

Drugs recently approved or pending approval

ELIGARD

Atrix Laboratories, Inc (Fort Collins, CO) received approval from the US Food and Drug Administration (FDA) to market Eligard (leuprolide acetate) for subcutaneous injection for treatment of advanced prostate cancer. The safety and efficacy of Eligard was tested in an open-label, multicenter study in which 120 patients with advanced prostate cancer were treated with 6 monthly injections of Eligard 7.5 mg. Of patients receiving Eligard, 89 had stage C disease and 31 had stage D disease. The study evaluated the achievement and maintenance of serum testosterone suppression over 6 months of therapy. The mean testosterone concentration increased from 361.3 ng/dL at baseline to 574.6 ng/dL at day 3 following the initial injection. The mean serum testosterone concentration then decreased to below baseline by day 10 and was 21.8 ng/dL on day 28. At the conclusion of the study (month 6), mean testosterone concentration was 6.1 ng/dL. Serum testosterone was suppressed to below the castrate threshold (≤ 50 ng/dL) by week 4 in 94.1% of patients remaining in the study, and the others all attained the castrate threshold by day 42. Once testosterone suppression was attained (ie, serum concentrations < 50 ng/dL), no patients demonstrated breakthrough (ie, concentration > 50 ng/dL) subsequently. All patients in the study at month 6 ($n = 117$) had testosterone concentrations less than or equal to 50 ng/dL. Common adverse effects of Eligard include transient burning/stinging, pain, erythema, and mild bruising, all localized events that did not recur over time. Eligard is contraindicated in women and pediatric patients. The recommended dose of Eligard is 1 injection monthly, which delivers 7.5 mg of leuprolide acetate, incorporated in a polymer formulation. The subcutaneous injection provides continuous release of leuprolide for 1 month.



ENBREL

Approval was granted by the FDA to Immunex Corporation (Seattle, WA) and Wyeth-Ayerst Laboratories (Philadelphia, PA) to market Enbrel (etanercept) to treat patients with psoriatic arthritis. Enbrel can be used alone or in combination with methotrexate in patients who do not respond adequately to methotrexate alone. A 24-week, multicenter, randomized, double-blind, placebo-controlled, phase 3 study assessed the efficacy and tolerability of Enbrel or placebo in 205 patients with psoriatic arthritis. Patients were between age 18 and 70 years and had active psoriatic arthritis. Doses of Enbrel 25 mg or placebo were administered subcutaneously twice

weekly for 6 months. The primary endpoint was measured by the proportion of patients who met the American College of Rheumatology (ACR) preliminary criteria for improvement, which includes tender and swollen joint counts, a patient and a physician global assessment, patient assessment of pain, a disability index, and acute phase reactant. At 6 months, the ACR 20/50/70 responses were achieved by 50%, 37%, and 9%, respectively, of patients receiving Enbrel, compared with 13%, 4%, and 1% of patients receiving placebo. Common adverse effects included injection-site reactions and upper respiratory tract infections. Enbrel is contraindicated in patients with sepsis or known hypersensitivity to the drug or any of its components. The recommended dose of Enbrel for adult patients with psoriatic arthritis is 25 mg given twice weekly as a subcutaneous injection (72 to 96 hours apart).

XOPENEX

The FDA has approved marketing of Xopenex (levalbuterol HCl) by Sepracor, Inc (Marlborough, MA) for the treatment or prevention of bronchospasm in children age 6 to 11 years with reversible obstructive airway disease (eg, asthma). A multicenter, randomized, double-blind, placebo-controlled pediatric study ($n = 338$) evaluated the safety and efficacy of levalbuterol and racemic albuterol inhalation solutions (versus placebo) in patients with mild to moderate asthma. Subjects received 21 days of treatment with nebulized levalbuterol 3 times daily (0.31 mg or 0.63 mg), racemic albuterol (1.25 mg or 2.5 mg), or placebo. The primary endpoint was peak percentage change in forced expiratory volume in 1 second (FEV_1). All active treatments significantly improved the primary endpoint in comparison with placebo, with significant differences in FEV_1 noted immediately after nebulization. Xopenex was clinically comparable to 4- to 8-fold higher doses of racemic albuterol and demonstrated a more favorable safety profile. Xopenex is contraindicated in patients with a history of hypersensitivity to levalbuterol HCl or racemic albuterol. The most common adverse effects of the drug are flu syndrome, tachycardia, nervousness, and tremor. The recommended starting dosage of Xopenex for patients age 6 to 11 years is 0.31 mg 3 times daily by nebulization. Routine dosing should not exceed 0.63 mg 3 times daily.

buterol and racemic albuterol inhalation solutions (versus placebo) in patients with mild to moderate asthma. Subjects received 21 days of treatment with nebulized levalbuterol 3 times daily (0.31 mg or 0.63 mg), racemic albuterol (1.25 mg or 2.5 mg), or placebo. The primary endpoint was peak percentage change in forced expiratory volume in 1 second (FEV_1). All active treatments significantly improved the primary endpoint in comparison with placebo, with significant differences in FEV_1 noted immediately after nebulization. Xopenex was clinically comparable to 4- to 8-fold higher doses of racemic albuterol and demonstrated a more favorable safety profile. Xopenex is contraindicated in patients with a history of hypersensitivity to levalbuterol HCl or racemic albuterol. The most common adverse effects of the drug are flu syndrome, tachycardia, nervousness, and tremor. The recommended starting dosage of Xopenex for patients age 6 to 11 years is 0.31 mg 3 times daily by nebulization. Routine dosing should not exceed 0.63 mg 3 times daily.

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