Drugs recently approved or pending approval

EVITHROM

The US Food and Drug Administration (FDA) has given approval to Ethicon, Inc. (Somerville, NJ) to market Evithrom (human thrombin) as a topical aid to help control oozing and minor bleeding from capillaries and small venules during surgery. Evithrom was evaluated in a phase 3, prospective, randomized, controlled, double-blind study in 305 patients at 22 centers in the United States. Patients undergoing elective cardiovascular, neurologic, or general surgical procedures had either Evithrom (n = 153) or bovine thrombin (n = 152) applied when there was oozing or bleeding of mild intensity that could not be controlled by other surgical techniques. The primary efficacy endpoint was hemostasis within 10 minutes of product application, and the secondary efficacy endpoints were hemostasis within 6 and 3 minutes of product application. In both study groups, more than 90% of patients from all surgeries achieved hemostasis at the 6-minute and 10-minute time points, and more than 70% of patients achieved hemostasis at the 3-minute time point. The most common adverse effects associated with Evithrom were procedural complications and pruritus.

RECLAST

Novaritis Pharmaceuticals Corporation (East Hanover, NJ) has been given FDA approval to market Reclast (zoledronic acid) injection for the once-yearly treatment of osteoporosis in postmenopausal women. Reclast was evaluated in a randomized, double-blind, placebo-controlled, multinational study involving 7736 women aged 65 to 89 years with a femoral neck bone mineral density (BMD) T-score of –1.5 or less and at least 2 mild or 1 moderate existing vertebral fracture(s); or a femoral neck BMD T-score of –2.5 or less with or without evidence of an existing vertebral fracture(s). Women were stratified into 2 groups: no concomitant use of osteoporosis therapy (n = 5661); and baseline concomitant use of osteoporosis therapies (n = 2075), including calcitonin, raloxifene, tamoxifen, or hormone therapy. Reclast was administered once a year for 3 consecutive years as a single 5-mg dose (3 doses total) in a 100 mL solution infused over 15 minutes or more. Patients also received 1000 to 1500 mg of elemental calcium plus 400 to 1200 IU of vitamin D supplementation daily. The 2 primary efficacy endpoints were the incidence of morphometric vertebral fractures at 3 years and the incidence of hip fractures over a median duration of 3 years. Reclast significantly decreased the incidence of morphometric vertebral fractures over 3 years (60% in year 1, 71% in year 2, 70% in year 3; $P < 0.0001$). Reclast also reduced the risk of hip fractures by 41%, with an event rate of 1.4% versus 2.5% for placebo. The most common adverse effects in patients treated with Reclast were pyrexia, influenza-like illness, chills, headache, bone pain, and nausea.

RISPERDAL

The FDA has given approval to Janssen LP (Titusville, NJ) to market Risperdal (risperidone) for the treatment of schizophrenia in adolescents aged 13 to 17 years and for the short-term treatment of bipolar mania associated with manic or mixed episodes of bipolar I disorder in children and adolescents aged 10 to 17 years. The efficacy of Risperdal was evaluated in 2 short-term (6 and 8 wk), randomized, double-blind, placebo-controlled trials of adolescents aged 13 to 17 years who met DSM-IV criteria for schizophrenia (study 1 and study 2) and a 3-week, multicenter, randomized, double-blind, placebo-controlled trial of patients aged 10 to 17 years who were experiencing a manic or mixed episode of bipolar I disorder (study 3). In study 1, patients received either Risperdal 1 to 3 mg/day, Risperdal 4 to 6 mg/day, or placebo. In study 2, patients received either Risperdal 0.15 to 0.6 mg/day or Risperdal 1.5 to 6 mg/day. In studies 1 and 2, study medication was initiated at a low dose, titrated to the target dose range by day 7, and then increased to the maximum tolerated dose within the target dose range by day 14. The primary efficacy measure in both studies was the mean change from baseline in total Positive and Negative Syndrome Scale (PANSS) score. Risperdal-treated patients in all dose groups from 1 to 6 mg/day demonstrated a significant reduction in total PANSS score as compared with placebo-treated patients. In study 3, patients received Risperdal 0.5 to 2.5 mg/day, Risperdal 3 to 6 mg/day, or placebo. Study medication was initiated at 0.5 mg/day, titrated to the target dose range by day 7, and then increased to the maximum tolerated dose range by day 10. The primary efficacy measure was the mean change from baseline in the total Young Mania Rating Scale (YMRS). Risperdal-treated patients with both dose groups demonstrated a significant reduction in total YMRS score as compared with placebo-treated patients. The most common adverse effects in all studies were somnolence, increased appetite, fatigue, and rhinitis.

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