Drugs recently approved or pending approval

ABILIFY

The US Food and Drug Administration (FDA) granted approval to Bristol-Myers Squibb Co of Princeton, NJ, and Otsuka America Pharmaceutical, Inc, of Rockville, MD, to comarket Abilify (aripiprazole) for the treatment of schizophrenia. In 3 clinical studies involving 1238 patients, Abilify was statistically superior to placebo in improving the symptoms of schizophrenia as evaluated by scores on the Positive and Negative Syndrome Scale (PANSS), the PANSS positive subscale, the PANSS negative subscale, and the Clinical Global Impression (CGI) of severity assessment. In a 4-week trial (n = 414) comparing 2 fixed doses of Abilify (15 or 30 mg daily) and haloperidol (10 mg daily) to placebo, both doses of Abilify were superior to placebo in the PANSS total score, PANSS positive subscale, and CGI of severity score. In addition, the 15-mg dose was superior to placebo in the PANSS negative subscale. In another 4-week trial (n = 404) comparing 2 fixed doses of Abilify (20 or 30 mg daily) and risperidone (6 mg daily) to placebo, both doses of Abilify were superior to placebo on all 4 primary measures. The most commonly reported adverse effects of Abilify in short-term clinical trials were headache, anxiety, and insomnia. The recommended starting and target dose for Abilify is 10 or 15 mg daily administered orally on a once-daily schedule, with or without food.

FORTEO

Eli Lilly and Co (Indianapolis, IN) received approval from the FDA to market Forteo (teriparatide [rDNA origin] injection) for the treatment of osteoporosis in postmenopausal women who are at high risk for fracture. Forteo is also indicated to increase bone mass in men with primary hypogonadal osteoporosis who are at high risk for fracture. The safety and efficacy of once-daily Forteo (20 µg) was examined over a median of 19 months in a double-blind, placebo-controlled study of 1637 postmenopausal women with osteoporosis. Data revealed that Forteo reduced the relative risk for new vertebral fractures by 65% (9.3% absolute risk reduction) and the relative risk for new nonvertebral fractures by 53% (2.9% absolute risk reduction), compared with placebo. Additionally, Forteo significantly increased lumbar spine bone mineral density (BMD) in postmenopausal women with osteoporosis, beginning at 3 months of treatment. In a separate study, 94% of men with idiopathic or hypogonadal osteoporosis who took Forteo had an increase in their spine BMD. Forteo should not be prescribed to pediatric patients or to patients with conditions causing an increased baseline risk for osteosarcoma. Reported adverse effects apparently increased by Forteo include dizziness and leg cramps. Forteo should be administered subcutaneously (sc) at a dose of 20 µg once daily.

HUMIRA

The FDA has approved marketing of Humira (adalimumab) by Abbott Laboratories (Abbott Park, IL) for reducing signs and symptoms and inhibiting progression of structural damage in adults with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response to 1 or more disease-modifying antirheumatic drugs (DMARDs). Humira was evaluated in 4 randomized, double-blind studies in adults with active RA diagnosed according to American College of Rheumatology (ACR) criteria. Humira was administered sc in combination with methotrexate (MTX) (12.5–25.0 mg, studies I and III) or as monotherapy (study II) or with other DMARDs (study IV). Study I evaluated 271 patients who failed therapy with at least 1 but no more than 4 DMARDs and had inadequate response to MTX alone. Doses of placebo or Humira 20, 40, or 80 mg were given every other week for 24 weeks. Study II evaluated 544 patients who had failed therapy with at least 1 DMARD. Doses of placebo or Humira 20 or 40 mg were given as monotherapy every other week or weekly for 26 weeks. In study I, patients treated with Humira 40 mg achieved ACR 20, 50, and 70 response rates of 65%, 52%, and 24%, respectively, compared with placebo responses of 13%, 7%, and 3%, respectively, at 6 months. In study II, patients treated every other week with Humira 40 mg achieved ACR 20, 50, and 70 response rates of 46%, 22%, and 12%, respectively, compared with placebo responses of 19%, 8%, and 2%, respectively, at 6 months. Humira is contraindicated in patients who have or develop active infections. The most frequent adverse effects of Humira are upper respiratory infection, injection site pain, headache, rash, and sinusitis. The recommended dose of Humira for adults with RA is 40 mg administered sc every other week.

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