Drugs recently approved or pending approval

CYMBALTA

The US Food and Drug Administration (FDA) has given approval to Eli Lilly and Company (Indianapolis, IN) to market Cymbalta (duloxetine HCl) for the treatment of major depressive disorder. Cymbalta was evaluated in 4 randomized, double-blind, placebo-controlled, fixed-dose studies in outpatients aged 18 to 83 years who met the DSM-IV criteria for major depression. In studies 1 and 2 (N = 512), patients were randomized to Cymbalta 60 mg once daily or placebo for 9 weeks. In study 3 (N = 266), patients were randomized to Cymbalta 20 mg or 40 mg twice daily or placebo for 8 weeks. In study 4 (N = 281), patients were randomized to Cymbalta 40 mg or 60 mg twice daily or placebo for 8 weeks. In all 4 studies, Cymbalta demonstrated superiority over placebo as measured by the 17-item Hamilton Depression Rating Scale total score. The most common adverse effects associated with Cymbalta use were nausea, dry mouth, insomnia, constipation, and dizziness. Cymbalta should be administered at a dose of 40 mg/d to 60 mg/d.

TOPAMAX

Ortho-McNeil Pharmaceuticals, Inc. (Raritan, NJ) has been given approval by the FDA to market Topamax (topiramate) tablets and Topamax sprinkle capsules for the prophylaxis of migraine headaches in adults. Topamax was evaluated in 2 multicenter, randomized, double-blind, placebo-controlled, parallel-group trials. Patients with a history of migraine, with or without aura, for at least 6 months, according to the International Headache Society were enrolled. Patients were required to complete a 2-week washout period of prior migraine medications before starting the baseline phase. Patients were equally randomized to either Topamax 50 mg, 100 mg, 200 mg, or placebo daily for 26 weeks (8-week titration, 18-week maintenance). In study 1 (N = 469), the change in mean 4-week migraine headache frequency from baseline to the double-blind phase was –1.3, –2.1, and –2.2 in the Topamax 50, 100, and 200 mg/day groups, respectively, versus –0.8 in the placebo group. The differences between Topamax 100 and 200 mg/day groups versus placebo were statistically significant ($P < 0.001$ for both comparisons). In study 2 (N = 468), the change in mean 4-week migraine headache frequency from baseline to the double-blind phase was –1.4, –2.1, and –2.4 in the Topamax 50, 100, and 200 mg/d groups versus –1.1 in the placebo group. The differences between Topamax 100 and 200 mg/d groups versus placebo were statistically significant ($P = 0.008$ and $P < 0.001$, respectively). The most common adverse effects associated with Topamax were paresthesia, fatigue, and loss of appetite. Topamax was previously approved as adjuvant therapy for adults and children aged 2 to 16 years with partial onset seizures or primary generalized tonic-clonic seizures, and in patients older than 2 years with seizures associated with Lennox-Gastaut syndrome.

ZELNORM

Novartis Pharmaceuticals Corporation, of East Hanover, NJ, has been given FDA approval to market Zelnorm (tegaserod maleate) for the treatment of chronic idiopathic constipation in men and women younger than 65 years. The effectiveness of Zelnorm was evaluated in 2 multicenter, double-blind, placebo-controlled trials. Patients (N = 2612) were randomized to receive either Zelnorm 6 mg twice daily, 2 mg twice daily, or placebo. Constipation was defined as less than 3 complete spontaneous bowel movements (CSBMs) per week and at least 1 of the following symptoms for at least 25% of defecations: straining, hard/very hard stools, and incomplete evacuation. Patients were classified as responders if they achieved an average increase of at least 1 CSBM per week during the first 4 weeks of treatment compared with baseline, and they must have participated at least 7 days in the study. For both studies, the response rate was higher in the Zelnorm 6-mg group as compared with placebo. The results of the Zelnorm 2-mg group showed significant changes during the first 4 weeks; however, in 1 study no statistically significant changes were seen after 12 weeks. Regardless of baseline, Zelnorm significantly increased the number of CSBMs compared with placebo at each week ($P < 0.05$). Zelnorm also increased the number of spontaneous bowel movements as compared with placebo each week ($P < 0.05$). Zelnorm-treated patients experienced a significant reduction in the individual symptoms of straining, abdominal distension/bloating, and abdominal discomfort/pain and a significant improvement in stool consistency and frequency as compared with placebo-treated patients when averaged over 12 weeks ($P < 0.05$). The most common adverse effects in Zelnorm-treated patients were diarrhea, abdominal pain, and nausea. Zelnorm was previously approved for the short-term treatment of women with irritable bowel syndrome whose primary bowel symptom is constipation.

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