

### Drugs recently approved or pending approval

#### AMEVIVE

The US Food and Drug Administration (FDA) granted approval to Biogen, Inc, of Cambridge, MA, to market Amevive (alefacept) for the treatment of moderate to severe chronic plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. Amevive was evaluated in 2 randomized, double-blind, placebo-controlled studies in patients age 16 to 84 years with chronic plaque psoriasis covering at least 10% of their total body surface area. In study 1, patients (N = 553) were randomized to receive 1 or 2 courses of Amevive 7.5 mg administered intravenously (IV); the first and second courses were separated by at least a 12-week interval. In the second study, 173 patients received Amevive 10 mg intramuscularly (IM), 166 patients received Amevive 15 mg IM, and 168 patients received placebo. Treatment response in both studies was defined as the proportion of patients with a reduction in score on the Psoriasis Area and Severity Index of at least 75% from baseline 2 weeks after the 12-week treatment period. In study 1 (IV route), the median duration of response was 3.5 months for Amevive-treated patients and 1 month for placebo-treated patients. In study 2 (IM route), the median duration of response was approximately 2 months for patients in both the Amevive and placebo groups. The most serious adverse reactions reported with Amevive were lymphopenia, malignancy, serious infection, and hypersensitivity reactions. The most frequent adverse events included pharyngitis, dizziness, cough, nausea, pruritus, chills, and injection site pain. The recommended dose of Amevive is 7.5 mg IV given once weekly or 15 mg IM given once weekly for a course of 12 weeks.



#### FINACEA

Berlex Laboratories, Inc, of Montville, NJ, received approval from the FDA to market Finacea (azelaic acid) Gel, 15%, for the topical treatment of inflammatory papules and pustules of mild to moderate rosacea. Finacea was evaluated in 2 multicenter, randomized, double-blind, vehicle-controlled clinical studies with identical protocols. In these studies, comprising 664 patients, Finacea or its vehicle was applied twice daily for 12 weeks; no other topical or systemic medication affecting the course of rosacea or its evaluability was to be used. The primary efficacy endpoints of the studies were (1) change from baseline in inflammatory lesion counts and (2) success defined as a score of clear or minimal with at least a 2-step reduction from baseline on the Investigator's Global Assessment. Significant treatment effects were discernible at 4 weeks, and progressive

improvement continued to be shown in following weeks. In study 1, Finacea reduced the number of inflammatory papules and pustules associated with rosacea by 57.9%, versus 39.9% with the vehicle. In study 2, Finacea reduced the number of inflammatory papules and pustules by 50%, versus 38.2% with the vehicle. Finacea is contraindicated in patients with a history of hypersensitivity to propylene glycol or any other component of the formulation. The most frequently reported adverse events related to Finacea included burning/tingling and itching. The recommended dosage of Finacea is a thin layer of the gel, gently massaged into the affected areas on the face twice daily, in the morning and evening.

#### SINGULAIR

The FDA has approved marketing of Singulair (montelukast sodium) by Merck & Co., Inc, of Whitehouse Station, NJ, for the relief of symptoms of seasonal allergic rhinitis in adults and pediatric patients 2 years of age and older. Singulair is also currently approved for the treatment of asthma. The efficacy of Singulair 10 mg was evaluated in patients with seasonal allergic rhinitis, ages 15 to 82 years, in 5 randomized double-blind, parallel-group, placebo- and active-controlled trials of similar design. The tri-

als enrolled a total of 5029 patients, of whom 1799 were treated with Singulair tablets. The treatment period was 2 weeks in 4 trials and 4 weeks in 1 trial. The primary outcome variable was mean change from baseline in daytime nasal symptoms score (the average of individual scores of nasal congestion, rhinorrhea, nasal itching, and sneezing) as assessed by patients on a scale of 0 to 3. Of the 5 trials, 4 showed a significant reduction in daytime nasal symptom scores with Singulair 10 mg, compared with placebo. The most commonly reported adverse effects of Singulair were headache, ear infection, sore throat, and upper respiratory infection. The recommended dosage of Singulair for adults and adolescents 15 years of age and older with seasonal allergic rhinitis is one 10-mg tablet daily. The dosage for pediatric patients 6 to 14 years of age is one 5-mg chewable tablet daily, and the dosage for pediatric patients 2 to 5 years of age is one 4-mg chewable tablet or one packet of 4-mg oral granules daily.

*Compiled from press reports and pharmaceutical company press releases. For more information, contact Jennifer M. Lehr, Hospital Physician, 125 Strafford Avenue, Suite 220, Wayne, PA 19087-3391.*