Drugs recently approved or pending approval

ELOXATIN

The US Food and Drug Administration (FDA) has given approval to Sanofi-Aventis (Paris, France) to market Eloxatin (oxaliplatin for injection) to be used in combination with conventional therapy (infusional 5-fluorouracil/leucovorin [5-FU/LV]) for the adjuvant treatment of patients with stage III colon cancer who have undergone complete resection of the primary tumor. This is the first new chemotherapy approval for the adjuvant treatment of colon cancer in over a decade. Eloxatin was evaluated in an international, multicenter, randomized study of patients with stage II or III colon cancer. Patients were randomized to receive either Eloxatin plus 5-FU/LV therapy (n =1123) or 5-FU/LV alone (n = 1123) and were treated for 6 months. At a median follow-up of 4 years, there was a statistically significant improvement in disease-free survival for the Eloxatin plus 5-FU/LV group as compared with those who were treated with 5-FU/LV alone (76% versus 69%). A statistically significant improvement in disease-free survival was observed in the stage III subgroup patients but was not seen in stage II patients. The most common adverse effects in Eloxatin-treated patients were nausea, diarrhea, vomiting, and fatigue. Eloxatin was previously approved to be used in combination with 5-FU/LV for the treatment of advanced carcinoma of the colon or rectum.

FEMARA

The FDA has given approval to Novartis Oncology (East Hanover, NJ) to market Femara (letrozole tablets) for the extended adjuvant treatment of early breast cancer in postmenopausal women who have received 5 years of adjuvant tamoxifen therapy. Femara was evaluated in a double-blind, randomized, placebo-controlled trial involving over 5100 postmenopausal women who met study requirements. The planned duration of treatment was 5 years, but the trial was terminated early because of an interim analysis showing a favorable Femara effects on time without recurrence or contralateral breast cancer. Women had been followed for a median of 28 months, 30% of patients had completed 3 years or more of follow-up, and less than 1% of patients had completed 5 years of follow-up. The most common adverse effects observed with Femara were hot flashes, arthralgia/arthritis, and myalgia. Femara has been previously approved for the first-line treatment of postmenopausal women with hormone receptor–positive or hormone receptor–unknown locally advanced or metastatic breast cancer and for the treatment of advanced breast cancer in postmenopausal women with disease progression following antiestrogen therapy.

FOSRENOL

Shire Pharmaceuticals, Inc. (Philadelphia, PA) has been given FDA approval to market Fosrenol (lanthanum carbonate) for reduction of serum phosphate in patients with end-stage renal disease (ESRD). The effectiveness of Fosrenol was demonstrated in 1 short-term, placebo-controlled, double-blind, dose-ranging study, 2 placebo-controlled randomized withdrawal studies (studies 2 and 3), and 2 long-term, active-controlled, open-label studies (studies 4 and 5). In the first study, patients (N = 144) with chronic renal failure undergoing hemodialysis and with elevated phosphate levels were randomized to a fixed dose of Fosrenol 225 mg, 675 mg, 1350 mg, 2250 mg, or placebo. Steady-state effects were achieved after 2 weeks. In studies 2 and 3, patients (N = 185) with ESRD undergoing either hemodialysis or peritoneal dialysis were enrolled. After titration of Fosrenol to achieve a phosphate level between 4.2 to 5.6 mg/dL (study 2) or ≤ 5.9 mg/dL (study 3) and maintenance through 6 weeks, patients were randomized to Fosrenol or placebo. After 4 weeks, the phosphorus concentration rose in the placebo group by 1.9 mg/dL in both studies relative to patients who remained on Fosrenol therapy. In studies 4 and 5, patients (N = 2028) with ESRD undergoing hemodialysis were randomized to Fosrenol or alternate phosphate binders for up to 6 months (study 4) and 2 years (study 5). Both Fosrenol treatment groups had similar reductions in serum phosphate levels. Maintenance of reduction was observed for up to 3 years in Fosrenol-treated patients. The most common adverse effects seen with Fosrenol were nausea, vomiting, and diarrhea. The total daily dose of Fosrenol (recommended initial dose, 750–1500 mg) should be divided and taken with meals.

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