THE TOOLS

ILLUSTRATION/GETTY IMAGES

[Approved Drugs]

■ The Abbreviated New Drug Application (ANDA) for **Carboplatin Injection (liquid form)** in a 600 mg multi-dose vial has been approved by the FDA, American Pharmaceutical Partners Inc., (Schaumburg, Ill.) announced. The FDA also approved the company's ANDAs for **Octreotide Acetate Injection**, single-dose and multiple dose vials.

■ ImClone Systems, Inc. and Bristol-Myers Squibb, Co. (New York, N.Y. and Princeton, N.J.) announced that the Food and Drug Administration (FDA) has approved **Erbitux® (cetuximab)** for use in combination with radiation therapy for the treatment of locally or regionally advanced squamous cell carcinoma of the head and neck (SCCHN) and as a single agent in recurrent or metastatic SCCHN where prior platinum-based chemotherapy has failed. These indications are based on a Phase III study that demonstrated a survival and locoregional control advantage when Erbitux was added to radiation therapy, and a Phase II study, where Erbitux therapy alone reduced tumor size.

Erbitux is an IgG1 monoclonal antibody designed to inhibit the function of epidermal growth factor receptor (EGFR), a molecule structure linked to tumor growth.

■ Sanofi-aventis (Bridgewater, N.J.) announced that following a priority review of the supplemental new drug application (sNDA), the FDA has approved **Taxotere® (docetaxel) Injection Concentrate** in combination with cisplatin and 5-fluorouracil for the treatment of patients with advanced stomach (gastric) cancer, including cancer of the gastro esophageal junction, who have not received prior chemotherapy for advanced disease.

The FDA based its decision on results from the TAX 325 study, the largest international Phase III clinical trial in previously untreated advanced stomach cancer, involving 445 patients. Patients treated with the Taxotere-based chemotherapy regimen (Taxotere plus cisplatin and 5-fluorouracil, TCF) experienced a significant 23 percent reduction in the risk of death compared to patients who received a current standard treatment of cisplatin and 5-flurouracil, (median follow-up: 23 months). The median overall survival was significantly longer with the Taxotere-containing regimen (9.2 vs 8.6 months, p=<0.02).

[Drugs in the News]

■ Amgen (Thousand Oaks, Calif.) announced that the FDA has approved every-three-week dosing of **Aranesp® (darbepoetin alfa)** for the treatment of chemotherapy-induced anemia in patients with non-myeloid malignancies. Aranesp is the only erythropoiesis-stimulating agent approved by the FDA for every-three-week administration.

■ AstraZeneca Pharmaceuticals, LP, (Wilmington, Del.) announced its intention to discontinue the commercial manufacture of brand name **Nolvadex® (tamoxifen citrate) Tablets** in the U.S. by the end of June 2006. Once commercial supplies are exhausted, patients will no longer be able to obtain brand name Nolvadex tablets—both new prescriptions and refills. With the wide availability of generic tamoxifen, the discontinuation of Nolvadex should in no way affect patient access to this medication, according to an AstraZeneca press release.

■ ChemGenex Pharmaceuticals Limmited (Melbourne, Australia

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Fast Facts

Factors that Matter When Choosing a Prescription Drug Plan

	Adults 65+ Oct. 2005	Adults 65+ Feb. 2006	Seniors in a Medicare Drug Plan
The Cost of Patient Copays and Deductibles	40%	42%	57%
The Cost of the Monthly Premium	32%	27%	24%
The Choice of Prescription Drugs Covered by the Plan	18%	16%	14%
The Network of Pharmacies that Can be Used to Fill Prescriptions	3%	3%	4%
Other Considerations	8%	12%	2%

Source: Wall Street Journal Online/Harris Interactive Health-Care Poll. Choosing a Medicare Plan More of a Challenge for Seniors than Using one. Volume 5, Issue 4, 2006.

and Menlo Park, Calif.) announced that the U.S. FDA has granted orphan drug status for **Ceflatonin®** for the treatment of chronic myeloid leukemia. Ceflatonin (HHT) is a potent inducer of apoptosis in myeloid cells and inhibits angiogenesis. Ceflatonin is not approved by the FDA as a treatment for any indication and is currently being evaluated in clinical trials for efficacy and safety for future regulatory applications.

■ Genta, Inc. (Berkeley Heights, N.J.) announced that the FDA has accepted the New Drug Application (NDA) for **Genasense® (oblimersen sodium) Injection.** The NDA proposes the use of Genasense plus fludarabine and cyclophosphamide for the treatment of patients with relapsed or refractory chronic lymphocytic leukemia.

■ Genentech, Inc. (South San Francisco, Calif.) announced submission of a supplemental Biologics License (sBLA) with the FDA for use of **Herceptin® (trastuzumab)** to treat early-stage, HER2-positive breast cancer. Genentech has requested a priority review designation from the FDA.

■ The FDA has granted priority review to GlaxoSmithKline's (Philadelphia, Pa.) sNDA for **Hycamtin® (topotecan HCl) for Injection.** The sNDA seeks marketing approval for the new use of Hycamtin in combination with cisplatin for the treatment of Stage IVB recurrent or persistent carcinoma of the cervix not amenable to curative treatment with surgery and/or radiation therapy. The application is based on results from a randomized, multicenter Phase III trial, designed and conducted by the Gynecologic Oncology Group.

■ Morphotek, Inc. announced the FDA has accepted its investigational new drug application (IND) for **MORAb-009** for the treatment of mesothelin-expressing cancers.

■ The FDA has granted priority review designation to Celgene Corporation's (Summit, N.J.) sNDA for **Revlimid® (lenalidomide)** for treatment of relapsed or refractory multiple myeloma. Celgene is seeking approval to market Revlimid in combination with dexamethasone as a proposed indication for the treatment of multiple myeloma patients who have received at least one prior therapy subject to FDA review and approval.

■ YM BioSciences (Mississauga, Canada) has received FDA fast track designation for **tesmilifene** for use in combination with an anthracycline chemotherapic for treatment of women with advanced breast cancer. While the company is seeking clarification from the FDA on certain aspects of the letter, the letter confirms that the drug meets the criteria for fast track designation for treatment of metastatic/recurrent breast cancer.

■ The FDA has granted orphan drug designation to SciClone Pharmaceuticals, Inc.'s (San Mateo, Calif.) investigational drug **Zadaxin®** (thymalfasin) for the treatment of stage IIb through stage IV malignant melanoma.

[Devices]

■ MediSpectra, Inc., (Lexington, Mass.) announced that **LUMA™ Cervical Imaging System** has received FDA approval. The LUMA System is the first optical imaging device approved as an aid to clinicians examining women with abnormal Pap tests. The LUMA system scans tissue with a combination of fluorescence spectroscopy, white light diffuse reflectance spectroscopy, and video imaging. A complete scan takes 12 seconds, with results available to the clinician during the examination.

■ The FDA has granted Siemens Medical Solutions (Malvern, Penn.) 510(k) clearance for its **MVision™ Megavoltage Cone Beam (MVCB) Imaging Package**. MVision is a volumetric inline target imaging solution for image-guided radiation therapy (IGRT). The system is the first commercial implementation of cone beam technology utilizing a standard radiotherapy treatment beam, making it possible for the megavoltage source used for treatment to also create a 3D image of the patient.

PHOTOGRAPH/JUPITER IMAGES

ACCC's website, **www.accc-cancer.org**, as well as those of an ACCC Member institute and the Oncology Nursing Society (ONS) were recognized by Medicine on the Net's 2006 Web Excellence Awards. See page 50.

■ **www.mmhs.com**, the website of Martin Memorial Health System, was recognized as "Best Overall Winner" in the category of hospital health systems. From its homepage, users can choose from options, such as: Find a Doctor, Email a Patient, and View My Bill. Its wide range of patient services is listed by both type and location. Choosing "Cancer" brings you immediately to ACCC Member Institution, the Robert and Carol Weissman Cancer Center. In addition to information about its cancer service line, users can find resources on clinical trials, genetic screening, nutrition counseling, and social and support services.

■ The website of the Oncology Nursing Society, **www.ons.org**, was recognized twice for "Best User Interface" in the Healthcare Professional Portal category and as "Outstanding Content Winner" in the Medical Association category. The website offers comprehensive information on subjects such as cancer prevention and treatment, symptom management, and supportive and palliative care. Under "CE Central" visitors will find numerous continuing education resources, including conferences, online courses, Webcasts, and virtual sessions. ONS also offers a wide variety of patient education products.