Drugs recently approved or pending approval

ALIMTA

The US Food and Drug Administration (FDA) has given approval to Eli Lilly and Company (Indianapolis, IN) to market Alimta (pemetrexed disodium) injection to be used in combination with cisplatin therapy for the initial treatment of patients with locally advanced or metastatic nonsquamous non–small cell lung cancer (NSCLC). Alimta was evaluated in a multicenter, randomized, open-label study involving 1725 chemonaive patients with stage IIIb/IV NSCLC. Patients received up to 6 cycles of either Alimta 500 mg/m^2 intravenously (IV) over 10 min or gemcitabine 1250 mg/m^2 on days 1 and 8; both drugs were given in combination with cisplatin 75 mg/m^2 IV after Alimta/gemcitabine administration on day 1 of each 21-day cycle. All patients received a median of 5 cycles of treatment and were given folic acid, vitamin B_{12}, and dexamethasone. The primary endpoint was overall survival (OS). The median OS was 10.3 months for both treatment arms (adjusted hazard ratio [HR], 0.94 [95% confidence interval {CI}, 0.84–1.05]). Median progression-free survival was 4.8 and 5.1 months for Alimta plus cisplatin and gemcitabine plus cisplatin arms, respectively (adjusted HR, 1.04 [95% CI, 0.94–1.15]). Overall response rates were similar between the 2 arms (27.1% for Alimta/cisplatin and 24.7% for gemcitabine/cisplatin). In a prespecified analysis of the impact of NSCLC histology on OS, patients with nonsquamous NSCLC had a median OS of 11.0 months when treated with Alimta plus cisplatin versus 10.1 months with gemcitabine plus cisplatin (adjusted HR, 0.84 [95% CI, 0.74–0.96]). The most common adverse effects were vomiting, neutropenia, and leukopenia.

KOGENATE FS

FDA approval was granted to Bayer HealthCare LLC (Tarrytown, NY) to market Kogenate FS (antihemophilic factor [recombinant] formulated with sucrose) as routine prophylaxis for reducing the frequency of bleeding episodes and the risk of joint damage in children with no preexisting joint damage. Kogenate FS was evaluated in a multicenter, open-label, prospective, randomized controlled study involving 65 boys (age, < 30 mo) with severe hemophilia A and with 2 or fewer bleeds into each index joint (ie, ankles, knees, or elbows) and normal baseline joint imaging. Patients received either Kogenate FS 25 IU/kg IV every other day as primary prophylaxis (n = 32) or at least 3 doses of enhanced episodic therapy totaling a minimum of 80 IU/kg at the time of a bleeding episode (n = 33) and were observed for up to 5.5 years. Joint damage (defined as bone and/or cartilage damage including subchondral cysts, erosions, and cartilage loss with narrowing of joint space) was evaluated by magnetic resonance imaging (MRI) or radiography as well as by the frequency of bleeding episodes. The incidence of joint damage assessed by MRI or radiography in the index joints was statistically significantly lower for patients receiving Kogenate FS as compared with patients receiving episodic therapy (7% versus 42%; $P = 0.002$); however, there was no statistically significant difference between the 2 groups when joint damage was assessed by radiography alone. The mean rate of index joint hemorrhages for patients on episodic therapy was 4.89 bleeds per year as compared with 0.63 bleeds per year for patients taking prophylactic Kogenate FS; 10% of patients taking episodic therapy experienced recurrent life-threatening bleeds (intracranial, gastrointestinal) versus 0% of patients taking Kogenate FS. The most common adverse effects were inhibitor formation in previously untreated or minimally treated patients, rash, and pruritus.

REYATAZ

Bristol-Myers Squibb Company (Princeton, NJ) has received FDA approval to market Reyataz (atazanavir sulfate) capsules boosted with ritonavir to be used in combination with other antiretroviral agents for the management of treatment-naive patients with HIV-1 infection. The efficacy and safety of Reyataz/ritonavir was established in a 96-week, open-label, randomized, multicenter study involving 878 treatment-naive HIV-1–infected patients. Patients were given Reyataz (300 mg/day) with ritonavir (100 mg/day) or lopinavir with ritonavir (400/100 mg twice daily), each in combination with fixed-dose tenofovir with emtricitabine (300/200 mg once daily). Through week 48, the proportion of responders among patients with a baseline HIV RNA of 100,000 copies/mL or greater was comparable between the Reyataz/ritonavir and lopinavir/ritonavir groups (74% and 73%). The median increase from baseline in CD4+ cell count was 191 and 200 cells/mm^3 for the Reyataz/ritonavir and lopinavir/ritonavir groups, respectively. The most common adverse effects were nausea, jaundice/scleral icterus, and rash.

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.*