

### Drugs recently approved or pending approval

#### ALTOCOR

The US Food and Drug Administration (FDA) has approved marketing of Altocor (lovastatin), an extended release formulation, by Andrx Corporation (Fort Lauderdale, FL) as an adjunct to diet to decrease elevated serum levels of total cholesterol, low-density lipoprotein (LDL) cholesterol, apolipoprotein B, and triglycerides (TG) and to increase high-density lipoprotein (HDL) serum levels in patients with primary hypercholesterolemia. Altocor is also indicated to slow the progression of coronary atherosclerosis in patients with coronary artery disease by lowering total and LDL cholesterol serum levels to target levels. In a 12-week, multicenter, placebo-controlled, double-blind, dose-response study in adult men and women age 21 to 70 years with primary hypercholesterolemia, once-daily evening administration of Altocor 10 to 60 mg was compared with a similar regimen of placebo. Altocor produced dose-related reductions in serum levels of LDL cholesterol and total cholesterol and mean reductions in serum levels of TG across all doses, varying from approximately 10% to 25%. Altocor also produced mean increases in serum HDL cholesterol levels across all doses, varying from 9% to 13%. Altocor is contraindicated in patients with active liver disease, unexplained persistent elevations of serum transaminase levels, or hypersensitivity to medication contents. The most common adverse reactions to Altocor were nausea, abdominal pain, dyspepsia, headache, asthenia, and myalgia. The usual recommended starting dosage of Altocor is 20, 40, or 60 mg (depending on therapeutic goal) once daily in the evening; treatment should be combined with a diet restricted in saturated fat and cholesterol.



#### DAPTACEL

Aventis Pasteur, Inc, of Swiftwater, PA, received approval from the FDA to market Daptacel (diphtheria and tetanus toxoids and acellular pertussis vaccine, adsorbed) for routine immunization in infants and children age 6 weeks through 6 years. A large cohort of approximately 10,000 infants was evaluated in a National Institutes of Health-sponsored pertussis study in Sweden. Daptacel showed a high degree of effectiveness (84.9%) against pertussis using World Health Organization criteria. US and Canadian studies of Daptacel as a preventive agent against diphtheria and tetanus in children showed that, after 4 doses of the vaccine, close to 100% of inoculated subjects had diphtheria and tetanus antitoxin levels greater than or equal to a serologic correlate of protection. Daptacel is con-

traindicated in anyone who is age 7 or older or who has hypersensitivity to any vaccine component. The chief adverse effects associated with Daptacel were drowsiness, irritability, anorexia, and injection site irritation. A 0.5-mL dose of Daptacel should be administered intramuscularly in 4 consecutive doses, optimally at age 2 months, 4 months, 6 months, and 17 to 20 months. The preferred injection site in children younger than 1 year is the anterolateral aspect of the thigh; in older children, the deltoid muscle is usually large enough for injection. The vaccine should not be injected into the gluteal or other areas where there may be a major nerve trunk.

#### GEODON FOR INJECTION

Pfizer Inc, of New York, NY, received approval from the FDA to market Geodon for Injection (ziprasidone mesylate) for the rapid treatment of acute agitation in patients with schizophrenia. The efficacy of Geodon for Injection was established in 2 short-term, double-blind trials of patients with schizophrenia who were considered by investigators to be acutely agitated and in need of intramuscular antipsychotic medication and who had at least 3 of the following symptoms: anxiety, tension, hostility, and excitement. Evaluation measures included analysis of the area under the curve (AUC) of

the Behavioural Activity Rating Scale (BARS) and Clinical Global Impression severity rating. Both trials (79 patients/117 patients) showed a larger dose (20 mg/10 mg) of Geodon for Injection to be statistically superior to a 2-mg dose as assessed by AUC of the BARS (at 0-4 hours/at 0-2 hours). Geodon for Injection is contraindicated in patients with a known history of QT prolongation (including congenital long QT syndrome), with recent myocardial infarction, or with uncompensated heart failure. The most common adverse effects associated with Geodon for Injection were somnolence, headache, and nausea. The recommended dose of Geodon for Injection is 10 to 20 mg administered as required, to a maximum dose of 40 mg per day. Doses of 10 mg may be administered every 2 hours; doses of 20 mg may be administered every 4 hours. Dosing of Geodon for Injection for more than 3 days has not been studied.

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