

### Drugs recently approved or pending approval

#### CRESTOR

The US Food and Drug Administration (FDA) granted approval to AstraZeneca Pharmaceuticals LP (Wilmington, DE) to market Crestor (rosuvastatin calcium) as a dietary adjunct to treat various lipid disorders, including primary hypercholesterolemia, mixed dyslipidemia, and isolated triglyceridemia. In a 6-week, dose-ranging, placebo-controlled study using a 5-mg, 10-mg, 20-mg, or 40-mg dose (N = 82), Crestor lowered low-density lipoprotein (LDL) cholesterol 45% to 63% compared with a 7% reduction for placebo. In the same trial, Crestor increased high-density lipoprotein cholesterol by 8% to 14% compared with a 3% increase for placebo. In another multicenter, open-label, dose-ranging study, patients (N = 2240) were treated for 6 weeks with a single daily dose of either Crestor, atorvastatin, simvastatin, or pravastatin. Crestor 10 mg reduced LDL cholesterol significantly more than atorvastatin 10 mg; pravastatin 10 mg, 20 mg, and 40 mg; and simvastatin 10 mg, 20 mg, and 40 mg ( $P < .002$ ). Crestor 20 mg reduced LDL cholesterol significantly more than atorvastatin 20 mg and 40 mg; pravastatin 20 mg and 40 mg; and simvastatin 20 mg, 40 mg, and 80 mg ( $P < .002$ ). Crestor 40 mg reduced LDL cholesterol significantly more than atorvastatin 40 mg; pravastatin 40 mg; simvastatin 40 mg and 80 mg ( $P < .002$ ). The most commonly reported adverse effects associated with Crestor were myalgia, constipation, asthenia, abdominal pain, and nausea. Crestor is contraindicated in patients with active liver disease or unexplained persistent elevations of serum transaminases and in women who are pregnant or may become pregnant.



#### GAMUNEX

Bayer Healthcare LLC, of Research Triangle Park, NC, was granted approval by the FDA to market Gamunex (immune globulin intravenous [human], 10% caprylate/chromatography purified), which is indicated as replacement therapy of primary immunodeficiency states in which severe impairment of antibody forming capacity has been shown. Gamunex also is indicated for patients with idiopathic thrombocytopenia purpura. In a double-blind, randomized, parallel group trial, patients (N = 146) with primary humoral immunodeficiencies were administered either Gamunex or Gamimune (immune globulin intravenous [human], 10% solvent/detergent treated). The annual rate of validated infections was less in the Gamunex group compared with the Gamimune group (0.18 versus 0.43;  $P = .023$ ). The most common adverse effects associated with

Gamunex were headache, vomiting, fever, nausea, rash, and back pain. For patients with primary humoral immunodeficiency, Gamunex doses between 300 mg and 600 mg/kg body weight may be used for infection prophylaxis. The dose should be individualized taking into account dosing intervals (3–4 weeks). For patients with idiopathic thrombocytopenic purpura, Gamunex may be administered at a total dose of 2 g/kg, divided into either 2 doses of 1 g/kg on 2 consecutive days or 5 doses of 0.4 g/kg on 5 consecutive days.

#### LEVITRA

Bayer Healthcare (West Haven, CT) and GlaxoSmithKline (Philadelphia, PA) were given approval by the FDA to market Levitra (vardenafil HCl) for the treatment of erectile dysfunction (ED). Levitra was evaluated in 4 major double-blind, randomized, placebo-controlled, fixed-dose, parallel design, multicenter trials involving 2431 men aged 20 to 83 years (mean age, 57 years). Two of these trials were conducted in the general ED population and 2 in special ED populations (ie, one in patients with diabetes mellitus and one in postprostatectomy patients). The primary endpoints were assessed at 3 months. Primary efficacy assessment in all 4 trials was by erectile function domain score of the validated

International Index of Erectile Function Questionnaire and 2 questions from the Sexual Encounter Profile dealing with the ability to achieve vaginal penetration and the ability to maintain an erection long enough for successful intercourse. In all 4 trials, Levitra showed clinically and statistically significant improvement in the erectile function domain, vaginal penetration ability, and ability to maintain erection for successful intercourse compared with placebo. The mean baseline erectile function domain score was 11.8 in all 4 trials (range, 0–30, where lower scores represent more severe disease). Men who take nitrate drugs or  $\alpha$ -blockers should not take Levitra. The most common adverse effects reported with Levitra were headache, flushing, and stuffy or runny nose. Levitra should be taken 60 minutes prior to sexual activity. Men who experience erection for more than 4 hours should seek immediate medical attention. The recommended starting dose of Levitra is 10 mg.

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Compiled from press reports and pharmaceutical company press releases. For more information, contact Tricia Carbone, Hospital Physician, 125 Stafford Avenue, Suite 220, Wayne, PA 19087-3391.

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