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GENERIC DRUG NAME / COMPOUND NUMBER: Etanercept / PF-05208752

PROTOCOL NO.: 0881A6-318-EU (B1801277)

PROTOCOL TITLE: A Multicenter, Parallel, Randomized, Double-Blind, Placebo-Controlled Trial Evaluating the Safety and Efficacy of Etanercept 50 mg Once Weekly in Subjects with Moderate to Severe Plaque Psoriasis.

Study Centers: A total of29 centers who took part in the study and enrolled subjects which included 6 in Germany , 5 in Romania , 4 in Poland , 4 in Belgium , 3 in France , 2 in Hungary , 2 in Spain , 2 in The Netherlands , and 1 in Italy .

Study Initiation Date and Final Completion Dates: 24 May 2006 to 07 May 2007

Phase of Development: Phase 3

Study Objectives:

Primary Objective:

The primary objective is to assess the efficacy and safety of etanercept 50 mg administered once weekly in subjects with psoriasis over 12 weeks.

Secondary Objective:

The secondary objective is to evaluate the quality of life, pharmacokinetics as well as the open-label safety and efficacy of etanercept administered once weekly for up to 24 weeks.

METHODS

Study Design: This was a multicenter, parallel, randomized, double-blind, placebo-controlled study in subjects with moderate to severe plaque psoriasis. The study consisted of 2 parts: a 12-week, double-blind treatment period (Part A) and a 12-week, open-label treatment period (Part B). During Part A of the study, subjects were randomly assigned to 1 of 2 treatment regimens: etanercept 50 mg once weekly (QW) or placebo QW, administered subcutaneously (SC) according to a 2:1 treatment allocation. Subjects who completed 12 weeks of double-blind treatment continued into the open-label period of the study where all subjects received etanercept 50 mg QW.

A flowchart of study assessments appears below in Table 1.

Table 1: Study Flowchart

Study Procedures	Weeks -4 to -1	Week 0	Week 2	Week 4	Week 8	Week 12	Week 16	Week 20	Week 24	Early Withdrawal	Week 26
Study Interval	**Screening**	**Baseline**	**Double-Blind Treatment (Part A)**				**Open-Label Treatment (Part B)**				**Follow-up**
Signed informed consent	X										
Medical history/update	X	X									
Inclusion/exclusion criteria	X	X[a]									
Record prior medications	X	X									
Record concomitant medications			X	X	X	X	X	X	X	X	X[b]
Randomization		X									
Physical examination	X	X							X	X	
Vital sign measurements	X	X	X	X	X	X	X	X	X	X	
Height and weight	X								X[c]	X[c]	
Body surface area involvement	X	X	X	X	X	X	X	X	X	X	
Physician global assessment of psoriasis	X	X[a]	X	X	X	X	X	X	X	X	
Subject global assessment of psoriasis		X	X	X	X	X	X	X	X	X	
PASI	X	X[a]	X	X	X	X	X	X	X	X	
DLQI		X	X	X	X	X	X	X	X	X	
EQ-5D		X				X			X	X	
FACIT-Fatigue scale		X				X			X	X	
Pregnancy test[d]	X	X[a]							X	X	
Chemistry/hematology/urinalysis	X	X[a]				X			X	X	
Serum etanercept concentration (PK analysis)				X	X	X				X	
Chest x-ray[e]	X										
Adverse event evaluation		X	X	X	X	X	X	X	X	X	X
Conclusion of phase						X			X	X	
Conclusion of participation											X
Dispense diary card		X		X	X	X	X	X			
Dispense test article[f]		X		X	X	X	X	X			

DLQI = dermatology life quality index; EQ-5D = euro qol 5-dimension delf-report questionnaire; FACIT = functional assessment of chronic illness therapy; PASI = psoriasis area and severity index; PK = pharmacokinetic.

a. Waived if the first dose was within 14 days after the screening evaluation
b. To be recorded if the subject reported adverse events during the follow-up visit.
c. Weight only.
d. Serum pregnancy test for women who were of childbearing potential or were <1 year postmenopausal.
e. Waived if within 12 months and report was available and was included in subject's source documents.
f. Test article to be given subcutaneously once weekly for 24 weeks, with the first dose administered after baseline evaluations were completed.

Number of Subjects (Planned and Analyzed): It was planned to enroll 120 subjects in the study. A total of 143 were randomly assigned to treatment which included 32 in Poland, 31 in Germany, 26 in Romania, 16 in France, 13 in Hungary, 11 in Belgium, 7 in Spain, 5 in The Netherlands, and 2 in Italy. But 142 subjects received test article (96 received etanercept 50 mg QW and 46 received placebo), 16 were withdrawn from the double-blind period and 126 completed 12 weeks of therapy; 126 entered the open-label period; 4 were withdrawn from the open-label period and 122 completed the study.

Diagnosis and Main Criteria for Inclusion: Adults greater than or equal to 18 years of age with clinically stable plaque psoriasis involving greater than or equal to 10% of the body surface and a minimum Psoriasis Area and Severity Index (PASI) score of 10 at screening and failure to respond to, or have a contraindication to, or intolerant to at least 1 of the following systemic or phototherapies at an adequate dose of sufficient duration: methotrexate (MTX), acitretin, cyclosporine, ultraviolet A (UVA), ultraviolet B (UVB), psoralen with ultraviolet A (PUVA), or fumarate. Exclusion Criteria included previous treatment with etanercept, antibody to tumor necrosis factor (TNF) or other TNF inhibitors and presence of active guttate, erythrodermic, or pustular psoriasis at the time of the screening or Baseline.

Study Treatment: Test article was supplied as either placebo or etanercept 50 mg in a sterile lyophilized powder for SC injection QW for 12-weeks (Part A). After completion of Part A, all subject received etanercept 50 mg in a sterile lyophilized powder for SC injection QW for 12-weeks during Part B. The lyophilized etanercept 50 mg and matching placebo were to be reconstituted by the subject for injection.

Test article was to be administered at approximately the same time of day on the same day of the week. Once-weekly doses were to be separated by approximately 7 days. If administration of test article did not occur on the day that it was scheduled, every effort was to be made to resume the QW dosing schedule. Test article was never to be administered consecutively in the same location. Instead, alternate sites (arms, thighs, abdomen, left right) were to be used with each injection.

Efficacy Endpoints:

Primary Efficacy:

The primary efficacy endpoint is the PASI 75 response at Week 12. PASI 75 is defined as a 75% or greater improvement in PASI score from Baseline.

Secondary Efficacy:

The secondary efficacy endpoints include:

- PASI 50
- PASI 75 (at visit other than Week 12)
- PASI 90

- PASI 100 (open label period only)
- PASI score
- Percent improvement in PASI score
- Physician global assessment (PGA) of 0 or 1 (clear or minimal)
- PGA of 0, 1, 2 (clear, minimal, mild)
- PGA Distribution score
- Physician's assessment of psoriasis body surface area
- Subject global assessment of Psoriasis
- Time to achieve PASI 50, 75, and 90.
- Dermatology Life Quality Index (DLQI) score
- DLQI response (proportion of subjects with a DLQI score of 0 or with an improvement of ≥5 points from baseline)
- Percent improvement in DLQI score
- Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue response (proportion of subject with improvement of ≥3 points from baseline)
- FACIT-Fatigue score
- Euro Qol 5-Dimension Self-report Questionnaire (EQ-5D) score

The secondary end points are described below in more detail.

PASI score:

PASI score is calculated as:

$PASI = 0.1(E_h + I_h + D_h)\ A_h + 0.3\ (E_t + I_t + D_t)\ A_t + 0.2\ (E_u + I_u + D_u)\ A_u + 0.4\ (E_l + I_l + D_l)\ A_l$, where Ex, Ix, and Dx denote the severity of Erythema, Infiltration and Desquamation at different body areas (x = h, t, u, l; where h = head, t = trunk, u = upper extremities, and l = lower extremities).

Possible PASI scores include:

- 0 = no symptoms present
- 1 = slight symptoms

- 2 = moderate symptoms
- 3 = striking symptoms
- 4 = exceptionally striking symptoms

A_x (x = h, t, u, l) denotes the area of psoriatic involvement at different body areas, the possible values are:

- 0 = no involvement
- 1 = < 10% involvement
- 2 = 10 to < 30% involvement
- 3 = 30 to < 50% involvement
- 4 = 50 to < 70% involvement
- 5 = 70 to < 90% involvement
- 6 = 90 to 100% involvement

The PASI varies in steps of 0.1 units from 0.0 to 72.0. The last figure thus represents complete erythroderma of the severest possible degree, while 0.0 means no psoriatic lesions at all.

Percent improvement PASI score:

PASI score percent improvement = 100*(baseline score-PASI score)/baseline score.

PASI 75 (50, 90):

PASI 75 (50, 90) is defined as a 75% (50%, 90%) or greater improvement in PASI score from baseline.

DLQI:

The DLQI is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. The higher the score, the more quality of life is impaired. The DLQI can be analyzed under six headings as follows:

- Symptoms and feelings, Questions 1 and 2, maximum score of 6
- Daily activities, Questions 3 and 4, maximum score of 6
- Leisure, Questions 5 and 6, maximum score of 6

- Work and School, Questions 7, maximum score of 3
- Personal relationships, Questions 8 and 9, maximum score of 6
- Treatment, Questions 10, maximum score of 3

Missing data handling:

- If one question is left unanswered, this is scored 0 and the scores are summed and expressed as usual out of a maximum of 30.
- If two or more questions are left unanswered the questionnaire is not scored.
- If Question 7 is answered 'yes' this is scored 3. If Question 7 is answered 'no' or 'not relevant' but then either 'a lot' or 'a little' is ticked this is then scored 2 or 1.
- If two or more response options are ticked, the response option with the highest score should be recorded.
- If there is a response between two tick boxes, the lower of the two score options should be recorded.
- If one item is missing from a two-item subscale that subscale should not be scored.

Percent improvement DLQI score:

DLQI score percent improvement = 100*(baseline score-DLQI score)/baseline score.

FACIT-Fatigue:

The scores for Questions 7 and 8 should be reversed. The total FACIT-Fatigue score is the sum of no missing item scores; divided by the number of non-missing items, then multiplied by 13. If more than 6 items are missing, the total score is missing.

EQ-5D:

EQ-5D includes a 5-dimensional classification for self-reported description of health problems and a VAS "thermometer" for eliciting a self-rating of health status. The 5 dimensions are mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Each dimension comprises three levels generating a total of 243 theoretically possible health states.

- Level 1 No problem
- Level 2 Some or moderate problems
- Level 3 Unable, or extreme problems

The general health state score is derived from the 5-dimensions. The score for full health (1 1 1 1 1) is 1.0. For other health states, the score is derived as: subtract the scores (see below Table 2) for each dimension from 1.0, then subtract constant 0.081. If there is one or more level 3, then subtract additional constant (N3) 0.269. For example, if the health state is (1 1 2 2 3), the general health state score is 1.0 – 0.036 – 0.123 – 0.236 – 0.081 – 0.269 = 0.255. The worst general health state (3 3 3 3 3) score is 1.0 – 0.314 – 0.214 – 0.094 – 0.386 – 0.236 – 0.081 – 0.269 = –0.594.

Table 2: EQ-5D state scores

Dimension	Level 1	Level 2	Level 3
Mobility	0	0.069	0.314
Self-care	0	0.104	0.214
Usual activity	0	0.036	0.094
Pain / discomfort	0	0.123	0.386
Anxiety / depression	0	0.071	0.236
		Constant = 0.081	N3 = 0.269

N3 = additional constant

PASI, the physician and subject global assessments, and DLQI were assessed at Baseline and Weeks 2, 4, 8, and 12 (double-blind period) and Weeks 16, 20, and 24 (open-label period). The subjects answered the EQ-5D and FACIT-Fatigue scales at Baseline and Weeks 12 and 24.

Safety Evaluations: Safety variables including the reporting of adverse events (AEs) and serious adverse events (SAEs), vital sign measurements, physical examinations, chemistry profile, hematology profile, and urinalysis were assessed throughout the course of the study.

Statistical Methods: The primary population for efficacy and safety analysis in Part A (double-blind period) was the modified intent-to-treat (mITT) population which is defined as all randomized subjects who received at least 1 dose of test article. Major efficacy parameters were also analyzed for the per-protocol population (also known as the valid for efficacy or VFE population), which was defined as a subset of mITT population excluding subjects who had major protocol violations in the double-blind period. The need to exclude subjects for the per-protocol population analysis was determined and documented by the medical monitor, clinical scientist and protocol statistician before the treatment codes were unblinded.

The baseline value was defined as the last measurement before the first test article. Statistical comparison of the treatment groups was conducted for demographic and baseline characteristics. One-way analysis of variance (ANOVA) model with treatment group as a factor was used to compare groups for all variables except nominal attributes (eg, sex), which was compared by Fisher's exact test.

The primary endpoint of PASI 75 at Week 12 was analyzed using Fisher's exact test. All secondary binary endpoints in Part A were analyzed using the Fisher's exact test as well. Ordinal endpoints were analyzed using Cochran-Mantel-Haenszel (CMH) test. All continuous variables were summarized using descriptive statistics, including number of

subjects, mean, standard deviation, median, minimum, and maximum. The van Elteren's test (Wilcoxon's rank sum test) was used to compare etanercept with placebo. Missing efficacy data were imputed using the method of last observation carried forward (LOCF) as the primary analysis. Observed case analysis was also performed.

The primary efficacy endpoint PASI 75 at Week 12 was also summarized by study country, and selected demographic and baseline characteristics (eg, duration of disease, baseline PASI score).

In the open-label period (Part B), all efficacy endpoints were summarized by the original randomized treatment group in the double-blind period, as well as 1 group using descriptive statistics. No statistical inferences were made. The original baseline from the double-blind period was used. LOCF analysis was performed.

The incidence of all AEs, treatment-emergent adverse events (TEAEs), potentially clinically important laboratory measurements, and premature discontinuations during the study were compared between treatment groups using Fisher's exact test. For continuous variables such as vital signs and routine laboratory parameters, 1-way analyses of covariance with treatment group as the factor and baseline value as the covariate was performed.

For subjects in the etanercept group during the double-blind period, the original baseline from double-blind period was used as the open-label period baseline. For subjects in the placebo group during the double-blind period, the open-label period baseline was defined as the last observation before the first dose of the open-label period.

For an AE that started in the double-blind period and continued to the open-label period, if the subject was in the etanercept group in the double-blind period then this AE was counted as a TEAE in both the double-blind period and open-label period, and if the subject was in the placebo group in the double-blind period then this AE was not counted as a TEAE in the open-label period.

Time to discontinuation was compared using the Log-Rank test in double-blind period.

RESULTS

Subject Disposition and Demography: Subject disposition details for double-blind period (Part A) is summarized in Table 3 and for open-label period (Part B) is summarized in Table 4.

Table 3: Summary of Subject Participation in the Double-Blind Period: Number (%) of Subjects

Conclusion Status Reason[a]	Overall p-Value[b]	Etan 50 mg QW (N = 96)	Placebo (N = 46)
Total		96 (100)	46 (100)
Completed	0.010**	90 (93.8)	36 (78.3)
Discontinued	0.010**	6 (6.3)	10 (21.7)
Adverse Event	0.389	3 (3.1)	3 (6.5)
Lost to Follow-up	0.324	0	1 (2.2)
Protocol Violation	0.545	1 (1.0)	1 (2.2)
Subject Request	0.324	0	1 (2.2)
Unsatisfactory Response - Efficacy	0.087	2 (2.1)[c]	4 (8.7)[d]

Statistical significance during the double-blind period at the 0.01 level is denoted **.
Etan = etanercept; N = total number of subjects per treatment group; QW = once weekly.
a. Total discontinued is the sum of individual reasons since they are mutually exclusive by subject.
b. Overall p-value: Fisher's exact test p-value (2-tailed).
c. Both subjects discontinued because of an adverse event of psoriasis (verbatim was 'exacerbation of psoriasis' or 'extension of psoriasis').
d. Two (2) of the subjects discontinued because of an adverse event of psoriasis (verbatim was 'worsening of psoriasis').

Table 4: Summary of Subject Participation in the Open-Label Period: Number (%) of Subjects

Conclusion Status Reason[a]	Overall p-Value[b]	Etan 50 mg QW (N = 90)	Placebo / Etan 50 mg QW[c] (N = 36)	Total (N = 126)
Total		90 (100)	36 (100)	126 (100)
Completed	0.070	89 (98.9)	33 (91.7)	122 (96.8)
Discontinued	0.070	1 (1.1)	3 (8.3)	4 (3.2)
Adverse Event	0.080	0	2 (5.6)	2 (1.6)
Unsatisfactory Response - Efficacy	0.491	1 (1.1)	1 (2.8)[d]	2 (1.6)

Etan = etanercept; N = total number of subjects per treatment; QW = once weekly.
a. Total discontinued is the sum of individual reasons since they are mutually exclusive by subject.
b. Overall p-value: Fisher's exact test p-value (2-tailed).
c. All subjects received etanercept 50 mg QW during the open-label period.
d. This subject discontinued because of an adverse event of psoriasis (verbatim was 'extension of psoriasis with pain and discomfort').

Demographic information for the mITT population that comprised all subjects who received at least 1 dose of the test article (142 subjects) is presented in Table 5. In general, the demographic characteristics of the subjects in the 2 treatment groups were well balanced. The differences between the 2 treatment groups were not statistically significant.

Table 5: Demographic Characteristics of the mITT Population

Characteristic	p-Value	Treatment	
		Etan 50 mg QW (N = 96)	Placebo (N = 46)
Age (Years)			
N		96	46
Mean	0.316[a]	45.86	43.57
Standard Deviation		12.80	12.62
Minimum		19.00	18.00
Maximum		78.00	67.00
Median		46.50	45.00
Sex	0.468[b]		
Female		37 (38.54)	21 (45.65)
Male		59 (61.46)	25 (54.35)
Baseline Height (cm)			
N		96	46
Mean	0.134[a]	173.78	171.26
Standard Deviation		9.49	8.98
Minimum		152.00	150.00
Maximum		196.00	192.00
Median		174.50	170.00
Baseline Weight (kg)			
N		96	46
Mean	0.171[a]	83.43	79.11
Standard Deviation		16.03	20.21
Minimum		52.00	44.00
Maximum		128.00	117.00
Median		82.00	78.50
Body Mass Index (Kg/m^3)			
N		96	46
Mean	0.386[a]	27.50	26.76
Standard Deviation		4.14	5.85
Minimum		19.10	16.80
Maximum		37.70	37.00
Median		27.20	26.25
Body Surface Area (m^2)			
N		96	46
Mean	0.076[a]	2.00	1.92
Standard Deviation		0.24	0.30
Minimum		1.60	1.40
Maximum		2.60	2.40
Median		2.00	2.00

Etan = etanercept; mITT = modified intent-to-treat; N = total number of subjects per treatment group; QW = once weekly.

a. One-way analysis of variance with treatment as factor.

b. Fisher's exact test p-value (2-tailed).

Baseline disease characteristics for the mITT population that comprised all subjects who received at least 1 dose of the test article (142 subjects) are presented in Table 6. In general, the baseline disease characteristics of the subjects in the 2 treatment groups were comparable.

Table 6: Baseline Disease Characteristics of the mITT Population

Characteristic	p-Value	Treatment	
		Etan 50 mg QW (N = 96)	Placebo (N = 46)
Duration of Disease (year)			
N		96	46
Mean	0.273[a]	19.30	17.25
Standard Deviation		11.29	8.21
Minimum		0.36	4.08
Maximum		56.70	34.71
Median		17.64	15.12
Subject Global Assessment (Psoriasis Severity Over Past week)	0.409[b]		
0 (Good)		1 (1.04)	0
1		5 (5.21)	1 (2.22)
2		2 (2.08)	3 (6.67)
3		25 (26.04)	8 (17.78)
4		43 (44.79)	19 (42.22)
5 (Severe)		20 (20.83)	14 (31.11)
Missing		0	1
Physician Global assessment	0.277[b]		
0		0	0
1		0	0
2		5 (5.21)	6 (13.04)
3		38 (39.58)	19 (41.30)
4		45 (46.88)	16 (34.78)
5		8 (8.33)	5 (10.87)
Physician Assessment of Psoriasis Area (%)			
N		96	46
Mean	0.192[a]	26.52	30.26
Standard Deviation		14.97	17.75
Minimum		10.00	5.00
Maximum		73.00	75.00
Median		22.00	25.00
PASI Score			
N		96	46
Mean	0.843[a]	21.36	21.03
Standard Deviation		9.34	8.72
Minimum		10.00	10.60
Maximum		47.20	48.00
Median		18.35	17.80
Failed ≥ 1 Systemic Treatment	1.000[b]		
No		49 (51.04)	24 (52.17)
Yes		47 (48.96)	22 (47.83)
Failed ≥ 1 Phototherapy	1.000[b]		
No		29 (30.21)	14 (30.43)
Yes		67 (69.79)	32 (69.57)
Failed ≥ 1 Systemic Treatment/Phototherapy	0.791[b]		
No		13 (13.54)	5 (10.87)
Yes		83 (86.46)	41 (89.13)
Failure, Intolerance, Contraindication to ≥ 1 Systemic treatment/Phototherapy			
Yes		96 (100)	46 (100)
Number of Systemic Treatments Received			

Table 6: Baseline Disease Characteristics of the mITT Population

Characteristic	p-Value	Treatment	
		Etan 50 mg QW (N = 96)	Placebo (N = 46)
N		96	46
Mean	0.855[a]	1.25	1.28
Standard Deviation		0.93	1.11
Minimum		0.00	0.00
Maximum		4.00	4.00
Median		1.00	1.00
Number of Phototherapies Received			
N		96	46
Mean	0.792[a]	1.11	1.09
Standard Deviation		0.56	0.63
Minimum		0.00	0.00
Maximum		3.00	2.00
Median		1.00	1.00
Number of Systemic Treatments/Phototherapies Received			
N		96	46
Mean	0.979[a]	2.36	2.37
Standard Deviation		1.05	1.12
Minimum		1.00	1.00
Maximum		6.00	5.00
Median		2.00	2.00
Systemic Treatments Failed	0.253[b]		
0		49 (51.04)	24 (52.17)
1		33 (34.38)	10 (21.74)
2		10 (10.42)	8 (17.39)
3		4 (4.17)	4 (8.70)
Phototherapies Failed	0.692[b]		
0		29 (30.21)	14 (30.43)
1		54 (56.25)	23 (50.00)
2		12 (12.50)	9 (19.57)
3		1 (1.04)	
PUVA Received	0.367[b]		
No		44 (45.83)	17 (36.96)
Yes		52 (54.17)	29 (63.04)
UVA Received	1.000[b]		
No		83 (86.46)	40 (86.96)
Yes		13 (13.54)	6 (13.04)
UVB Received	0.272[b]		
No		54 (56.25)	31 (67.39)
Yes		42 (43.75)	15 (32.61)
Cyclosporine Received	0.509[b]		
No		78 (81.25)	35 (76.09)
Yes		18 (18.75)	11 (23.91)
Fumarate Received	0.828[b]		
No		74 (77.08)	37 (80.43)
Yes		22 (22.92)	9 (19.57)
Methotrexate Received	0.720[b]		
No		50 (52.08)	26 (56.52)
Yes		46 (47.92)	20 (43.48)
Oral Retinoid Received	0.849[b]		

Table 6: Baseline Disease Characteristics of the mITT Population

Characteristic	p-Value	Treatment	
		Etan 50 mg QW (N = 96)	Placebo (N = 46)
No		65 (67.71)	30 (65.22)
Yes		31 (32.29)	16 (34.78)
Other Systemic Treatment Received	0.100[b]		
No		95 (98.96)	43 (93.48)
Yes		1 (1.04)	3 (6.52)
Topical Steroids Received[c]	0.331[b]		
No		78 (81.25)	41 (89.13)
Yes		18 (18.75)	5 (10.87)

Etan = etanercept; mITT = modified intent-to-treat; N = total number of subjects per treatment group; QW = once weekly.
a. One-way analysis of variance with treatment as factor.
b. Fisher's exact test p-value (2-tailed).
c. Topical steroid use within 14 days of baseline visit.

Efficacy Results: The efficacy results are presented separately for the 12-week double-blind period (Part A) and the open-label period (Part B) of the study. The data for the open-label period are summarized by the original randomized treatment group in the double-blind period as well as 1 overall group.

Primary Endpoint Results:

PASI 75 Response at Week 12: Compared with the placebo group in which only 1 of 46 subjects (2.2%) achieved a PASI 75 response at Week 12, a significantly greater percentage of subjects in the etanercept 50 mg QW group (36 of 96 subjects; 37.5%) achieved a PASI 75 response at Week 12 as shown in Table 7.

Table 7: Number (%) of Subjects Achieving PASI 75 at Week 12 (mITT Population, LOCF Data)

Parameter	Etan 50 mg QW (N = 96)	Placebo (N = 46)	p-Value
PASI 75 at Week 12	36 (37.5)	1 (2.2)	<0.0001

p-Value is from the 2-sided Fisher's exact test.
Etan = etanercept; LOCF = last observation carried forward; mITT = modified intent-to-treat; N = total number of subjects per treatment group; PASI = psoriasis area and severity index; QW = once weekly.

Secondary Endpoint Results:

PASI 75 Response at Other Time Points: Table 8 shows the number of subjects achieving a PASI 75 response at Weeks 2, 4, and 8 of the double-blind period from the LOCF analysis. A significantly higher proportion of subjects in the etanercept 50 mg QW group had achieved a PASI 75 response by Week 8.

Table 8. Number (%) of Subjects Achieving PASI 75 Responses at Weeks 2, 4, and 8 of the Double-Blind Period (mITT Population, LOCF Data)

Parameter	Week on Therapy	Etan 50 mg QW (N = 96)	Placebo (N = 46)	p-Value
PASI 75	Week 2	1 (1.0)	0 (0.0)	1.0000
	Week 4	5 (5.2)	0 (0.0)	0.1744
	Week 8	20 (20.8)	2 (4.3)	0.0121

p-Value is from the 2-sided Fisher's exact test.
Etan = etanercept; LOCF = last observation carried forward; mITT = modified intent-to-treat;
N = total number of subjects per treatment group; PASI = psoriasis area and severity index; QW = once weekly.

Table 9 shows the number of subjects achieving a PASI 75 response during the open-label period, presented by original treatment assignment in the double-blind period. By Week 24 of the study, 71% of the subjects who had received etanercept throughout the entire study had achieved a PASI 75 response. After 12 weeks of open-label treatment, 44% of the placebo subjects who hadn't received etanercept until after Week 12 of the study had achieved a PASI 75 response, which is similar to the level of improvement observed by the etanercept group at Week 12 of the double-blind period.

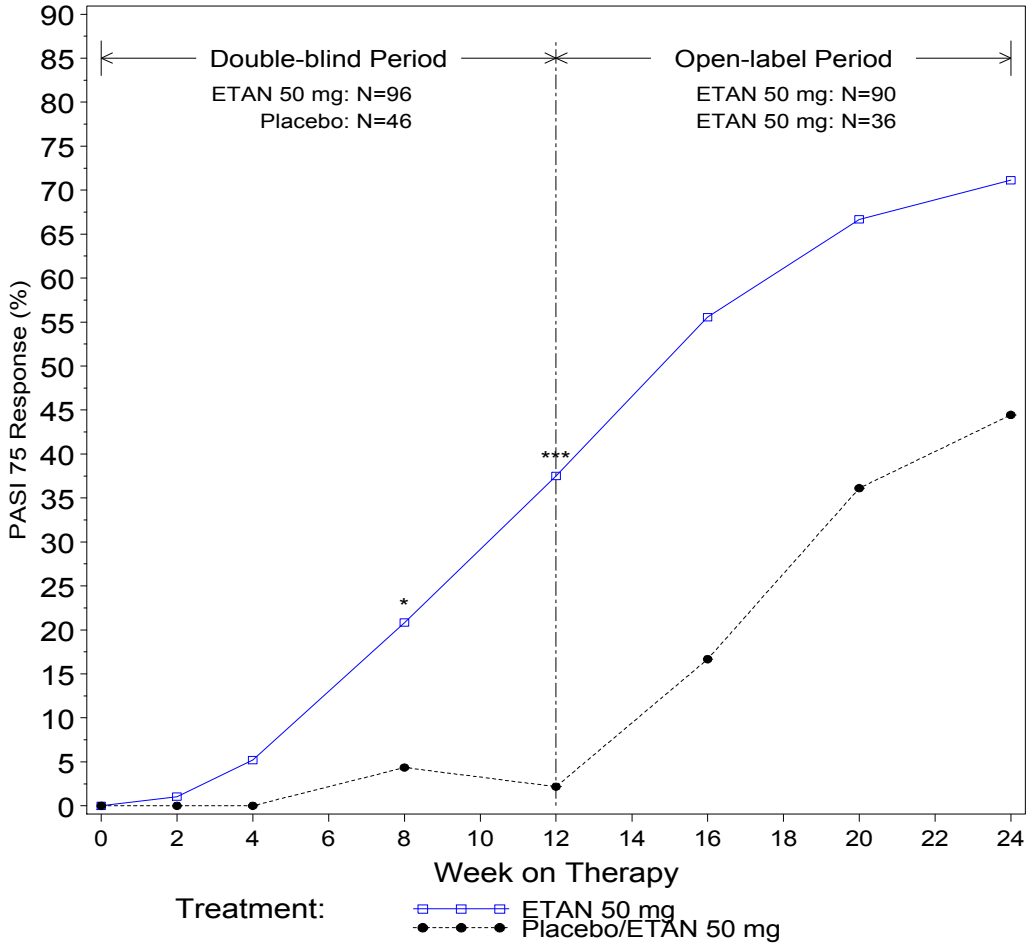
Table 9: Number (%) of Subjects Achieving PASI 75 Responses During the Open-Label Period (LOCF Data)

Parameter	Week on Therapy	Etan 50 mg QW (N = 90)	Placebo / Etan 50 mg QW[a] (N = 36)	Total (n = 126)
PASI 75	Week 16	50 (55.6)	6 (16.7)	56 (44.4)
	Week 20	60 (66.7)	13 (36.1)	73 (57.9)
	Week 24	64 (71.1)	16 (44.4)	80 (63.5)

Etan = etanercept; LOCF = last observation carried forward; N = total number of subjects per treatment group; n = total number of subjects achieving PASI responses; PASI = psoriasis area and severity index; QW = once weekly.
a. All subjects received etanercept 50 mg QW during the open-label period.

PASI 75 response over time for the entire study is shown in Figure 1. Subjects receiving etanercept 50 mg QW consistently improved over time and had better responses compared with subjects receiving placebo.

Figure 1: PASI 75 Responses over Time for Entire Study (LOCF Data)



Statistical significance during the double-blind period at the 0.05, and 0.001 levels is denoted by *, and *** respectively.
Etan = etanercept; LOCF = last observation carried forward; N = total number of subjects per treatment group; PASI = psoriasis area and severity index.

PASI 50 and PASI 90 Responses:

The number of subjects achieving PASI 50 and PASI 90 responses during the double-blind period are summarized in Table 10. Compared with the placebo group, a significantly higher proportion of subjects in the etanercept 50 mg QW group achieved a PASI 50 response at Weeks 4, 8 and 12, and a PASI 90 response at Week 12.

Table 10: Number (%) of Subjects Achieving PASI 50 and PASI 90 Responses During the Double-Blind Period (mITT Population, LOCF Data)

Parameter	Week On Therapy	Etan 50 mg QW (N = 96)	Placebo (N = 46)	p-Value
PASI 50	Week 2	6 (6.3)	1 (2.2)	0.4280
	Week 4	22 (22.9)	2 (4.3)	0.0072
	Week 8	49 (51.0)	4 (8.7)	<0.0001
	Week 12	66 (68.8)	4 (8.7)	<0.0001
PASI 90	Week 2	0 (0.0)	0 (0.0)	--
	Week 4	0 (0.0)	0 (0.0)	--
	Week 8	2 (2.1)	1 (2.2)	1.0000
	Week 12	13 (13.5)	1 (2.2)	0.0365

p-Value is from the 2-sided Fisher's exact test.
Abbreviations: Etan = etanercept; LOCF = last observation carried forward; mITT = modified intent-to-treat; N = total number of subjects per treatment group; PASI = psoriasis area and severity index; QW = once weekly.

The number of subjects achieving PASI 50, PASI 90, and PASI 100 responses during the open-label period are summarized in Table 11. As was seen with the PASI 75 response, the proportions of subjects achieving PASI 50 and PASI 90 responses continued to increase during the open-label period through Week 20.

Table 11: Number (%) of Subjects Achieving PASI 50, PASI 90, and PASI 100 Responses During the Open-Label Period (LOCF Data)

Parameter	Week On Therapy	Etan 50 mg QW (N = 90)	Placebo / Etan 50 mg QW[a] (N = 36)	Total (N = 126)
PASI 50	Week 16	73 (81.1)	14 (38.9)	87 (69.0)
	Week 20	76 (84.4)	22 (61.1)	98 (77.8)
	Week 24	75 (83.3)	25 (69.4)	100 (79.4)
PASI 90	Week 16	22 (24.4)	2 (5.6)	24 (19.0)
	Week 20	28 (31.1)	5 (13.9)	33 (26.2)
	Week 24	38 (42.2)	7 (19.4)	45 (35.7)
PASI 100	Week 16	6 (6.7)	2 (5.6)	8 (6.3)
	Week 20	10 (11.1)	1 (2.8)	11 (8.7)
	Week 24	10 (11.1)	2 (5.6)	12 (9.5)

Abbreviations: Etan = etanercept; LOCF = last observation carried forward; N = total number of subjects per treatment group; PASI = psoriasis area and severity index; QW = once weekly.
a. All subjects received etanercept 50 mg QW during the open-label period.

Improvement in PASI Score over Time:

The mean change and mean percent improvement in PASI score over time during the double-blind period is presented in Table 12. Compared with the placebo group, the etanercept 50 mg QW group had a significantly higher percentage improvement from Baseline at all time points studied (ie, Weeks 2, 4, 8, and 12).

Compared with the placebo group, subjects in the etanercept 50 mg QW group had a significantly higher percent improvement in PASI scores as early as 2 weeks. There was a slight worsening in the PASI score with time in the placebo-treated subjects.

Table 12: Mean PASI Score and Percentage Improvement During the Double-Blind Period (mITT Population, LOCF Data)

	Raw Mean		Mean Change (% Improvement)		p-Value
Week on Therapy	Etan 50 mg QW (N = 96)	Placebo (N = 46)	Etan 50 mg QW (N = 96)	Placebo (N = 46)	Percent Improvement
Baseline	21.4	21.0			
Week 2	18.0	22.5	3.3 (14.7)	-1.5 (-8.0)	<0.0001
Week 4	14.8	21.3	6.5 (28.5)	-0.3 (-5.1)	<0.0001
Week 8	11.6	21.2	9.8 (44.5)	-0.1 (-6.3)	<0.0001
Week 12	8.9	21.6	12.5 (55.4)	-0.6 (-9.4)	<0.0001

p-Values are from van Elteren's test
Abbreviations: Etan = etanercept; LOCF = last observation carried forward; mITT = modified intent-to-treat; N = total number of subjects per treatment group; PASI = psoriasis area and severity index; QW = once weekly.

The mean change and mean percent improvement in PASI score over time during the open-label period was presented in Table 13. PASI score continued to improve during the open-label period through Week 20.

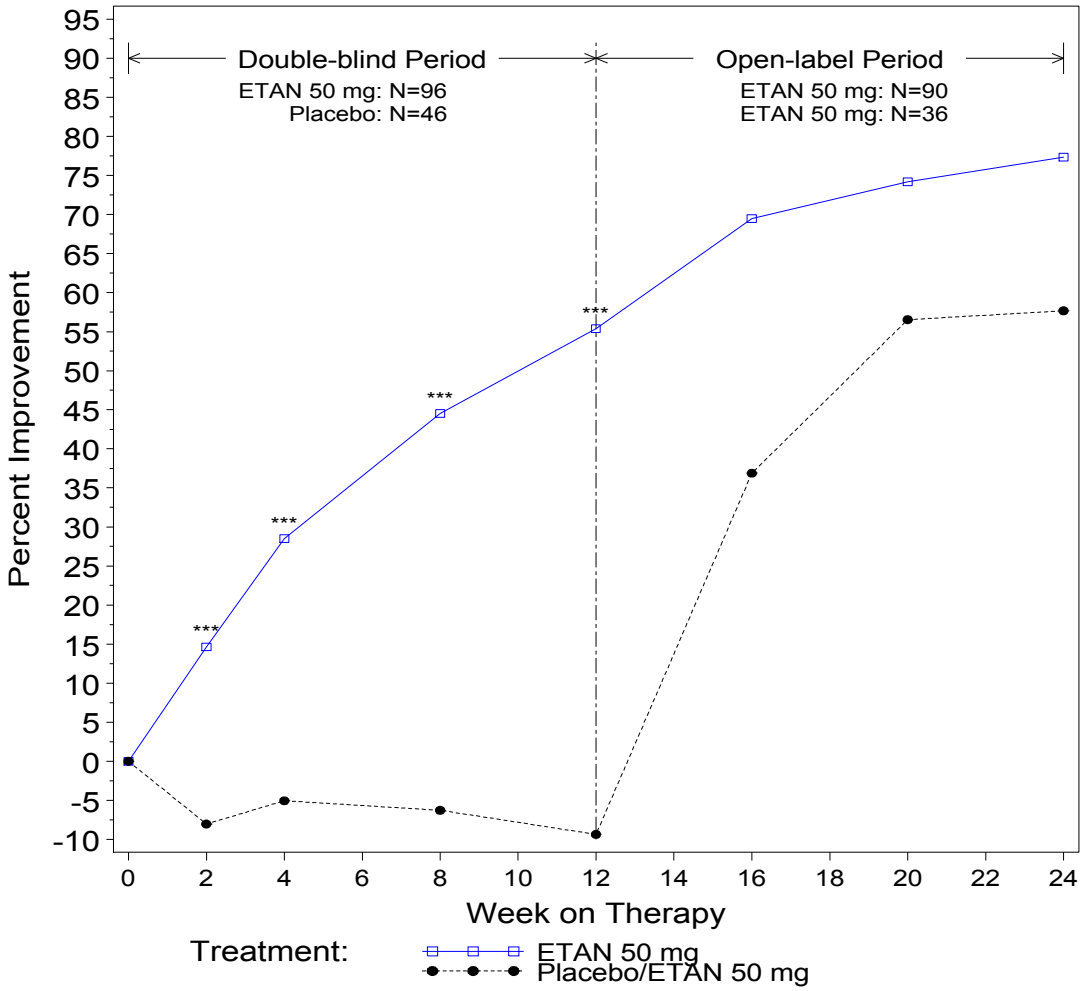
Table 13: Mean PASI Score and Percentage Improvement During the Open-Label Period (LOCF Data)

	Raw Mean			Mean Change (% Improvement)		
Week on Therapy	Etan 50 mg QW (N = 90)	Placebo/ Etan 50 mg QW[a] (N = 36)	Total (N = 126)	Etan 50 mg QW (N = 90)	Placebo/ Etan 50 mg QW[a] (N = 36)	Total (N = 126)
Baseline[b]	21.2	20.9	21.1			
Week 16	5.9	12.3	7.8	15.3 (69.5)	8.6 (36.9)	13.4 (60.2)
Week 20	5.1	8.7	6.2	16.1 (74.2)	12.1 (56.5)	15.0 (69.2)
Week 24	4.5	8.4	5.6	16.8 (77.4)	12.5 (57.7)	15.5 (71.7)

Abbreviations: Etan = etanercept; LOCF = last observation carried forward; N = total number of subjects per treatment group; PASI = psoriasis area and severity index; QW = once weekly.
a. All subjects received etanercept 50 mg QW during the open-label period.
b. Baseline is the double-blind period baseline.

The mean percent improvement from Baseline over time for the entire study is shown in Figure 2.

Figure 2: Mean Percentage Improvement in PASI Score for Entire Study (LOCF Data)



Statistical significance during the double-blind period at the 0.001 level is denoted by ***.
Etan = etanercept; LOCF = last observation carried forward; N = total number of subjects per treatment group; PASI = psoriasis area and severity index.

Physician Global Assessment of Psoriasis:

Table 14 presents the physician global assessment of psoriasis over time for the mITT population during the double-blind period. Compared with placebo-treated subjects, a significantly larger proportion of subjects in the etanercept 50 mg QW group had a PGA of "Clear/Almost Clear (0, 1)" at Weeks 8 and 12, and an assessment "Clear/Almost Clear/Mild (0, 1, 2)" at Weeks 4, 8, and 12. The results for PGA assessments over time of "Clear/Almost Clear" paralleled the PASI 75 response over time.

Table 14: Physician Global Assessment of Psoriasis During the Double-Blind Period (mITT Population, LOCF Data)

PGA of Psoriasis	Week on Therapy	Etan 50 mg QW (N = 96) n (%)	Placebo (N = 46) n (%)	p-Value
Clear (0)	Baseline	0 (0.0)	0 (0.0)	
	Week 2	0 (0.0)	0 (0.0)	
	Week 4	0 (0.0)	0 (0.0)	
	Week 8	2 (2.1)	1 (2.2)	1.0000
	Week 12	5 (5.2)	0 (0.0)	0.1744
Clear/Almost Clear (0, 1)	Baseline	0 (0.0)	0 (0.0)	
	Week 2	2 (2.1)	1 (2.2)	1.0000
	Week 4	10 (10.4)	2 (4.3)	0.3374
	Week 8	25 (26.0)	1 (2.2)	0.0003
	Week 12	37 (38.5)	2 (4.3)	<0.0001
Clear/Almost Clear/Mild (0, 1, 2)	Baseline	5 (5.2)	6 (13.0)	0.1757
	Week 2	24 (25.0)	10 (21.7)	0.8339
	Week 4	42 (43.8)	10 (21.7)	0.0151
	Week 8	62 (64.6)	11 (23.9)	<0.0001
	Week 12	77 (80.2)	10 (21.7)	<0.0001

p-Values are from the 2-sided Fisher's exact test.
Etan = etanercept; LOCF = last observation carried forward; mITT = modified intent-to-treat; N = total number of subjects per treatment group; n = number of subjects rated for physician global assessment of psoriasis; QW = once weekly.

Table 15 presents the physician global assessment of psoriasis during the open-label period. The proportion of subjects achieving a PGA status of clear increased with time, with 22% of subjects from the original etanercept group and 6% of subjects from the original placebo group achieving a PGA status of clear at Week 24. Similarly, the proportion of subjects achieving a PGA status of clear/almost clear also increased through Week 20; 64% of subjects from the original etanercept group and 42% of subjects from the original placebo group achieved a PGA status of clear/almost clear at Week 24.

Table 15: Physician Global Assessment of Psoriasis During the Open-Label Period (LOCF Data)

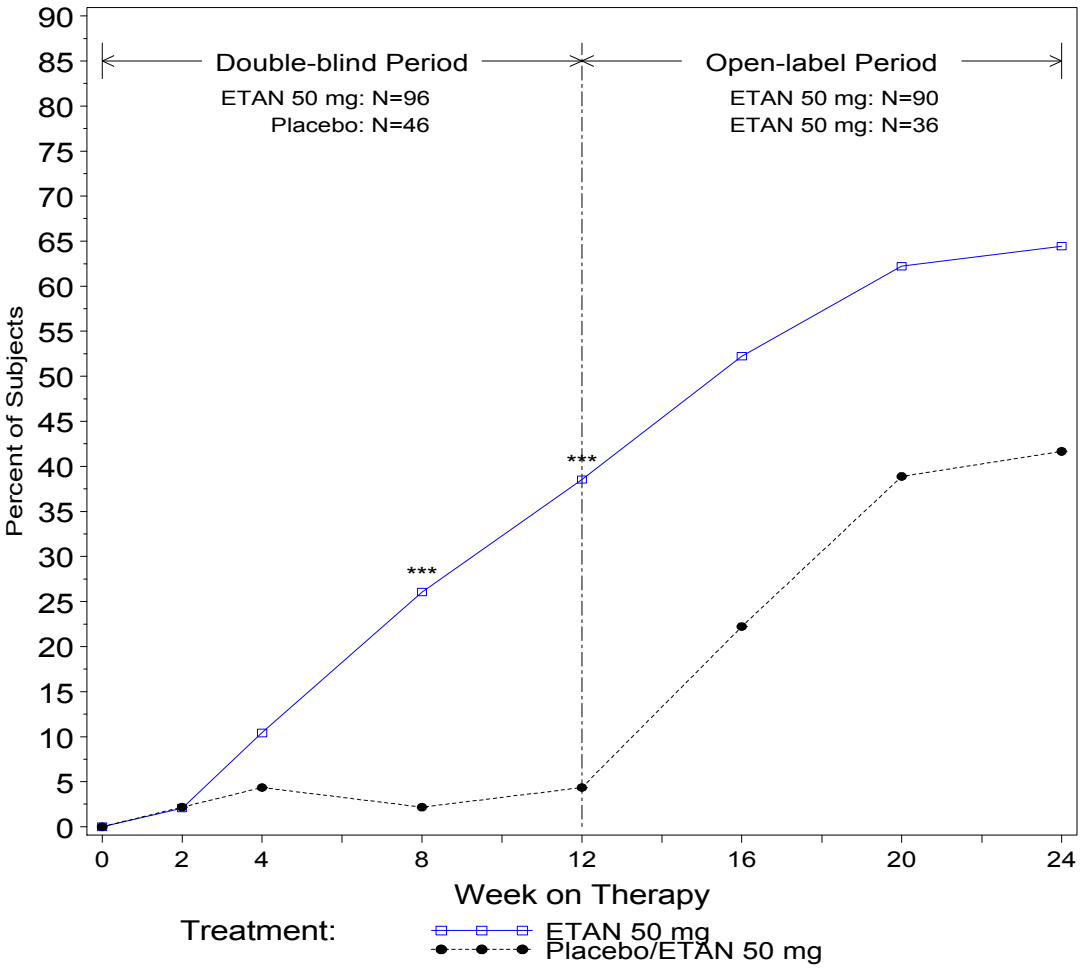
PGA of Psoriasis	Week on Therapy	Etan 50 mg QW (N = 90) n (%)	Placebo/ Etan 50 mg QW[a] (N = 36) n (%)	Total (N = 126) n (%)
Clear (0)	Baseline[b]	0 (0.0)	0 (0.0)	0 (0.0)
	Week 16	12 (13.3)	2 (5.6)	14 (11.1)
	Week 20	13 (14.4)	1 (2.8)	14 (11.1)
	Week 24	20 (22.2)	2 (5.6)	22 (17.5)
Clear/Almost Clear (0, 1)	Baseline[b]	0 (0.0)	0 (0.0)	0 (0.0)
	Week 16	47 (52.2)	8 (22.2)	55 (43.7)
	Week 20	56 (62.2)	14 (38.9)	70 (55.6)
	Week 24	58 (64.4)	15 (41.7)	73 (57.9)
Clear/Almost Clear/Mild (0, 1, 2)	Baseline[b]	5 (5.6)	6 (16.7)	11 (8.7)
	Week 16	78 (86.7)	22 (61.1)	100 (79.4)
	Week 20	79 (87.8)	27 (75.0)	106 (84.1)
	Week 24	80 (88.9)	27 (75.0)	107 (84.9)

Abbreviations: Etan = etanercept; LOCF = last observation carried forward; N = total number of subjects per treatment group; n = number of subjects rated for physician global assessment of Psoriasis
QW = once weekly.

a. All subjects received etanercept 50 mg QW during the open-label period.
b. Baseline is the double-blind period baseline.

Figure 3 presents the percent of subjects with PGA Clear/Almost Clear over time for the entire study.

Figure 3: Percent of Subjects with PGA Clear/Almost Clear for Entire Study (LOCF Data)



Statistical significance during the double-blind period at the 0.001 level is denoted by ***.
Etan = etanercept; LOCF = last observation carried forward; N = total number of subjects per treatment group; PGA = physician global assessment of psoriasis.

Subject Global Assessment of Psoriasis:

Table 16 presents the subject global assessment of psoriasis during the double-blind period. At Baseline, a high proportion of subjects in both treatment groups had scores of 3, 4, and 5 (on a scale of 0 to 5 with 0=Good and 5=Severe). At Week 12, a higher proportion of the etanercept-treated subjects had improvement in their psoriasis as shown by scores 0, 1, and 2. In contrast, the distribution of scores in the placebo-treated subjects remained relatively unchanged over the 12 weeks of the double-blind period.

Table 16: Distribution of Subject Global Assessment Scores During the Double-Blind Period (mITT Population, LOCF Data)

Week on Therapy	Score	Etan 50 mg QW (N = 96) n (%)	Placebo (N = 46) n (%)	p-Value
Baseline	0	1 (1.0)	0 (0.0)	0.2292
	1	5 (5.2)	1 (2.2)	
	2	2 (2.1)	3 (6.7)	
	3	25 (26.0)	8 (17.8)	
	4	43 (44.8)	19 (42.2)	
	5	20 (20.8)	14 (31.1)	
Week 2	0	3 (3.1)	1 (2.2)	0.0255
	1	3 (3.1)	1 (2.2)	
	2	15 (15.6)	4 (8.7)	
	3	40 (41.7)	12 (26.1)	
	4	22 (22.9)	17 (37.0)	
	5	13 (13.5)	11 (23.9)	
Week 4	0	6 (6.3)	0 (0.0)	0.0004
	1	7 (7.3)	1 (2.2)	
	2	22 (22.9)	9 (19.6)	
	3	33 (34.4)	11 (23.9)	
	4	20 (20.8)	10 (21.7)	
	5	8 (8.3)	15 (32.6)	
Week 8	0	6 (6.3)	1 (2.2)	<0.0001
	1	22 (22.9)	5 (10.9)	
	2	28 (29.2)	4 (8.7)	
	3	23 (24.0)	10 (21.7)	
	4	12 (12.5)	13 (28.3)	
	5	5 (5.2)	13 (28.3)	
Week 12	0	15 (15.6)	0 (0.0)	<0.0001
	1	26 (27.1)	3 (6.5)	
	2	26 (27.1)	6 (13.0)	
	3	14 (14.6)	11 (23.9)	
	4	11 (11.5)	9 (19.6)	
	5	4 (4.2)	17 (37.0)	

p-Values are from the 2-sided CMH test
Etan = etanercept; LOCF = last observation carried forward; mITT = modified intent-to-treat; N = total number of subjects per treatment group; n = number of subjects having a particular global assessment score (0 – 5) by therapy week time point; QW = once weekly.

Table 17 presents the subject global assessment of psoriasis during the open-label period. The proportion of subjects in the original etanercept group who achieved a 0 score continued to increase during the open-label period, with 37% of these subjects achieving a score of 0 at Week 24. At the end of the double-blind period no subjects in the placebo group had achieved a score of 0, but after converting to etanercept 50 mg QW in the open-label period, 19% of these subjects achieved a score of 0 at Week 24.

Table 17: Distribution of Subject Global Assessment Scores During the Open-Label Period (LOCF Data)

Week on Therapy	Score	Etan 50 mg QW (N = 90) n (%)	Placebo/ Etan 50 mg QW[a] (N = 36) n (%)	Total (N = 126) n (%)
Baseline[b]	0	1 (1.1)	0 (0.0)	1 (0.8)
	1	5 (5.6)	0 (0.0)	5 (4.0)
	2	2 (2.2)	3 (8.3)	5 (4.0)
	3	23 (25.6)	7 (19.4)	30 (23.8)
	4	42 (46.7)	17 (47.2)	59 (46.8)
	5	17 (18.9)	9 (25.0)	26 (20.6)
Week 16	0	22 (24.4)	2 (5.6)	24 (19.0)
	1	22 (24.4)	6 (16.7)	28 (22.2)
	2	25 (27.8)	10 (27.8)	35 (27.8)
	3	11 (12.2)	7 (19.4)	18 (14.3)
	4	8 (8.9)	7 (19.4)	15 (11.9)
	5	2 (2.2)	4 (11.1)	6 (4.8)
Week 20	0	26 (28.9)	3 (8.3)	29 (23.0)
	1	27 (30.0)	11 (30.6)	38 (30.2)
	2	19 (21.1)	10 (27.8)	29 (23.0)
	3	11 (12.2)	4 (11.1)	15 (11.9)
	4	5 (5.6)	5 (13.9)	10 (7.9)
	5	2 (2.2)	3 (8.3)	5 (4.0)
Week 24	0	33 (36.7)	7 (19.4)	40 (31.7)
	1	26 (28.9)	8 (22.2)	34 (27.0)
	2	18 (20.0)	9 (25.0)	27 (21.4)
	3	6 (6.7)	1 (2.8)	7 (5.6)
	4	5 (5.6)	7 (19.4)	12 (9.5)
	5	2 (2.2)	4 (11.1)	6 (4.8)

Etan = etanercept; LOCF = last observation carried forward; N = total number of subjects per treatment; n = number of subjects having a particular global assessment score (0 – 5) by therapy week time point; QW = once weekly.

a. All subjects received etanercept 50 mg QW during the open-label period.
b. Baseline is the double-blind period baseline.

Dermatology Life Quality Index (DLQI):

Table 18 shows that the mean change in DLQI score from Baseline and the percentage improvement from Baseline were significantly greater in the etanercept 50 mg QW group than in the placebo group during the entire double-blind period. This difference was seen as early as 2 weeks of treatment.

Table 18: Comparison for DLQI Score and Percentage Improvement During the Double-Blind Period (mITT Population, LOCF Data)

Week on Therapy	Raw Mean		Mean Change (% Improvement)		p-Value
	Etan 50 mg QW (N = 94)	Placebo (N = 45)	Etan 50 mg QW (N = 94)	Placebo (N = 45)	Percent Improvement
Baseline	13.2	13.6			
Week 2	10.1	13.0	3.1 (19.9)	0.5 (-6.6)	0.0164
Week 4	8.3	12.6	4.9 (35.9)	0.9 (-3.8)	0.0010
Week 8	6.7	12.6	6.5 (46.8)	1.0 (-3.5)	<0.0001
Week 12	5.8	12.3	7.4 (54.5)	1.2 (5.2)	<0.0001

p-Values are from van Elteren's test.
DLQI = dermatology life quality index; Etan = etanercept; LOCF = last observation carried forward; mITT = modified intent-to-treat; N = total number of mTT subjects per treatment; QW = once weekly.

Table 19 shows that the mean change in DLQI score from Baseline and the percentage improvement from Baseline continued to increase through Week 20 of the open-label period for the original etanercept group; an improvement of 71% from Baseline was observed at Week 24. At the end of the double-blind period subjects in the placebo group had only a 5% improvement from Baseline in DLQI score, but after converting to etanercept 50 mg QW in the open-label period, these subjects had a 56% improvement from Baseline at Week 24.

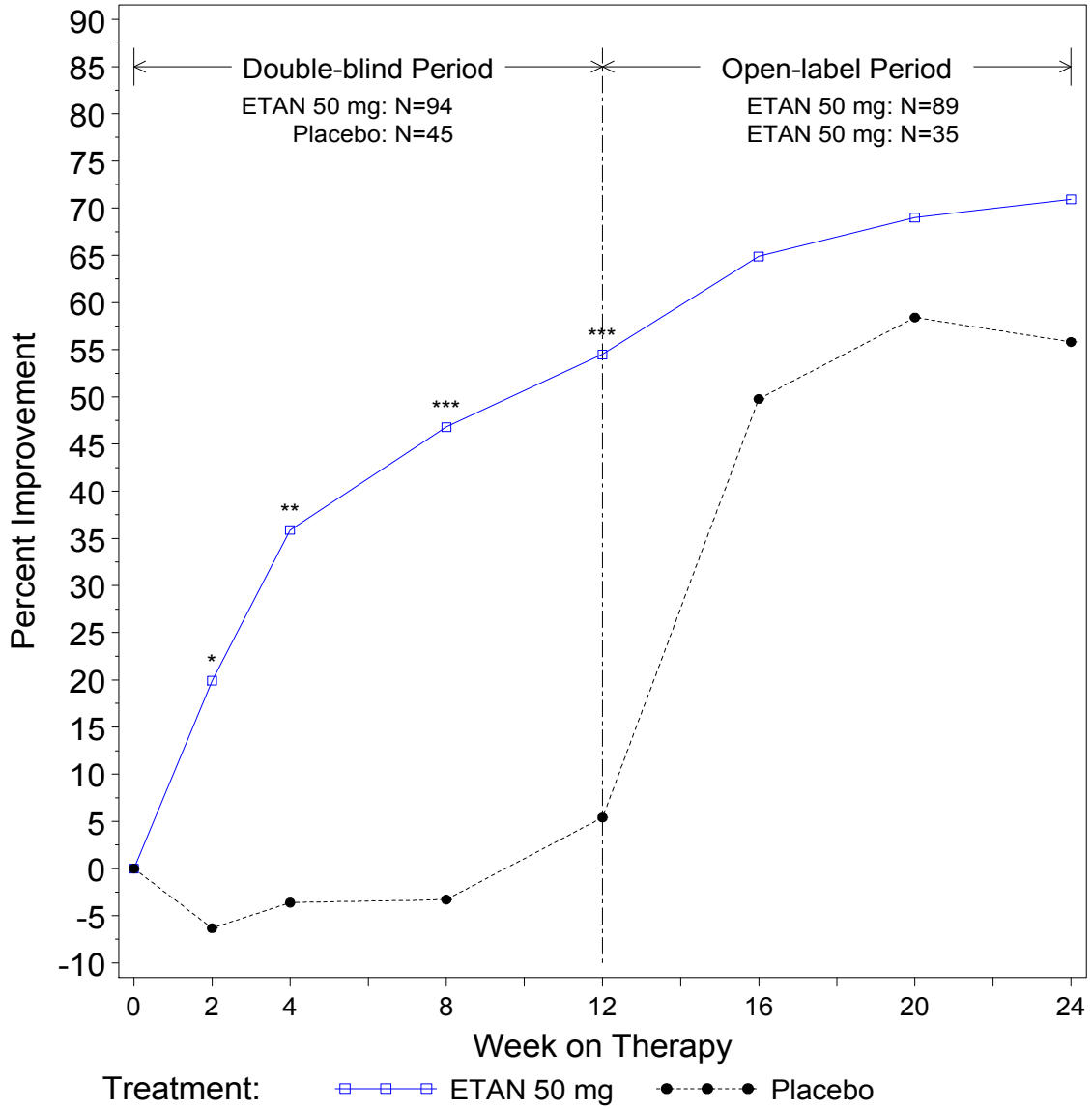
Table 19: Comparison for DLQI Score and Percentage Improvement During the Open-Label Period (LOCF Data)

Week on Therapy	Raw Mean			Mean Change (% Improvement)		
	Etan 50 mg QW (N = 89)	Placebo/ Etan 50 mg QW[a] (N = 35)	Total (N = 124)	Etan 50 mg QW (N = 89)	Placebo/ Etan 50 mg QW[a] (N = 35)	Total (N = 124)
Baseline[b]	13.2	13.5	13.3			
Week 16	4.3	7.6	5.3	8.8 (64.9)	5.9 (49.8)	8.0 (60.6)
Week 20	4.0	6.0	4.6	9.2 (69.0)	7.5 (58.4)	8.7 (66.0)
Week 24	3.6	6.3	4.3	9.6 (70.9)	7.1 (55.8)	8.9 (66.7)

DLQI = dermatology life quality index; Etan = etanercept; LOCF = last observation carried forward; N = total number of subjects per treatment; QW = once weekly.
a. All subjects received etanercept 50 mg QW during the open-label period.
b. Baseline is the double-blind period baseline.

Figure 4 presents the mean percentage improvement in DLQI score from Baseline during the entire study.

Figure 4: Mean Percentage Improvement in DLQI Score for Entire Study (LOCF Data)



Statistical significance during the double-blind period at the 0.05, 0.01, and 0.001 levels is denoted by *, **, and *** respectively.
DLQI = dermatology life quality index; Etan = etanercept; LOCF = last observation carried forward; N = total number of subjects per treatment and study phase.

Table 20 shows that the proportion of subjects with a DLQI response (0 score or an improvement of ≥5 points from Baseline) was significantly greater for the etanercept 50 mg QW group than for the placebo group at Weeks 4, 8, and 12 of the double-blind period.

Table 20: Number (%) of Subjects with a DLQI Score of 0 or with an Improvement of ≥5 Points from Baseline During the Double-Blind Period (mITT Population, LOCF Data)

DLQI Score	Week on Therapy	Etan 50 mg QW (N = 94) n (%)	Placebo (N = 45) n (%)	p-Value
0 Score	Week 2	1 (1.0)	0 (0.0)	1.0000
	Week 4	1 (1.0)	0 (0.0)	1.0000
	Week 8	12 (12.5)	0 (0.0)	0.0092
	Week 12	15 (15.6)	1 (2.2)	0.0210
0 Score or ≥5-point Improvement	Week 2	33 (35.1)	10 (22.2)	0.1696
	Week 4	45 (47.9)	13 (28.9)	0.0432
	Week 8	61 (64.9)	13 (28.9)	0.0001
	Week 12	67 (71.3)	12 (26.7)	<0.0001

p-Values are from the 2-sided Fisher's exact test.
DLQI = dermatology life quality index; Etan = etanercept; LOCF = last observation carried forward; mITT = modified intent-to-treat; N = total number of subjects per treatment group; n = number of subjects having a particular DLQI score; QW = once weekly.

Table 21 shows that the proportions of subjects with a DLQI response continued to increase during the open-label period through Week 20 for both the original etanercept 50 mg QW group and the original placebo group. At Week 24, approximately 30% of the subjects in the original etanercept group had a DLQI score of 0 and approximately 80% of subjects had an improvement in DLQI score of ≥5 points.

Table 21: Number (%) of Subjects with a DLQI Score of 0 or with an Improvement of ≥5 Points from Baseline During the Open-Label Period (LOCF Data)

DLQI Score	Week on Therapy	Etan 50 mg QW (N = 89) n (%)	Placebo/ Etan 50 mg QW[a] (N = 35) n (%)	Total (N = 124) n (%)
0 Score	Week 16	21 (23.3)	5 (13.9)	26 (20.6)
	Week 20	24 (26.7)	7 (19.4)	31 (24.6)
	Week 24	27 (30.0)	11 (30.6)	38 (30.2)
0 Score or ≥5-point Improvement	Week 16	70 (78.7)	23 (65.7)	93 (75.0)
	Week 20	72 (80.9)	26 (74.3)	98 (79.0)
	Week 24	71 (79.8)	25 (71.4)	96 (77.4)

Subjects without baseline data were excluded from the analysis.
DLQI = dermatology life quality index; Etan = etanercept; LOCF = last observation carried forward; N = total number of subjects per treatment; n = number of subjects with a particular DLQI score per time point; QW = once weekly.
a. All subjects received etanercept 50 mg QW during the open-label period.

Functional Assessment of Chronic Illness Therapy (FACIT)-Fatigue:

Table 22 presents the FACIT-Fatigue score at Week 12 of the double-blind period. There was no significant difference between the treatment groups in the mean change from Baseline and the mean percentage improvement scores. The FACIT-Fatigue score continued to improve during open-label period for both of the original treatment groups, with approximately 15% improvement at Week 24 (Table 23).

Table 22: Mean FACIT-Fatigue Score During the Double-Blind Period (mITT Population, LOCF Data)

	Raw Mean		Mean Change (% Improvement)		
Week on Therapy	Etan 50 mg QW (N = 96)	Placebo (N = 46)	Etan 50 mg QW (N = 96)	Placebo (N = 46)	p-Value
Baseline	39.4	39.2			
Week 12	40.7	39.5	1.3 (6.9)	0.3 (4.6)	0.2058

p-Values are from van Elteren's test for FACIT-Fatigue score change from baseline.
Etan = etanercept; FACIT = functional assessment of chronic illness Therapy; LOCF = last observation carried forward; mITT = modified intent-to-treat; N = total number of subjects per treatment group; QW = once weekly.

Table 23: Mean FACIT-Fatigue Score During the Open-Label Period (LOCF Data)

Week on Therapy	Raw Mean			Mean Change (% Improvement)		
	Etan 50 mg QW (N = 90)	Placebo/ Etan 50 mg QW[a] (N = 36)	Total (N = 126)	Etan 50 mg QW (N = 90)	Placebo/ Etan 50 mg QW[a] (N = 36)	Total (N = 126)
Baseline[b]	39.5	40.2	39.7			
Week 24	43.2	43.1	43.2	3.7 (15.2)	2.9 (15.6)	3.5 (15.3)

Etan = etanercept; FACIT = functional assessment of chronic illness therapy; LOCF = last observation carried forward; N = total number of subjects per treatment; QW = once weekly.
a. All subjects received etanercept 50 mg QW during the open-label period.
b. Baseline is the double-blind period baseline.

There was no significant difference of FACIT-Fatigue response (the proportion of subjects with improvement of ≥3 points from Baseline) between treatment groups at Week 12 of the double-blind period. The FACIT-Fatigue response was seen at Week 12 in 38.5% of subjects in the original etanercept group and 32.6% of subjects in the placebo/etanercept group.

The FACIT-Fatigue response continued to improve during open-label period for both of the original treatment groups, with 47.8% of subjects in the original etanercept group and with 50 % of subjects in placebo/etanercept group having a FACIT-Fatigue response at Week 24

The subscale scores for fatigue were examined further. Of the 13 questions in this subscale, only Question 1 mentions "fatigue" directly: "Are you fatigued?" For the fatigue subscale Question 1, the change from Baseline mean score (2.73) for the placebo group was significantly higher than that for the etanercept subjects at Week 12. A higher score indicates a lower level of fatigue.

Euro Qol 5-Dimension Self-report Questionnaire (EQ-5D) Score:

Table 24 presents the EQ-5D Feeling Thermometer Score and Utility Score at Baseline and at Week 12 of the double-blind period, as well as the mean change from Baseline at Week 12. Compared with the placebo group, the mean change from Baseline in both the feeling thermometer score and the utility score were significantly greater for the etanercept-treated subjects at Week 12.

Table 24: Mean EQ-5D Feeling Thermometer Score and Utility Score During the Double-Blind Period (mITT Population, LOCF Data)

		Raw Mean		Mean Change		
		Etan 50 mg QW (N = 95)	Placebo (N = 46)	Etan 50 mg QW (N = 95)	Placebo (N = 46)	p-Value
Feeling Thermometer Score						
	Baseline	59.4	58.9			
	Week 12	66.3	53.9	6.8	-4.9	0.0018
Utility Score		(N = 96)	(N = 45)			
	Baseline	0.698	0.662			
	Week 12	0.814	0.686	0.116	0.024	0.0174

p-Values are from van Elteren's test for EQ5D score change from baseline.
Subjects without baseline data were excluded from the analysis
Etan = etanercept; EQ-5D = euro qol 5-dimension self-report questionnaire; LOCF = last observation carried forward; mITT = modified intent-to-treat; N = total number of subjects per treatment; QW = once weekly.

Table 25 presents the EQ-5D Feeling Thermometer Score and Utility Score at Week 24 of the open-label period. The EQ-5D scores continued to improve during open-label period for both of the original treatment groups.

Table 25: Mean EQ-5D Feeling Thermometer Score and Utility Score During the Open-label Period (LOCF Data)

		Raw Mean			Mean Change		
		Etan 50 mg QW (N = 89)	Placebo/ Etan 50 mg QW[a] (N = 36)	Total (N = 125)	Etan 50 mg QW (N = 89)	Placebo/ Etan 50 mg QW[a] (N = 36)	Total (N = 125)
Feeling Thermometer Score							
	Baseline[b]	59.6	59.1	59.4			
	Week 24	76.5	63.0	72.6	17.0	3.9	13.2
Utility Score		(N= 90)	(N = 35)	(N = 125)	(N = 90)	(N = 35)	(N = 125)
	Baseline[b]	0.705	0.711	0.706			
	Week 24	0.860	0.781	0.838	0.156	0.070	0.132

Subjects without baseline data were excluded from the analysis
Etan = etanercept; EQ-5D = Euro Qol 5-Dimension Self-report Questionnaire; LOCF = last observation carried forward; N = total number of subjects per treatment; QW = once weekly.
a. All subjects received etanercept 50 mg QW during the open-label period.
b. Baseline is the double-blind period baseline.

It is concluded that etanercept 50 mg QW for 12 weeks is efficacious in the treatment of subjects with moderate to severe psoriasis compared with placebo. The treatment benefit continued through 24 weeks of treatment for subjects receiving 50 mg QW for the entire study.

Safety Results: One (1) or more AEs, excluding infections and injection site reactions (ISRs), were reported in 54.2% and 45.7% of subjects treated with etanercept 50 mg QW and

placebo, respectively, during the double-blind period. One (1) or more infections were reported in 32.3% and 26.1% of subjects treated with etanercept 50 mg QW and placebo, respectively during the double-blind period. Infections and ISRs were reported separately to clearly differentiate the infectious events and injection site reactions from general AEs.

Table 26 presents the TEAEs (excluding infections and ISRs) reported at an incidence of ≥3% during the double-blind period. There was no significant difference between the placebo and etanercept 50 mg QW groups in the overall incidence of TEAEs during the double-blind period (p = 0.374). The most common TEAEs (excluding infections and ISRs) were pruritus and headache in the etanercept 50 mg QW group, and pruritus in the placebo group. There were significantly more subjects in the etanercept group who reported headache than in the placebo group (p = 0.036).

Table 26: Number (%) of Subjects with Treatment-Emergent Adverse Events Excluding Infections and Injection Site Reactions During the Double-Blind Period, ≥3% Cutoff (mITT Population)

Body System Adverse Event	Overall p-Value[a]	Etan 50 mg QW (N = 96)	Placebo (N = 46)
Any Adverse Event	0.374	52 (54.2)	21 (45.7)
Body as a Whole			
Accidental Injury	0.551	3 (3.1)	0
Asthenia	0.174	5 (5.2)	0
Back Pain	0.245	1 (1.0)	2 (4.3)
Headache	0.036*	13 (13.5)	1 (2.2)
Pain	1.000	3 (3.1)	1 (2.2)
Cardiovascular System			
Hypertension	0.329	2 (2.1)	3 (6.5)
Digestive System			
Diarrhea	0.664	5 (5.2)	1 (2.2)
Dyspepsia	0.551	3 (3.1)	0
Musculoskeletal System			
Arthralgia	0.595	2 (2.1)	2 (4.3)
Skin And Appendages			
Pruritus	0.424	14 (14.6)	4 (8.7)
Psoriasis	0.329	2 (2.1)	3 (6.5)

Statistical significance at the 0.05, level is denoted by *. AEs and SAEs are not separated out.
Etan = etanercept; mITT = modified intent-to-treat; N = total number of subjects per treatment group; QW = once weekly.
a. Overall p-value: Fisher's exact test p-value (2-tailed).

Table 27 presents the TEAEs (excluding infections and ISRs) reported at an incidence of ≥3% during the open-label period. Overall, 36.5% of subjects experienced a TEAE during the open-label period. There were no significant differences in TEAEs based on original randomized treatment group assignment in the double-blind period. The most common TEAE (excluding infections and ISRs) during the open-label period was pruritus, as was observed in the double-blind period.

Table 27: Number (%) of Subjects with Treatment-Emergent Adverse Events Excluding Infections and Injection Site Reactions During the Open-Label Period, ≥3% Cutoff (mITT Population)

Body Systema Adverse Event	Overall p-Valuea	Etan 50 mg QW (N = 90)	Placebo/ Etan 50 mg QWb (N = 36)	Total (N = 126)b
Any Adverse Event	0.225	36 (40.0)	10 (27.8)	46 (36.5)
Body as a Whole				
Abdominal Pain	0.557	3 (3.3)	0	3 (2.4)
Asthenia	1.000	4 (4.4)	1 (2.8)	5 (4.0)
Back Pain	0.080	0	2 (5.6)	2 (1.6)
Cardiovascular System				
Hypertension	0.623	3 (3.3)	2 (5.6)	5 (4.0)
Musculoskeletal System				
Arthralgia	0.557	3 (3.3)	0	3 (2.4)
Nervous System				
Anxiety	0.557	3 (3.3)	0	3 (2.4)
Skin And Appendages				
Pruritus	0.723	8 (8.9)	2 (5.6)	10 (7.9)

AEs and SAEs are not separated out.
Etan = etanercept; mITT = modified intent-to-treat; N = number of subjects per treatment; QW = once weekly.
a. Overall p-Value: Fisher's exact test p-value (2-tailed).
b. All subjects received etanercept 50 mg QW during the open-label period.

Table 28 shows the number of subjects with treatment-emergent infections during the double-blind period. There was no significant difference between the treatment groups in the overall incidence of infections during the double-blind period (p = 0.551). With the exception of a significantly higher incidence of flu syndrome in subjects receiving etanercept 50 mg QW (p = 0.030), the incidence of individual treatment-emergent infections was similar between the 2 treatment groups. Flu syndrome was the preferred term for flu-like syndrome (2), flu (2), and flu syndrome (6). Most cases of flu syndrome were mild (7/10) and were considered not related to test article in 50% of the subjects.

Table 28: Number (%) of Subjects with Treatment-Emergent Infections During the Double-Blind Period, ≥3% Cutoff (mITT Population)

Body System Adverse Event	Overall p-Value[a]	Etan 50 mg QW (N = 96)	Placebo (N = 46)
Any Adverse Event	0.551	29 (30.2)	11 (23.9)
Pulmonary/Thoracic			
Bronchitis	0.245	1 (1.0)	2 (4.3)
Oropharynx			
Labialis	0.245	1 (1.0)	2 (4.3)
Pharyngitis/Laryngitis	0.664	5 (5.2)	1 (2.2)
Sinusitis	0.245	1 (1.0)	2 (4.3)
Upper Respiratory Infection	0.770	9 (9.4)	5 (10.9)
Respiratory			
Flu Syndrome	0.030*	10 (10.4)	0

Statistical significance at the 0.05 level is denoted by *.
Etan = etanercept; mITT = modified intent-to-treat; N = total number of subjects per treatment group; QW=once weekly.
a. Overall p-value: Fisher's exact test p-value (2-tailed).

Table 29 shows the number of subjects with treatment-emergent infections during the open-label period. Overall, 34.9% of subjects experienced a treatment-emergent infection during the open-label period. There were no significant differences in individual treatment-emergent infections based on original randomized treatment group assignment in the double-blind period; however, the overall number of treatment-emergent infections experienced by subjects from the original etanercept was greater than that experienced by subjects from the original placebo group (p = 0.024). The most common treatment-emergent infection during the open-label period was upper respiratory infection, as was observed during the double-blind period. The majority of cases of upper respiratory infection were mild (12 of 14) and considered not related to test article in 11 of 14 subjects. One (1) subject (etanercept group) had 3 episodes of upper respiratory infection that were mild and not related, and they resolved in a few days.

Table 29: Number (%) of Subjects with Treatment-Emergent Infections During the Open-Label Period, ≥3% Cutoff (mITT Population)

Body System Adverse Event	Overall p-Value[a]	Etan 50 mg QW (N = 90)	Placebo/ Etan 50 mg QWb (N = 36)	Total (N = 126)[b]
Any Adverse Event	0.024*	37 (41.1)	7 (19.4)	44 (34.9)
Pulmonary/Thoracic				
Bronchitis	0.577	4 (4.4)	0	4 (3.2)
Skin				
Cellulitis/Abscess	0.557	3 (3.3)	0	3 (2.4)
Oropharynx				
Pharyngitis/Laryngitis	0.714	6 (6.7)	3 (8.3)	9 (7.1)
Sinusitis	0.673	5 (5.6)	1 (2.8)	6 (4.8)
Upper Respiratory Infection	0.347	12 (13.3)	2 (5.6)	14 (11.1)
Respiratory				
Flu Syndrome	0.444	8 (8.9)	1 (2.8)	9 (7.1)

Etan = etanercept; mITT = modified intent-to-treat; N=number of subjects; QW=once weekly.
a. Overall p-value: Fisher's exact test p-value (2-tailed). Statistical significance at the 0.05 level is denoted by *.
b. All subjects received etanercept 50 mg QW during the open-label period.

Sixteen (16) subjects in the etanercept group versus 1 subject in the placebo group experienced at least 1 ISR during the double-blind period (p = 0.0121) (Table 30).

Table 30: Number (%) of Subjects with Injection Site Reactions During the Double-Blind Period (mITT Population)

Characteristic	Etan 50 mg QW (N = 96)	Placebo (N = 46)
At least 1 injection site reaction	16 (16.67)	1 (2.17)
Maximum intensity per subject		
None	80 (83.33)	45 (97.83)
Redness	9 (9.38)	0
Swelling	3 (3.13)	0
Pain	4 (4.17)	1 (2.17)
Ulceration	0	0

Etan = etanercept; mITT = modified intent-to-treat; N = total number of subjects per treatment group; QW = once weekly.

Five (5) ISRs were reported during the open-label period (Table 31). The number of ISRs decreased with time. Only 1 subject from the original placebo group experienced an ISR after starting treatment with etanercept 50 mg QW in the open-label period.

Table 31: Number (%) of Subjects with Injection Site Reactions During the Open-Label Period (mITT Population)

Characteristic	p-Value[a]	Etan 50 mg QW (N = 90)	Placebo/ Etan 50 mg QW[b] (N = 36)	Total (N = 126)[b]
At least 1 injection site reaction	1.000	4 (4.44)	1 (2.78)	5 (3.97)
Maximum intensity per subject	0.820			
None		86 (95.56)	35 (97.22)	121 (96.03)
Redness		1 (1.11)	1 (2.78)	2 (1.59)
Swelling		1 (1.11)	0	1 (0.79)
Pain		2 (2.22)	0	2 (1.59)

Days are calculated using the start of study drug administration as Day 1.
Etan = etanercept; mITT = modified intent-to-treat; N = total number of subjects per treatment group; QW = once weekly.
a. Fisher's exact test p-value (2-tailed).
b. All subjects received etanercept 50 mg QW during the open-label period.

Discontinuations Due to AEs: Adverse events, excluding infections and ISRs, were the cause for discontinuation of treatment for 4 subjects in the etanercept 50 mg QW group and 5 subjects in the placebo group during the double-blind period (Table 32). Of the 4 subjects in the etanercept group who withdrew because of adverse events, 2 withdrew for psoriasis and 1 each for anemia and urticaria.

Table 32: Number (%) of Subjects with Adverse Events Causing Withdrawal, Excluding Infections and Injection Site Reactions, During the Double-Blind Period (mITT Population)

Body System Adverse Event	Overall p-Value[a]	Etan 50 mg QW (N = 96)	Placebo (N = 46)
Any Adverse Event	0.149	4 (4.2)	5 (10.9)
Digestive System			
Hepatitis	0.324	0	1 (2.2)
Liver Function Tests Abnormal	0.324	0	1 (2.2)
Hemic and Lymphatic System			
Anemia	1.000	1 (1.0)	0
Skin and Appendages			
Psoriasis	0.595	2 (2.1)	2 (4.3)
Skin Benign Neoplasm	0.324	0	1 (2.2)
Urticaria	1.000	1 (1.0)	0

Etan = etanercept; N = total number of subjects per treatment group; QW = once weekly.
AEs and SAEs are not separated out.
a. Overall p-value: Fisher's exact test p-value (2-tailed).

Adverse events, excluding infections and ISRs, were the cause for discontinuation of treatment for 3 subjects during the open-label period (Table 33). All 3 subjects had previously received placebo during the double-blind period, and they withdrew during open-label treatment with etanercept 50 mg QW because of lymphadenopathy, serum glutamate pyruvate transaminase (SGPT) increased, and psoriasis.

Table 33: Number (%) of Subjects with Adverse Events Causing Withdrawal, Excluding Infections and Injection Site Reactions, During the Open-Label Period (mITT Population)

Body System Adverse Event	Overall p-Value[a]	Etan 50 mg QW (N = 90)	Placebo/ Etan 50 mg QW[b] (N = 36)	Total (N = 126) [b]
Any Adverse Event	0.022*	0	3 (8.3)	3 (2.4)
Hemic and Lymphatic System				
Lymphadenopathy	0.286	0	1 (2.8)	1 (0.8)
Metabolic and Nutritional				
SGPT Increased	0.286	0	1 (2.8)	1 (0.8)
Skin and Appendages				
Psoriasis	0.286	0	1 (2.8)	1 (0.8)

Statistical significance at the 0.05, level is denoted by *.
AEs and SAEs are not separated out.
Abbreviations: Etan = etanercept; mITT = modified intent-to-treat; N = total number of subjects per treatment; QW = once weekly; SGPT = serum glutamate pyruvate transaminase
a. Overall p-value: Fisher's exact test p-value (2-tailed).
b. All subjects received etanercept 50 mg QW during the open-label period.

One (1) subject discontinued from the study because of an infection. That subject had received etanercept 50 mg QW during the double-blind period and discontinued on study Day 27 for recurrent flu syndrome together with recurrent herpes labialis. The flu syndrome was considered moderate and not related to study drug.

Serious Adverse Event (SAE): Five (5; 3.5%) subjects (3 in the placebo group and 2 in the etanercept group) experienced noninfectious SAEs during the double-blind period (Table 34). No subjects experienced a serious infection during the double-blind period. Each SAE was reported in 1 subject each, except for the SAE of psoriasis which was reported in 2 subjects.

Table 34: Number (%) of Subjects with Serious Adverse Events Excluding Infections and Injection Site Reactions During the Double-Blind Period (mITT Population)

Body System Adverse Event	Overall p-Value[a]	Etan 50 mg QW (N = 96)	Placebo (N = 46)
Any Adverse Event	0.329	2 (2.1)	3 (6.5)
Cardiovascular System			
Cerebral Ischemia	1.000	1 (1.0)	0
Digestive System			
Hepatitis	0.324	0	1 (2.2)
Respiratory System			
Laryngeal Neoplasia	0.324	0	1 (2.2)
Skin and Appendages			
Psoriasis	0.545	1 (1.0)	1 (2.2)

Etan = etanercept; mITT = modified intent-to-treat; N = total number of subjects per treatment group; QW = once weekly.
a. Overall p-value: Fisher's exact test p-value (2-tailed).

Two (2; 1.6%) subjects experienced noninfectious SAEs (valvular heart disease and psoriasis) during the open-label period (Table 35). No subjects experienced a serious infection during the open-label period.

Table 35: Number (%) of Subjects with Serious Adverse Events Excluding Infections and Injection Site Reactions During the Open-Label Period (mITT Population)

Body System Adverse Event	Overall p-Value[a]	Etan 50 mg QW (N = 90)	Placebo/ Etan 50 mg QW[b] (N = 36)	Total (N = 126)[b]
Any Adverse Event	0.491	1 (1.1)	1 (2.8)	2 (1.6)
Cardiovascular System				
Valvular Heart Disease	1.000	1 (1.1)	0	1 (0.8)
Skin and Appendages				
Psoriasis	0.286	0	1 (2.8)	1 (0.8)

Etan = etanercept; mITT = modified intent-to-treat; N = total number of subjects per treatment; QW = once weekly.
a. Overall p-value: Fisher's exact test p-value (2-tailed).
b. All subjects received etanercept 50 mg QW during the open-label period.

Deaths: There were no deaths reported during this study.

Clinical Laboratory Evaluations: National Cancer Institute (NCI) criteria for determining laboratory test results of potential clinical importance were used in this study. Table 36 and Table 37 present the number of subjects who had potentially clinically important laboratory test results (NCI Grades 3) during the double-blind and open-label periods, respectively, grouped by laboratory assessment. There were no NCI Grade 4 laboratory abnormalities during the study. There were no significant differences between the 2 treatment groups in the number of subjects with any of the Grade 3 laboratory test results reported during the study.

Table 36: Number (%) of Subjects With Grade 3 Laboratory Test Results During the Double-Blind Period (mITT Population)

Category Test[a] + Units	Overall p-Value[b]	Etan 50 mg QW n/N (%)[c]	Placebo n/N (%)[c]
Total	0.676	4/ 95 (4.2)	3/ 42 (7.1)
Blood Chemistry	0.373	3/ 94 (3.2)	3/ 42 (7.1)
Total Bilirubin µmol/L			
Grade 3	1.000	3/ 94 (3.2)	1/ 42 (2.4)
SGOT mu/mL			
Grade 3	0.309	0/ 94	1/ 42 (2.4)
Alkaline Phosphatase mu/mL			
Grade 3	0.309	0/ 94	1/ 42 (2.4)
Hematology	1.000	1/ 93 (1.1)	0/ 41
Hemoglobin g/L			
Grade 3	1.000	1/ 93 (1.1)	0/ 41

Etan = etanercept; mITT = modified intent-to-treat; N = total number of subjects per treatment group; n = number of subjects with Grade 3 laboratory test results; QW = once weekly;
SGOT = serum glutamic oxaloacetic transaminase.
a. For each test only maximum grade per subject counted.
b. Overall p-value: Fisher's exact test p-value (2-tailed).
c. Percentages based on the number of subjects tested.

Table 37: Number (%) of Subjects With Grade 3 Laboratory Test Results During the Open-label Period (mITT Population)

Category Test[a] + Units	Overall p-Value[b]	Etan 50 mg QW n/N (%)	Placebo/ Etan 50 mg QW n/N (%)[c]	Total n/N (%)[c]
Total	1.000	2/ 89 (2.2)	1/ 35 (2.9)	3/124 (2.4)
Blood Chemistry	1.000	2/ 89 (2.2)	1/ 35 (2.9)	3/124 (2.4)
Total Bilirubin µmol/L				
Grade 3	1.000	2/ 89 (2.2)	1/ 35 (2.9)	3/124 (2.4)

Etan = etanercept; mITT = modified intent-to-treat; N = total number of subjects per treatment group; n = number of subjects with Grade 3 laboratory test results; QW = once weekly;
SGOT = serum glutamic oxaloacetic transaminase.
a. For each test only maximum grade per subject counted.
b. Overall p-value: Fisher's exact test p-value (2-tailed).
c. All subjects received etanercept 50 mg QW during the open-label period.

Vital Signs, Physical Findings, and Other Observations Related to Safety:

There were no clinically significant changes at the end of the study compared with Baseline for vital signs and physical characteristics. There were no differences between treatment groups in the number of subjects who had an increase in diastolic blood pressure of ≥10 mm Hg during the double-blind (Table 38) and open-label periods (Table 39), broken out by baseline diastolic blood pressure.

Table 38: Number (%) of Subjects with an Increase in Diastolic Blood Pressure of ≥10 mm Hg During the Double-Blind Period (mITT Population)

Baseline Diastolic Blood Pressure	Overall p-Value[a]	Etan 50 mg QW n/N (%)	Placebo n/N (%)
< 90 mm Hg	0.687	41/86 (47.7)	18/34 (52.9)
≥90 mm Hg	0.348	4/10 (40.0)	2/12 (16.7)

Etan = etanercept; mITT = modified intent-to-treat; N = total number of subjects per treatment group; n = number of subjects with increase in blood pressure; QW = once weekly.
a. Overall p-value: Fisher's exact test p-value (2-tailed).

Table 39: Number (%) of Subjects with an Increase in Diastolic Blood Pressure of ≥10 mm Hg During the Open-Label Period

Baseline Diastolic Blood Pressure	Overall p-Value[a]	Etan 50 mg QW n/N (%)	Placebo/ Etan 50 mg QW n/N (%)[b]
< 90 mm Hg	0.536	38/80 (47.5)	13/32 (40.6)
≥ 90 mm Hg	1.000	3/10 (30.0)	1/4 (25.0)

Etan = etanercept; mITT = modified intent-to-treat; N = total number of subjects per treatment group; n =number of subjects with increase in blood pressure; QW = once weekly.
a. Overall p-value: Fisher's exact test p-value (2-tailed).
b. All subjects received etanercept 50 mg QW during the open-label period.

CONCLUSIONS: The primary endpoint (PASI 75 at Week 12) was met in this study. Compared to placebo, administration of etanercept 50 mg QW provided an efficacious treatment option for the treatment of psoriasis.

The efficacy of 50 mg QW provided at least as much control of psoriasis as etanercept 25 mg twice weekly (BIW), as indicated by the results of previous studies. Etanercept 50 mg QW was generally well tolerated in this study, and no new findings occurred in terms of the safety profile for etanercept.