Drugs recently approved or pending approval

KAPIDEX

The US Food and Drug Administration (FDA) has given approval to Takeda Pharmaceuticals America, Inc. (Deerfield, IL) to market Kapidex (dexlansoprazole) for the healing of all grades of erosive esophagitis (EE), maintaining healing of EE, and treating heartburn associated with nonerosive gastroesophageal reflux disease (GERD). Kapidex was evaluated in 4 multicenter, double-blind, randomized studies involving patients with endoscopically confirmed EE (studies 1 and 2; n = 4092), endoscopically confirmed healed EE (study 3; n = 445), and symptomatic nonerosive GERD (study 4; n = 947). In studies 1 and 2, patients who were *Helicobacter pylori*–negative or without Barrett's esophagus and/or no definite dysplastic changes at baseline received Kapidex 60 or 90 mg daily or lansoprazole 30 mg daily for 8 weeks. In both studies, Kapidex 60 mg produced similar overall healing rates at 8 weeks as compared with lansoprazole 30 mg (study 1, 87% versus 85% [95% confidence interval {CI}, –1.5 to 6.1]; study 2, 85% versus 79% [95% CI, 2.2–10.5]). In study 3, patients who successfully completed an EE study and demonstrated endoscopically healed EE were randomized to once-daily Kapidex 30 or 60 mg or placebo for 6 months. At 6 months, 66.4% of patients treated with Kapidex 30 mg remained healed of EE as compared with 14.3% of placebo-treated patients. In study 4, patients who had a history of heartburn for 6 months or longer, heartburn on at least 4 of 7 days immediately prior to randomization, and no esophageal erosions received Kapidex 30 or 60 mg daily or placebo for 4 weeks. More patients taking Kapidex 30 mg experienced more days of 24-hour heartburn-free periods as compared with placebo as assessed by daily diary over 4 weeks (54.9% versus 18.5%). In all studies, Kapidex 60 mg provided no additional clinical benefit over Kapidex 30 mg. The most common adverse effects were diarrhea, abdominal pain, and nausea.

SYMBICORT

The FDA has given approval to AstraZeneca (Wilmington, DE) to market Symbicort (budesonide/formoterol fumarate dihydrate) 160/4.5 µg for the twice-daily maintenance treatment of airflow obstruction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. The efficacy of Symbicort 160/4.5 µg was evaluated in 2 randomized, double-blind, placebo-controlled multinational studies involving 3668 patients (≥ 40 yr) with a forced expiratory volume in one second (FEV_1) of 50% predicted or less, a clinical diagnosis of COPD with symptoms for at least 2 years, and a smoking history of at least 10 pack years. In study 1, patients were randomized to Symbicort 160/4.5 or 80/4.5 µg, budesonide 160 µg plus formoterol 4.5 µg, budesonide 160 µg, formoterol 4.5 µg, or placebo for 6 months. In study 2, patients received Symbicort 160/4.5 or 80/4.5 µg, formoterol 4.5 µg, or placebo for 12 months. The primary endpoints for both studies were the change from baseline in pre-dose FEV_1 and 1-hour postdose FEV_1 averaged over the treatment period. Symbicort 160/4.5 µg significantly improved predose FEV_1 as compared with formoterol 4.5 µg and placebo (study 1, 10.7% versus 6.9% and 2.2%, respectively; study 2, 10.8% versus 7.2% and 2.8%, respectively). Symbicort 160/4.5 µg also improved 1-hour postdose FEV_1 (study 1, 22.6%; study 2, 24.0%) as compared with budesonide 160 µg (study 1, 4.9%) and placebo (study 1, 4.1%; study 2, 5.2%). The most common adverse effects were nasopharyngitis, oral candidiasis, bronchitis, sinusitis, and viral upper respiratory tract infection.

ULORIC

Takeda Pharmaceuticals America, Inc. (Deerfield, IL) has received FDA approval to market Uloric (febuxostat) for the chronic management of hyperuricemia in patients with gout. The efficacy of Uloric was evaluated in 3 randomized, double-blind, controlled trials involving 3402 patients with hyperuricemia (defined as a baseline serum uric acid level ≥ 8 mg/dL) and gout. Patients were randomized to Uloric 40 or 80 mg daily or allopurinol for 6 months (study 1); Uloric 80, 120, or 240 mg daily or allopurinol for 6 months (study 2); or Uloric 80 or 120 mg daily or allopurinol 300 mg daily for 1 year (study 3). All patients received naproxen 250 mg twice daily or colchicine 0.6 mg once or twice daily for gout flare prophylaxis. Uloric 80 mg was superior to allopurinol in lowering serum uric acid to less than 6 mg/dL at the final visit (study 1, 67% versus 42%; study 2, 72% versus 39%; study 3, 74% versus 36%). Uloric 40 mg was effective in lowering serum uric acid to less than 6 mg/dL at the final visit but was not superior to allopurinol (45% versus 42%). The most common adverse effects were liver function abnormalities, nausea, arthralgia, and rash.

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.*