Drugs recently approved or pending approval

JANUVIA

The US Food and Drug Administration (FDA) has given approval to Merck & Co., Inc. (Whitehouse Station, NJ) to market Januvia (sitagliptin phosphate) as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. Januvia can be used as monotherapy or in combination therapy with metformin or a peroxisome proliferator-activated receptor γ agonist (eg, thiazolidinediones) when a single agent does not provide adequate glycemic control. Januvia is the first DPP-4 inhibitor approved in the United States for treatment of type 2 diabetes. The safety and efficacy of Januvia were evaluated in 2 double-blind, placebo-controlled monotherapy trials (18 and 24 weeks) and 2 randomized, double-blind, placebo-controlled combination trials (1 with metformin, 1 with pioglitazone). All patients underwent a run-in period prior to randomization. In the monotherapy trials, 1262 patients were randomized to Januvia 100 mg or 200 mg or placebo. Patients treated with Januvia 100 mg experienced significant improvements in hemoglobin A_{1c}, fasting plasma glucose (FPG), and 2-hour postprandial glucose (PPG) compared with placebo-treated patients. In the metformin combination study, 701 patients were randomized to the addition of Januvia 100 mg or placebo once daily. In combination with metformin, Januvia provided significant improvements in hemoglobin A_{1c}, FPG, and 2-hour PPG compared with placebo and metformin. In the pioglitazone combination trial, 353 patients were randomized to the addition of Januvia 100 mg or placebo once daily. In combination with pioglitazone, Januvia provided significant improvements in hemoglobin A_{1c} and FPG compared with placebo and pioglitazone. Patients in all trials who failed to meet specific glycemic goals were treated with rescue therapy. There were no body weight changes observed in Januvia-treated patients compared with placebo-treated patients in all 4 trials. The most common adverse effects were upper respiratory tract infection, nasopharyngitis, and headache. The recommended dose of Januvia is 100 mg once daily.

LAMICTAL

GlaxoSmithKline (Research Triangle Park, NC) has been given FDA approval to market Lamictal (lamotrigine) for adjunctive treatment of primary generalized tonic-clonic (PGTC) seizures in adults and pediatric patients (aged ≥ 2 years). Lamictal was evaluated in a multicenter, double-blind, placebo-controlled trial of 117 pediatric and adult patients who had at least 3 PGTC seizures during an 8-week baseline phase. Patients were randomized to 19 to 24 weeks of treatment with fixed-dose Lamictal (range, 3–12 mg/kg/day for pediatric patients and 200–400 mg/day for adults) or placebo added to their current antiepileptic drug regimen (≤ 2 drugs). The primary efficacy endpoint was change from baseline in PGTC seizures. Lamictal-treated patients had a statistically significant mean percent reduction in PGTC seizures as compared with placebo-treated patients (66% versus 34%; $P = 0.006$). Efficacy was similar across age-groups. The most common Lamictal-related adverse effects were dizziness, drowsiness, and nausea. Lamictal is also approved as monotherapy in adults with partial seizures who are receiving treatment with carbamazepine, phenytoin, phenobarbital, primidone, or valproate as the single antiepileptic drug; as adjunctive treatment of partial seizures and generalized seizures of Lennox-Gastaut syndrome; and for the maintenance treatment of bipolar I disorder.

TYZEKA

The FDA has given approval to Novartis Pharmaceuticals Corporation (East Hanover, NJ) to market Tyzeka (telbivudine) for the treatment of chronic hepatitis B in adult patients with evidence of viral replication and either evidence of persistent elevations in serum aminotransferases or histologically active disease. The safety and efficacy of Tyzeka were evaluated in a phase III, randomized, double-blind, multinational study (GLOBE) involving 1367 nucleoside-naive chronic hepatitis B e-antigen (HBeAg)–positive and HBeAg-negative patients. Patients were randomized to Tyzeka 600 mg once daily or lamivudine 100 mg once daily for up to 104 weeks. The primary endpoint was therapeutic response at 1 year, as measured by a composite serologic endpoint requiring suppression of hepatitis B virus DNA to fewer than 5 $\log_{10}$ copies/mL in addition to either loss of serum HBeAg or normalized alanine aminotransferase. In HBeAg-positive patients, therapeutic response was achieved in 75% of Tyzeka-treated patients compared with 67% of lamivudine-treated patients. In HBeAg-negative patients, 75% of Tyzeka-treated patients achieved therapeutic response compared with 77% of lamivudine-treated patients. The most common adverse effects were upper respiratory tract infection, fatigue and malaise, abdominal pain, nasopharyngitis, and headache. The recommended dose of Tyzeka is 600 mg taken orally once daily with or without food.

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.*