

### Drugs recently approved or pending approval

#### CONCERTA

The United States Food and Drug Administration approved marketing of Concerta (methylphenidate HCl) extended-release tablets CII (Alza Corporation, Mountain View, CA), indicated for the treatment of attention deficit hyperactivity disorder (ADHD). The efficacy of Concerta for the treatment of ADHD was measured in 3 controlled trials of children ages 6 to 12 who met the *DSM-IV* criteria for ADHD. The controlled studies compared Concerta, administered once daily (18, 36, or 54 mg), methylphenidate administered 3 times daily over 12 hours (15, 30, or 45 mg total daily dose), and placebo in two single-center, 3-week crossover studies and in a multicenter, 4-week, parallel-group comparison. Symptoms of ADHD were evaluated by community schoolteachers using the Inattention/Overactivity With Aggression (IOWA) Conners scale. Statistically significant reduction in the inattention/overactivity subscale versus placebo was shown consistently across all three controlled studies for Concerta. Potential adverse events associated with Concerta include headache, upper respiratory infection (URI), and abdominal pain. Concerta is contraindicated in patients with marked anxiety, tension, and agitation; in persons with glaucoma; in persons with motor tics or with a history or diagnosis of Tourette's syndrome; during treatment with monoamine oxidase inhibitors (MAOIs); and also within a minimum of 14 days following discontinuation of a MAOI. Concerta should be administered orally once daily in the morning. Each tablet contains 18 or 36 mg of methylphenidate HCl.



#### PULMICORT RESPULES

Astra Pharmaceuticals (Wayne, PA) received approval to market Pulmicort Respules (budesonide inhalation suspension) for use via nebulizer for the maintenance treatment of asthma and as prophylactic therapy in children 12 months to 8 years old. Three double-blind, placebo-controlled, parallel group clinical trials of 12-weeks' duration randomized pediatric patients (N = 1018) to various dosages of Pulmicort Respules or placebo. Pulmicort Respules significantly decreased both nighttime and daytime symptom scores of asthma compared with placebo. Potential adverse events associated with Pulmicort Respules include respiratory infection, otitis media, rhinitis, coughing, gastroenteritis, and ear infection. The recommended starting dosage and highest recommended dosage are based on prior therapy. For previous therapy with bronchodilators alone or with inhaled corticosteroids, a 0.5 mg total daily

dose administered either once daily or twice daily in divided doses is recommended. For previous therapy with oral corticosteroids, a 1 mg total daily dose administered either as 0.5 mg twice daily or 1 mg once daily is recommended. Particular care is needed for patients who are transferred from oral to inhaled corticosteroids because of the risk of adrenal insufficiency.

#### GLUCOVANCE

Approval was granted to Bristol-Myers Squibb Company (Princeton, NJ) to market Glucovance (glyburide and metformin HCl tablets) for use as initial therapy, as an adjunct to diet and exercise, to improve glycemic control in patients with type 2 diabetes. The drug was also approved as a second-line therapy for patients with type 2 diabetes who cannot achieve adequate glycemic control with diet, exercise, and initial treatment with a sulfonylurea or metformin. Efficacy of Glucovance

as initial therapy for type 2 diabetes was measured in a 20-week, double-blind, multicenter trial. Drug-naïve patients (N = 806) with type 2 diabetes, whose hyperglycemia was not adequately controlled with diet and exercise alone, were randomized to placebo, 2.5 mg glyburide, 500 mg metformin, Glucovance 1.25 mg glyburide/250 mg metformin, or Glucovance 2.5 mg/500 mg. Patients

in the 1.25 mg/250 mg Glucovance arm experienced an average decrease of 41.5 mg/dL in fasting plasma glucose (FPG) levels, compared with a 35.7 mg/dL decrease and a 21.2 mg/dL decrease in the glyburide-alone and metformin-alone arms, respectively. Patients in the 2.5 mg/500 mg Glucovance arm experienced a slightly less significant result than that seen in the lower-dose Glucovance group. Glucovance is contraindicated in patients with renal disease or dysfunction, congestive heart failure, or acute or chronic metabolic acidosis. It is not recommended for use during pregnancy or in pediatric patients. In rare cases, Glucovance may cause lactic acidosis, which is fatal in approximately 50% of cases. Potential adverse events associated with Glucovance include URI, diarrhea, headache, nausea/vomiting, abdominal pain, and dizziness. The recommended starting dosage when used as initial therapy is 1.25 mg/250 mg once or twice daily with meals. As second-line therapy, the recommended dosage is 2.5 mg/500 mg or 5 mg/500 mg twice daily with meals.

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