An open-label study evaluating the efficacy and tolerability of alefacept for the treatment of scalp psoriasis

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Background: Almost 50% of patients with psoriasis also have scalp psoriasis. Although alefacept is safe and effective for the treatment of generalized plaque psoriasis, its efficacy specifically for treating scalp psoriasis has not been formally evaluated.

Objective: We sought to evaluate the efficacy and tolerability of alefacept in treating scalp psoriasis.

Methods: Patients (n = 30) with psoriatic plaques covering 30% or more of scalp surface received 15 mg of intramuscular alefacept once weekly for 16 weeks (course 1), followed by 12 weeks of rest. Patients were evaluated for the condition of their scalp psoriasis using the scalp Physician's Global Assessment, a modified Psoriasis Area and Severity Index for the scalp, and scalp Patient's Global Assessment 6 weeks after course 1. Patients who had scalp Physician's Global Assessment scores greater than or equal to 1 at any time between this evaluation and 5 months after the rest period received an additional 12-week course of once-weekly intramuscular alefacept (15 mg) (course 2). Treatment success was defined as attaining scalp Physician's Global Assessment of clear (0) or almost clear (1) at 6 weeks after either treatment course.

Results: Six weeks after course 1, 5 (16.7%) patients achieved clear or almost clear status of their scalp psoriasis. All 3 patients whose scalp psoriasis cleared remained clear until the end of the study. Six weeks after course 2, cumulatively, 8 (26.7%) patients achieved treatment success. Not all patients received both courses. There were no treatment-related serious adverse events.

Limitations: This was a single-arm, open-label, noncomparative trial.

Conclusion: Alefacept is effective in a subset of patients with scalp psoriasis and is well tolerated. (J Am Acad Dermatol 2008;58:609-16.)

Psoriasis is a chronic inflammatory skin condition characterized by exacerbations and remissions. It is estimated to affect approximately 2.6% of the US population.[1] Scalp psoriasis occurs in approximately 50% of patients with psoriasis.[2,3] It is pruritic and sometimes painful, severely affects quality of life, and is commonly treated with topical formulations containing corticosteroids.[4,5] When the disease is recalcitrant, systemic immunosuppressive treatments, eg, methotrexate or

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Conflicts of interest: Dr Krell has been a consultant, investigator, and speaker for Biogen Idec and Astellas Pharma US Inc, and has received funding for research from both companies. He has also been a consultant, investigator, and speaker for Genentech; an investigator and speaker for Abbott Pharmaceuticals and Amgen; and a speaker for Centocor. Dr Miller, Ms Nelson, and Ms Spencer have no conflicts of interest to declare.

Results of this study have been presented at the 63rd Annual Meeting of the American Academy of Dermatology, New Orleans, LA, February 18-22, 2005; the 65th Annual Meeting of the American Academy of Dermatology, Washington, DC, February 2-6, 2007; and the Fall Clinical Dermatology Conference, Las Vegas, NV, October 18-21, 2007.

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Abbreviations used:

PASI:	Psoriasis Area and Severity Index
S-mPASI:	modified Psoriasis Area and Severity Index specific to the scalp
S-PaGA:	scalp Patient's Global Assessment
S-PGA:	scalp Physician's Global Assessment
UV:	ultraviolet

cyclosporine, are used.[4,6] However, toxicities from these drugs limit their long-term use.[6,7] Recently, biologic drugs for psoriasis (alefacept, efalizumab, etanercept, and infliximab) have become available,[8-10] but their use specifically in treating scalp psoriasis has not been formally evaluated. The objective of this open-label, descriptive phase-IV study was to evaluate the efficacy and safety of alefacept, an immunomodulatory biologic agent that targets T cells,[11] in treating scalp psoriasis in adults.

METHODS

Patients

Patients with scalp psoriasis (n = 30) were enrolled in this study. Major inclusion criteria were: age 19 to 75 years; greater than or equal to 30% of scalp surface afflicted with psoriatic plaques; and presence of psoriasis on the body, other than the scalp, at any time. Major exclusion criteria were: use of any other systemic psoriatic medication within 28 days before administration of alefacept; low $CD4^+$ T-lymphocyte count at study entry; serious local or systemic infection within 3 months before administration of alefacept; presence of any other skin disorder that would affect the evaluation of treatment of scalp psoriasis; known HIV infection, viral hepatitis, or tuberculosis; pregnancy or lactation; and unwillingness of women with reproductive potential to practice effective contraceptive measures during the study.

Study design

The primary goal of the study was to determine the proportion of patients who achieved treatment success that was defined as scalp Physician's Global Assessment (S-PGA) score 0 (clear) or S-PGA score 1 (almost clear) at 6 weeks after the last injection of either course. A schematic of the study design is presented in Fig 1. The initial screening was performed within 4 weeks of study initiation. Patients received alefacept once weekly from weeks 1 to 16 (course 1). This was followed by a 12-week rest period (to week 28) during which patients received no treatment. Patients were evaluated at week 22 (6 weeks after treatment termination) for the condition of their scalp psoriasis using a S-PGA scale (Table I). Patients who were given a rating of clear (S-PGA 0) for their scalp psoriasis received once-monthly evaluations from week 28 for the next 5 months, or until their S-PGA score was greater than or equal to 1, whichever was earlier. The screening for course 2 was performed within 1 week before the initiation of treatment. In course 2, patients received alefacept once weekly for 12 weeks. Patients were evaluated 6 weeks after the last dose of course 2. All visits, other than the first visit in either course, were allowed a window of ± 2 days. The study was approved by the institutional review board and all patients provided written informed consent.

Concomitant treatments

Application of topical steroids to the scalp was discontinued 2 weeks before initiation of the study with two exceptions. Use of fluocinolone (0.01%) or hydrocortisone butyrate (0.01%) was permitted during the first 6 weeks of study to avoid flare. If the investigator found the need to prescribe scalp medication for a flare, clobetasol solution was permitted at any time during the study, but only during the initial period of the flare. If flaring persisted, the patient was to withdraw from the study.

All systemic therapies for psoriasis, including biologic therapies, required a 28-day washout period immediately before study initiation. Live vaccines were not permitted during the study. Injectable, but not intranasal, influenza vaccines were permitted.

The use of over-the-counter medicated shampoos was allowed. Topical treatments for psoriasis of the body (excluding the scalp), and ultraviolet (UV) treatment with UVB or psoralen plus UVA, with scalp shielded, were also allowed during the study.

Treatment with alefacept

All patients received 16 once-weekly 15-mg intramuscular doses (course 1) followed by a 12-week rest period during which no prescription medications were permitted. Patients who did not achieve clearing of their scalp psoriasis (ie, had S-PGA $\geq$ 1) at 6 weeks after course 1, and those who did not maintain clear status of their scalp psoriasis for at least 5 months after week 28, received a second treatment course (course 2). Patients who achieved clearing of their scalp psoriasis (ie, S-PGA 0) at 6 weeks after course 1, and remained clear for 5 months after week 28 did not receive further courses. Course 2 could be initiated within 5 months from the end of week 28, and consisted of 12 once-weekly intramuscular doses of 15 mg of alefacept. Course 2 was initiated after the 12-week rest period if the patient did not remain at S-PGA score of 0 at week 28.