THE TOOLS

PHOTOGRAPH/ CORBIS

[Approved Drugs]

■ Novartis (Basel, Switzerland) announced FDA approval of **Femara® (letrozole)** as treatment for use after surgery in postmenopausal women with hormone-sensitive early breast cancer (adjuvant setting). The approval was based on results of the BIG 1-98 study, which were published for the first time in the Dec. 29, 2005, *New England Journal of Medicine*. BIG 1-98 compared the effectiveness and tolerability of Femara versus tamoxifen when used as initial therapy after surgery (adjuvant setting) in postmenopausal women with hormone-sensitive early breast cancer.

■ The FDA has approved **Nexavar (sorafenib tosylate)**, distributed and marketed by Bayer Pharmaceuticals Corporation (West Haven, Conn.), for treatment of advanced renal cell carcinoma, the most common type of kidney cancer.

The FDA approved the anticancer drug based on Phase III data from the largest randomized, placebo-controlled trial ever conducted in patients with advanced renal cell cancer. In the Phase III study, Nexavar doubled progression-free survival when compared to placebo to a median value of six months in patients receiving Nexavar as compared to three months for patients receiving placebo.

Nexavar, co-developed by Onyx Pharmaceuticals and Bayer and formerly known as Bay 43-9006, is the first oral multikinase inhibitor that targets serine/threonine and receptor tyrosine kinases in both the tumor cell and tumor vasculature. In preclinical models, sorafenib targeted members of two classes of kinases known to be involved in both tumor cell proliferation (tumor growth) and tumor angiogenesis (tumor blood supply)—two important cancer growth activities. These kinases included RAF kinase, VEGFR-2, VEGFR-3, PDGFR-β, KIT, FLT-3, and RET.

■ Celgene Corporation (Summit, N.J.) announced that the FDA granted approval of **Revlimid (lenalidomide)**, which is indicated for the treatment of patients with transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities. Revlimid will be available through a Revlimid Education and Prescribing Safety Program, called RevAssist via contracted pharmacies. Most initial shipments of Revlimid will be distributed in early 2006. The safety profile for Revlimid has shown that neutropenia and/or thrombocytopenia were the most common adverse event and that patients may require a dose adjustment.

■ Genentech, Inc. (San Francisco, Calif.) and Biogen Idec., Inc. (Cambridge, Mass.) announced that the FDA has approved **Rituxan® (rituximab)** for use in the first-line treatment of patients with diffuse large B-cell, CD20-positive, non-Hodgkin's lymphoma, in combination with CHOP or other anthracycline-based chemotherapy regimens. Rituxan has previously been approved as a single agent for use in relapsed or refractory, low-grade follicular, CD20-positive, B-cell, non-Hodgkin's lymphoma.

■ The FDA has approved **Sutent® (sunitinib malate)** (Pfizer, Inc., New York, N.Y.) capsules to treat advanced renal cell carcinoma and malignant gastrointestinal stromal tumor, after disease progression or because of intolerance to imabtinib mesylate. Sutent is an oral therapy belonging to a new class of multikinase inhibitors that attack cancer by inhibiting both tumor growth and blood supply.

[Drugs in the News]

■ Genmab A/S (Copenhagen, Denmark) announced that **HuMax-EGFr** has received FDA fast track designation for patients with head and neck cancer who have previously failed standard therapies. HuMax-EGFr is a fully human, high-affinity antibody targeted at the Epidermal Growth Factor receptor (EGFr). EGFr is a receptor molecule found on the surface of many cancer cells. Activation of EGFr by the appropriate growth factor molecule promotes the growth of tumor cells.

■ The FDA has accepted GW Pharmaceuticals' (London, U.K.) investigational new drug (IND) application for **Sativex®**, a cannabis-derived, oro-mucosal spray composed primarily of tetrahydrocannabinal and cannabidiol, a non-psychoactive cannabinoid, for the treatment of pain in patients with advanced cancer that has not been adequately relieved by opioid medications.

Sativex is a pharmaceutical product standardized by both

Fast Facts

Medicines in Development for Cancer*

Cancer Type	Number of Drugs in the Pipeline
Solid Tumors	85
Lung Cancer	62
Leukemia	52
Lymphoma	51
Prostate Cancer	50
Breast Cancer	49
Skin Cancer	39
Colon Cancer	35
Pancreatic Cancer	25
Kidney Cancer	26
Ovarian Cancer	21
Multiple Myeloma	20
Head/Neck Cancer	15
Stomach Cancer	15
Cervical Cancer	13
Liver Cancer	13
Sarcoma	8
Bladder Cancer	6
Neuroblastoma	3

*Some medicines are listed in more than one category.

Source: *Medicines in Development for Cancer, 2005.* Published by the Pharmaceutical Research and Manufacturers of America.

composition and dose that is supplied in small vials as a oromucosal spray. Sativex is thought to act via cannabinoid receptors that are distributed throughout the central nervous system and in immune cells. These receptors are distributed throughout the pain pathways of the nervous system, and their activation is known to reduce pain in relevant pain models.

■ Berlex Oncology (Seattle, Wash.), a unit of Berlex Laboratories, announced that its granulocyte macrophage stimulating colony factor (GM-CSF) **Leukine® (sargramostim)** 500-mcg/mL vial has been reformulated to deliver extended shelf life.

The new formulation of Leukine, a growth factor that helps fight infection in appropriate patients by enhancing cells of the immune system, now includes the preservative EDTA.

As part of the formulation change, the Leukine 500-mcg/mL vial will also have new packaging, as well as a new NDC number: 50419-595-05. The current NDC number (50419-050-30) will remain on the market for a limited time period; therefore, customers should not delete or inactivate it in their systems.

The 250 mcg vial (NDC number 50419-002-33) of Leukine will continue to be marketed in its current formulation of lyophilized powder.

The reformulation will not affect reimbursement or claims submissions, as the HCPCS code (J2820, sargramostim 50 mcg) remains the same for both formations, and claims can be filed in the usual manner. The indications and usage, as well as the dosage and administration, of this reformulated version of Leukine remain the same.

■ The FDA has granted PharmaMar (Madrid, Spain) its IND for the clinical testing of **Zalypsis® (PM00104/50),** the company's novel marine anti-tumor agent.

■ AstraZeneca (Wilmington, Del.) announced that its drug **Zactima™ (ZD6474)** has been granted FDA fast track designation in treating medullary thyroid carcinoma. For advanced thyroid cancer, there is currently no curative modality or approved chemotherapy.

Last year, Zactima received orphan-drug designation for the treatment of patients with follicular, medullary, anaplastic, and locally advanced and metastatic papillary thyroid cancer.

The drug is being evaluated in a Phase II clinical trial in medullary thyroid cancer. AstraZeneca is currently enrolling patients in a single arm Phase II Zactima study in locally advanced or metastatic hereditary medullary thyroid cancer.

[Devices in the News]

■ Varian Medical Systems, Inc. (Palo Alto, Calif.) has received FDA 510(K) clearance for **Eclipse™ Proton Eye Dose Calculation software** that has been made part of the company's Eclipse™ treatment planning system for planning radiation therapies for the treatment of cancer. The new proton eye dose calculation module enables doctors to create the highly complex treatment plans necessary for precisely delivering proton radiation beams for treatment of ocular cancers while maximizing protection for the many small, essential critical structures in and around the human eye.

■ Xoft, Inc. (Fremont, Calif.) announced that the **Axxent™ Electronic Brachytherapy System** for the treatment of breast cancer has received U.S. FDA clearance. Electronic brachytherapy is a proprietary technology platform designed to deliver localized, non-radioactive, isotope-free radiation treatment in a minimally-shielded clinical setting under the supervision of a radiation oncologist.

The Axxent Electronic Brachytherapy System uses disposable micro-miniature X-ray radiation sources to deliver ionizing radiation treatment directly to tumor beds. In its first indication for use, the Axxent System can be used to deliver a course of radiation therapy for early stage breast cancer. It gives radiation oncologists the flexibility to deliver radiation at multiple energy levels, while at the same time eliminating the need for heavily shielded environments so that it can be used in a broader range of clinical settings.