

Drugs recently approved or pending approval

ARIMIDEX

The United States Food and Drug Administration approved marketing of Arimidex (anastrozole) tablets by AstraZeneca (Wilmington, DE). Arimidex is now indicated for the first-line treatment of postmenopausal women with hormone receptor-positive or hormone receptor-unknown locally advanced or metastatic breast cancer. Efficacy of Arimidex as a first-line therapy was measured in 2 double-blind, clinical studies of similar design. A total of 1021 patients between the ages of 30 and 92 years were randomized to receive 1 mg of Arimidex once daily or 20 mg of tamoxifen once daily. The North American trial showed Arimidex had a statistically significant advantage over tamoxifen for time to tumor progression (11.1 months versus 5.6 months). The objective tumor response rates were not significantly different between the 2 groups. The European trial showed Arimidex was as effective as tamoxifen with respect to both tumor response rate and time to tumor progression. Patients with estrogen receptor-positive breast cancer received the greatest benefit from Arimidex. Women who are pregnant should not take Arimidex. Adverse effects include nausea, asthenia, gastrointestinal disturbance, and hot flashes. Dosage is one 1-mg tablet daily; therapy is continued until tumor progression is evident.



MIFEPREX

Approval was granted to Danco Laboratories, LLC (New York, NY) to market Mifeprex (mifepristone) for the medical termination of early intrauterine pregnancy (defined as ≤ 49 days). In clinical efficacy trials in the United States, 92.1% of the 827 subjects had a complete medical abortion. In 52 women (6.3%), expulsion occurred within 2 days and resulted from the action of Mifeprex alone, unaided by misoprostol, an analog of prostaglandin E₂. Women without an apparent expulsion took a 400- μ g dose of misoprostol on day 3. In 2 French trials (N = 1681), complete medical abortion occurred in 95.5% of the subjects, with 89 women (5.3%) having a complete abortion within 2 days of taking Mifeprex. In total, 4.5% of women in the French trials and 7.9% of women in the U.S. trials received surgical intervention for excessive bleeding, incomplete abortions, or ongoing pregnancies. Administration of Mifeprex is contraindicated in patients with confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass; intrauterine device in place; chronic adrenal failure; concurrent long-term corticosteroid therapy; history of allergy to mifepristone, miso-

prostol, or other prostaglandins; hemorrhagic disorders or concurrent anticoagulant therapy; or inherited porphyrias. Adverse effects include abdominal pain and cramping, nausea, vomiting, and diarrhea. Bleeding or spotting may occur for 9 to 16 days. The approved treatment regimen entails 3 office visits to a physician: on day 1, three 200-mg tablets of Mifeprex are taken in a single oral dose; on day 3, two 200- μ g tablets of misoprostol are taken, unless abortion has been confirmed. On day 14, the patient returns to her physician to determine whether a complete termination of pregnancy has occurred.

ADVAIR DISKUS

Glaxo Wellcome (Research Triangle Park, NC) received approval to market Advair Diskus (fluticasone propionate and salmeterol inhalation powder) for the long-term, twice-daily, maintenance treatment of asthma in patients 12 years and older. Three clinical trials evaluated the efficacy of Advair Diskus in its available strengths. A placebo-controlled, 12-week, U.S. study compared Advair Diskus 100/50 with its individual components, fluticasone propionate 100 μ g and salmeterol 50 μ g. Patients receiving Advair Diskus 100/50

had significantly greater improvements in forced expiratory volume in 1 second (FEV₁) (0.51 L, 25%), compared with fluticasone propionate (0.28 L, 15%), salmeterol (0.11 L, 5%), and placebo (0.01 L, 1%). A second, similar U.S. study (N = 349) of Advair Diskus 250/50 yielded comparable results. In the third trial, a 28-week, non-U.S. study, Advair Diskus 500/50 was compared with fluticasone propionate 500 μ g alone and with concurrent therapy (salmeterol 50 μ g) in 503 patients using inhaled corticosteroids. Morning peak expiratory flow (PEF) was collected daily for the first 12 weeks of the study. (Safety data was collected during weeks 13 to 28.) Morning PEF improved significantly (~16%) with Advair Diskus 500/50, compared with fluticasone propionate 500 μ g (~6%). Advair Diskus is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required, and it should not be used for transferring patients from systemic corticosteroid therapy. Adverse effects with Advair Diskus may include upper respiratory tract infection, sore throat, bronchitis, and headache. The recommended dosage is 1 inhalation twice daily.

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