Drugs recently approved or pending approval

MERREM IV

The US Food and Drug Administration (FDA) has granted approval to AstraZeneca LP (Wilmington, DE) to market Merrem IV (meropenem for injection) for treatment of complicated skin and skin structure infections (cSSSI) in adults and children. The safety, efficacy, and tolerability of Merrem IV was evaluated in an international, phase 3, randomized, double-blind, multicenter clinical trial of adult and pediatric patients (N = 1037) with cSSSI. Patients were randomized to receive either Merrem IV (500 mg intravenously [IV] every 8 hours) or imipenem-cilastatin (500 mg IV every 8 hours). The primary endpoint was clinical outcome (test-of-cure) at follow-up in the clinically evaluable and modified intention-to-treat (MITT; patients who met eligibility criteria and received ≥ 1 dose of study drug) populations. In clinically evaluable patients, 86% taking Merrem IV were cured versus 83% taking imipenem-cilastatin (95% confidence interval [CI], –2.8 to 9.3). In MITT patients, 73% taking Merrem IV were cured versus 75% taking imipenem-cilastatin (95% CI, –8.4 to 4.7). The frequency of adverse events and drug-related adverse events were similar between treatment groups. The most common adverse events in both groups were headache, nausea, and constipation. The recommend adult dosage for Merrem IV is 500 mg IV bolus administered every 8 hours. For children, Merrem IV should be administered in 10 mg/kg (up to a maximum dose of 500 mg) every 8 hours.

REQUIP

GlaxoSmithKline (Research Triangle, NC) has received FDA approval to market Requip (ropinirole HCl) for treatment of moderate to severe primary restless legs syndrome (RLS) in adults; Requip is the first and only FDA approved product for treating this condition. The efficacy of Requip was demonstrated in 3 randomized, double-blind, placebo-controlled studies in adults with RLS who had at least 15 RLS episodes per month, a score of 15 or more on the International RLS Rating Scale (IRLS), and who did not have any secondary conditions. All patients receiving Requip were started on a dose of 0.25 mg once daily, which could be titrated up to 4 mg once daily. In the US study, 187 patients were randomized to Requip and 193 to placebo. In a multinational study that excluded US participants, 146 were randomized to Requip and 138 to placebo. In a multinational study including US participants, 131 were randomized to Requip and 136 to placebo. At week 12, a statistically significant difference between the Requip and placebo groups was detected in all 3 studies for both the mean change from baseline in the IRLS total score and the percentage of patients who responded to therapy as assessed by the Clinical Global Impression-Global Improvement (CGI-I) scale. In all 3 studies, there was a greater decrease in mean IRLS scores from baseline in the Requip versus placebo groups. Likewise, there was a higher percentage of responders per the CGI-I scale in the Requip group than in the placebo group for all 3 studies. The most commonly observed adverse events associated with Requip were nausea, somnolence, vomiting, dizziness, and fatigue. The recommended starting dosage for Requip is 0.25 mg once daily taken 1 to 3 hours before bedtime.

REVATIO

Pfizer Inc. (New York, NY) has been given FDA approval to market Revatio (sildenafil citrate) for the treatment of pulmonary arterial hypertension (PAH) to improve exercise ability. Revatio was evaluated in a randomized, double-blind, placebo-controlled study involving patients with PAH (defined as a mean pulmonary artery pressure of ≥ 25 mm Hg at rest with a pulmonary capillary wedge pressure of < 15 mm Hg). Patients were randomized to receive placebo (n = 70) or Revatio 20 mg (n = 69), 40 mg (n = 67), or 80 mg (n = 71) 3 times daily for a period of 12 weeks. The primary endpoint was the change from baseline to week 12 in 6-minute walk distance at least 4 hours after the last dose. Placebo-corrected mean increases in walk distance of 45 to 50 meters were observed with all doses of Revatio. Patients on all Revatio doses achieved a statistically significant reduction in mean pulmonary arterial pressure compared with those on placebo. Doses of Revatio 20 mg, 40 mg, and 80 mg 3 times daily produced a placebo-corrected decrease in mean pulmonary arterial pressure of –2.7 mm Hg, –3.0 mm Hg, and –5.1 mm Hg, respectively. There was no evidence of a difference in effect between Revatio 20 mg 3 times daily and the higher doses studied. The most common adverse effects observed with Revatio were headache, dyspepsia, flushing, epistaxis, and insomnia. The recommended dose of Revatio is 20 mg 3 times daily taken approximately 4 to 6 hours apart.

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.*