

Drugs recently approved or pending approval

ELOXATIN

Sanofi-Synthelabo, Inc, of New York, NY, received accelerated approval from the US Food and Drug Administration (FDA) to market Eloxatin (oxaliplatin for injection) for use in combination with infusional 5-fluorouracil and leucovorin (5-FU/LV) for the treatment of patients with metastatic colorectal cancer whose disease has recurred or progressed after first-line therapy with bolus 5-FU/LV plus irinotecan. Approval of Eloxatin is based on results of an ongoing, multicenter, randomized, controlled study in the United States and Canada comparing safety and efficacy of Eloxatin in combination with infusional 5-FU/LV with that of infusional 5-FU/LV alone and with Eloxatin alone. Tumor response was assessed every 6 weeks. The confirmed objective response rates ($\geq 30\%$ reduction in overall tumor size maintained for ≥ 4 weeks) were 9% for the Eloxatin plus infusional 5-FU/LV group ($n = 152$), 0% for the infusional 5-FU/LV only group ($n = 151$), and 1% for the Eloxatin only group ($n = 156$). The median time to tumor progression in the Eloxatin plus 5-FU/LV arm was 4.6 months, compared with 2.7 months and 1.6 months for the 5-FU/LV only arm and the Eloxatin only arm, respectively. Eloxatin is contraindicated in patients with known allergy to platinum compounds. Adverse effects associated with Eloxatin include anaphylactic-like reactions, peripheral neurosensory events, fatigue, diarrhea, nausea, and vomiting. The recommended dosage of Eloxatin given every 2 weeks is 85 mg/m² of Eloxatin (2-hour infusion) plus 200 mg/m² of LV (2-hour infusion) followed by 400 mg/m² of 5-FU (bolus given over 2–4 minutes) and 600 mg/m² of 5-FU (22-hour infusion) on day 1 and the same doses of LV and 5-FU on day 2.

LEXAPRO

The FDA granted approval to Forest Laboratories, Inc, of New York, NY, to market Lexapro (escitalopram oxalate) for initial and maintenance treatment of major depressive disorder. Lexapro's approval was based on efficacy and safety data from clinical trials involving more than 1100 patients, including men and women age 18 to 65 years with moderate and severe depression. In a double-blind, placebo-controlled, multicenter study, 491 patients were randomized for 8 weeks to 1 of 4 trial arms: placebo, Lexapro 10 mg daily, Lexapro 20 mg daily, or citalopram (Celexa) 40 mg daily. The 10 mg daily and 20 mg daily Lexapro treatment groups showed similar signifi-

cantly greater mean improvement compared with placebo on the Montgomery Asberg Depression Rating Scale. Additionally, Lexapro 10 mg was shown to be as effective as citalopram 40 mg on the major efficacy outcome variables. Lexapro is contraindicated in patients taking a monoamine oxidase inhibitor. The most common adverse effects associated with Lexapro were nausea, insomnia, ejaculation disorder, somnolence, increased sweating, and fatigue. The recommended starting dosage of Lexapro is 10 mg once daily. If the dose is increased to 20 mg, a minimum of 1 week from start of therapy should intervene.

PREVACID

The FDA has approved marketing of Prevacid (lansoprazole) by TAP Pharmaceuticals, Inc, of Lake Forest, IL, for use in a new patient population; Prevacid is now indicated for the short-term treatment of symptomatic gastroesophageal reflux disease (GERD) and erosive esophagitis in children between age 1 and 11 years. In an uncontrolled, open-label, multicenter study, 66 pediatric patients (age 1–11 years) with GERD were assigned to receive an initial dosage of either Prevacid 15 mg daily (body weight ≤ 30 kg) or Prevacid 30 mg daily (body weight > 30 kg) for 8 to 12 weeks. The Prevacid dose was increased (up to 30 mg twice daily) in 24 of 66 patients after 2 or more weeks of treatment if they remained symptomatic. At baseline, 85% of patients had mild to moderate overall GERD symptoms; 58% of patients had nonerosive GERD and 42% had erosive esophagitis. After 8 to 12 weeks of Prevacid treatment, the intent-to-treat analysis showed an approximately 50% reduction in frequency and severity of GERD symptoms. Of 27 patients with erosive esophagitis, 21 were healed at 8 weeks, and 100% of patients were healed at 12 weeks. In pediatric patients with GERD, the most common adverse effects of Prevacid treatment were constipation and headache. The recommended dosage of Prevacid for pediatric patients with symptomatic GERD or erosive esophagitis is either 15 mg (body weight ≤ 30 kg) or 30 mg (body weight > 30 kg) once daily for up to 12 weeks.



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.