THE TOOLS

[Approved Drugs]

■ The U.S. Food and Drug Administration (FDA) has approved GlaxoSmithKline's (Philadelphia, Pa.) **Arranon® (nelarabine) Injection,** a chemotherapy agent, for the treatment of patients with T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma whose disease has not responded to or has relapsed following treatment with at least two chemotherapy regimens. This use is based on the induction of complete responses. Randomized trials demonstrating increased survival or other clinical benefit have not been conducted. Arranon also received orphan drug designation from the FDA.

■ The FDA announced Dec. 20 that **Nexavar® (sorafenib tosylate)**, distributed and marketed by Bayer Pharmaceuticals Corporation (Emeryville, Calif.), was approved for treatment of advanced renal cell carcinoma, the most common type of kidney cancer. 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.

■ OSI Pharmaceuticals, Inc., and Genentech, Inc. (Melville, N.Y., and South San Francisco, Calif.) have received FDA approval for **Tarceva® (erlotinib)** in combination with gemcitabine chemotheraphy for the treatment of advanced pancreatic cancer in patients who have not received previous chemotherapy. Tarceva is the first drug in a Phase III trial to have shown significant improvement in overall survival when added to gemcitabine chemotherapy as initial treatment for pancreatic cancer. Tarceva is a once-daily oral tablet already approved for use in patients with non-small cell lung cancer whose disease has progressed after one or more courses of chemotherapy.

[Drugs in the News]

■ Avalon Pharmaceuticals, Inc. (Germantown, Md.) announced activation of the investigational new drug (IND) submission for **AVN944** by the FDA. The allowance permits Avalon to initiate a Phase I clinical trial in patients with advanced hematological malignancies. AVN944 is an oral, small molecule inhibitor of the enzyme inosine monophosphate dehydrogenase (IMPDH), an enzyme that is essential for the de novo synthesis of the nucleotide guanosine triphosphate (GTP). AVN944 appears to inhibit cell proliferation by denying dividing cells of the GTP necessary for synthesis of DNA and RNA. IMPDH is highly upregulated in hematologic cancers, but many other types of cancer cells are also sensitive to IMPDH inhibition.

■ Vion Pharmaceuticals, Inc. (New Haven, Conn.) announced that the FDA has granted fast track designation to its anticancer agent **Cloretazine®** for induction treatment of patients over 60 years of age with poor-risk acute myelogenous leukemia. This is the second indication for which Cloretazine has received fast track designation.

■ The FDA has accepted the supplemental Biologics License Application (sBLA) for **Erbitux® (cetuximab)** (ImClone Systems Incorporated and Bristol-Myers Squibb Company, New York and Princeton, N.J.) in the treatment of squamous cell carcinoma of the head and neck. The sBLA seeks approval to use the IgG1 monoclonal antibody in combination with radiation for locally or regionally advanced head and neck cancer, and as monotherapy in patients with recurrent and/or metastatic disease where prior platinum-based chemotherapy has failed or where platinum-based therapy would not be appropriate. The Erbitux sBLA has been granted priority review.

■ ZymoGenetics, Inc. (Seattle, Wash.) announced that the FDA has granted orphan drug designation to **Interleukin 21 (IL-21)** for the treatment of melanoma patients with advanced or aggressive disease. ZymoGenetics is testing IL-21 in an ongoing Phase Ib clinical trial in melanoma and renal cell carcinoma with a dosing regimen administered in an outpatient setting. IL-21 is a novel cytokine with potent effects on a number of immune effector cells such as cytotoxic T cells and natural killer cells.

■ The FDA has granted orphan drug designation to **picoplatin**

PHOTOGRAPH/CORBIS

Fast Facts

Top Challenges for Physicians in Private Practices

Challenges	Oncologists	National Sample
Managing accounts receivable	59%	54%
Managing non-coverage of treatment and medications by third-party payers	57%	46%
Processing paperwork	55%	55%
Managing slow third-party reimbursement	54%	57%
Expanding patient base	52%	53%
Finding and keeping the right staff	52%	66%
Managing malpractice insurance costs and coverage	45%	60%
Automating patient records electronically	42%	47%
Acquiring adequate net income to compensate partners	37%	31%
Finding the right providers or adding additional providers	32%	19%
Adding and updating medical equipment	31%	34%
Retaining providers	32%	19%
Determining an appropriate buy-in or buy-out for partners	14%	16%
Finding financing to expand	11%	7%

Source: OPEN Practice Medical Monitor. A survey by American Express and Harris Interactive. November 2004.

(NeoRx Corporation, Seattle, Wash.) for the treatment of small cell lung cancer. Picoplatin is an intravenous platinum chemotherapeutic agent specifically designed to overcome platinum resistance. The drug is currently being studied in an ongoing randomized, open-label, multi-center Phase II clinical trial in patients with platinum-resistant or refractory small cell lung cancer.

■ Dendreon Corporation announced that the FDA has granted fast track review status to **Provenge® (sipuleucel-T)** for its proposed use in the treatment of asymptomatic men with metastatic, androgen-independent prostate cancer.

■ Viventia Biotech, Inc. (Toronto, Canada) announced that FDA has given fast track designation to **Proxinium™** for the treatment of patients with recurrent squamous cell carcinoma of the head and neck. Viventia has been cleared by the FDA and Health Canada to initiate a Phase II trial of Proxinium for chemotherapy-refractory recurrent head and neck cancer. Proxinium has received orphan drug designation for the treatment of head and neck cancers in the U.S. and Europe.

■ Telik, Inc. (Palo Alto, Calif.) has received FDA permission to proceed, under an IND application, with the clinical study of an oral formulation of **Telintra™.** The initial clinical trial will be conducted in patients with myelodysplastic syndrome and is in addition to the ongoing clinical trial using the parenteral formulation of the drug. Telintra is a novel small molecule that has been shown in preclinical testing to have myelorestorative activity when administered orally or by infusion.

■ **Troxatyl™** (SGX Pharmaceuticals, Inc., San Diego, Calif.), an investigational drug in a pivotal Phase II/III clinical trial, has received FDA fast track designation for third-line treatment of acute myeloid leukemia in adults. SGX announced in May 2005 that Troxatyl had received orphan drug designation in the U.S. for the treatment of acute myeloid leukemia.

■ AstraZeneca's (Wilmington, Del.) **Zactima™ (ZD6474)** has been granted FDA orphan drug designation for the treatment of patients with follicular, medullary, anaplastic, and locally advanced and metastatic papillary thyroid cancer. Zactima is a multi-targeted compound directed to the inhibition of key cell signaling pathways involved in tumor growth and spread. The investigational drug is being evaluated in Phase II clinical trials in medullary thyroid cancer and Phase III clinical trials in advanced non-small cell lung cancer.

[Devices in the News]

■ Cedara Software Corp., (Toronto, Canada, and Milwaukee, Wisc.) announced that **Cedara B-CAD™** has received 510(K) clearance from the FDA. B-CAD assists radiologists in the analysis of breast ultrasound images through automated segmentation, characterization, classification, annotation, and report generation.

■ IRadimed Corp.'s (Winter Park, Fla.) **MRidium™ MRI Infusion Pump** has been granted 510(k) clearance by the FDA. The device is a non-magnetic smart infusion system designed for the magnetic resonance (MR) environment, enabling patients to receive intravenous medications continuously during the course of a scanning procedure.

■ The FDA has granted 510(k) clearance to North American Scientific, Inc.'s (Chatsworth, Calif.) NOMOS® Radiation Oncology Division to market **nTRAK™,** a stereotactic image guidance system used to position and monitor patients during radiation therapy treatments for head and neck cancers.

■ TriPath Imaging and Ventana Medical Systems, Inc. (Burlington, N.C., and Tucson, Ariz.) announced that the FDA has granted 510(k) clearance for the **Ventana Image Analysis System** (VIAS) when used with tissues stained for Estrogen Receptor (ER) and Progesterone Receptor (PR).