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 HCI) for the management of fibromyalgia. The efficacy of Cymbalta was evaluated in 2 randomized, double-blind, placebo-controlled, fixed-dose studies in adults who met the American College of Rheumatology criteria for fibromyalgia. Patients had a baseline pain score of 6.5 on an 11-point scale ranging from 0 (no pain) to 10 (worst possible pain). In study 1, 354 women were randomized to Cymbalta (60 mg once daily or 120 mg daily given in divided doses) or placebo for 3 months. In study 2, 520 men and women received once-daily Cymbalta 60 or 120 mg or placebo for 6 months. A 20-mg dose of Cymbalta was compared with placebo during the initial 3 months of the 6-month study. In both studies, Cymbalta 60 or 120 mg daily statistically significantly improved the mean pain scores from baseline and increased the proportion of patients with at least a 50% reduction in pain score from baseline. Decreased pain was reported with Cymbalta as early as the first week. Neither study showed benefit of Cymbalta 120 mg as compared with 60 mg. The most common adverse effects were nausea, dry mouth, constipation, somnolence, hyperhidrosis, and decreased appetite. The recommended dose is 60 mg once daily. Cymbalta is also indicated for the management of diabetic peripheral neuropathic pain and treatment of major depressive disorder and generalized anxiety disorder.

ENTEREG

GlaxoSmithKline (Research Triangle Park, NC) has been given FDA approval to market Entereg (alvimopan) to accelerate upper and lower gastrointestinal (GI) recovery following partial large or small bowel resection surgery with primary anastomosis. The efficacy of Entereg was established in 5 multicenter, randomized, double-blind, parallel-group, placebo-controlled studies (4 US studies and 1 non-US study) involving 1877 patients (aged, ≥ 18 yr) undergoing bowel resection. All patients were randomized to oral doses of Entereg 12 mg or matching placebo. The initial dose was administered at least 30 minutes and up to 5 hours prior to the scheduled start of surgery for most patients. Subsequent doses were given twice daily starting on the first postoperative day and continued until hospital discharge or up to 7 days. The primary endpoint for all studies was time to achieve recovery of upper and lower GI function, as measured by toleration of solid food and first bowel movement. The length of hospital stay was defined as time from the end of surgery to when the discharge order was written. In all studies, Entereg accelerated the time to recovery of GI function and time to discharge order written as compared with placebo. GI recovery in Entereg-treated versus placebo-treated patients was as follows: study 1, 92 versus 111.8 hours (hazard ratio [HR], 1.53 [95% confidence interval {CI}, 1.29–1.82]); study 2, 105.9 versus 132.0 hours (HR, 1.63 [95% CI, 1.26–2.10]); study 3, 116.4 versus 130.3 hours (HR, 1.37 [95% CI, 1.06–1.76]); study 4, 106.7 versus 119.9 hours (HR, 1.4 [95% CI, 1.04–1.89]); and study 5, 98.8 versus 109.5 hours (HR, 1.23 [95% CI, 1.07–1.58]). Across the 4 US studies, Entereg-treated patients had their discharge order written approximately 13 to 21 hours earlier than placebo-treated patients. The most common adverse effects were anemia, dyspepsia, hypokalemia, back pain, and urinary retention. Entereg is available only for short-term (15 doses) use in hospitalized patients.

PRANDIMET

The FDA has given approval to Sciele Pharma, Inc. (Atlanta, GA) and Novo Nordisk Inc. (Princeton, NJ) to comarket PrandiMet (repaglinide and metformin HCl) tablets as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus who are already treated with a meglitinide and metformin HCl or who have inadequate glycemic control on meglitinide alone or metformin HCl alone. PrandiMet was evaluated in a randomized, double-blind trial involving 83 patients with type 2 diabetes with inadequate glycemic control on metformin HCl monotherapy. Patients were randomized to add-on repaglinide (ie, PrandiMet), repaglinide monotherapy, or continued treatment with metformin HCl alone. The repaglinide dose was titrated for 4 to 8 weeks, followed by a 3-month dose maintenance period. Compared with the repaglinide and metformin HCl monotherapies, PrandiMet statistically significantly improved hemoglobin A_{1c} (–1.4% versus –0.4% and –0.3%, respectively; $P < 0.05$) and fasting plasma glucose (–39 mg/dL versus 9 mg/dL and –5 mg/dL, respectively; $P < 0.05$). The most common adverse effects were hypoglycemia and headache.

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

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