Drugs recently approved or pending approval

COMTAN

The United States Food and Drug Administration approved marketing of Comtan (entacapone) by Novartis (East Hanover, NJ). Comtan is indicated as an adjunct to levodopa/carbidopa in the treatment of patients with idiopathic Parkinson's disease who experience the signs and symptoms of end-of-dose "wearing off." Drug efficacy was evaluated in three randomized, double-blind, placebo-controlled studies of 24 weeks' duration. In one study, patients with fluctuating Parkinson's disease (n = 205), characterized by periods of "On" (relatively good functioning) and periods of "Off" (relatively poor functioning), were randomized to placebo or Comtan (200 mg) administered concomitantly with each dose of levodopa/carbidopa, averaging 4 to 6 doses daily. Amount of time spent in the On and Off periods was recorded by the patients periodically in a journal. The primary endpoint of the study was the amount of awake time spent in the On state. Secondary endpoints included amount of time spent in the Off state as well as scores based on the Unified Parkinson's Disease Rating Scale (UPDRS), investigator's and patient's global assessment of clinical condition, and change in daily levodopa/carbidopa dose. The change in percent of awake time in the On state from baseline was + 2 for the placebo arm compared with + 6.7 for the Comtan arm. The percent of improvement in investigator's global assessment from baseline was 21% for the placebo arm compared with 34% for the Comtan arm; percent of improvement in patient's global assessment was 20% in the placebo arm and 31% in the Comtan arm. Total UPDRS score changes from baseline were + 2.8 for the placebo arm compared with –0.6 for the Comtan arm. Potential adverse events associated with Comtan include dyskinesia/hyperkinesia, nausea, urine discoloration, diarrhea, and abdominal pain. The recommended dose of Comtan is one 200-mg tablet administered concomitantly with each levodopa/carbidopa dose up to a maximum of 1600 mg/day.

VIDEX

Bristol-Myers Squibb (Princeton, NJ) received approval for once-daily dosing of Videx (didanosine). Videx is indicated in combination with other antiretroviral agents for the treatment of HIV-1 infection. Drug efficacy was measured in an on-going, randomized, open-label study. Treatment-naive patients with HIV (n = 756) were randomized to Videx (400 mg once daily) plus stavudine plus nelfinavir or zidovudine plus lamivudine plus nelfinavir. Data from the study demonstrated that the number of patients with reductions in HIV RNA levels to below 400 copies/mL and increases in CD4 cell counts was similar in both treatment arms through 24 weeks. Possible adverse reactions associated with Videx include diarrhea, peripheral neuropathy, rash/pruritus, abdominal pain, and pancreatitis. The recommended once-daily dose of Videx (Tablets) is 400 mg for adults weighing 60 kg or more and 250 mg for adults weighing less than 60 kg. Videx must be taken 30 minutes before or 2 hours after a meal.

AROMASIN

The Food and Drug Administration granted approval to Pharmacia & Upjohn (Kalamazoo, MI) to market Aromasin (exemestane). Aromasin is indicated for the treatment of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy. Drug effectiveness was evaluated in one double-blind, multicenter, comparative study and two multicenter single-arm studies. In the comparative study, postmenopausal women (n = 769) with advanced breast cancer that had progressed after tamoxifen treatment were randomized to Aromasin 25 mg once daily (n = 366) or megestrol acetate 40 mg four times daily (n = 403). The study's primary endpoint was measure of objective response rates based on World Health Organization criteria. Secondary endpoints were time to tumor progression and overall survival. The objective response rates were 15% for the Aromasin arm compared with 12.4% for the megestrol acetate arm. Median time to tumor progression was 20.3 weeks in the Aromasin arm compared with 16.6 weeks in the megestrol acetate arm. The number of deaths was too small to reach any conclusions about overall survival in the two treatment arms. Adverse events associated with Aromasin may include hot flashes, nausea, fatigue, increased perspiring, and increased appetite. The recommended dose of Aromasin is 25 mg once daily after a meal.

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