

Drugs recently approved or pending approval

FEMRING

The US Food and Drug Administration (FDA) granted approval to Galen Holdings PLC, of Rockaway, NJ, to market Femring (estradiol acetate vaginal ring) for the treatment of moderate-to-severe vasomotor symptoms and moderate-to-severe vulvar and vaginal atrophy associated with menopause. Femring was evaluated in a 13-week double-blind, placebo-controlled trial in postmenopausal women between the ages of 29 and 85 years who had at least 7 moderate to severe hot flushes daily or at least 56 moderate to severe hot flushes per week before randomization. Patients (N = 333) were randomized to receive either placebo, Femring 0.05 mg/day, or Femring 0.10 mg/day. Femring 0.05 mg/day and Femring 0.10 mg/day were shown to relieve both frequency and severity of moderate-to-severe vasomotor symptoms. In the same trial, vaginal superficial cells increased by a mean of 16.0% and 18.9% for Femring 0.05 mg/day and Femring 0.10 mg/day, respectively. The most frequent adverse events included headache, intermenstrual bleeding, vaginal candidiasis, and breast tenderness. Femring should not be used in individuals with breast cancer, estrogen-dependent neoplasia, active or a history of deep vein thrombosis or pulmonary embolism, active or recent arterial thromboembolic disease, undiagnosed abnormal genital bleeding, or pregnancy. Femring is available in 2 strengths: 0.05 mg/day and 0.10 mg/day and is intended to remain in place for 3 months.



FUZEON

Roche Laboratories, Inc (Nutley, NJ) and Trimeris, Inc (Durham, NC) received accelerated approval from the FDA to market Fuzeon (enfuvirtide), an HIV-1 fusion inhibitor, for the treatment of HIV-1 infection in treatment-experienced patients with evidence of HIV-1 replication despite ongoing antiretroviral therapy. Studies are ongoing, randomized, controlled, open-label, multicenter trials in HIV-1 infected subjects. All patients received an individualized background regimen consisting of 3 to 5 antiretroviral agents selected according to the patient's prior treatment history. They were then randomized at a 2:1 ratio to Fuzeon 90 mg twice daily with background regimen or background regimen alone. Based on data from two 24-week phase III studies of approximately 1000 patients, treatment-experienced patients receiving Fuzeon plus an individualized combination of anti-HIV drugs experienced greater immunologic improvements and were twice as likely to achieve unde-

tectable plasma levels of HIV compared to patients receiving an individualized regimen alone. The most common adverse event reported was local injection site reactions, with 98% of patients having at least 1 local injection site reaction. Other adverse events included diarrhea, nausea, and fatigue. The recommended dosage of Fuzeon in adults is 90 mg twice daily injected subcutaneously. Fuzeon can be used in pediatric patients ages 6 to 16 years, at a dose of 2 mg per kg of body weight administered twice daily.

SOMAVERT

The FDA has approved marketing of Somavert (pegvisomant) by Pharmacia Corporation, of Peapack, NJ, for the treatment of acromegaly in patients who have had an inadequate response to surgery and/or radiation therapy and/or other medical therapies or for whom these therapies are not appropriate. Patients (N = 112) were evaluated in a 12-week, randomized, double-blind, multicenter study comparing placebo and Somavert. 80 patients were randomized to treatment with a Somavert subcutaneous loading dose, followed by 10, 15, or 20 mg/day subcutaneously. The 3 groups that received Somavert showed dose-dependent reductions in serum levels of insulin-like growth factor-1 (IGF-1), free IGF-1, IGF binding protein-3, and the acid-labile subunit. Another cohort of patients (N = 38) with acromegaly participated in a long-term, open-label, dose-titration study and received at least 12 consecutive months of Somavert daily. Thirty-five (92%) patients achieved a normal IGF-1 concentration. The most common adverse events reported were infection, pain, diarrhea, nausea, flu syndrome, abnormal liver function tests, and injection-site reactions. Nine patients (9.6%) withdrew from the clinical studies because of adverse events. The stopper on the vial of Somavert contains latex. The recommended dosage of Somavert is a loading dose of 40 mg subcutaneously followed by 10 mg subcutaneous injections daily. Serum IGF-1 concentrations should be measured every 4 to 6 weeks, at which time Somavert should be adjusted in 5-mg increments or decrements, depending on serum IGF-1 levels. Maximum daily maintenance dosage should not exceed 30 mg.

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

Copyright 2003 by Turner White Communications Inc., Wayne, PA. All rights reserved.