Rx Update

Drugs recently approved or pending approval

ALIMTA

The US Food and Drug Administration (FDA) has granted approval to Eli Lilly and Company (Indianapolis, IN) to market Alimta (pemetrexed for injection) to be used in combination with cisplatin for the treatment of patients with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery. The safety and efficacy of Alimta were evaluated in a multicenter, randomized, single-blind study involving chemonaive patients with malignant pleural mesothelioma (N = 448). Patients were randomized to receive Alimta and cisplatin combination (n = 226) or cisplatin alone (n = 222). Alimta 500 mg/m^2 was administered intravenously over a 10-minute period. Thirty minutes later, cisplatin was administered intravenously at a dose of 75 mg/m^2 over a 2-hour period. Both drugs were given on day 1 of each 21-day cycle. After 112 patients were treated, leukocyte and gastrointestinal toxicity led to supplementation of the remaining patients with folic acid and vitamin B_{12}. The median survival for the Alimta/cisplatin group was 12.1 months (95% confidence interval [CI], 10.0–14.4) compared with 9.3 months with cisplatin alone (95% CI, 7.8–10.7). The most common adverse effects seen with Alimta were neutropenia, thrombocytopenia, anemia, nausea, vomiting, fatigue, diarrhea, skin rash, and pain.

AVASTIN

Genentech, Inc. (San Francisco, CA) was granted approval by the FDA to market Avastin (bevacizumab, rhuMAb-VEGF) to be used in combination with intravenous (IV) 5-fluorouracil (5-FU)–based chemotherapy for first-line treatment of patients with metastatic carcinoma of the colon or rectum. Avastin is an angiogenesis inhibitor. Avastin was evaluated in 2 clinical trials. In the first double-blind, active-controlled clinical trial, patients (N = 923) were randomized to bolus-IFL (irinotecan 125 mg/m^2 IV, 5-FU 500 mg/m^2 IV, and leucovorin [LV] 20 mg/m^2 once weekly for 4 weeks every 6 weeks) plus placebo, or bolus-IFL plus Avastin (5 mg/kg every 2 weeks). A third treatment arm was discontinued once the bolus-IFL regimen was deemed acceptable. Overall survival was prolonged in the IFL/Avastin treatment arm compared with IFL/placebo (20.3 months versus 15.6 months), and progression-free survival was improved in the IFL/Avastin arm compared with IFL/placebo (10.6 months versus 6.4 months). Study 2 was a randomized, active-controlled trial. Patients (N = 104) received 5-FU/LV (5-FU 500 mg/m^2, LV 500 mg/m^2 weekly for 6 weeks every 8 weeks), 5-FU/LV plus Avastin 5 mg/kg every 2 weeks, or 5-FU/LV plus Avastin 10 mg/kg every 2 weeks. Patients were treated until disease progression. Progression-free survival was significantly better in patients receiving 5-FU/LV plus Avastin 5 mg/kg when compared with those not receiving Avastin (9.0 months versus 5.2 months). Overall survival and overall response rate were not significantly different. The most common adverse effects associated with Avastin were asthenia, pain, abdominal pain, headache, hypertension, diarrhea, nausea, vomiting, anorexia, stomatitis, constipation, upper respiratory infection, epistaxis, dyspnea, exfoliative dermatitis, and proteinuria.

MYFORTIC

The FDA has granted approval to Novartis Pharmaceuticals Corporation, of East Hanover, NJ, to market Myfortic (mycophenolic acid), an enteric-coated, delayed-release tablet, to be used in combination with cyclosporine and corticosteroids for the prophylaxis of organ rejection in patients receiving allogeneic renal transplants. Myfortic was assessed in 2 multicenter, randomized, double-blind trials involving de novo and maintenance renal transplant patients. Patients in the de novo study (N = 423) were administered either Myfortic 1.44 g/day or mycophenolate mofetil (MMF) 2 g/day within 48 hours post-transplant for 12 months in combination with cyclosporine and corticosteroids. Treatment failure was defined as the first occurrence of biopsy-proven acute rejection, graft loss, death, or loss to follow-up at 6 months. The incidence of treatment failure was similar in Myfortic- and MMF-treated patients at 6 and 12 months in study 1. The maintenance study involved renal transplant patients (N = 322) who were at least 6 months post-transplant receiving 2 g/day MMF in combination with cyclosporine, with or without corticosteroids, for at least 2 weeks prior to study enrollment. Patients were randomized to Myfortic 1.44 g/day or MMF 2 g/day for 12 months. The incidences of treatment failure at 6 and 12 months were similar in Myfortic- and MMF-treated patients in study 2. The most common adverse effects associated with Myfortic were constipation, nausea, and urinary tract infection in de novo patients, and nausea, diarrhea, and nasopharyngitis in maintenance patients.

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