Drugs recently approved or pending approval

APRISO

The US Food and Drug Administration (FDA) has given approval to Salix Pharmaceuticals, Ltd. (Raleigh, NC) to market Apriso (mesalamine) extended-release capsules for the maintenance of remission of ulcerative colitis (UC) in adults. Apriso was evaluated in 2 randomized, double-blind, placebo-controlled, multicenter studies involving 562 adult patients in remission from UC. UC disease activity was measured by a modified Sutherland Disease Activity Index (DAI), a sum of 4 subscores (range, 0–3) based on stool frequency, rectal bleeding, mucosal appearance on endoscopy, and physician's rating of disease activity. At baseline, approximately 80% of patients had a total DAI score of 0 or 1. Patients were randomized 2:1 to either Apriso 1.5 g or placebo once daily in the morning for 6 months; they were assessed at baseline and at 1, 3, and 6 months, with endoscopy performed at baseline, at end of study, or if clinical symptoms developed. Relapse was defined as a rectal bleeding score of 1 or more and a mucosal appearance score of 2 or more using the DAI or a premature withdrawal from the study. In both studies, more Apriso-treated patients remained relapse-free at 6 months as compared with placebo-treated patients (study 1, 68% versus 51% [$P < 0.001$]; study 2, 71% versus 59% [$P = 0.046$]). The most common adverse effects were headache, diarrhea, upper abdominal pain, and nausea.

BANZEL

The FDA has given approval to Eisai Corporation of North America (Woodcliff Lake, NJ) to market Banzel (rufinamide) for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in children aged 4 years and older and adults. The effectiveness of Banzel was evaluated in a multicenter, double-blind, placebo-controlled, randomized, parallel-group study involving 138 patients (age, 4–30 yr) who had at least 90 seizures in the month prior to study entry, had a diagnosis of inadequately controlled seizures associated with Lennox-Gastaut syndrome, and were treated with 1 to 3 concomitant stable dose antiepileptic drugs. After completing a 4-week baseline phase on stable therapy, patients either added Banzel or placebo to their ongoing therapy during the 12-week double-blind phase, which consisted of 2 periods: the titration period (1–2 wk, with a target dose of approximately 45 mg/kg/day twice daily) and the maintenance period (10 wk). The primary efficacy endpoints were the percent changes in total and tonic-atonic (drop attacks) seizure frequencies per 28 days and seizure severity (a 7-point assessment performed at the end of the double-blind phase) from the Parent/Guardian Global Evaluation of the patient's condition. A score of +3, 0, or –3 indicated that the patient's seizure severity was very much improved, unchanged, or very much worse, respectively. Banzel was more effective in reducing total seizure frequency as compared with placebo (median reduction, 32.7% versus 11.7%). Tonic-atonic seizure frequency was reduced by a median of 42.5% in Banzel-treated patients, as compared with a 1.4% median increase in placebo-treated patients. Improvement in seizure severity rating was higher in Banzel-treated patients than in placebo-treated patients (53.4 versus 30.6). The most common adverse effects were headache, dizziness, fatigue, somnolence, and nausea.

RAPAFLO

Watson Pharmaceuticals, Inc. (Corona, CA) has received FDA approval to market Rapaflo (silodosin) for treatment of signs and symptoms of benign prostatic hyperplasia. Rapaflo was evaluated in two 12-week, randomized, double-blind, placebo-controlled, multicenter studies involving 923 patients (mean age, 64.6 yr) with benign prostatic hyperplasia. Patients received either Rapaflo 8 mg daily or placebo. The primary efficacy endpoint was the International Prostate Symptom Score, which evaluated irritative (frequency, urgency, and nocturia) and obstructive (hesitancy, incomplete emptying, intermittency, and weak stream) symptoms. Maximum urine flow rate was a secondary endpoint. In both studies, mean changes from baseline to week 12 in total International Prostate Symptom Score were statistically significantly greater for patients treated with Rapaflo than patients treated with placebo (study 1, –6.5 versus –3.6; study 2, –6.3 versus –3.4 [$P < 0.0001$ for both]). Rapaflo also statistically significantly increased maximum urine flow rates from baseline to week 12 versus placebo in both studies (study 1, 2.2 versus 1.2 [$P = 0.006$]; study 2, 2.9 versus 1.9 [$P = 0.0431$]). The most common adverse effect was retrograde ejaculation.

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.*