

Drugs recently approved or pending approval

HERCEPTIN

The US Food and Drug Administration (FDA) has given approval to Genentech, Inc. (South San Francisco, CA) to market Herceptin (trastuzumab) as part of a regimen containing doxorubicin, cyclophosphamide, and paclitaxel for the adjuvant treatment of patients with HER2-overexpressing, node-positive breast cancer. The safety and efficacy of Herceptin were evaluated in 2 randomized, open-label clinical trials involving 3752 patients. Breast tumor specimens were required to show HER2 overexpression (3+ by immunohistochemistry) or gene amplification (by fluorescence in situ hybridization). Data from study 1 and study 2 were pooled for efficacy analysis. Patients were randomized to receive four 21-day cycles of doxorubicin 60 mg/m² and cyclophosphamide 600 mg/m² followed by paclitaxel alone or in combination with Herceptin. Paclitaxel was administered weekly at 80 mg/m² or every 3 weeks at 175 mg/m² for 12 weeks in study 1, and study 2 patients were administered paclitaxel on a weekly schedule. Herceptin was administered at 4 mg/kg on the day of initiation of paclitaxel and then at 2 mg/kg weekly for 52 weeks. The primary endpoint of the combined efficacy analysis was disease-free survival, defined as the time from randomization to recurrence, occurrence of contralateral breast cancer, other second primary cancer, or death. Compared with standard adjuvant therapy, the addition of Herceptin to standard adjuvant therapy significantly reduced the risk of breast cancer recurrence by 52% (hazard ratio, 0.48 [95% confidence interval, 0.39–0.59]; $P < 0.0001$). The most common adverse effects associated with Herceptin were fever, nausea, vomiting, infusion reactions, and diarrhea.

MIRAPEX

The FDA has given approval to Boehringer Ingelheim Pharmaceuticals, Inc. (Ridgefield, CT) to market Mirapex (pramipexole dihydrochloride) tablets for the treatment of moderate to severe primary restless legs syndrome (RLS). The efficacy of Mirapex was evaluated in 4 randomized, double-blind, placebo-controlled trials involving approximately 1000 patients with moderate to severe primary RLS. All patients were administered Mirapex (in doses of 0.125 mg, 0.25 mg, 0.5 mg, or 0.75 mg) or placebo once daily 2 to 3 hours before bedtime (treatment duration, 3 wk–9 mo). Across the 4 studies, the mean duration of RLS was 4.6 years (range, 0–56 yr), mean age was approximately 55 years (range, 18–81 yr), and approximately 66.6% of patients were women. Mirapex-treated patients experienced statistically and clinically significant improvements in RLS symptoms over

the short and long term versus placebo, as measured by changes from baseline in the International RLS Rating Scale (IRLS) and Clinical Global Impression-Improvement (CGI-I) assessment. The IRLS is a 10-item scale designed to assess severity of sensory and motor symptoms, sleep disturbance, daytime somnolence, and impact on activities of daily living and mood associated with RLS (range, 0–40; higher scores equal more severe symptoms). The CGI-I is designed to assess clinical progress (global improvement) on a 7-point scale. In 3 studies, the mean change from baseline in total IRLS scores for Mirapex-treated patients was statistically significantly greater compared with placebo-treated patients. In the fourth study, Mirapex-treated patients experienced improvements in symptoms over a 9-month period, including a 6-month open-label treatment period followed

by a 12-week placebo-controlled withdrawal period. The most common adverse effects were nausea, headache, fatigue, and somnolence. Mirapex is also approved to treat signs and symptoms of idiopathic Parkinson's disease.

VELCADE

Millennium Pharmaceuticals, Inc. (Cambridge, MA) has been given FDA approval to market

Velcade (bortezomib) for injection for the treatment of patients with mantle cell lymphoma who have received at least 1 prior therapy. The safety and efficacy of Velcade were evaluated in an open-label, single-arm, multicenter study involving 155 patients with progressive disease who had received at least 1 prior therapy (an anthracycline or mitoxantrone, cyclophosphamide, or rituximab). Velcade 1.3 mg/m²/dose was administered intravenously as a bolus injection twice weekly for 2 weeks on days 1, 4, 8, and 11, followed by a 10-day rest period for a maximum of 17 treatment cycles. Response rates were measured using the International Workshop Criteria based on independent radiologic review of computed tomography scans. Of 155 Velcade-treated patients, 48 (31%) responded to treatment (95% confidence interval, 24%–39%). Median time to response was 40 days (range, 31–204 days). The most common adverse effects associated with Velcade were asthenic conditions (ie, fatigue, malaise, weakness), nausea, diarrhea, constipation, and peripheral neuropathy. Velcade is also indicated for the treatment of patients with multiple myeloma who have received at least 1 prior therapy.



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

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