Drugs recently approved or pending approval

AZOR

The US Food and Drug Administration (FDA) has given approval to Daiichi Sankyo, Inc. (Parsippany, NJ) to market Azor (amlodipine and olmesartan medoxomil) tablets for the treatment of hypertension. Once-daily Azor was evaluated in an 8-week multicenter, randomized, double-blind, placebo-controlled, parallel group factorial study involving 1940 patients. Patients were randomized equally to 1 of the following 12 treatment arms: placebo; amlodipine monotherapy 5 mg or 10 mg; olmesartan medoxomil monotherapy 10 mg, 20 mg, or 40 mg; or Azor 5/10 mg, 5/20 mg, 5/40 mg, 10/10 mg, 10/20 mg, and 10/40 mg. Patients treated with Azor 10/40 mg experienced a mean reduction in seated systolic and diastolic blood pressure of 30 mm Hg and 19 mm Hg, respectively, as compared with reductions of 20 mm Hg and 13 mm Hg in patients treated with amlodipine 10 mg monotherapy. Mean reductions in seated systolic and diastolic blood pressure in placebo-treated patients were 5 mm Hg and 3 mm Hg, respectively. Azor had a similar antihypertensive effect in patients with and without prior antihypertensive medication use, in patients with and without diabetes, in patients aged 65 years and older and those younger than 65 years, and in women and men. In black patients (usually a low-renin population) who received Azor, the magnitude of blood pressure reduction approached that observed in non-black patients. Upon completing the study, 1684 patients entered a 44-week open-label extension and received Azor 5/40 mg. During the open-label extension, patients whose blood pressure did not decrease to less than 140/90 mm Hg (or < 130/80 mm Hg for patients with diabetes) on Azor 5/40 mg were titrated to Azor 10/40 mg. The most common adverse effects associated with Azor were edema, headache, and dizziness. Azor may be administered with other antihypertensive agents, and the maximum recommended dose of Azor is 10/40 mg.

EVISTA

Eli Lilly and Company (Indianapolis, IN) has been given FDA approval to market Evista (raloxifene HCl) as an approach to reducing the risk of invasive breast cancer in postmenopausal women with osteoporosis and in postmenopausal women at high risk for invasive breast cancer. Evista was evaluated in 2 trials of postmenopausal women with osteoporosis (MORE and CORE trials) and in 1 trial of postmenopausal women at high risk for invasive breast cancer (STAR trial). The MORE trial was a 4-year randomized, placebo-controlled, double-blind, multinational osteoporosis treatment trial. Patients in the MORE trial were randomized to either Evista 60 mg once daily or placebo. The CORE trial was a 4-year follow-up study conducted in a subset of postmenopausal women originally enrolled in the MORE trial. The treatment assignment from the MORE trial was carried forward to the CORE trial. In the MORE trial, Evista reduced the incidence of invasive breast cancer by 71% as compared with placebo (absolute risk reduction, 3.1/1000 women-years); in CORE, Evista reduced the incidence of invasive breast cancer by 56% as compared with placebo (absolute risk reduction, 3.0/1000 women-years). The STAR trial was a randomized, double-blind trial involving 19,747 postmenopausal women. Patients were allocated to Evista 60 mg/day or tamoxifen 20 mg/day over 5 years. Incidence rates of invasive breast cancer were similar between Evista- and tamoxifen-treated patients (4.3/1000 versus 4.4/1000 women-years, respectively). The most common adverse effects in patients treated with Evista were hot flashes and leg cramps. The recommended dose of Evista is 60 mg once daily. Evista is also indicated for the treatment and prevention of osteoporosis in postmenopausal women.

TAXOTERE

The FDA has given approval to sanofi-aventis (Bridgewater, NJ) to market Taxotere (docetaxel) to be used in combination with cisplatin and 5-fluorouracil (5-FU) for the treatment of inoperable locally advanced squamous cell carcinoma of the head and neck. The safety and efficacy of Taxotere were evaluated in a multicenter, open-label, randomized trial involving 358 patients with squamous cell carcinoma of the head and neck. Patients were treated every 3 weeks for 4 cycles with Taxotere 75 mg/m^2 plus cisplatin 75 mg/m^2 on day 1 followed by 5-FU 750 mg/m^2/day on days 1 through 5 (TPF) or cisplatin 100 mg/m^2 on day 1 followed by 5-FU 1000 mg/m^2/day on days 1 through 5 (PF). Progression-free survival, the primary endpoint, was significantly longer in the TPF treatment arm as compared with the PF treatment arm (median progression-free survival, 11.4 versus 8.3 mo, respectively; $P = 0.0077$). Additionally, TPF-treated patients had a significantly longer median overall survival compared with PF-treated patients (18.6 versus 14.2 mo; $P = 0.0055$). The most common adverse effects were neutropenia, neutropenic infection, dizziness, alopecia, and diarrhea.

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