

### Drugs recently approved or pending approval

#### AVANDIA

The United States Food and Drug Administration approved marketing of Avandia (rosiglitazone maleate) by SmithKline Beecham (Philadelphia, PA). Avandia is indicated as monotherapy as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus. Avandia is also indicated in combination with metformin when diet, exercise, and Avandia alone or diet, exercise, and metformin alone do not provide adequate glycemic control for patients with type 2 diabetes. Drug efficacy as monotherapy was measured in six double-blind studies. In one 26-week study, patients with type 2 diabetes, previously treated inadequately with diet alone or antidiabetic medication(s), were randomized to placebo ( $n = 158$ ), 2 mg of Avandia twice daily ( $n = 166$ ), or 4 mg of Avandia twice daily ( $n = 169$ ). The study's primary endpoints were reductions from baseline in fasting plasma glucose (FPG) levels and glycosylated hemoglobin ( $HbA_{1c}$ ) levels. The proportion of patients who responded with decreases in FPG equal to or greater than 30 mg/dL was 16% in the placebo arm compared with 54% in the 2 mg-twice-daily Avandia arm and 64% in the 4 mg-twice-daily Avandia arm. The proportion of patients who responded with decreases in  $HbA_{1c}$  levels equal to or greater than 0.7 % was 6% in the placebo arm compared with 40% in the 2 mg-twice-daily Avandia arm and 42% in the 4 mg-twice-daily Avandia arm. Adverse events associated with Avandia may include upper respiratory tract infection, injury, headache, and back pain. The recommended starting dose of Avandia is 4 mg administered as a single dose or divided into two doses daily; dosage should be adjusted based on individual patient response.



#### BAYCOL

Bayer (West Haven, CT) received approval to market Baycol (cerivastatin sodium tablets) in a new 0.4-mg dose and for an expanded indication. Baycol, previously indicated as an adjunct to diet for the reduction of elevated total cholesterol and low-density lipoprotein (LDL) cholesterol in patients with hypercholesterolemia and mixed dyslipidemia, is also indicated as an adjunct to diet for the reduction of apolipoprotein B (apo B) and triglyceride levels in patients with primary hypercholesterolemia and mixed dyslipidemia (Frederickson types IIa and IIb) when the response to dietary restriction of saturated fats and cholesterol and other non-pharmacologic measures alone has been inadequate. Drug effectiveness was evaluated in several clinical studies. Pooled results of three multicenter studies

involving patients with primary hypercholesterolemia demonstrate significant reductions in mean total cholesterol, LDL cholesterol, apo B, and triglyceride levels from baseline to 8 weeks. The placebo arm ( $n = 427$ ) showed mean increases in total cholesterol, LDL cholesterol, and apo B levels of +1, +1, and +2, respectively, compared with the Baycol (0.4 mg/day) arm ( $n = 571$ ), which showed mean reductions of total cholesterol, LDL cholesterol, and apo B levels of -24, -34, and -26, respectively. The placebo arm showed a mean reduction in triglyceride levels of -1 compared with -16 in the Baycol arm. Baycol is contraindicated in patients with acute liver disease or unexplained persistent elevations of serum transaminases and in pregnant or lactating women. Potential adverse reactions associated with Baycol may include pharyngitis, rhinitis, and headache. The recommended dose of Baycol is 0.4 mg/day (in the evening) in combination with a cholesterol-lowering diet.

#### VIOXX

The Food and Drug Administration granted approval to Merck and Company (West Point, PA) to market Vioxx (rofecoxib). Vioxx is indicated for the relief of signs and symptoms of osteoarthritis (OA), the management of acute pain in adults, and the treatment of primary dysmenorrhea. Drug efficacy for the treatment of signs

and symptoms of OA of the knee and hip was evaluated in several clinical studies. Treatment with Vioxx (12.5 mg/day or 25 mg/day) improved measures of pain, stiffness, and function on the Western Ontario and McMaster Universities OA questionnaire and demonstrated effectiveness similar to ibuprofen (300 mg three times daily) or diclofenac (50 mg three times daily). For the management of acute pain and dysmenorrhea, a single 50-mg dose of Vioxx provided pain relief similar to 550 mg of naproxen sodium or 400 mg of ibuprofen. Vioxx is contraindicated in patients who have experienced asthma, urticaria, or allergic-type reactions after using aspirin or other nonsteroidal anti-inflammatory drugs. Adverse events that may be associated with Vioxx include upper respiratory infection, diarrhea, and nausea. The recommended initial dose of Vioxx for the treatment of signs and symptoms of OA is 12.5 mg/day with a maximum recommended daily dose of 25 mg/day. For the management of acute pain and primary dysmenorrhea, the recommended dose is 50 mg/day.

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