Drugs recently approved or pending approval

AMITIZA

The US Food and Drug Administration (FDA) has given approval to Sucampo Pharmaceuticals, Inc. (Bethesda, MD) and Takeda Pharmaceuticals America, Inc. (Deerfield, IL) to comarket Amitiza (lubiprostone) for the treatment of irritable bowel syndrome with constipation in women aged 18 years and older. Amitiza was evaluated in 2 double-blind, randomized, placebo-controlled studies involving 1154 patients. Enrolled patients had abdominal pain or discomfort occurring for at least 6 months with 2 of the following: (1) fewer than 3 spontaneous bowel movements per week, (2) more than 25% hard stools, and (3) more than 25% of spontaneous bowel movements associated with straining. Patients were randomized to twice-daily Amitiza 8 µg or placebo for 12 weeks. The primary endpoint was assessed weekly using the patient's response to a global symptom relief question based on a 7-point balanced scale. For each arm, the proportion of overall responders was compared (ie, patients reporting "significantly relieved" for ≥ 2 wk of the month or "moderately relieved" for 4 wk of the month for ≥ 2 mo). In both studies, more Amitiza-treated patients qualified as overall responders compared with placebo-treated patients (study 1, 13.8% vs. 7.8%; study 2, 12.1% vs. 5.7%). In both studies, treatment differences between the Amitiza and placebo groups were statistically significant. The most common adverse effects were nausea, diarrhea, and abdominal pain.

ORENCIA

Bristol-Myers Squibb Company (Princeton, NJ) has received FDA approval to market Orencia (abatacept) for reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis (JIA) in patients aged 6 years and older. The safety and efficacy of Orencia were established in a 3-part study of 190 patients with polyarticular JIA who inadequately responded to 1 or more disease-modifying antirheumatic drugs. In part 1, patients received Orencia 10 mg/kg intravenously on days 1, 15, and 29, and monthly thereafter. Response was assessed using the American College of Rheumatology (ACR) Pediatric 30 (defined as ≥ 30% improvement in ≥ 3 of 6 JIA core set variables and ≥ 30% worsening in ≤ 1 of 6 JIA core set variables). Patients demonstrating a response at the end of part 1 were randomized into part 2 and received either Orencia or placebo for 6 months or until disease flare. In part 3, patients continued on Orencia for 1 year. At the end of part 1, pediatric ACR 30, 50, and 70 responses were 65%, 50%, and 28%. During part 2, Orencia-treated patients experienced significantly fewer disease flares compared with placebo-treated patients (20% vs. 53%). The most common adverse effects were upper respiratory tract infection, nasopharyngitis, and headache.

RELISTOR

The FDA has given approval to Wyeth Pharmaceuticals, Inc. (Philadelphia, PA) to market Relistor (methylnaltrexone bromide) subcutaneous injection for the treatment of opioid-induced constipation in patients with advanced illness receiving palliative care when response to laxative therapy has been insufficient. Relistor was evaluated in 2 randomized, double-blind, placebo-controlled studies. In study 1, 154 patients received a single, double-blind dose of Relistor 0.15 or 0.3 mg/kg or placebo, followed by a 4-week, open-label period during which Relistor could be used as needed. The primary endpoint was the proportion of patients with rescue-free laxation within 4 hours of the double-blind dose. Patients treated with Relistor 0.15 and 0.3 mg/kg had a significantly higher rate of laxation within 4 hours as compared with placebo-treated patients (62% and 58% vs. 14%; $P < 0.0001$ for each comparison). In study 2, 133 patients receiving opioids for more than 2 weeks were randomized to double-blind Relistor given every other day for 2 weeks or placebo. During the first week, patients received Relistor 0.15 mg/kg or placebo. During the second week, a patient's assigned dose could be increased to 0.3 mg/kg if the patient had 2 or fewer rescue-free laxations up to day 8. Two primary endpoints were assessed: the proportion of patients with (1) a rescue-free laxation within 4 hours of the first dose of study medication and (2) a rescue-free laxation within 4 hours after at least 2 of the first 4 doses of study medication. Relistor-treated patients had a higher rate of laxation within 4 hours of first dosing compared with placebo-treated patients (48% vs. 16%; $P < 0.0001$). For the second primary endpoint, Relistor-treated patients also had higher rates of laxation compared with placebo-treated patients (52% vs. 9%; $P < 0.0001$). In both studies, approximately 30% of patients experienced laxation within 30 minutes of Relistor administration. The most common adverse effects were abdominal pain, flatulence, nausea, dizziness, and diarrhea.

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.*