EXUBERA

The US Food and Drug Administration (FDA) has given approval to Pfizer, Inc. (New York, NY) to market Exubera (insulin human [rDNA origin]) inhalation powder for the treatment of adult patients with diabetes mellitus (type 1 or type 2) for the control of hyperglycemia. Exubera is the first inhaled form of insulin and the first insulin option that does not need to be administered as an injection. The safety and efficacy of Exubera were evaluated in approximately 2500 adults with type 1 and type 2 diabetes. The primary efficacy measure for most studies was glycemic control (reduction from baseline in hemoglobin A1c [HbA1c]). Exubera was studied in two 24-week, open-label, randomized, active-controlled studies involving patients with type 1 diabetes. Exubera was administered in combination with either Ultralente (human insulin extended zinc suspension) or NPH human insulin and evaluated against comparator treatments. Exubera-treated patients had a greater reduction in fasting plasma glucose than comparator-treated patients, and reductions in HbA1c and rates of hypoglycemia were comparable between treatment groups. Exubera was also evaluated in 5 trials of various designs as both monotherapy and combination therapy in type 2 diabetes patients with both controlled and poorly controlled disease. On the whole, Exubera used as monotherapy or in combination with another diabetes medication (ie, metformin, thiazolidinedione, sulfonylurea, or Ultralente injection) reduced HbA1c levels from baseline. The most common adverse effects were hypoglycemia, respiratory tract infection, chest pain, increased cough, dry mouth, and pharyngitis. Patients should not take Exubera if they smoke or have stopped smoking less than 6 months prior to initiation of Exubera.

RANEXA

CV Therapeutics, Inc. (Palo Alto, CA) has been given FDA approval to market Ranexa (ranolazine extended-release tablets) for the treatment of chronic angina in combination with amiodipine, β-blockers, or nitrates. Because Ranexa prolongs the QT interval, it should be reserved for patients who have not achieved adequate response with other antianginal drugs. Ranexa has been evaluated in 2 studies. In study 1, patients (N = 565) were randomized to Ranexa 500 mg twice daily or placebo for 1 week, followed by Ranexa 1000 mg twice daily or placebo in addition to amiodipine 10 mg daily for 6 weeks. Statistically significant decreases in angina attack frequency (P = 0.028) and nitroglycerin use (P = 0.014) were observed with Ranexa as compared with placebo. In study 2, patients (N = 823) were randomized to Ranexa 750 mg, 1000 mg, or placebo twice daily and daily doses of atenolol 50 mg, amiodipine 5 mg, or diltiazem CD 180 mg. Statistically significant (P < 0.05) increases in modified Bruce treadmill exercise duration and time to angina were observed for each Ranexa dose as compared with placebo at both trough and peak plasma levels, with minimal effects on blood pressure and heart rate. No increase in effect on exercise was observed at the 1000 mg Ranexa dose compared with the 750 mg dose. The most common adverse effects were constipation, dizziness, nausea, and headache. Ranexa should be initiated at 500 mg twice daily and increased to 1000 mg twice daily as needed based on clinical symptoms. Baseline and follow-up electrocardiograms should be obtained to evaluate effects on QT interval.

ROTATEQ

The FDA has given approval to Merck & Co., Inc. (Whitehouse Station, NJ) to market RotaTeq (rotavirus vaccine, live, oral, pentavalent) for the prevention of rotavirus gastroenteritis in infants and children caused by serotypes G1, G2, G3, and G4 when administered as a 3-dose series to infants between the ages of 6 and 32 weeks. RotaTeq is the only vaccine available in the United States to prevent rotavirus gastroenteritis. RotaTeq was evaluated in 3 randomized, placebo-controlled, phase 3 studies in 11 countries on 3 continents (N = 72,324; n = 6983 from the United States and Finland). RotaTeq prevented 98% of severe cases of rotavirus gastroenteritis and prevented 74% of rotavirus gastroenteritis cases of any severity caused by serotypes G1, G2, G3, and G4 compared with placebo. RotaTeq also significantly reduced hospitalizations for rotavirus gastroenteritis (serotypes G1–G4) through the first 2 years after the third dose (95.8% [95% confidence interval, 90.5%–98.2%]). The efficacy of RotaTeq beyond the second season postvaccination was not evaluated. The most common adverse effects were bronchiolitis, gastroenteritis, pneumonia, fever, and urinary tract infection. RotaTeq should be administered orally in 3 doses starting at age 6 to 12 weeks, with the 2 subsequent doses administered at 4- to 10-week intervals (not beyond age 32 weeks).

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.