

Drugs recently approved or pending approval

ELITEK

Sanofi-Synthelabo, Inc, of New York, NY, received approval from the US Food and Drug Administration (FDA) to market Elitek (rasburicase) for the initial management of plasma uric acid (UA) levels in pediatric patients with leukemia, lymphoma, and solid tumor malignancies who are receiving anticancer therapy expected to result in tumor lysis and subsequent elevation of plasma UA. The efficacy of Elitek was evaluated in 3 studies of 265 patients with acute leukemia or non-Hodgkin's lymphoma who received Elitek in conjunction with antitumor therapy with systemic chemotherapy or steroids. In a randomized, open-label, controlled study conducted at 6 institutions, 52 pediatric patients received either Elitek 0.20 mg/kg once or twice daily (n = 27) or allopurinol (n = 25). The UA concentration was significantly lower in the Elitek group than in the allopurinol group. In a multi-institutional, single-arm study of 89 pediatric and 18 adult patients with hematologic malignancies who received Elitek 0.15 mg/kg daily, 99% of patients maintained UA concentrations below a specified level after 48 hours. Elitek is contraindicated in patients deficient in glucose-6-phosphate dehydrogenase and in patients with a history of anaphylaxis or hypersensitivity reactions, hemolytic reactions, or methemoglobinemia reactions to Elitek or any of its excipients. The most common adverse reactions to Elitek included vomiting, fever, nausea, and headache. Elitek should be administered as a single daily dose of 0.15 or 0.20 mg/kg intravenously for no more than 5 days.



XYREM

The FDA granted approval to Orphan Medical, Inc, of Minnetonka, MN, to market Xyrem (sodium oxybate) oral solution for the treatment of cataplexy in patients with narcolepsy. Xyrem's efficacy was established in 2 randomized, double-blind, placebo-controlled trials in patients with narcolepsy who were also being treated with central nervous system (CNS) stimulants. In trial 1, narcoleptic patients (N = 136) with a median of 21 cataplexy attacks per week randomly received placebo or Xyrem 3 g, 6 g, or 9 g daily. In trial 2, narcoleptic patients (N = 55) who had been taking open-label Xyrem for 7 to 44 months and who had at least 5 cataplexy attacks weekly prior to treatment were randomized to continued treatment with Xyrem or to placebo. In trial 1, the 6-g and 9-g daily doses significantly reduced the frequency of cataplexy attacks; the 3 g daily dose had little effect. In trial 2, following the discontinuation of long-term Xyrem therapy, patients receiving placebo experienced a significant increase in cataplexy,

evidencing Xyrem's long-term efficacy. Xyrem is contraindicated in patients taking sedative hypnotic agents and in patients with succinic semialdehyde dehydrogenase deficiency; it should not be used with alcohol or other CNS depressants. The most common adverse effects are dizziness, headache, and nausea. Xyrem must be taken at bedtime and again 2.5 to 4 hours later. The recommended starting dose is 4.5 g daily, divided into 2 equal doses of 2.25 g. The dosage can be increased to a maximum of 9 g daily in increments of 1.5 g daily. Xyrem is a Schedule III controlled substance.

ZELNORM

The FDA has approved marketing of Zelnorm (tegaserod maleate) by Novartis Pharmaceuticals Corporation (East Hanover, NJ) for the short-term treatment of women with irritable bowel syndrome (IBS) whose primary bowel symptom is constipation. Approval is based on results from 3 multicenter, double-blind, placebo-controlled trials involving 2470 women (age 17-89 years) with at least a 3-month history of IBS symptoms including abdominal pain, bloating, and constipation. Patients received Zelnorm 6 mg twice daily or placebo for 3 months. Each week, subjects rated their responses to the "Subject's Global Assessment of Relief" measurement tool. During the first month, 8% to 11% more Zelnorm-treated patients than placebo-treated patients were responders for (ie, had more relief from) abdominal pain/discomfort. Similarly, 9% to 12% more Zelnorm-treated patients than placebo-treated patients were responders for bloating. Corresponding differences at month 3 were 1% to 10% for abdominal pain/discomfort and 4% to 11% for bloating. Zelnorm should not be taken by patients who currently or frequently experience diarrhea and is contraindicated in patients with severe renal impairment, moderate or severe hepatic impairment, or a history of bowel obstruction, symptomatic gallbladder disease, suspected sphincter of Oddi dysfunction, or abdominal adhesions. The most common adverse effects were headache, abdominal pain, and diarrhea. The recommended dosage of Zelnorm is 6 mg taken twice daily orally before meals for 4 to 6 weeks. An additional 4- to 6-week course can be considered for those patients who respond to therapy.

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