Efficacy and Safety Observed During 24 Weeks of Efalizumab Therapy in Patients With Moderate to Severe Plaque Psoriasis

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Objective: To assess the efficacy and safety of a 24-week course of efalizumab.

Design: Phase 3, randomized, double-blind, parallel-group, placebo-controlled 12-week study followed by a 12-week open-label study.

Setting: Outpatient dermatology clinics.

Patients: A total of 556 patients with moderate to severe chronic plaque psoriasis who were seeing an outpatient dermatologist were included in the study.

Intervention: For weeks 1 to 12, the 556 patients were randomized to receive 1 mg/kg of efalizumab weekly or placebo subcutaneously. For weeks 13 to 24, 516 of these patients received 1 mg/kg of efalizumab weekly.

Main Outcome Measures: Proportion of patients with a 75% or greater improvement in Psoriasis Area and Severity Index (PASI-75), a 50% or greater improvement in PASI (PASI-50), static Physician’s Global Assessment (sPGA) rating of minimal or clear, and improvements in Dermatology Life Quality Index (DLQI), itching scale, and Psoriasis Symptom Assessment (PSA) frequency and severity scores at weeks 12 and 24. Safety was evaluated by reviewing adverse events, laboratory parameters, vital signs, and anti-efalizumab antibodies.

Results: At week 12, 26.6% of efalizumab-treated patients achieved PASI-75 and 58.5% achieved PASI-50. After 24 weeks of continuous efalizumab therapy, PASI responses increased: 43.8% of patients achieved PASI-75 and 66.6% achieved PASI-50. The percentage of patients who achieved an sPGA rating of minimal or clear increased from 25.7% to 35.9%. The mean percentage of improvement in all patient-reported outcomes (DLQI, itching scale, and PSA frequency and severity scores) at week 12 was maintained at week 24 (DLQI, 49.2%; itching scale, 42.2%; PSA frequency and severity scores, 47.6%; PSA severity, 47.3%). There was a decline in overall reported adverse events from weeks 1 to 12 (80.4%) to weeks 13 to 24 (63.2%) without evidence of cumulative toxic effects.

Conclusion: Extending efalizumab treatment from 12 to 24 weeks leads to improved efficacy and maintenance of quality of life with no evidence of cumulative toxic effects noted in patients with moderate to severe chronic plaque psoriasis.

Arch Dermatol. 2005;141:31-38
ture of the impact of this disease, both physically and mentally. There is a significant need for psoriasis therapies not only to reduce the visible symptoms of psoriasis but also to reduce subjective symptoms such as itching, an under-recognized key symptom, and to improve patients’ functional status and their physical and emotional well-being.

The development of targeted biologic therapies during the past decade has brought much needed attention to psoriasis, one of the most prevalent of all immunemediated disorders. Efalizumab is a humanized monoclonal IgG1 antibody against CD11a, the α-subunit of leukocyte function–associated antigen-1. Leukocyte function–associated antigen-1 and intercellular adhesion molecule 1 are costimulatory molecules expressed on T cells and antigen-presenting cells, respectively, that facilitate multiple T-cell–mediated events. By interfering with leukocyte function–associated antigen-1 and intercellular adhesion molecule 1 binding, efalizumab inhibits multiple key steps in the immunologic cascade that lead to the generation of psoriasis plaques: the activation of T cells in the lymph nodes, trafficking of T cells from the circulation into dermal and epidermal tissue, and their reactivation in those sites. A 12-week course of efalizumab is well tolerated and results in improvement in both physician- and patient-assessed evaluations in patients with moderate to severe chronic plaque psoriasis. The present phase 3 study assessed the safety, efficacy, and impact on patient-reported outcome measures of 24 weeks of efalizumab therapy in patients with moderate to severe plaque psoriasis, with the objective of assessing clinical responses and safety of extended efalizumab therapy for the treatment of this chronic disease.

**METHODS**

**PROTOCOL**

This study was a phase 3, randomized, double-blind, parallel-group, placebo-controlled, 12-week multicenter trial immediately followed by an additional 12-week open-label, extended treatment period conducted from April 2002 through October 2002. Eligible patients were aged 18 to 75 years, were diagnosed as having plaque psoriasis for at least 6 months with 10% or more of total body surface area affected, had a minimum Psoriasis Area and Severity Index (PASI) of 12.0 at screening, and were candidates for systemic therapy. Patients could withdraw from the study at any time. All patients provided a signed informed consent document, and all sites received institutional review board approval before initiating the study.

Following a 4-week screening period, patients were randomized. An unblinded statistician at Genentech Inc (South San Francisco, Calif) generated allocation sequences and provided them to the interactive voice response system vendor. The sites enrolled and randomized patients by calling the interactive voice response system vendor. Patients could withdraw from the study at any time. All patients provided a signed informed consent document, and all sites received institutional review board approval before initiating the study.

Following a 4-week screening period, patients were randomized. An unblinded statistician at Genentech Inc (South San Francisco, Calif) generated allocation sequences and provided them to the interactive voice response system vendor. The sites enrolled and randomized patients by calling the interactive voice response system, which at baseline (day 0) assigned patients to receive subcutaneous efalizumab or placebo during weeks 1 to 12. Randomization was achieved via a permuted block design to obtain approximately a 2:1 ratio within categories defined by the stratification variables: baseline PASI (≤16.0 or ≥16.1), prior treatment for psoriasis (yes/no), and study center.

For the analyses conducted during weeks 1 to 12, the planned sample size of 333 patients in the efalizumab group and 167 patients in the placebo group had 99% power to detect a difference between the projected placebo response rate of 3% compared with the assumed efalizumab response rate of 23% at the α = 0.05 significance level using a 2-sided Fisher exact
The baseline value used to determine improvements were performed in the as-treated population. At least 1 dose of efalizumab during weeks 13 to 24. Safety analyses conducted in weeks 1 to 12 were previously described. The baseline value used to determine improvement at week 24 depended on treatment assignment during the first 12 weeks. For patients who received efalizumab during weeks 1 to 12, the baseline value used for comparison was day 0. For patients who received placebo during weeks 1 to 12 followed by efalizumab during weeks 13 to 24, the baseline value was day 84. For the PASI-75 response rate and proportion of patients who achieved an sPGA rating of minimal or clear at week 24 relative to day 0, 95% confidence intervals (CIs) were obtained based on an exact method for binomial proportions. Additionally, 95% CIs were obtained for the mean change in DLQI, itching scale, and PSA frequency and severity subscales. Additional analyses that have been used to assess the efficacy of biologic therapies are the PASI-75 and PASI-50 rates achieved at any time during the treatment course.

**RESULTS**

**PATIENT CHARACTERISTICS**

At baseline, 556 patients were randomized into the study: 369 to the efalizumab group (1 mg/kg per week) and 187 to the placebo group (Figure 1). There were no significant differences between the efalizumab and placebo groups with regard to baseline characteristics and severity of psoriasis (Table 2). Details concerning the first 12-week treatment period are published elsewhere.

Of the 345 patients who received efalizumab and completed the first 12-week treatment period, 342 entered the open-label treatment period for an additional 12 weeks of 1 mg/kg of efalizumab (Figure 1). Of the 175 patients who received placebo and completed the first 12 weeks of the study, 174 entered the open-label treatment period and received 1 mg/kg of efalizumab for 12 weeks as their first-time exposure to efalizumab. In total, 516 patients were treated during weeks 13 to 24. During weeks 13 to 24, 50 (9.7%) of the 516 patients discontinued treatment. Reasons for discontinuation were adverse events (23 patients), patient’s decision (16), use of excluded medication (6), physician’s decision (3), and loss to follow-up (2). Of the 516 patients, 466 (90.3%) completed the open-label treatment phase, including 308 patients who completed 24 weeks of continuous efalizumab treatment (Figure 1).
**TREATMENT EFFICACY: PHYSICIAN-ASSESSED OUTCOMES**

**Psoriasis Area and Severity Index**

As reported previously, at week 12, 216 (58.5%) of 369 efalizumab-treated patients achieved a PASI-50 response (vs 26 [13.9%] of 187 with placebo, *P* < .001), 98 (26.6%) of 369 achieved a PASI-75 response (vs 8 [4.3%] of 187 with placebo, *P* < .001), and 19 (5.1%) of 369 achieved a 90% or greater improvement in PASI (PASI-90) response (vs 1 [0.5%] of 187 with placebo). The PASI continued to improve when the duration of efalizumab therapy was extended from 12 to 24 weeks. At week 24, 245 (66.6%) of 368 efalizumab-treated patients (95% CI, 61.5%-71.4%) achieved a PASI-50 response, 161 (43.8%) of 368 patients (95% CI, 38.6%-49.0%) achieved a PASI-75 response (*Figure 2*), and 55 (14.9%) of 368 patients achieved a PASI-90 response. The mean percentage of PASI improvement relative to baseline increased from 52.2% at week 12 to 67.2% (*Figure 3*) at week 24. The median percentage of PASI improvement increased from 59.9% at week 12 to 76.4% at week 24. A total of 290 (78.6%) of 369 patients achieved a PASI-50 response at any time during 24 weeks of efalizumab therapy, and 202 (54.7%) of 369 achieved a PASI-75 response at any time. *Figure 4* shows a patient with continued PASI improvement.
When patients crossed over from placebo (weeks 1 through 12) to efalizumab (weeks 13 through 24), they demonstrated a rapid improvement in their PASI. In this group, 60.3% achieved PASI-50 and 24.1% achieved PASI-75 at the end of the 12-week, open-label efalizumab treatment phase. The mean percentage of PASI improvement after 12 weeks of efalizumab therapy in this patient group was 53.4% (Figure 3).

**Static Physician’s Global Assessment**

At week 24, the proportion of efalizumab-treated patients who achieved an sPGA rating of minimal or clear was 35.9% (95% CI, 31.0%-41.0%) compared with 25.7% at week 12. Of the patients who received placebo followed by efalizumab, 28.7% achieved an sPGA rating of minimal or clear at the end of the 12-week efalizumab treatment phase.

**Dermatology Life Quality Index**

For efalizumab-treated patients, the mean improvement from baseline in DLQI scores at week 12 was 5.6 (vs 1.6 with placebo, *P*<.001).21 The mean improvement in DLQI scores for patients who received 24 weeks of continuous efalizumab therapy was maintained at 5.9 (95% CI, 5.1-6.7), representing a 49.2% improvement from baseline. The greatest mean improvement in score was reported for the individual questions that pertained to psoriasis symptoms (eg, itching, soreness, pain, or stinging) (1.1), how embarrassed or self-conscious the patient felt (1.1), and the extent to which psoriasis affected clothing choices (1.0). For patients who received placebo followed by efalizumab, the mean improvement in DLQI score was 4.8 (95% CI, 3.8-5.8), representing a 49.0% improvement from baseline after 12 weeks of efalizumab treatment.

**Itching Scale**

The mean improvement in itching score for patients receiving 12 weeks of efalizumab therapy was 2.8 (vs 0.7 with placebo, *P*<.001),21 and for patients receiving 24 weeks of continuous efalizumab therapy, the mean improvement was maintained at 3.0 (95% CI, 2.7-3.4), representing a 42.2% improvement from baseline when excluding patients with a baseline itching score of 0. The mean improvement in itching score at week 24 for patients who received placebo followed by efalizumab was 2.8 (95% CI, 2.3-3.2), representing a 39.6% improvement from baseline after 12 weeks of efalizumab treatment.

**PSA Frequency and Severity Subscales**

As previously reported, the mean improvement in PSA frequency score at 12 weeks was 6.8 (vs 2.6 with placebo,
Efalizumab therapy was generally well tolerated. All adverse events that occurred in 5% or more of all patients during the two 12-week treatment segments are shown in Table 3. During weeks 1 to 12, headache, chills, fever, myalgia, and generalized pain occurred at least 5% more frequently in the efalizumab group than in the placebo group. However, most of these events were prespecified acute adverse events (defined as headache, nausea, chills, fever, myalgia, and vomiting that occurred within 48 hours of administration) and were associated with the first 2 doses of efalizumab. By the third and all subsequent doses, the frequency of acute adverse events was similar between efalizumab- and placebo-treated patients. Given the decrease in the incidence of acute adverse events by week 3, it is evident that the flulike symptoms common to biologic therapies are associated with the initiation of efalizumab therapy and do not persist with continued treatment beyond this period.

During weeks 1 to 12, the percentage of patients with at least 1 adverse event in the efalizumab and placebo groups was 80.4% and 71.1%, respectively (Table 3). During weeks 13 through 24, the percentage of patients who reported at least 1 adverse event declined to 63.2% in the group receiving 24 weeks of continuous efalizumab therapy. In patients who received placebo during weeks 1 through 12 and then crossed over to receive efalizumab, 70.7% reported at least 1 adverse event during weeks 13 to 24 (Table 3).

Adverse events observed in 5% or more of patients during weeks 13 to 24 in the 24-week efalizumab treatment group were nonspecific infection (11.1%), headache (6.1%), and arthritis (5.6%). During this second 12-week treatment period, there was no placebo comparator. During the first 12 weeks of therapy, there was no statistically significant difference in the incidence of arthritis adverse events between the efalizumab and placebo groups (2.7% vs 1.6%, P = .56). During weeks 13 to 24, there were 19 adverse events of arthritis (5.6%) among 342 patients who received 24 weeks of efalizumab therapy. Twelve (63%) of these 19 patients had a history of arthritis. In only 1 case did the patient achieve a PASI-75 response. The remaining arthritis adverse events were reported in patients who did not achieve PASI-50 (14 patients) or who achieved 50% to 74% PASI improvement (4 patients) at week 24. During this open-label period, 4.0% of patients who originally received placebo and then crossed over to receive efalizumab experienced arthritis-related adverse events.

During 24 weeks of efalizumab therapy, there was a reduction in acute adverse events during weeks 13 to 24, and there was no evidence of cumulative toxic effects noted. Comparing weeks 1 to 12 with weeks 13 to 24, the incidence of several parameters of adverse events were

<table>
<thead>
<tr>
<th>No. (%) of Patients</th>
<th>Placebo (n = 187)</th>
<th>Efalizumab (n = 368)</th>
<th>P/E (n = 174)</th>
<th>E/E (n = 342)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adverse Event</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Weeks 1-12</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Placebo</td>
<td>133 (71.1)</td>
<td>296 (80.4)</td>
<td>123 (70.7)</td>
<td>216 (63.2)</td>
</tr>
<tr>
<td>Efalizumab</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total†</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td>39 (20.9)</td>
<td>123 (33.4)</td>
<td>44 (25.3)</td>
<td>21 (6.1)</td>
</tr>
<tr>
<td>Infection, NOS</td>
<td>23 (12.3)</td>
<td>46 (12.5)</td>
<td>17 (9.8)</td>
<td>38 (11.1)</td>
</tr>
<tr>
<td>Chills</td>
<td>10 (5.3)</td>
<td>44 (12.0)</td>
<td>10 (5.7)</td>
<td>5 (1.5)</td>
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<tr>
<td>Nausea</td>
<td>13 (7.0)</td>
<td>39 (10.6)</td>
<td>9 (5.2)</td>
<td>13 (3.8)</td>
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<tr>
<td>Myalgia</td>
<td>8 (4.3)</td>
<td>38 (10.3)</td>
<td>7 (4.0)</td>
<td>9 (2.6)</td>
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<td>Generalized pain</td>
<td>9 (4.8)</td>
<td>37 (10.1)</td>
<td>17 (9.8)</td>
<td>11 (3.2)</td>
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<td>Pharyngitis</td>
<td>10 (5.3)</td>
<td>27 (7.3)</td>
<td>8 (4.6)</td>
<td>10 (2.9)</td>
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<tr>
<td>Flulike syndrome</td>
<td>7 (3.7)</td>
<td>27 (7.3)</td>
<td>8 (4.6)</td>
<td>10 (2.9)</td>
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<tr>
<td>Fever</td>
<td>3 (1.6)</td>
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<td>6 (3.4)</td>
<td>3 (0.9)</td>
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<td>23 (6.3)</td>
<td>8 (4.6)</td>
<td>7 (2.0)</td>
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<tr>
<td>Asthenia</td>
<td>9 (4.8)</td>
<td>22 (6.0)</td>
<td>6 (3.4)</td>
<td>7 (2.0)</td>
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<tr>
<td>Diarrhea</td>
<td>10 (5.3)</td>
<td>20 (5.4)</td>
<td>11 (6.3)</td>
<td>14 (4.1)</td>
</tr>
<tr>
<td>Unintentional injury</td>
<td>19 (10.2)</td>
<td>17 (4.8)</td>
<td>9 (5.2)</td>
<td>15 (4.4)</td>
</tr>
<tr>
<td>Arthritis</td>
<td>3 (1.6)</td>
<td>10 (2.7)</td>
<td>7 (4.0)</td>
<td>19 (5.6)</td>
</tr>
</tbody>
</table>

Abbreviations: E/E, patients who received efalizumab in weeks 1 to 12; NOS, not otherwise specified; P/E, patients who received placebo in weeks 1 to 12.

*Represents the as-treated population.
†Number of patients with at least 1 adverse event.
Results of the present study support the clinical benefits of continuous efalizumab therapy in patients with moderate to severe chronic plaque psoriasis and show that efficacy is improved and maintained with extended treatment. The PASI-50 response rate increased from 58.2% at week 12 to 66.6% at week 24, the PASI-75 response rate improved from 26.6% to 43.8%, and the PASI-90 response rate increased from 5.1% to 14.9%, suggesting that extending the duration of efalizumab therapy beyond 12 weeks increases the clinical efficacy. Efalizumab treatment resulted in rapid and significant improvement in the mean percentage increase in PASI, from 52.2% at week 12 to 67.2% at week 24. Similarly, the median percentage of PASI improvement increased from 59.9% at week 12 to 76.4% at week 24. The sPGA responses were also improved, supporting the improvement in PASI responses.

The PASI and sPGA response rates observed at week 24 in patients who received placebo during weeks 1 through 12 and then crossed over to receive efalizumab are consistent with the responses observed in patients initially treated with efalizumab during weeks 1 to 12, which supports the interpretation that the increase in PASI response rates in patients who received 24 weeks of continuous therapy is caused by the extended duration of treatment. Although all patients who entered the second 12-week period received active treatment, blinding regarding the first 12 weeks of therapy was maintained until the study was completed.

Given the potential for a significant adverse impact of chronic plaque psoriasis on HRQL, assessment of the effects of treatment on HRQL is also an important consideration. Efalizumab-treated patients reported rapid and sustained improvement in HRQL throughout the 24-week treatment period. The improvement in all patient-reported outcomes (DLQI, itching scale, and PSA frequency and severity subscales) at week 12 was significantly greater in the efalizumab-treated patients compared with the placebo-treated patients (P < .001 for each measure), and the improvement in each of the measures was maintained at week 24 for patients who received extended efalizumab treatment. Collectively, the results indicate that 24 weeks of continuous efalizumab therapy maintained improvements in dermatologic-related functionality and well-being and reduced the frequency and bothersome nature of psoriasis symptoms, in addition to significantly improving the clinical features of psoriasis.

Efalizumab was well tolerated during 24 weeks of therapy, with a decline in overall reported adverse events from weeks 1 to 12 to weeks 13 to 24. On initiation of efalizumab, patients experienced transient, mild to moderate flu-like symptoms that decreased in incidence from week 3 onward to equal those in the placebo group. There was no evidence of cumulative toxic effects or end-organ damage observed during 24 weeks of efalizumab therapy. The incidence of serious adverse events was similar between the efalizumab and placebo groups during weeks 1 to 12 and did not increase with extended treatment. This study demonstrates and supports prior findings that white blood cell and lymphocyte counts previously noted to increase during the initial 12-week course of therapy stabilized within the normal range and did not increase further with extended therapy. The incidence of arthritis-related adverse events appeared to increase slightly during weeks 13 through 24; however, interpretation of these findings needs to be made cautiously because there was no placebo comparator during this open-label period. The results of a recently completed phase 2 trial of 24 weeks of efalizumab therapy (weeks 1 through 12 were placebo controlled followed by a 12-week open-label extension) in patients with psoriatic arthritis demonstrated no adverse events of psoriatic arthritis or worsening of psoriatic arthritis during treatment or the 4-week treatment-free follow-up period (Genentech Inc, data on file). Ongoing studies evaluating continuous efalizumab therapy for longer periods do not appear to suggest that patients are at risk for cumulative toxic effects, including arthritis-related adverse events (Genentech Inc, data on file).

Current systemic therapies and phototherapy must often be discontinued or rotated at various intervals to minimize the risk of cumulative toxic effects. It is hoped that the targeted nature of biologic therapies such as efalizumab will improve their safety, particularly relative to traditional systemic therapies, thus allowing for longer-term administration and disease control. During this study, efalizumab had a demonstrated safety profile throughout a 24-week period, with many patients maintaining the treatment effect or experiencing continued improvement during 24 weeks of treatment. If these clinical and quality-of-life benefits persist for longer periods without a change in the safety profile, they would represent a significant advance in psoriasis therapies.

The safety data observed in this 24-week continuous treatment study are favorable. A longer-term (36-month) maintenance study currently under way will further define the ability to use continuous efalizumab therapy for this lifelong chronic disease, affording patients with psoriasis the same opportunity for long-term control of clinical disease and impact on quality-of-life parameters on a par with that of patients who have other chronic immunologic-based diseases, such as rheumatoid arthritis and Crohn disease.

Accepted for Publication: June 7, 2004.

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Montreal, Quebec (Dr Carey); Atlanta Dermatology, Vein and Research Center LLC, Atlanta, Ga (Dr Hamilton); Glazer Dermatology, Buffalo Grove, Ill (Dr Glazer); Genentech Inc, South San Francisco, Calif (Drs Caro and Li); and Newlab Clinical Research, St Johns, Newfoundland (Dr Gulliver).

Financial Disclosure: Drs Menter, Gordon, Carey, Hamilton, Glazer, and Gulliver received compensation to conduct the clinical research. Drs Caro and Li are employees of Genentech Inc. Dr Menter is a consultant and speaker for Abbott Laboratories, Allergan Inc, Amgen Inc, Biogen Idec, Centocor Inc, Genentech Inc, and Serono International SA and has received grant and research support from Abbott Laboratories, Allergan Inc, Allermed Laboratories Inc, Amgen Inc, Astralis Group PLC, Berlex Laboratories, Biogen Idec, Centocor Inc, Corixa Corporation, Dermik Laboratories, Dow Pharmaceutical Sciences, Ferndale Laboratories Inc, Fujisawa Healthcare Inc, Genentech Inc, Medicis, Novartis Pharmaceuticals, Thermosurgery Technologies Inc, and XOMA LLC.

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Funding/Support: The data presented herein are derived from a clinical trial sponsored by Genentech Inc (South San Francisco, Calif). Genentech Inc and its investigators, including the authors of this article, designed this study.

Acknowledgment: We gratefully acknowledge the contribution of Kirsten Duncan, PharmD, to the development of the manuscript.

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