

Drugs recently approved or pending approval

EMEND

The US Food and Drug Administration (FDA) approved marketing of Emend (aprepitant) by Merck & Co., Inc, of Whitehouse Station, NJ, for prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of chemotherapy, including high-dose cisplatin. It is to be used in combination with other anti-nausea and anti-emetic drugs. Emend was evaluated in 2 multicenter, randomized, parallel, double-blind, controlled studies in patients aged 14 to 84 years who were receiving a chemotherapy regimen that included cisplatin > 50 mg/m² body surface area. Patients (N = 1105) were randomized to either the Emend regimen (n = 550) or standard therapy (n = 555). The antiemetic activity of Emend was assessed during the acute phase (0 to 24 h post-cisplatin treatment), the delayed phase (25 to 120 h post-cisplatin treatment), and overall (0 to 120 h post-cisplatin treatment). In both studies, the estimated time to first emesis after initiation of cisplatin treatment was longer with the Emend regimen, and the incidence of first emesis was reduced in the Emend group compared with the standard therapy group. The most common adverse effects reported were fatigue, nausea, hiccups, and constipation. Emend should not be used concurrently with pimozone, terfenadine, astemizole, or cisapride, and may interact with some chemotherapies, birth control pills, blood thinners, and other drugs.



FABRAZYME

Genzyme General, of Cambridge, MA, received orphan drug status and approval from the FDA to market Fabrazyme (agalsidase beta) for the treatment of Fabry disease, a rare, inherited illness involving enzyme malfunction. The safety and efficacy of Fabrazyme was evaluated in a randomized, double-blind, placebo-controlled, multinational, multicenter study of Fabry patients aged 16 to 61 years who were naive to enzyme replacement therapy. Patients (N = 58) received either 1.0 mg/kg body weight of Fabrazyme or placebo every 2 weeks for 20 weeks, for a total of 11 infusions. The primary efficacy endpoint of GL-3 inclusions in renal interstitial capillary cells was assessed by light microscopy and graded on an inclusion severity score ranging from 0 (normal or near-normal) to 3 (severe). A GL-3 inclusion score of 0 was achieved in 20 of 29 (69%) patients treated with Fabrazyme compared with 0 of 29 patients treated with placebo ($P < .001$). No differences between groups in symptoms or renal function were observed during this study. The most common adverse effects were infusion-related reactions

including fever, rigors, hypertension, hypotension, chest pain, dyspnea, and rash. The recommended dosage of Fabrazyme is 1.0 mg/kg body weight infused every 2 weeks as an intravenous infusion. Initial infusion rate should be no more than 0.25 mg/min (15 mg/h) and may be slowed if the patient experiences infusion-related reactions. After tolerance to infusion is established, the infusion rate may be increased in increments of 0.05 to 0.08 mg/min (increments of 3–5 mg/h) each subsequent infusion. The reduction of GL-3 inclusions suggests that Fabrazyme may ameliorate disease expression; however, this relationship has not been established.

FACTIVE

The FDA granted approval to GeneSoft Pharmaceuticals, Inc. (South San Francisco, CA) to market Factive (gemifloxacin), a quinolone antibacterial agent, for the treatment of mild-to-moderate community-acquired pneumonia (CAP) and acute bacterial exacerbation of chronic bronchitis (ABECB). The efficacy of Factive for CAP was evaluated in 3 double-blind, randomized, actively controlled studies; 1 open, actively controlled study; and 2 uncontrolled studies. Factive for ABECB was evaluated in 3 double-blind, randomized, actively controlled clinical trials (N = 1391). Based

on the efficacy parameter of clinical response at follow-up, the ABECB studies demonstrated that Factive administration once daily for 5 days was at least as good as comparators given for 7 days. A study for CAP (N = 228) comparing a 7-day course of Factive with a 10-day course of amoxicillin/clavulanate (1 g/125 mg three times daily) demonstrated similar success rates between both treatment arms. The results of 3 comparative studies with varying treatment durations (7–14 days) also were supportive of Factive treatment in CAP. The most common adverse effects included diarrhea, rash, nausea, and headache. Antacids containing magnesium or aluminum, ferrous sulfate products, multivitamins that contain zinc or other metals, and Videx (didanosine) should not be taken within 3 hours before Factive or 2 hours after Factive because they may interfere with absorption. The recommended dose of Factive one is 320 mg caplet daily. The duration of treatment is 5 days for ABECB and 7 days for CAP.

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