Drugs recently approved or pending approval

ADVAIR DISKUS

GlaxoSmithKline (Research Triangle Park, NC) has received approval from the US Food and Drug Administration (FDA) to market Advair Diskus 250/50 (fluticasone propionate/salmeterol) for the treatment of chronic obstructive pulmonary disease (COPD) associated with chronic bronchitis. This is the first product containing an anti-inflammatory and a long-acting bronchodilator that has been approved for this condition. In a randomized, double-blind, parallel-group, 24-week trial, improvements in lung function (predose and postdose forced expiratory volume in 1 second) were significantly greater with Advair Diskus 250/50 than with fluticasone propionate 250 μg, salmeterol 50 μg, or placebo. Patients treated with Advair Diskus 250/50 did not have a significant reduction in chronic bronchitis symptoms (as measured by the Chronic Bronchitis Symptom Questionnaire) or in COPD exacerbations compared with patients treated with placebo over the 24 weeks of therapy. Advair Diskus 500/50 is not recommended for use in COPD. The most common adverse effects associated with Advair Diskus 250/50 were headache, candidiasis of the mouth/throat, musculoskeletal pain, and throat irritation. Advair Diskus 250/50 is indicated for the twice-daily maintenance treatment of airflow obstruction in patients with COPD associated with chronic bronchitis. Advair Diskus was previously approved for the maintenance treatment of asthma.

CIALIS

The FDA has given Eli Lilly and Company (Indianapolis, IN) approval to market Cialis (tadalafil) for the treatment of erectile dysfunction. Cialis was evaluated in 22 clinical trials of up to 24 weeks' duration involving over 4000 patients; in some trials, patients had multiple comorbid conditions (ie, diabetes mellitus, hypertension, cardiovascular disease). Primary outcome measures were the Erectile Function domain of the International Index of Erectile Function and questions 2 and 3 from the Sexual Encounter Profile. In most trials, Cialis showed clinically meaningful and statistically significant improvements in all 3 primary efficacy endpoints. In all trials, Cialis improved the ability for patients to achieve and maintain a penile erection. Sexual activity was improved in some patients at 30 minutes after taking Cialis. The most common adverse effects associated with Cialis were headache, indigestion, back pain, muscle aches, flushing, and stuffy or runny nose. Cialis should not be taken with nitrates or alpha blockers (except Flomax [tamsulosin HCl] 0.4 mg). The recommended dose of Cialis is 10 mg taken prior to anticipated sexual activity, and it should not be used more than once per day. Based on individual efficacy and tolerability, the dose may be increased to 20 mg or decreased to 5 mg. Cialis is not recommended in patients who have suffered a heart attack or stroke within the past 6 months or in patients who have significantly low blood pressure, uncontrolled high blood pressure, unstable angina, severe liver impairment, or retinitis pigmentosa.

PLENAXIS

Praecis Pharmaceuticals, Inc., of Waltham, MA, announced that the FDA has given approval to market Plenaxis (abarelix). Plenaxis is indicated for the palliative treatment of men with advanced symptomatic prostate cancer, in whom luteinizing hormone–releasing hormone agonist therapy is not appropriate and who refuse surgical castration, and have 1 or more of the following: (1) risk of neurologic compromise due to metastases, (2) ureteral or bladder outlet obstruction due to local encroachment or metastatic disease, or (3) severe bone pain from skeletal metastases persisting on narcotic analgesia. Plenaxis was evaluated in an open-label, multicenter, uncontrolled, single-arm study involving 81 men with advanced symptomatic prostate cancer who were at risk for clinical exacerbation if treated with a luteinizing hormone–releasing hormone agonist. Of the 81 patients, 9 were excluded. The primary endpoint was avoidance of orchiectomy at 4 and 12 weeks of treatment. Plenaxis 100 mg was administered intramuscularly on days 1, 15, and 29, and then 4 weeks thereafter. Upon study completion, none of the 72 patients required orchiectomy while being treated with Plenaxis. The most common adverse effects associated with Plenaxis were hot flushes, sleep disturbance, pain, breast enlargement, breast pain/nipple tenderness, back pain, and constipation. Because of increased risk of potentially life-threatening allergic reactions, the distribution of Plenaxis is restricted to physicians and hospital pharmacies enrolled in a voluntary risk management program implemented by Praecis.

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