Drugs recently approved or pending approval

AVASTIN

The US Food and Drug Administration (FDA) has given approval to Genentech, Inc. (San Francisco, CA) to market Avastin (bevacizumab) to be used in combination with paclitaxel for treating patients with metastatic human epidermal growth factor receptor 2 (HER2)–negative breast cancer. Avastin was evaluated in 2 single, open-label, randomized, multicenter studies in patients with metastatic breast cancer. In study 1, patients (n = 722) who had not received chemotherapy for locally recurrent or metastatic breast cancer were randomized to paclitaxel (90 mg/m^2 intravenous [IV] infusion once weekly for 3 out of 4 wk) alone or in combination with Avastin (10 mg/kg IV infusion every 2 wk). In study 2, patients (n = 462) who had received prior anthracycline and taxane therapy in the adjuvant setting or for metastatic breast cancer were randomized to capecitabine alone or in combination with Avastin. The primary endpoint for both studies was progression-free survival (PFS). In study 1, PFS was significantly longer in the Avastin/paclitaxel arm versus the paclitaxel arm (median PFS, 11.3 versus 5.8 mo; $P < 0.0001$). In study 2, the median PFS was 4.2 months in the capecitabine arm and 4.9 months in the Avastin/capecitabine arm ($P = 0.86$). The most common adverse effects were hypertension, proteinuria, and headache.

EMEND

The FDA has given approval to Merck & Co., Inc. (Whitehouse Station, NJ) to market Emend (fosaprepitant dimeglumine) for injection to be used in combination with other antiemetic agents for preventing acute and delayed nausea and vomiting associated with highly and moderately emetogenic cancer chemotherapy such as high-dose cisplatin. Emend was evaluated in 3 multicenter, randomized, double-blind, parallel-group studies in patients (n = 1105) receiving a chemotherapy regimen that included cisplatin (studies 1 and 2) and in breast cancer patients (n = 866) receiving a chemotherapy regimen that included cyclophosphamide alone, cyclophosphamide and doxorubicin, or epirubicin (study 3). All patients were randomized to standard therapy or to Emend, ondansetron, and dexamethasone. The primary endpoint was complete response (defined as no emetic episodes and no use of rescue therapy from 0–120 hr posttreatment). In all studies, significantly more Emend-treated patients had a complete response than patients who received standard therapy (study 1, 73% versus 52% [$P < 0.001$]; study 2, 63% versus 43% [$P < 0.001$]; study 3, 51% versus 42% [$P = 0.015$]). The most common adverse effects were asthenia/fatigue, nausea, and hiccups.

SIMCOR

Abbott Laboratories, Inc. (Abbott Park, IL) received FDA approval to market Simcor (niacin extended-release [ER]/simvastatin) to reduce total cholesterol, low-density lipoprotein cholesterol (LDL-C), apolipoprotein B, non–high-density lipoprotein cholesterol (HDL-C), or triglycerides or to increase HDL-C in patients with primary hypercholesterolemia and mixed dislipidemia for whom simvastatin or niacin ER monotherapy is inadequate. Simcor was evaluated in a double-blind, randomized, multicenter, 24-week study in patients (N = 641) with type 2 hyperlipidemia or mixed dyslipidemia. Patients on simvastatin 20 mg monotherapy with elevated non–HDL-C levels and LDL-C levels (group A) received Simcor 1000/20 mg or 2000/20 mg or simvastatin 20 mg. Patients on simvastatin 40 mg monotherapy with elevated non–HDL-C levels (LDL-C levels not considered; group B) received Simcor 1000/40 mg or 2000/40 mg or simvastatin 80 mg. Therapy was initiated at 500 mg and increased by 500 mg every 4 weeks; patients were titrated to 1000 mg after 4 weeks and to 2000 mg after 12 weeks. Patients in the simvastatin monotherapy groups received niacin 50 mg/day to prevent unblinding due to flushing, and all patients took aspirin 325 mg or ibuprofen 200 mg to minimize flushing. In group A, the primary endpoint was the mean percent change in non–HDL-C levels between Simcor 2000/200 mg and simvastatin 20 mg. In group B, the primary endpoint was a determination of noninferiority in the mean percent change of non–HDL-C between Simcor 2000/40 mg and simvastatin 80 mg. The non–HDL-C lowering with Simcor 2000/20 mg and Simcor 1000/20 mg was statistically significantly greater than that achieved with simvastatin 20 mg (–19.5% and –13.6% versus –5%; $P < 0.05$). The non–HDL-C lowering with Simcor 2000/40 mg and Simcor 1000/40 mg was noninferior to that achieved with simvastatin 80 mg (–7.6% and –6.7% versus –6%). In both groups, Simcor was not superior to simvastatin in lowering LDL-C but was superior in lowering triglycerides and raising HDL-C. The most common adverse effects were flushing, headache, and pruritus.

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.*