Drugs recently approved or pending approval

DIOVAN

The US Food and Drug Administration (FDA) has given approval to Novartis Pharmaceuticals Corporation (East Hanover, NJ) to market Diovan (valsartan) tablets for the treatment of hypertension in children and adolescents aged 6 to 16 years. The effectiveness of Diovan was established in 2 randomized, double-blind clinical studies involving 261 hypertensive pediatric patients. Patients who weighed less than 35 kg received 10, 40, or 80 mg of Diovan daily, and patients who weighted 35 kg or more received 20, 80, or 160 mg of Diovan daily. After 2 weeks, Diovan reduced both systolic and diastolic blood pressure in all subgroups in a dose-dependent manner. Low, medium, and high doses of Diovan significantly reduced systolic blood pressure by 8, 10, and 12 mm Hg from baseline, respectively. Patients were re-randomized to continue receiving the same dose of Diovan or switched to placebo. Patients who received medium and high doses of Diovan had systolic blood pressure at trough 4 and 7 mm Hg lower than patients who received placebo. Systolic blood pressure at trough in patients receiving the low dose of Diovan was comparable with that of patients receiving placebo. The most common adverse effects associated with Diovan were headache, dizziness, upper respiratory infection, cough, diarrhea, and rhinitis. The recommended starting dose of Diovan is 1.3 mg/kg once daily for children (age, 6–16 yr) who can swallow tablets. Diovan is also indicated for the treatment of adult hypertension, heart failure, and postmyocardial infarction.

MIRCERA

Hoffmann-La Roche Inc. (Nutley, NJ) has been given FDA approval to market Mircera (methoxy polyethylene glycol-epoetin beta) for the treatment of anemia associated with chronic renal failure (CRF) in adults, regardless of whether patients are undergoing dialysis. The efficacy and safety of Mircera were evaluated in 6 open-label, multicenter clinical studies (2 studies of patients not treated with an erythropoiesis-stimulating agent [ESA; studies 1 and 2] and 4 studies of patients receiving an ESA [studies 3–6]) involving 2299 anemic patients with CRF. All included patients were clinically stable at baseline and without evidence of infection or inflammation as determined by history and laboratory data, including C-reactive protein. Patients who were not receiving dialysis in study 1 (N = 324) were randomized to Mircera (0.6 µg/kg subcutaneously [SC] once every 2 wk) or darbepoetin alfa (0.45 µg/kg SC once weekly) for 28 weeks, and patients in study 2 on dialysis (N = 181) were allocated to Mircera (0.4 µg/kg intravenously [IV] once every 2 wk) or another ESA (at recommended dose IV 3 times/wk) for 24 weeks. In studies 1 and 2, Mircera was as effective as the other agents in treating anemia by achieving target hemoglobin levels (≥ 11 g/dL). In studies 3 to 6, patients (N = 1794) were randomized to receive Mircera (once every 2 or 4 wk) or to continue their current ESA dose and schedule. Mircera-treated patients maintained hemoglobin concentrations within the targeted range (10–13.5 g/dL). The most common adverse effects in patients treated with Mircera were hypertension, diarrhea, nasopharyngitis, headache, and upper respiratory tract infection.

TASIGNA

The FDA has given approval to Novartis Pharmaceuticals Corporation (East Hanover, NJ) to market Tasigna (nilotinib) for the treatment of chronic phase (CP) and accelerated phase (AP) Philadelphia chromosome–positive chronic myelogenous leukemia (CML) in adult patients resistant or intolerant to imatinib. The safety and efficacy of Tasigna were evaluated in an open-label multicenter study involving 385 patients with CP-CML and AP-CML. The median highest prior doses of imatinib for CML-CP and CML-AP patients were 600 and 800 mg/day, respectively. The median time of prior imatinib treatment was approximately 31 months, and the median duration of Tasigna treatment was 8.7 and 5.6 months in CML-CP and CML-AP patients, respectively. The primary endpoint for CML-CP patients was unconfirmed major cytogenetic response, and the primary endpoint for CML-AP patients was confirmed hematologic response. After a minimum follow-up of 6 months, 40% of CML-CP patients (n = 232) had a major cytogenetic response. Complete hematologic response was achieved in 18% of CML-AP patients after a minimum follow-up of 4 months. The most common adverse effects in patients treated with Tasigna were rash, pruritis, nausea, fatigue, headache, constipation, diarrhea, and vomiting. The recommended dose of Tasigna is 400 mg orally twice daily.

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.*