

Drugs recently approved or pending approval

ENABLEX

The US Food and Drug Administration (FDA) has given approval to Novartis Pharmaceuticals Corporation (East Hanover, NJ) to market Enablex (darifenacin) for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency. Enablex was evaluated in 3 randomized, fixed-dose, placebo-controlled, multicenter, 12-week studies and 1 randomized, double-blind, placebo-controlled, multicenter, dose-titration study. Patients with symptoms of overactive bladder for at least 6 months were eligible if they demonstrated at least 8 micturitions and at least 1 episode of urinary urgency per day and at least 5 episodes of urge urinary incontinence per week. In all 4 studies, patients taking Enablex experienced decreased frequency of incontinence and urination episodes, increased bladder capacity, and decreased feelings of urgency. The most common adverse effects reported with Enablex were dry mouth and constipation. Enablex is contraindicated in patients with or at risk for urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma. The recommended dose of Enablex is 7.5 mg once daily; this may be increased to 15 mg once daily after 2 weeks based on patient response.



MACUGEN

Eyetech Pharmaceuticals, Inc. (New York, NY) and Pfizer Inc. (New York, NY) have been given approval by the FDA to market Macugen (pegaptanib sodium injection) for the treatment of neovascular (wet) age-related macular degeneration. Macugen was evaluated in 2 controlled, double-masked, identically designed randomized studies. Patients (N = 1190) were randomized to receive control (sham treatment) or 0.3 mg, 1 mg, or 3 mg Macugen administered as intravitreal injections every 6 weeks for 48 weeks. Patients (N = 1050) were then re-randomized to receive treatment or no treatment during year 2 of the studies. The primary efficacy endpoint was the proportion of patients losing less than 15 letters of visual acuity from baseline to 54-week assessment. At 1 year in both studies, patients treated with Macugen 0.3 mg exhibited a statistically significant result for the primary endpoint as compared with sham treatment (study 1: 73% versus 60%, respectively; study 2: 67% versus 53% respectively). At year 2, Macugen was less effective than the previous year (study 1: 57% versus 56%; study 2: 61% versus 34%). Doses above 0.3 mg did not demonstrate any additional benefits. All patients continued to experience vision loss; however, the rate of decline in Macugen-treated patients

was slower as compared with sham-treated patients. The most common adverse effects associated with Macugen were anterior chamber inflammation, blurred vision, cataract, conjunctival hemorrhage, corneal edema, eye discharge, eye irritation, eye pain, and hypertension. Macugen use is contraindicated in patients with ocular or periocular infections. The recommended dose of Macugen is 0.3 mg administered once every 6 weeks by intravitreal injection into the eye to be treated.

NASONEX

Schering-Plough Corporation (Kenilworth, NJ) has been given FDA approval to market Nasonex (mometasone furoate monohydrate) 50 µg for the treatment of nasal polyps in patients aged 18 years and older. Nasonex was evaluated in 2 randomized, double-blind, placebo-controlled, parallel group, multicenter studies involving patients (N = 664) with nasal polyps.

Patients were randomized to receive Nasonex nasal spray 200 µg once daily, 200 µg twice daily, or placebo for a period of 4 months. The coprimary efficacy points were change from baseline in nasal congestion/obstruction averaged over the first month of treatment and change from baseline to last assessment in bilateral polyp grade during the entire 4 months of treatment as assessed by endoscopy. Nasonex 200 µg twice daily demonstrated significant reduction of polyp grade compared with placebo, and patients receiving 200 µg once daily demonstrated a numerical but not significant reduction in polyp grade. Both studies showed a statistically significant reduction in congestion for both doses versus the placebo group. The most common adverse effects observed with Nasonex were headache, viral infection, sore throat, nosebleeds, and coughing. The recommended Nasonex dose is 2 sprays (50 µg in each spray) in each nostril twice daily. Nasonex has been previously approved for the treatment of nasal symptoms of seasonal allergic and perennial allergic rhinitis in adults and pediatric patients aged 2 years and older and for the prophylaxis of nasal symptoms of seasonal allergic rhinitis in adult and adolescent patients aged 12 years and older.

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