Drugs recently approved or pending approval

DEPODUR

The US Food and Drug Administration (FDA) has granted approval to SkyePharma Inc. (San Diego, CA) and Endo Pharmaceuticals Inc. (Chadds Ford, PA) to market DepoDur (morphine sulfate extended-release liposome injection) for the treatment of pain following major surgery. The efficacy of DepoDur was evaluated in 4 clinical trials: 2 trials in patients undergoing hip arthroplasty (N = 314), 1 trial of patients undergoing lower abdominal surgery (N = 487), and 1 trial of patients undergoing elective cesarean section under intrathecal analgesia (N = 75). In the hip arthroplasty studies, single epidural administration of DepoDur 15, 20, and 25 mg provided similar analgesic efficacy compared with placebo (epidural saline injection followed by intravenous fentanyl patient-controlled analgesia) as measured by decreased fentanyl use and visual analog scores. In the lower abdominal surgery study, a dose response was observed using 10, 15, 20, and 25 mg of DepoDur as compared with 5 mg DepoDur or 5 mg morphine sulfate, demonstrating a reduction in intravenous fentanyl use over a 48-hour period. In the cesarean section study, DepoDur doses of 10 and 15 mg resulted in reduced use of rescue medication and improved postoperative analgesia based on area under the curve analysis of visual analog scores at rest and with activity compared with average morphine sulfate use over a 48-hour period. The most common adverse effects associated with DepoDur were decreased oxygen saturation, hypotension, urinary retention, vomiting, constipation, nausea, pruritus, anemia, headache, and dizziness. Recommended doses of DepoDur in major orthopaedic surgery of the lower extremity, lower abdominal surgery, and cesarean section are 15 mg, 10 to 15 mg, and 10 mg, respectively.

MENOSTAR

Berlex (Montville, NJ) was given approval by the FDA to market Menostar (estradiol transdermal system) for the prevention of postmenopausal osteoporosis. Menostar was evaluated in a 2-year, double-blind, placebo-controlled, multicenter study involving postmenopausal women (N = 417) aged 60 to 80 years with an intact uterus. All participants were given supplemental calcium and vitamin D. Menostar produced greater increases in bone mass than placebo, as measured by dual-energy x-ray absorptiometric scan of hip and lumbar spine bone mineral density (BMD). Changes in hip and spine BMD from baseline were statistically significantly greater during Menostar therapy as compared with placebo after 1 and 2 years ($P < 0.001$). Overall, estimated treatment effects on total hip and lumbar spine BMD after 2 years were approximately twice as large in the subgroup with baseline estradiol levels less than 5 pg/mL than in the subgroup with baseline estradiol levels of at least 5 pg/mL. Menostar therapy also resulted in consistent, statistically significant suppression of bone turnover, as reflected by changes in serum and urine markers of bone formation and resorption. The most common adverse effects observed with Menostar were application site reaction, joint pain, and leukorrhea. Menostar should not be used in women with abnormal genital bleeding, breast cancer, estrogen-dependent neoplasia, active deep vein thrombosis or pulmonary embolism, active or recent arterial thromboembolic disease, liver dysfunction or disease, or pregnancy.

PREVACID I.V.

The FDA has given approval to TAP Pharmaceutical Products Inc. (Lake Forest, IL) to market Prevacid I.V. (lansoprazole) for Injection as an alternative for the short-term treatment (up to 7 days) of all grades of erosive esophagitis. Prevacid I.V. was evaluated in a multicenter, double-blind, 2-period, placebo-controlled, pharmacodynamic study. Participants received 30-mg oral Prevacid for 7 days in period 1, and then were immediately switched to receive either 30-mg Prevacid I.V. or placebo (intravenous normal saline) for 7 days in period 2. Maximum acid output and basal acid output were determined 21 hours after the last doses of oral and intravenous administration. The oral and intravenous dosage forms of Prevacid were similar in their ability to suppress maximum acid output and basal acid output. Also, patients treated with oral Prevacid who were switched to placebo experienced a significant increase in acid output within 48 hours of their last oral dose. The most common adverse effects associated with Prevacid I.V. administration were headache, injection site pain, injection site reaction, and nausea. Treatment with Prevacid I.V. should be discontinued as soon as the patient is able to resume treatment with oral formulations.

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.*