Drugs recently approved or pending approval

ACTONEL

The US Food and Drug Administration (FDA) has given approval to Sanofi-Aventis US LLC (Bridgewater, NJ) to market Actonel (risedronate sodium tablets) for treatment to increase bone mass in men with osteoporosis. Actonel 35 mg once weekly was evaluated in a 2-year, double-blind, placebo-controlled, multicenter study involving 285 men with osteoporosis (mean age, 60.6 years; range, 36–84 years). All patients had either a bone mineral density (BMD) T-score of –2 or lower at the femoral neck and of –1 or lower at the lumbar spine or a BMD T-score of –1 or lower at the femoral neck and of –2.5 or lower at the lumbar spine. Mean lumbar spine and femoral neck T-scores at baseline were –3.21 and –2.38, respectively. Patients also received supplemental calcium (1000 mg/day) and vitamin D (400–500 IU/day). Compared with placebo, Actonel led to significant mean increases in BMD, with a 4.5% treatment difference in the lumbar spine, 1.1% in the femoral neck, 2.2% in the trochanter, and 1.5% in the total proximal femur. The most common adverse effects associated with Actonel were constipation, back pain, arthralgia, influenza, and nasopharyngitis. The recommended dose of Actonel for men with osteoporosis is 35 mg/wk orally. Actonel is also approved for the treatment and prevention of osteoporosis in postmenopausal women, for glucocorticoid-induced osteoporosis in men and women who are either initiating or continuing systemic glucocorticoid treatment for chronic diseases, and for the treatment of Paget's disease of bone in men and women.

HUMIRA

The FDA has given approval to Abbott Laboratories (North Chicago, IL) to market Humira (adalimumab) for reducing signs and symptoms in patients with active ankylosing spondylitis (AS). The safety and efficacy of Humira 40 mg every other week was evaluated in a randomized, 24-week, double-blind, placebo-controlled trial (N = 315). Active AS was defined as the presence of 2 of the following criteria: (1) a Bath AS Disease Activity Index score of at least 4 cm, (2) a Visual Analog Score for total back pain of at least 40 mm, and (3) morning stiffness of at least 1 hour. After completing the blinded period, patients received 40 mg of Humira every other week for up to an additional 28 weeks. Improvement in disease activity measures were observed at week 2 and were maintained through week 24. At 12 weeks, Assessment in AS 20/50/70 responses were achieved by 58%, 38%, and 23% of Humira-treated patients, respectively, compared with 21%, 10%, and 4% of placebo-treated patients ($P < 0.001$). Twenty-two percent of Humira-treated patients achieved a low level of disease activity at 24 weeks compared with 6% of placebo-treated patients. A second randomized, multicenter, double-blind, placebo-controlled trial of 82 AS patients had similar results. The most common adverse effects were nasopharyngitis, injection site reactions, and headache.

PLAVIX

Sanofi-Aventis (Bridgewater, NJ) and Bristol-Myers Squibb Company (Princeton, NJ) have been given FDA approval to market Plavix (clopidogrel bisulfate tablets) to reduce the rate of death from any cause and the rate of a combined endpoint of reinfarction, stroke, or death in patients with acute ST-segment elevation myocardial infarction (STEMI). Plavix was evaluated in 2 clinical trials: ClOpidogrel and Metoprolol in Myocardial Infarction Trial (COMMIT/CCS-2), a randomized, double-blind, placebo-controlled, 2 × 2 factorial design trial (N = 45,852); and CLopidogrel as Adjunctive Reperfusion TherapY–Thrombolysis In Myocardial Infarction Study 28 (CLARITY-TIMI 28), a randomized, double-blind, placebo-controlled trial (N = 3491). In COMMIT, patients were randomized to Plavix (75 mg/day) or placebo in combination with aspirin (162 mg/day) for 28 days or until hospital discharge. Primary endpoints were death from any cause and the first occurrence of reinfarction, stroke, or death. Plavix significantly reduced the relative risk of death from any cause by 7% and the relative risk of the combination of reinfarction, stroke, or death by 9%. In CLARITY, patients were randomized to Plavix (loading dose of 300 mg and 75 mg/day thereafter) or placebo in combination with aspirin (150–325-mg loading dose and 75–162 mg/day thereafter), a fibrinolytic agent, and heparin for 48 hours (when appropriate) until angioplasty, discharge, or day 8. The primary endpoint was occurrence of occluded infarct-related artery on the predischarge angiogram or death or recurrent myocardial infarction by the start of coronary angiography. The primary endpoint occurred in 262 Plavix-treated patients compared with 377 placebo-treated patients. The rates of major bleeding and intracranial hemorrhage were similar in both Plavix and placebo arms of the COMMIT and CLARITY trials.

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.*