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Poster Abstracts

American Academy of Dermatology
63rd Annual Meeting
February 18-22, 2005
New Orleans, LA

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POSTER DISCUSSION SESSIONS

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REBOUND IN PATIENTS ABRUPTLY DISCONTINUED FROM ETANERCEPT

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Psoriasis is a chronic disease that gradually returns after discontinuation of therapy. In some cases, disease can return to a greater extent than when treatment was initiated. Psoriasis relapse and rebound have been documented in multiple case reports of patients withdrawn from psoriasis treatment.[1-6] To provide a clear definition for relapse and rebound, the Medical Advisory Board of the National Psoriasis Foundation defined rebound as "PASI of 125% or greater from baseline or new generalized pustular, erythrodermic or more inflammatory psoriasis occurring within 3 months of stopping therapy."[7] Etanercept, an anti—tumor necrosis factor (TNF)-α targeted fusion protein, was recently approved for the treatment of moderate to severe chronic plaque psoriasis. During the clinical trials, rebound occurred in 1 of 409 patients (0.2%) during the 12-week observation period after etanercept treatment. Patients in clinical practice often present a variety of unique challenges that may differ markedly from the experience gathered during clinical trials. Four patients who developed conversion of morphology or significant worsening of psoriasis during commercial treatment with etanercept will be discussed. Three of these patients were successfully controlled with etanercept but experienced significant disease worsening on discontinuation of treatment. The fourth patient experienced a dramatic flare while receiving etanercept therapy. The management of these 4 patients will be described. These case reports highlight the importance of close clinical follow-up with patients whenever systemic psoriasis therapies are used.

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Dr. Leonardi is on the Advisory Boards of Amgen, Genentech, Centocor, and Serono; has received grant support from Amgen and Genentech; and is a member of the speakers' bureau for Amgen, Genentech, and Serono.

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REFRACTORY ERYTHRODERMA: CASE REPORT (JUST PSORIASIS OR PSYCHIATRIC DISORDER?)

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A 51-year-old male history teacher was admitted to our clinic in April 2003 with erythroderma of 2 months' duration. He had suffered from bipolar disorder since the age of 26; he had re-started lithium carbonate therapy a few days before the appearance of the dermatosis, after a 10-year interval. His father and grandfather had had psoriasis.

During hospitalization, biopsies were performed, which disclosed "drug eruption." Lithium carbonate therapy was discontinued, and he started prednisolone therapy (30 mg daily), with rapid improvement; he was discharged with steroid and carbamazepine therapy (psychiatrist's prescription). Two weeks later there was a new flare of generalized erythema, chills, and fever, which led to the suspension of carbamazepine thereapy and readmission to the hospital after 20 days.

We started prednisolone and increased the dosage to 70 mg/d. New biopsies showed "eczema." After 2 weeks of high-dose steroid therapy without improvement, it was gradually tapered and 4 new biopsies revealed "psoriasis." Five weeks after admission, acitretin was started. Meanwhile, because the patient was not medicated with any mood stabilizer, he had been allowed to spend his weekends at home; we observed a slight worsening every Monday/Tuesday. We started measuring lithium blood levels and noticed a repetitive pattern: positive values (although subtherapeutic) at the beginning and no measurable values at the end of the week. Confronted with this fact, both the patient and close family members strongly denied ingestion of the drug.

Nine weeks after admission we started intramuscularly administered methotrexate (25 mg weekly), discontinued acitretin, and suspended the "weekend break," with gradual clinical improvement and normalization of lithium blood levels. He was dismissed at the third month, with moderate clinical improvement, and was closely monitored in our outpatient clinic; blood lithium levels were again positive, and there was worsening of his clinical condition.

After being submitted to a medical committee in order to retire earlier from his job because of the skin disease, he showed a gradual clinical improvement. Methotrexate was tapered and he attended our clinic irregularly for some months. In a later outpatient visit, we observed a complete remission. The patient told us he was already retired.

Nothing to disclose.

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REPEATED COURSES OF ALEFACEPT ARE COST-EFFECTIVE FOR THE LONG-TERM MANAGEMENT OF PSORIASIS

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Physicians attempting to obtain a second course of alefacept therapy are often confronted with payers questioning the cost-effectiveness of continued treatment. Alefacept is a safe remittive agent, with a proportion of patients maintaining response after completion of treatment. The purpose of this study was to assess the cost-effectiveness of alefacept in patients for whom the decision has been made to continue therapy. Cost-efficacy per day is calculated for each of the 3 biologic agents approved for psoriasis: alefacept 15 mg intramuscularly weekly; efalizumab 1 mg/kg subcutaneously (SC) weekly; and etanercept 50 mg SC twice weekly for 3 months, followed by 25 mg SC twice weekly. The analysis examines total direct costs (including drug costs, office visit fees, injection fees) and costs for laboratory monitoring during treatment as per product labeling. These direct utilization-related costs are divided by the efficacy as determined by PASI 75 response rates from large-scale clinical trials. The cost-efficacy is then divided by the number of days for 18- and 24-month periods to provide cost-efficacy per day. For PASI 75 responders to alefacept, median remission periods of 7 months for the first course and 12 months for the second course were assumed based on clinical trials.[1,2] At 18 months, cost-efficacy per day was $122 for alefacept (2 courses of the drug), $203 for efalizumab, and $123 for etanercept. At 24 months, cost-efficacy per day was $91 for alefacept, $203 for efalizumab, and $119 for etanercept. Advantages of alefacept are due in part to the long treatment-free remission periods and its safety profile. Repeated courses of alefacept are cost-effective for the long-term management of patients with psoriasis.

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Dr. Feldman is a consultant for Biogen Idec, Inc.

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RESULTS OF A PHASE 2 DOSE-RANGING AND SAFETY EXTENSION STUDY OF A NOVEL ORAL FUMARATE, BG-12, IN PATIENTS WITH SEVERE PSORIASIS

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Fumaric acid esters have been used to treat patients with psoriasis for more than 10 years in Germany, but their use is limited by gastrointestinal adverse events, which frequently lead to discontinuation. A novel oral fumarate, BG-12, has been developed to improve the efficacy and tolerability of fumaric acid esters in patients with psoriasis. A phase II multicenter, double-blind, placebo-controlled, dose-ranging trial was conducted in Poland to evaluate the efficacy, safety, and tolerability of BG-12. The trial also included a 24-week, open-label, safety extension phase. Patients with chronic plaque, exanthematic guttate, erythrodermic, palmoplantar, or pustular psoriasis for 1 year or longer and a baseline PASI score of 16 to 24 were eligible. Therapies for psoriasis were discontinued before study enrollment, except for topical salicylic acid and emollients. In the double-blind phase, patients (N = 144) were equally randomized to 1 of 4 treatment groups: placebo or BG-12 120 mg (1 capsule), 360 mg (3 capsules), or 720 mg (6 capsules) daily (study drug dosed 3 times per day) for 12 weeks. Patients who completed the double-blind phase or who withdrew after 8 weeks because of lack of efficacy were eligible to enroll in the open-label phase. Assessments included PASI, Physician's Clinical Global Impression, patient's global assessment, quality of life, and reported adverse events. Improvement in psoriasis was observed as early as 2 weeks and was dose-related. BG-12 was well tolerated, with infrequent gastrointestinal complaints. The open-label extension phase enrolled 108 patients (28 from each of the placebo and 120-mg BG-12 groups and 26 each from the 360-mg and 720-mg BG-12 groups). The results of this phase II study are promising, with substantial efficacy and good tolerability for this novel oral fumarate.

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