Drugs recently approved or pending approval

STARLIX

Novartis Pharmaceuticals Corporation (East Hanover, NJ) received approval to market Starlix (nateglinide) for use as both monotherapy and in combination with metformin to lower blood glucose in patients with type 2 diabetes whose hyperglycemia cannot be adequately controlled by diet and exercise. A total of 3164 patients were randomized in 8 double-blind, placebo- or active-controlled studies of 8 to 24 weeks' duration to evaluate the safety and efficacy of Starlix. In one 24-week, active- and placebo-controlled study, patients with type 2 diabetes were randomized to receive Starlix 120 mg (3 times daily before meals), metformin 500 mg (3 times daily), a combination of Starlix 120 mg (3 times daily) and metformin 500 mg (3 times daily), or placebo. Baseline average hemoglobin A_{1c} levels (HbA_{1c}) were 8.3% or 8.4%, and baseline average fasting plasma glucose (FPG) levels ranged from 194.0 to 197.7 mg/dL. The combination of Starlix and metformin resulted in a reduction of 1.5 percentage points from baseline in HbA_{1c} and a reduction of 44.9 mg/dL from baseline FPG. Both of these reductions from the baseline values were statistically significant compared with either Starlix or metformin monotherapy. Starlix monotherapy resulted in significant reductions in mean HbA_{1c} and mean FPG compared to placebo. Hypoglycemia in 2.4% of patients was the only treatment-emergent adverse reaction observed. Starlix is contraindicated in patients with type 1 diabetes or diabetic ketoacidosis. Common adverse events associated with Starlix include hypoglycemia, upper respiratory infection, dizziness, and flulike symptoms. The recommended starting and maintenance dose of Starlix alone or in combination with metformin is 120 mg 3 times daily taken 1 to 30 minutes before meals.

ANGIOMAX

Approval was granted to The Medicines Company (Cambridge, MA) to market Angiomax (bivalirudin) for use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty (PTCA). Angiomax is intended for use with aspirin and has been studied only in patients receiving concomitant aspirin. In Phase III double-blinded clinical trials comparing Angiomax with heparin in 4312 patients undergoing PTCA for treatment of unstable angina, Angiomax patients exhibited lower rates of ischemic complications (death, myocardial infarction, or repeat revascularization) (6.2% vs 7.9%, $P = 0.039$). Angiomax patients also experienced a lower rate of major hemorrhage (3.5% vs 9.3%, $P < 0.001$) and lower requirements for erythrocyte transfusions of at least 2 units (2.0% vs 5.7%, $P < 0.001$), as compared with patients receiving full-dose unfractionated heparin. (Major hemorrhage was defined as intracranial or retroperitoneal bleeding, or clinically overt bleeding with a decrease in hemoglobin of ≥ 3 g/dL or leading to a transfusion of ≥ 2 units of blood.) Angiomax is contraindicated in patients with active major bleeding and should be used together with aspirin during pregnancy only if clearly needed. The most frequent treatment-emergent adverse events reported in clinical trials with Angiomax were back pain, pain, nausea, headache, and hypotension. The recommended dosage of Angiomax is an intravenous (IV) bolus dose of 1.0 mg/kg body weight followed by a 4-hour IV infusion at a rate of 2.5 mg/kg body weight per hour. After completion of the initial 4-hour infusion, an additional IV infusion may be initiated at a rate of 0.2 mg/kg body weight per hour for up to 20 hours, if needed.

ORAPRED

Ascent Pediatrics, Inc (Wilmington, MA) received approval from the US Food and Drug Administration to market Orapred (prednisolone sodium phosphate oral solution) as a treatment for children with asthma and other inflammatory conditions. Although there are a number of approved indications for Orapred, its primary use by pediatricians is in the treatment of asthma in children. Each 5 mL contains 20.2 mg prednisolone sodium phosphate (equivalent to 15 mg prednisolone base). Orapred utilizes a taste-masking technology to improve palatability. A blinded taste test was performed in a total of 50 children, ranging in age from 4 to 11 years who, after sampling Orapred and Prelone (prednisolone syrup, USP) 15 mg/5 mL, were asked to state a preference. Seventy percent of children preferred the taste of grape-flavored Orapred to Prelone. Orapred is not generically equivalent to Prelone. As with all liquid corticosteroids, Orapred is not recommended for persons with systemic fungal infections. Potential adverse reactions associated with Orapred include dermatologic and gastrointestinal disturbances. The initial dose of Orapred may vary from 1.67 to 20 mL (5 to 60 mg prednisolone base) daily, depending on the specific disease being treated and the response of the patient.

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