)	12 (4.3)
Nasopharyngitis	6 (4.1)	1 (0.8)	7 (2.6)	3 (11.1)	14 (5.0)
Headache	3 (2.0)	2 (1.6)	5 (1.8)	0 (0)	2 (0.7)
Arthralgia	3 (2.0)	0 (0)	3 (1.1)	0 (0)	6 (2.2)
Diarrhoea	2 (1.4)	1 (0.8)	3 (1.1)	0 (0)	3 (1.1)
Pruritus	2 (1.4)	1 (0.8)	3 (1.1)	0 (0)	1 (0.4)
Pain in extremity	2 (1.4)	1 (0.8)	3 (1.1)	0 (0)	1 (0.4)
Psoriasis	2 (1.4)	0 (0)	2 (0.7)	0 (0)	5 (1.8)
Psoriatic arthropathy	2 (1.4)	0 (0)	2 (0.7)	0 (0)	3 (1.1)
Feeling hot	2 (1.4)	0 (0)	2 (0.7)	0 (0)	0 (0)
Viral upper respiratory tract infection	2 (1.4)	0 (0)	2 (0.7)	0 (0)	0 (0)
Hypercholesterolaemia	2 (1.4)	0 (0)	2 (0.7)	0 (0)	0 (0)
Paraesthesia	2 (1.4)	0 (0)	2 (0.7)	0 (0)	0 (0)
Gout	1 (0.7)	0 (0)	1 (0.4)	0 (0)	3 (1.1)
Eczema	0 (0)	0 (0)	0 (0)	0 (0)	3 (1.1)
Urethral haemorrhage	0 (0)	0 (0)	0 (0)	1 (3.7)	0 (0)

AEs are sorted in descending order of frequency in the “Any AIN457 dose” group.

Serious Adverse Events and Deaths

Deaths, other serious or clinically significant adverse events or related discontinuations – entire treatment period (Safety set)

	Any AIN457 150 mg N=469 n (%)	Any AIN457 300 mg N=467 n (%)	Any AIN457 dose N=936 n (%)	Placebo N=327 n (%)	Etanercept N=323 n (%)
Subjects with any AE(s)	367 (78.3)	376 (80.5)	743 (79.4)	168 (51.4)	255 (78.9)
Subjects with serious or other significant events					
Death	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Non fatal SAE(s)	24 (5.1)	27 (5.8)	51 (5.4)	7 (2.1)	20 (6.2)
Discontinued study treatment due to any AE(s)	9 (1.9)	14 (3.0)	23 (2.5)	3 (0.9)	12 (3.7)

Deaths, other serious or clinically significant adverse events – Follow up Period (Safety set)

	Any AIN457 150 mg N=148 n (%)	Any AIN457 300 mg N=125 n (%)	Any AIN457 dose N=273 n (%)	Placebo N=27 n (%)	Etanercept N=278 n (%)
Subjects with any AE(s)	32 (21.6)	21 (16.8)	53 (19.4)	7 (25.9)	90 (32.4)
Subjects with serious or other significant events					
Death	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Non-fatal SAE(s)	2 (1.4)	2 (1.6)	4 (1.5)	0 (0.0)	2 (0.7)

Number of participants developing anti-secukinumab antibodies

	AIN457 150 mg	AIN457 300 mg	Placebo - AIN457 150 mg	Placebo - AIN457 300 mg	Placebo	Etanercept
Number of Participants Analyzed	327	327	142	142	17	326
Number of participants developing anti-secukinumab antibodies	2	3	0	0	0	6

Describes the number of participants tested positive for anti-secukinumab antibodies (52 Wk treatment and 8 Wk treatment –free follow up. It refers to the number of patients who had no positive values at baseline but developed them only after start of active study treatment (AIN457 or etanercept).

Conclusion

Secukinumab demonstrated a rapid onset of efficacy with superior efficacy over placebo and etanercept in the treatment of patients with moderate to severe chronic plaque-type psoriasis. Secukinumab 300 mg and 150 mg were both significantly superior to placebo and etanercept with respect to PASI 75 and to IGA mod 2011 0 or 1 response at Week 12. Moreover, both secukinumab doses were superior to placebo in the PASI 90 response at Week 12. Rapid onset of efficacy was demonstrated with the higher efficacy of 300 mg and 150 mg secukinumab relative to placebo and etanercept appearing as early as Week 2 for PASI 50, Week 3 for PASI 75 and IGA mod 2011 0 or 1, and Week 4 for PASI 90, with a peak effect seen around Week 16 for PASI 75 and IGA mod 2011 0 or 1 responders. A higher percentage of responders were observed in the secukinumab 300 mg group than in the secukinumab 150 mg group. The efficacy of secukinumab was sustained up to 52 weeks of treatment with a statistically significantly greater percentage of patients achieving PASI 75 response and IGA mod 2011 0 or 1 response at Week 52 compared with etanercept and placebo. Secukinumab 300 mg improved responses rates, particularly for IGA mod 2011 0 or 1 responders, PASI 90 and PASI 100; all endpoints reflecting higher levels of plaque clearance. Both secukinumab doses were superior to placebo and showed greater improvement vs. etanercept in the Psoriasis Symptom Diary items itching, pain, and scaling at Week 12. The safety profile of secukinumab at both doses showed no new or unexpected safety signals. Infection rates were comparable for any secukinumab dose group and the etanercept group, and both were higher than in the placebo group. The incidence of serious infections was low and comparable across treatments.

Date of Clinical Trial Report

Week 52 CSR: 25 Sep 2013

Week 60 Follow up Period CSR: 21 Mar 2014

Date of Initial Inclusion on Novartis Clinical Trial Results website

March 13, 2015

Date of Latest Update

July 9, 2015

Reason for Update

Addition of Randomized center table