Drugs recently approved or pending approval

LEVOLEUCOVORIN

The US Food and Drug Administration (FDA) has given approval to Spectrum Pharmaceuticals, Inc. (Irvine, CA) to market Levoleucovorin (levoleucovorin), a folate analog, for rescue after high-dose methotrexate therapy in osteosarcoma and to diminish the toxicity and counteract the effects of impaired methotrexate elimination and of inadvertent overdosage of folic acid antagonists. Levoleucovorin rescue was evaluated following high-dose methotrexate in patients (N = 16; aged, 6–21 yr) who received 58 courses of therapy for osteosarcoma. Thirteen patients received methotrexate 12 g/m^2 intravenously over 4 hours, followed by Levoleucovorin 7.5 mg every 6 hours for 60 hours or longer beginning 24 hours after completion of methotrexate. Three patients received methotrexate 12.5 g/m^2 intravenously over 6 hours, followed by Levoleucovorin 7.5 mg every 3 hours for 18 doses beginning 12 hours after completion of methotrexate. The mean total dose of Levoleucovorin per course was 350 mg. The effectiveness of Levoleucovorin was based on the frequency of adverse reactions that occurred with drug administration. Nine of 16 (56.3%) patients were evaluable for toxicity occurrence. The most common adverse effects associated with Levoleucovorin were stomatitis, vomiting, and nausea, which occurred in 6 (37.5%), 6 (37.5%), and 3 (18.8%) patients, respectively. Grade 3 or greater stomatitis was observed in 1 patient, and grade 3 or greater typhlitis occurred in 1 patient. Serum creatinine and methotrexate levels should be measured at least once daily. Levoleucovorin administration, hydration, and urinary alkalinization (pH ≥ 7.0) should be continued until the methotrexate level is less than 0.05 mmol.

PRISTIQ

Wyeth Pharmaceuticals Inc. (Philadelphia, PA) has been given FDA approval to market Pristiq (desvenlafaxine), a selective serotonin-norepinephrine reuptake inhibitor, for the treatment of major depressive disorder. Pristiq was evaluated in four 8-week, randomized, double-blind, placebo-controlled, fixed-dose studies in patients who met the *Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition* criteria for major depressive disorder. In study 1, patients (n = 461) received once daily Pristiq 100, 200, or 400 mg or placebo. In study 2, patients (n = 369) received once daily Pristiq 200 or 400 mg or placebo. In studies 3 and 4, patients (n = 930) received once daily Pristiq 50 or 100 mg or placebo. The primary endpoint was improvement in the 17-item Hamilton Rating Scale for Depression total score and in the Clinical Global Impressions Scale-Improvement score. Pristiq was superior to placebo in 4 studies based on improvements in the 17-item Hamilton Rating Scale for Depression and in 3 of 4 studies based on improvements in the Clinical Global Impressions Scale-Improvement. In studies 3 and 4, the 100 mg/day dose did not have a greater effect as compared with the 50 mg/day dose. The most common adverse effects were nausea, dizziness, insomnia, hyperhidrosis, constipation, somnolence, decreased appetite, anxiety, and specific male sexual function disorders. The recommended dose of Pristiq is 50 mg once daily. Pristiq is not approved for use in pediatric patients.

TREANDA

The FDA has given approval to Cephalon, Inc. (Frazer, PA) to market Treanda (bendamustine hydrochloride) for injection for the treatment of patients with chronic lymphocytic leukemia. The safety and efficacy of Treanda were evaluated in an open-label, randomized, controlled, multicenter trial involving 301 previously untreated patients with Binet stage B or stage C chronic lymphocytic leukemia requiring treatment (ie, those with hematopoietic insufficiency, B symptoms, rapidly progressive disease, or risk of complications from bulky lymphadenopathy). Patients were randomized to intravenous Treanda 100 mg/m^2 over 30 minutes on days 1 and 2 or oral chlorambucil 0.8 mg/kg on days 1 and 15 of each 28-day cycle. Ninety percent of patients in both treatment groups had immunophenotypic confirmation of chronic lymphocytic leukemia. The primary endpoints were objective response rate and progression-free survival (defined as time from randomization to progression or death from any cause). Treanda-treated patients had a significantly higher overall response rate as compared with chlorambucil-treated patients (59% versus 26%; $P < 0.0001$). The median progression-free survival was 18 months in the Treanda group and 6 months in the chlorambucil group (hazard ratio, 0.27 [95% confidence interval, 0.17–0.43]; $P < 0.0001$). The most common adverse effects were neutropenia, pyrexia, thrombocytopenia, nausea, anemia, leukopenia, and vomiting. The recommended dose of Treanda is 100 mg/m^2 administered intravenously over 30 minutes on days 1 and 2 of a 28-day cycle for up to 6 cycles.

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.*

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