Drugs recently approved or pending approval

MOBIC

The United States Food and Drug Administration approved marketing of MOBIC (meloxicam) by Boehringer Ingelheim Pharmaceuticals (Ridgefield, CT) for relief of the signs and symptoms of osteoarthritis. Drug efficacy was evaluated in several double-blind, active-controlled studies. In one study, patients with signs and symptoms of osteoarthritis of the knee and hip (n = 464) received placebo or MOBIC (3.75 mg, 7.5 mg, or 15 mg daily) for 12 weeks. The study's primary endpoints were investigator's global assessment, patient global assessment, patient pain assessment, and total WOMAC score (a self-administered questionnaire assessing pain, function and stiffness). Patients in the 7.5-mg and 15-mg MOBIC arms showed significant improvement in all endpoints compared with the placebo arm. Potential adverse events associated with MOBIC include headache, diarrhea, influenza-like symptoms, dyspepsia, and edema. The recommended dose of MOBIC is 7.5 mg/day.

ZYVOX

Pharmacia and Upjohn (Kalamazoo, MI) received approval to market Zyvox (linezolid). Zyvox is indicated for treatment of the following infections caused by susceptible strains of the designated microorganisms: vancomycin-resistant *Enterococcus faecium* infections; nosocomial pneumonia caused by methicillin-susceptible and methicillin-resistant *Staphylococcus aureus* or penicillin-susceptible *Streptococcus pneumoniae;* complicated skin and skin structure infections caused by *S. aureus* (methicillin-susceptible and methicillin-resistant strains), *Streptococcus pyogenes*, or *Streptococcus agalactiae;* uncomplicated skin and skin structure infections caused by *S. aureus* (methicillin-susceptible strains) or *S. pyogenes;* and community-acquired pneumonia caused by penicillin-susceptible *S. pneumoniae* or methicillin-susceptible *S. aureus.* Drug efficacy for treatment of vancomycin-resistant enterococcal infections was evaluated in a randomized, multicenter, double-blind trial. Patients with documented or suspected vancomycin-resistant enterococcal infection were randomized to intravenous (IV) or oral Zyvox 600 mg (n = 79) or 200 mg (n = 66) every 12 hours for 7 to 28 days. Of the evaluable patients, the cure rate for infection at any site was 67% in the 600-mg arm compared with 52% in the 200-mg arm. Drug efficacy in the treatment of nosocomial pneumonia was evaluated in a randomized, multicenter, double-blind trial. Patients with clinically and radiologically documented nosocomial pneumonia were randomized to IV Zyvox 600 mg (n = 203) or IV vancomycin 1 g (n = 193) every 12 hours for 7 to 21 days. The cure rates in the clinically evaluable patients were 57% for the Zyvox arm compared with 60% for the vancomycin arm. Drug efficacy in the treatment of complicated skin and skin structure infections was evaluated in a randomized, multicenter, double-blind, double-dummy trial. Patients with clinically documented skin and skin structure infections were randomized to IV Zyvox 600 mg every 12 hours followed by Zyvox tablets 600 mg every 12 hours (n = 400) or IV oxacillin 2 g every 6 hours followed by oral dicloxacillin 500 mg every 6 hours (n = 419). The cure rates in the clinically evaluable patients were 90% in the Zyvox arm compared with 85% in the oxacillin arm. Potential adverse reactions associated with Zyvox include diarrhea, headache, and nausea. The recommended dosage depends on the type of infection.

ACTONEL

The Food and Drug Administration approved marketing of Actonel (risedronate sodium tablets) by Procter and Gamble Pharmaceuticals (Cincinnati, OH) and Aventis Pharmaceuticals (Kansas City, MO) for the treatment and prevention of osteoporosis in postmenopausal women. Fracture efficacy in the treatment of postmenopausal osteoporosis was measured in two randomized, placebo-controlled, double-blind studies. In one study, patients with radiographic evidence of previous vertebral fracture were randomized to Actonel 5 mg/day (n = 696) or placebo (n = 678); spinal radiographs were performed annually for 3 years. The study's primary endpoint was the incidence of new and worsening vertebral fractures. The incidence of new and worsening vertebral fractures at 3 years was 13.9% in the Actonel arm compared with 18.5% in the placebo arm. Actonel is contraindicated in patients who have hypocalcemia or are unable to stand or sit upright for at least 30 minutes. Adverse events associated with Actonel include infection, back pain, and arthralgia. The recommended dose for treatment and prevention of postmenopausal osteoporosis is 5 mg/day taken at least 30 minutes before the first meal of the day.

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