

### Drugs recently approved or pending approval

#### SONATA

The United States Food and Drug Administration approved marketing of Sonata (zaleplon) by American Home Products (Madison, NJ) and Wyeth-Ayerst (Philadelphia, PA). Sonata is indicated for the short-term treatment of insomnia. Drug efficacy was evaluated in 11 placebo- and active-controlled studies. Patients with chronic insomnia ( $n = 3298$ ) were randomized to Sonata (5, 10, or 20 mg) or placebo. In three double-blind parallel-group studies, the primary endpoint was improvement in a subjective measure of time to sleep onset (TSO). The 10- and 20-mg Sonata arms were consistently superior to the placebo arms for TSO. In five double-blind parallel-group sleep laboratory studies varying from 1 night to 28 nights, the primary endpoint was improvement in latency to persistent sleep (LPS). The 10- and 20-mg Sonata arms demonstrated significant reduction in LPS from baseline compared with the placebo arms for the first 2 nights. After the first 2 nights, reductions in LPS were not statistically different between the Sonata arms and the placebo arms. Potential adverse reactions associated with long-term (28 nights) trials of Sonata include headache, nausea, and dizziness. The recommended dose of Sonata for nonelderly adults is 10 mg taken immediately before bedtime or when difficulty falling asleep occurs.



#### ACIPHEX

Eisai Inc (Teaneck, NJ) and Janssen Pharmaceutica (Titusville, NJ) received approval to market Aciphex (rabeprazole sodium). Aciphex is indicated for short-term (4 to 8 weeks) treatment in the healing and symptomatic relief of erosive or ulcerative gastroesophageal reflux disease (GERD); maintaining healing and reducing relapse rates of heartburn symptoms in patients with GERD; short-term (up to 4 weeks) treatment in the healing and symptomatic relief of duodenal ulcers; and long-term treatment of pathologic hypersecretory conditions. Drug effectiveness was measured in a multicenter double-blind study. Patients ( $n = 103$ ) with GERD symptoms and esophagitis of grade 2 or higher (based on the modified Hetzel-Dent grading scale) were randomized to Aciphex (10, 20, or 40 mg) or placebo. After 8 weeks of treatment, the percentage of patients healed was 12% for the placebo arm compared with 93%, 84%, and 85% for the 10-, 20-, and 40-mg Aciphex arms, respectively. The adverse event most often associated with Aciphex is headache. The recommended dose of Aciphex for healing or maintenance of GERD is

one 20-mg delayed-release tablet taken daily for 4 to 8 weeks; for healing of duodenal ulcers the tablet should be taken once daily after the morning meal for up to 4 weeks. The recommended starting dose for treatment of pathologic hypersecretory conditions is 60 mg once daily.

#### TEMODAR

The Food and Drug Administration granted approval to market Temodar (temozolomide) by Schering-Plough (Madison, NJ). Temodar is indicated for the treatment of adult patients with refractory anaplastic astrocytoma (ie, patients at first relapse who have experienced disease progression on a drug regimen containing a nitrosourea and procarbazine). Drug efficacy was evaluated in a single-arm multicenter study involving patients ( $n = 162$ ) with anaplastic astrocytoma at first relapse and a baseline Karnofsky performance status of 70 or greater. Patients had received previous radiation therapy and may have received a nitrosourea with or without chemotherapy. Temodar (150 mg/m<sup>2</sup>/day) was administered for the first 5 consecutive days of a 28-day cycle. If the nadir absolute neutrophil count was equal to or greater than  $1.5 \times 10^9$ /L and the nadir platelet count was greater than  $100 \times 10^9$ /L on day 29, the Temodar dose was increased to 200 mg/m<sup>2</sup>/day for the first 5 consecutive days of a new 28-day cycle. The overall tumor response rate was 22% (median duration of responses was 50 weeks) and the complete response rate was 9% (median duration of responses was 64 weeks). Progression-free survival was 45% at 6 months and 29% at 12 months; median progression-free survival was 4.4 months. Overall survival was 74% at 6 months and 65% at 12 months; median overall survival was 15.9 months. Temodar is contraindicated in patients who are hypersensitive to dacarbazine. Possible adverse reactions associated with Temodar include nausea, vomiting, headache, and fatigue. The recommended initial dose of Temodar is 150 mg/m<sup>2</sup> orally once daily for 5 consecutive days per 28-day treatment cycle. Dosage must be adjusted based on nadir neutrophil and platelet counts; the next dose of Temodar should not be initiated until the absolute neutrophil count exceeds  $1.5 \times 10^9$ /L and the platelet count exceeds  $100 \times 10^9$ /L.

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