Drugs recently approved or pending approval

APIDRA

The US Food and Drug Administration (FDA) has given approval to Aventis Pharmaceuticals Inc, of Bridgewater, NJ, to market Apidra (insulin glulisine [rDNA origin] injection) for the treatment of adults with diabetes mellitus (DM) for the control of hyperglycemia. Apidra was evaluated in 4 studies. In study 1, type 1 DM patients were randomized to Apidra (n = 339) or insulin lispro (n = 333) administered subcutaneously within 15 minutes preprandial. Insulin glargine was given once daily in the evening as a basal insulin. In study 2, type 2 DM patients were randomized to Apidra (n = 435) given within 15 minutes preprandial or regular human insulin (n = 441) given 30 to 45 minutes preprandial. Neutral protamine Hagedorn insulin was given twice daily as a basal insulin. In study 3, type 1 DM patients were randomized to either Apidra (n = 286) 15 minutes preprandial, Apidra (n = 296) immediately postprandial, or regular human insulin (n = 278) 30 to 45 minutes preprandial. Insulin glargine was given once daily at bedtime. In study 4, to evaluate use with an external pump, type 1 DM patients were randomized to Apidra (n = 29) or insulin aspart (n = 30). Glycemic control (measured by hemoglobin A_{1C}) and rates of hypoglycemia were comparable between all treatment regimens in all 4 studies. The most common adverse effects observed with Apidra were allergic reaction, injection site reaction, lipodystrophy, pruritus, rash, and hypoglycemia. Apidra should be given within 15 minutes before a meal or within 20 minutes after starting a meal.

ENBREL

The FDA has granted approval to Amgen Inc., (Thousand Oaks, CA) and Wyeth Pharmaceuticals Inc., (Collegeville, PA) to market Enbrel (etanercept) for the treatment of adult patients with chronic moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Enbrel was evaluated in 2 randomized, double-blind, placebo-controlled studies in adults with chronic stable plaque psoriasis involving ≥ 10% of body surface area, a minimum Psoriasis Area and Severity Index (PASI) of 10, and who had received or were candidates for systemic antipsoriatic therapy or phototherapy. In study 1, patients (N = 672) received Enbrel 25 mg once weekly, 25 mg twice weekly, 50 mg twice weekly, or placebo for 3 months. After 3 months, patients on Enbrel continued on their original blinded treatments and those on placebo were given blinded Enbrel 25 mg twice weekly for an additional 3 months. In study 2, patients (N = 611) received Enbrel 25 mg or 50 mg twice weekly or placebo for 3 months. After 3 months, all patients received open-label Enbrel 25 mg twice weekly for 9 more months. Response to treatment, assessed at 3 months, was defined as a ≥ 75% reduction in PASI score from baseline. In both studies, more patients taking to Enbrel than placebo achieved a response to treatment as defined, with a dose response relationship across all doses given. The most common adverse effects associated with Enbrel were injection site reaction, infection, and headache. The recommended starting dose of Enbrel is 50 mg twice weekly administered 3 to 4 days apart for 3 months, followed by a reduction to a maintenance dose of 50 mg per week. Enbrel has previously been approved for the treatment of moderate-to-severe rheumatoid arthritis, moderate-to-severe juvenile arthritis, psoriatic arthritis, and active ankylosing spondylitis.

VIDAZA

Pharmion Corporation (Boulder, CO) has been given FDA approval to market their orphan drug Vidaza (azacitidine) for the treatment of patients with myelodysplastic syndromes. Vidaza was evaluated in 2 nonrandomized studies and 1 randomized, controlled study involving 311 patients with all subtypes of myelodysplastic syndrome. Approximately 19% of patients in all 3 studies met criteria for improvement, with a median duration of 195 days. Responses consisted of complete or partial normalization of blood counts and of immature cell percentages in the bone marrow. In responders, the need for transfusions was eliminated. The most common adverse effects seen with Vidaza were nausea, anemia, thrombocytopenia, diarrhea, fatigue, injection site reaction, and constipation. The recommended starting dose of Vidaza is 75 mg/m^2 subcutaneously daily for 7 days every 4 weeks. Patients should be premedicated for nausea and vomiting. Treatment should be administered for a minimum of 4 cycles and continued as long as the patient benefits.

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.*