

Drugs recently approved or pending approval

BENICAR

The US Food and Drug Administration (FDA) has approved marketing of Benicar (olmesartan medoxomil) by Sankyo Pharma, Inc, of Parsippany, NJ, for the treatment of hypertension. The antihypertensive effects of Benicar were shown in 7 placebo-controlled studies at doses ranging from 2.5 to 80 mg for 6 to 12 weeks, with each showing statistically significant reductions in peak and trough blood pressure. A total of 2693 patients (2145 Benicar, 548 placebo) with essential hypertension were studied. Benicar administered once daily lowered diastolic and systolic blood pressure; response was dose related. In clinical trials, the only adverse event that occurred in more than 1% of patients treated with Benicar (and occurred more frequently than in those receiving placebo) was dizziness (3% vs 1%). Benicar is contraindicated in patients who are hypersensitive to any of the product's components. The recommended starting dose of Benicar is 20 mg once daily when used as monotherapy in patients who are not volume contracted. For patients needing further reduction in blood pressure after 2 weeks of therapy, the dose can be increased to 40 mg. Benicar can be administered with or without food.

BOTOX COSMETIC

Allergan, Inc, of Irvine, CA, received approval from the FDA to market Botox Cosmetic (botulinum toxin type A) for the temporary improvement in the appearance of moderate to severe glabellar lines in adult men and women age 65 years or younger; approval specifically applies to treatment of vertical lines between the eyebrows. Two phase 3 randomized, multicenter, double-blind, placebo-controlled, parallel-group studies of identical design were conducted to evaluate Botox Cosmetic. The studies enrolled 537 healthy adult patients (age 18–75 years) with glabellar lines of at least moderate severity at maximum frown. Subjects received a single treatment of 5 intramuscular injections of either Botox Cosmetic (n = 405) or placebo (n = 132). The maximum response rate occurred at day 30, with investigators rating 80.2% of the subjects treated with Botox Cosmetic versus 3.0% of those treated with placebo as responders to therapy as assessed by reduction in the severity of glabellar lines at maximum frown. A significant improvement in brow furrow appearance as rated by subjects' self-assessment also occurred in 89.4% of those treated with Botox Cosmetic versus 6.8% of the placebo group. The most frequently reported adverse events were headache, respiratory infection, blepharoptosis, nausea, and flu syndrome. Botox

Cosmetic is contraindicated in persons with infection at the proposed injection site(s) and in those with known hypersensitivity to any ingredient of the formulation. Botox Cosmetic should be reconstituted with 0.9% sterile, nonpreserved saline (100 units in 2.5 mL saline) prior to intramuscular injection. A dose of 0.1 mL should be injected in each of 5 sites (2 doses in each corrugator muscle, 1 dose in the procerus muscle), resulting in a total treatment dose of 20 U in 0.5 mL. The duration of activity of Botox Cosmetic is approximately 3 to 4 months.

FASLODEX

The FDA granted approval to AstraZeneca (Wilmington, DE) to market Faslodex (fulvestrant) Injection for treatment of hormone receptor-positive metastatic breast cancer in postmenopausal women with disease progression following anti-estrogen therapy (eg, tamoxifen). Efficacy of Faslodex was established by comparison to the selective aromatase inhibitor anastrozole in two phase 3, randomized, multicenter, controlled clinical trials (1 in North America, 1 in Europe). The women in the trials (N = 851) were postmenopausal with various involved sites and had been treated with 1 course of prior hormonal therapy (in most cases tamoxifen). The effectiveness of Faslodex compared to

anastrozole was measured by objective response rate and time to progression (TTP). Objective response rate in the North American trial was 17% with Faslodex vs 17% with anastrozole and in the European trial was 20% with Faslodex vs 15% with anastrozole. The reported TTP for Faslodex vs anastrozole was 5.5 vs 3.5 months in the North American trial and 5.5 vs 5.2 months in the European trial. The most commonly reported adverse effects of Faslodex were gastrointestinal symptoms, vomiting, constipation, diarrhea, abdominal pain, headache, back pain, hot flushes, and pharyngitis. Faslodex is contraindicated in pregnant women and in persons with known hypersensitivity to the drug or its components. The recommended dose is 250 mg administered intramuscularly into the buttock at 1-month intervals as either a single 5-mL (50 mg/mL) injection or 2 concurrent 2.5-mL injections, administered slowly.



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.