Drugs recently approved or pending approval

ALINIA

The US Food and Drug Administration (FDA) granted approval to Romark Laboratories (Tampa, FL) to market Alinia (nitazoxanide) for Oral Suspension for the treatment of diarrhea caused by *Cryptosporidium parvum* and *Giardia lamblia* in children age 1 to 11 years. Alinia's efficacy against *C. parvum* was established in 2 double-blind, controlled studies of pediatric patients with diarrhea who received a 3-day course of Alinia (100 mg twice daily in patients age 12–47 months; 200 mg twice daily in patients age 4–11 years) or placebo. In the first study, 88% of outpatients age 1 to 11 years responded to treatment with Alinia, compared with 38% of those given placebo. In the second study, 56% of malnourished inpatients age 12 to 35 months responded to treatment with Alinia, compared with 23% of those given placebo. In a randomized, controlled study of children age 24 to 47 months with diarrhea caused by *G. lamblia*, 85% of patients responded to treatment with Alinia, compared with 80% of patients treated with metronidazole. The most frequent adverse effects of Alinia were abdominal pain, diarrhea, vomiting, and headache. The recommended dosage of Alinia for Oral Suspension is 5 mL (100 mg nitazoxanide) every 12 hours for 3 days in patients age 12 to 47 months and 10 mL (200 mg nitazoxanide) every 12 hours for 3 days in patients age 4 to 11 years. Alinia should be taken with food.

METAGLIP

Bristol-Myers Squibb Company (Princeton, NJ) received approval from the FDA to market Metaglip (glipizide and metformin HCl) tablets as initial therapy (with diet and exercise) to improve glycemic control in patients with type 2 diabetes mellitus (DM) whose hyperglycemia cannot be managed satisfactorily with diet and exercise alone. Metaglip was also approved as second-line therapy for patients with type 2 DM when diet, exercise, and treatment with a sulfonylurea or metformin provide inadequate glycemic control. In a 24-week, double-blind, active-controlled, multicenter international trial, patients with type 2 DM inadequately controlled with diet and exercise (hemoglobin A_{1c} [HbA_{1c}] > 7.5% and ≤ 12%; fasting plasma glucose [FPG] < 300 mg/dL) randomly received initial therapy with glipizide 5 mg, metformin 500 mg, Metaglip 2.5 mg/250 mg, or Metaglip 2.5 mg/500 mg. After 2 weeks, the dose was progressively increased (for up to 12 weeks) to reach a target mean daily glucose level of 130 mg/dL or less. Results at 24 weeks showed that patients in both Metaglip arms had significantly greater reductions in HbA_{1c} and FPG, compared with patients taking glipizide or metformin alone. Metaglip is contraindicated in patients with known hypersensitivity to either of its components, renal disease or dysfunction, congestive heart failure requiring pharmacologic treatment, and acute or chronic metabolic acidosis. The most common adverse effects of Metaglip are diarrhea, nausea/vomiting, and abdominal pain. The recommended starting dose of Metaglip is 2.5 mg/250 mg once daily with a meal. As second-line therapy, the recommended starting dose is 2.5 mg/500 mg or 5 mg/500 mg twice daily with the morning and evening meals.

STRATTERA

The FDA has approved marketing of Strattera (atomoxetine HCl) by Eli Lilly and Company (Indianapolis, IN) for the treatment of attention-deficit/hyperactivity disorder (ADHD). The effectiveness of Strattera was established in 4 placebo-controlled trials involving 758 children and adolescents and 2 placebo-controlled trials involving 536 adults who met DSM-IV criteria for ADHD. In all studies, symptoms of ADHD improved more significantly in patients receiving Strattera than in those receiving placebo. Strattera is contraindicated in patients with narrow-angle glaucoma and should not be taken with or within 2 weeks of initiating or discontinuing a monoamine oxidase inhibitor. Some children may lose weight when starting treatment with Strattera, so growth should be monitored. The most common adverse effects of Strattera in children and adolescents are upper abdominal pain, dyspepsia, nausea, vomiting, fatigue, decreased appetite, dizziness, and mood swings and in adults are constipation, dry mouth, nausea, decreased appetite, dizziness, insomnia, urinary problems, and sexual problems. In children and adolescents weighing 70 kg or less, the initial total daily dosage of Strattera should be approximately 0.5 mg/kg body weight, increased after a minimum of 3 days to a target total daily dose of approximately 1.2 mg/kg. In children and adolescents weighing more than 70 kg and in adults, Strattera should be initiated at a total daily dose of 40 mg and increased after a minimum of 3 days to a target total daily dose of approximately 80 mg.

Compiled from press reports and pharmaceutical company press releases. For more information, contact Jennifer M. Lehr, Hospital Physician, *125 Strafford Avenue, Suite 220, Wayne, PA 19087-3391.*