Drugs recently approved or pending approval

DUETACT

The US Food and Drug Administration (FDA) has given approval to Takeda Pharmaceuticals America, Inc. (Lincolnshire, IL) to market Duetact (pioglitazone HCl and glimepiride) as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus who are already treated with a combination of pioglitazone and a sulfonylurea or whose diabetes is not adequately controlled with a sulfonylurea alone, or for patients who have initially responded to pioglitazone alone and require additional glycemic control. Although no clinical efficacy studies have been conducted with Duetact, the efficacy and safety of the separate components have been previously established in 2 treatment-randomized, controlled studies. In the first study, 560 patients were randomized to pioglitazone 15 mg or 30 mg or placebo once daily in addition to their current sulfonylurea regimen for 16 weeks. The addition of pioglitazone 15 or 30 mg significantly reduced the mean hemoglobin A_{1c} by 0.88% and 1.28% and mean fasting plasma glucose by 39.4 mg/dL and 57.9 mg/dL, respectively, compared with sulfonylurea treatment alone. In the second study, 702 patients were randomized to pioglitazone 30 mg or 45 mg once daily in addition to their current sulfonylurea regimen for 24 weeks. From baseline to week 24, pioglitazone 30 or 45 mg significantly reduced the mean hemoglobin A_{1c} by 1.55% and 1.67% and mean fasting plasma glucose by 51.5 mg/dL and 56.1 mg/dL, respectively. Based on the results from both studies, the addition of pioglitazone to sulfonylurea resulted in significant improvements in glycemic control regardless of the sulfonylurea dose. The most common adverse effects were hypoglycemia, upper respiratory tract infection, weight gain, and lower limb edema. Duetact should be administered once daily with the first main meal, and the dose should be individualized based on the patient's current regimen.

ELAPRASE

Shire PLC (Philadelphia, PA) has been given FDA approval to market Elaprase (idursulfase), which is a human enzyme replacement therapy for the treatment of Hunter syndrome (also known as mucopolysaccharidosis II). Elaprase is the only drug approved for treatment of Hunter syndrome, a rare genetic disorder in which iduronate-2-sulfatase, an enzyme needed to breakdown complex sugars, cannot be produced. Elaprase was evaluated in a 53-week, randomized, double-blind, placebo-controlled phase II/III study involving 96 patients with Hunter syndrome. The primary efficacy endpoints were changes in 6-minute walk test and percentage predicted forced vital capacity from baseline to the end of the study. Compared with placebo-treated patients, those who received weekly infusions of Elaprase had a mean increase of 35 meters in distance walked in 6 minutes. The most common adverse effects associated with Elaprase were pyrexia, headache, and arthralgia. Patients who are administered Elaprase may experience severe hypersensitivity reactions, such as respiratory distress, a drop in blood pressure, or seizure; therefore, Elaprase should be administered in the presence of appropriate medical support.

KEPPRA

The FDA has given approval to UCB, Inc. (Smyrna, GA) to market Keppra (levetiracetam) injection for use as adjunctive therapy in the treatment of partial onset seizures in adults with epilepsy when oral administration is temporarily not feasible. There have been no studies to demonstrate the efficacy of Keppra injection; however, Keppra injection and tablets are bioequivalent, and therefore efficacy data can be derived from studies evaluating oral formulations. Keppra was evaluated in 3 multicenter, randomized, double-blind, placebo-controlled studies. Patients in studies 1 and 2 had refractory partial onset seizures for 2 years or more and had taken at least 2 antiepileptic drugs (AEDs). Patients in study 3 had refractory partial onset seizures for 1 year or more and had taken 1 AED. Study patients were randomized to the following: study 1 (N = 293), Keppra 1000 or 3000 mg/day or placebo; study 2 (N = 322), Keppra 1000 or 2000 mg/day or placebo; and study 3 (N = 284), Keppra 3000 mg/day or placebo. In all studies, the primary efficacy measure was a between-group comparison of the percent reduction in weekly seizure frequency relative to placebo over the entire randomized treatment period (titration and evaluation). The percent reductions in partial seizure frequency over placebo were as follows: study 1, 26.1% and 30.1% for Keppra 1000 and 3000 mg/day, respectively ($P < 0.001$); study 2, 17.1% and 21.4% for Keppra 1000 and 2000 mg/day, respectively ($P \leq 0.001$); and study 3, 23% for Keppra 3000 mg/day ($P < 0.001$). The most common adverse effects were somnolence, asthenia, infection, and dizziness. Keppra injection should be diluted prior to use and administered as a 15-minute intravenous infusion.

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.*