

Drugs recently approved or pending approval

AXERT

The US Food and Drug Administration has approved marketing of Axert (almotriptan malate tablets) by Pharmacia Corporation (Peapack, NJ) for the acute treatment of migraine with or without aura in adults. Three multicenter, randomized, double-blind, placebo-controlled, European trials evaluated the efficacy of Axert. Patients in the studies were primarily female (86%) and white (more than 98%), with a mean age of 41 years. In the groups who took Axert 12.5 mg to treat a moderate to severe migraine headache, 57% to 65% of patients achieved a response (mild or no pain) 2 hours after treatment. In the groups who took Axert 6.25 mg, 55% to 56% of patients achieved the same type of response. Response rates for the placebo group ranged from 33% to 40%. Axert is not intended for the prophylactic therapy of migraine or for the management of hemiplegic or basilar migraine. Axert is contraindicated in patients with ischemic heart disease or uncontrolled hypertension and should not be administered within 24 hours of another serotonin agonist or an ergotamine-containing or ergot-type medication. The most common adverse events reported with Axert are nausea, dry mouth, and paresthesia. The recommended dose of Axert is one 12.5-mg or 6.25-mg tablet. In studies, a higher percentage of patients reported pain relief with the 12.5-mg dose than with the 6.25-mg dose. If the headache returns, the dose may be repeated after 2 hours, but no more than 2 doses should be taken within a 24-hour period.



GLEEVEC

Approval was granted to Novartis Pharmaceuticals Corporation (East Hanover, NJ) to market Gleevec (imatinib mesylate) capsules for the treatment of patients with chronic myeloid leukemia (CML) in blast crisis, accelerated phase, or chronic phase after failure of interferon- α therapy. Approval of Gleevec was based on data from 3 Phase II open-label, single-arm studies that showed a hematologic response and a major cytogenetic response (complete, 0% Ph⁺ metaphases; partial, up to 35% Ph⁺ metaphases) in patients with advanced stages of CML. Patients with accelerated phase CML (n = 235) achieved a 63% hematologic response and a 21% major cytogenetic response (95% confidence interval). Patients in myeloid blast crisis (n = 260) achieved a 26% hematologic response and a 13.5% major cytogenetic response (95% confidence interval). Patients with chronic phase CML after failure with interferon therapy (n = 532) achieved an 88% hematologic response and a 49%

major cytogenetic response (95% confidence interval). Women of childbearing potential should be advised to avoid becoming pregnant while taking Gleevec. The most frequently reported adverse events associated with Gleevec are nausea, vomiting, edema, and muscle cramps. The recommended dosage of Gleevec is 400 mg daily for patients with chronic phase CML and 600 mg daily for patients with accelerated phase or blast crisis. The prescribed dose should be administered orally, once daily with a meal and a large glass of water. Treatment should be continued as long as the patient continues to benefit.

XELODA

Hoffmann-La Roche Inc (Nutley, NJ) received approval to market Xeloda (capecitabine) tablets as first-line treatment of patients with metastatic colorectal carcinoma when treatment with fluoropyrimidine therapy alone is preferred. Xeloda was previously indicated for the treatment of patients with metastatic breast cancer resistant to both paclitaxel and an anthracycline-containing chemotherapy regimen or resistant to paclitaxel and for whom further anthracycline therapy is not indicated. Two open-label, multicenter, randomized, controlled clinical trials involving 1207 patients evaluated the efficacy of Xeloda in its new indication. Approximately half of the patients received Xeloda 1250 mg/m² twice daily

for 2 weeks followed by a 1-week rest period. The other half received intravenous 5-fluorouracil (5-FU) and leucovorin (LV). In one study (N = 605), patients receiving Xeloda achieved an overall response rate of 21%, compared with 11% in the 5-FU/LV group. Median time to disease progression was 128 days for the Xeloda group and 131 days for the 5-FU/LV group, and median survival time was 380 days for the Xeloda group and 407 days for the 5-FU/LV group. The second study had similar results. Xeloda is contraindicated in patients with severe renal impairment. The most common adverse effects associated with Xeloda include hand-and-foot syndrome, diarrhea, nausea, vomiting, decreased appetite, and dehydration. The recommended dose of Xeloda is 1250 mg/m² administered orally twice daily with morning and evening meals for 2 weeks followed by a 1-week rest period, given as 3-week cycles.

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

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