Drugs recently approved or pending approval

ASMANEX TWISTHALER

The US Food and Drug Administration (FDA) has given approval to Schering-Plough Corporation (Kenilworth, NJ) to market Asmanex Twisthaler 220 µg (mometasone furoate inhalation powder) for the first-line maintenance treatment of asthma as prophylactic therapy in patients aged 12 years and older. Asmanex is the only inhaled asthma controller therapy approved for once-daily initiation and management of asthma in patients previously treated with bronchodilators alone or inhaled corticosteroids. Asmanex Twisthaler was evaluated in varying dosages in 7 double-blind, placebo-controlled, 12-week studies involving 1941 patients aged ≥ 12 years with asthma of varying degrees maintained on either bronchodilators alone (n = 737), inhaled corticosteroids (n = 1072), or oral corticosteroids (n = 132). Among patients maintained on bronchodilators alone, patients treated with Asmanex had significant improvement in morning force expiratory volume in 1 second (FEV_1) compared with placebo-treated patients. Among patients maintained on inhaled corticosteroids, Asmanex-treated patients maintained or increased morning FEV_1 compared with placebo-treated patients. Among patients maintained on oral corticosteroids, Asmanex-treated patients had significant improvement in lung function compared with placebo-treated patients. The most common adverse effects reported were headache, allergic rhinitis, pharyngitis, and upper respiratory infection.

MYCAMINE

Fujisawa Healthcare, Inc. (Deerfield, IL) has been given FDA approval to market Mycamine (micafungin sodium) for the treatment of patients with esophageal candidiasis and for prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplantation. Mycamine is a member of a new class of antifungal agents, the echinocandins. Mycamine was evaluated in a phase 3, double-blind study involving 518 patients with esophageal candidiasis (study 1) and a randomized, double-blind study involving 882 patients undergoing an autologous or syngeneic or allogeneic stem cell transplant (study 2). In study 1, patients were randomized to Mycamine 150 mg/d (n = 260) or intravenous fluconazole 200 mg/d (n = 258). Endoscopic cure, clinical cure, overall therapeutic cure, and mycologic cure were comparable for patients in both treatment arms. In study 2, patients were randomized to Mycamine 50 mg/d (n = 425) or fluconazole 400 mg/d (n = 457). Successful prophylaxis was documented in 80.7% of Mycamine-treated patients as compared with 73.7% of fluconazole-treated patients. The most common adverse effects seen with Mycamine were phlebitis, rash, leukopenia, and nausea (study 1) and hyperbilirubinemia, nausea, diarrhea, and hypokalemia (study 2). The recommended dose of Mycamine is 150 mg/d for patients with esophageal candidiasis and 50 mg/d for prophylaxis of *Candida* infections in patients undergoing hematopoietic stem cell transplantation.

SYMLIN

The FDA has given approval to Amylin Pharmaceuticals, Inc. (San Diego, CA) to market Symlin (pramlintide acetate) injection as an adjunct treatment for adults with type 1 or type 2 diabetes who use mealtime insulin therapy and who have failed to achieve desired glucose control despite optimal insulin therapy, with or without a current sulfonylurea agent and/or metformin (type 2 diabetes patients only). The efficacy of Symlin was evaluated in several placebo-controlled and open-label trials involving patients with type 2 diabetes who use insulin (n = 1688) and patients with type 1 diabetes (n = 2375). Two studies evaluating type 2 diabetes patients used fixed-dose insulin therapy, and 1 study allowed a flexible dosing regimen. Two studies evaluating type 1 diabetes patients used minimal insulin adjustments, 2 studies made insulin adjustments according to standard medical practice, and 1 study used a flexible dosing insulin regimen. In all studies, Symlin therapy was associated with improvements in blood glucose control (as measured by hemoglobin A_{1c}) and weight loss. The most common adverse effects reported with Symlin therapy were nausea and headache in type 2 diabetes patients and nausea, inflicted injury, and vomiting in type 1 diabetes patients. In insulin-using type 2 diabetes patients, Symlin should be initiated at a dose of 60 µg and increased to 120 µg as tolerated. In type 1 diabetes patients, Symlin should be initiated at a dose of 15 µg and titrated at 15 µg increments to a maintenance dose of 30 µg or 60 µg as tolerated. The prescribing information for Symlin carries a black-box warning noting that coadministration of Symlin with insulin may increase the risk of insulin-induced hypoglycemia, particularly in patients with type 1 diabetes.

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.*