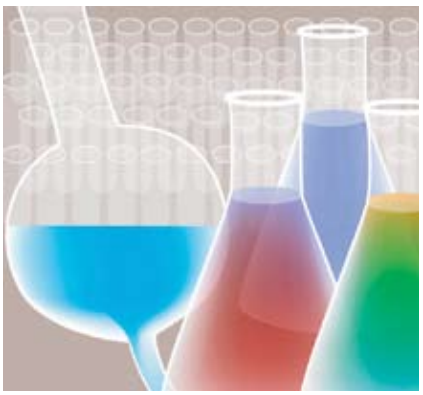
THE TOOLS



ILLUSTRATION/GETTY IMAGES

[Approved Drugs]

■ **Avastin® (bevacizumab)** (Genentech, South San Francisco, Calif.) has received a new indication from the USP DI compendium for treatment of metastatic breast carcinoma, HER2-negative disease, first line therapy in combination with paclitaxel.

■ Valeant Pharmaceuticals International (Costa Mesa, Calif.) announced that the Food and Drug Administration (FDA) has given marketing approval for **Cesamet™ (CII) (nabilone) oral capsules** for treatment of nausea and vomiting associated with cancer chemotherapy in patients who have failed to respond adequately to conventional anti-emetic treatments.

Cesamet is a synthetic cannabinoid that is thought to act as an omnineuromodulator—interacting with the cannabinoid receptor, CB1, which is present throughout the nervous system.

■ The FDA has approved the anti-smoking pill, **Chantix™ (varenicline)** by Pfizer, Inc. (New York, N.Y.) FDA approval was based on a comprehensive clinical trial program including four pivotal trials involving more than 2,000 cigarette smokers.

■ MGI Pharma, Inc., and SuperGen, Inc., (Minneapolis, Minn. and Dublin, Calif.) announced that the FDA has approved **Dacogen™ (decitabine) for Injection.** Dacogen is indicated for treatment of patients with myelodysplastic syndromes (MDS), including previously treated and untreated, de novo, and secondary MDS of all French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, refractory anemia with excess blasts in transformation, and chronic myelomonocytic leukemia), and Intermediate-1, Intermediate-2, and High-Risk International Prognostic Scoring System groups.

■ **Eloxatin™ (oxaliplatin)** (sanofi-aventis, Paris) has received a new indication from the USP DI compendium for the treatment of gastric carcinoma, advanced/metastatic.

■ **Gleevec (imatinib mesylate)** (Novartis) has received a new indication from the USP DI compendium for the treatment of acute lymphoblastic leukemia, Philadelphia chromosome-positive, newly diagnosed, as part of combination therapy.

[Drugs in the News]

■ OXiGENE, Inc. (Waltham, Mass.) announced that the FDA has granted orphan drug designation to the company's vascular disrupting agent, **Combretastatin A4P (CA4P)**, for the treatment of ovarian cancer. CA4P is being evaluated in a Phase II clinical trial in combination with the widely used chemotherapy regimen, carboplatin and paclitaxel, for the treatment of platinum resistant ovarian cancer.

CA4P works via two potentially synergistic processes that selectively target pericyte-depleted neovessels, which lack ensheathment from smooth muscle support cells.

■ The FDA has approved the investigational new drug (IND) application for **CYT-500**, Cytogen Corporation's (Princeton, N.J.) lead therapeutic candidate targeting prostate-specific membrane antigen (PSMA). CYT-500 uses the same monoclonal antibody from Cytogen's Prostascint® (capromab pendetide) molecular imaging agent, but is linked, through a higher affinity linker than is used for Prostascint, to a therapeutic as opposed to an imaging radionuclide. The drug is designed to enable targeted delivery of a cytotoxic agent to PSMA-expressing cells.

Subject to IRB approval at the planned clinical site, Cytogen expects to soon begin the first U.S. Phase I clinical trial of CYT-500 in patients with hormone-refractory prostate cancer.

■ Cell Genesys, Inc. (South San Francisco, Calif.) announced that the FDA has granted fast track designation for **GVAX® immunotherapy for prostate cancer**, for the treatment of advanced prostate cancer.

GVAX immunotherapy for prostate cancer is currently being studied in two Phase III clinical trials expected to enroll approximately 1,200 patients with metastatic hormone-refractory prostate cancer. The first trial (VITAL-1) is enrolling chemotherapy naïve, asymptomatic patients without cancer-related pain and will compare GVAX cancer immunotherapy to Taxotere chemotherapy plus prednisone. The second trial (VITAL-2) is enrolling patients who are symptomatic with cancer-related pain and will compare GVAX cancer immunotherapy plus Taxotere chemotherapy to Taxotere plus prednisone.

■ The FDA has granted Cephalon, Inc.'s (Frazer, Pa.) **lestaurtinib (CEP-701)** orphan drug designation for the treatment of acute myeloid leukemia (AML).

Lestaurtinib is a potent inhibitor

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of several tyrosine kinases, including FLT-3 and TrkA. This orally active, investigational compound is in a Phase II/III clinical trial. It is a targeted agent against AML in patients at first relapse from standard induction chemotherapy and whose disease presents with a genetic alteration known as a FLT-3 activating mutation.

■ Bayer Pharmaceuticals Corporation and Onyx Pharmaceuticals, Inc. (West Haven, Conn., and Emeryville, Calif.) announced that **Nexavar® (sorafenib) tablets** has been granted orphan drug status for the treatment of hepatocellular carcinoma by the FDA.

A multi-kinase inhibitor that targets both the tumor cell and tumor vasculature, Nexavar is currently in Phase III clinical trials for the treatment of liver cancer, metastatic melanoma, and non-small cell lung cancer.

In December 2005, Nexavar received approval from the FDA to treat patients with advanced renal cell carcinoma.

■ Marshall Edwards, Inc. announced that under the special protocol assessment (SPA) process, it has reached agreement with the FDA on the design of a study protocol for its investigational anti-cancer drug, **phenoxodiol** (Novogen Limited, Sydney, Australia). The trial (the OVATURE study) is designed to test the ability of phenoxodiol to restore sensitivity of late-stage ovarian cancers to carboplatin, a standard form of therapy for ovarian cancer. The trial will involve up to 60 sites in the United States, the United Kingdom, Europe, and Australia. As an investiational drug, Phenoxodiol is not commercially available.

■ The FDA has approved Neotropix, Inc.'s (Malvern, Penn.) IND application for **Seneca Valley Virus (SVV-001).** SVV-001 is a naturally occurring virus that specifically kills cancer cells with features similar to those found in many small cell lung cancers.

A dose-escalating Phase I study will determine if SVV-001 can be systemically administered safely to patients with certain types of advanced neuroendocrine cancers, including small cell lung cancer. The study will also examine the distribution of the virus in the body, the elimination of it from the body, the immune response to the virus, and whether it affects the patients' tumors.

■ **Urocidin™ (mycobacterial cell wall-DNA Complex or MCC)** (Bioniche Life Sciences Inc., Belleville, Ontario) has been granted FDA fast track designation for the treatment of non-muscle invasive bladder cancer in patients who are refractory to Bacillus Calmette-Guerin, the current standard therapy.

Formulated from Mycobacterium phlei, a non-pathogenic strain of mycobacteria, MCC has been shown to have immune stimulatory and apoptosis activity against cancer cells. The product is a sterile biological composition in a sub-micron suspension.

Fast Facts

Are U.S. Industries Doing a Good or Bad Job Serving Consumers?

Industry	Good Job	Bad Job	Not Sure/ Refused to Answer
Supermarkets	91%	8%	1%
Banks	80%	19%	1%
Hospitals	74%	23%	3%
Airlines	66%	24%	9%
Life Insurance Companies	64%	22%	13%
Pharmaceutical & Drug Companies	61%	36%	3%
Health Insurance Companies	46%	49%	5%
Managed Care Companies, such as HMOs	41%	44%	15%
Oil Companies	36%	60%	3%
Tobacco Companies	34%	59%	7%

Source: *Healthcare News*. Vol. 6, Issue 4, May 5, 2006.

[Devices in the News]

■ TriPath Imaging Inc. 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 Ki-67.** In 2005, VIAS obtained FDA clearances when used with the Ventana Estrogen Receptor (ER), Progesterone Receptor (PR), and HER-2/neu assays. A cell proliferation biomarker that is used by pathologists as an adjunct to histopathology, Ki-67 is used to assist with diagnosis and prognostic assessment of cancer.

■ The **Cool-tip™ RF ablation system** (Valleylab, Boulder, Colo.) has received marketing clearance by the FDA for use in ablating non-resectable liver tumors.

The device combines a radiofrequency generator with a 17-gauge internally cooled needle electrode to deliver therapeutic energy directly to the tumor. The electrode is inserted through the tissue and is guided to the tumor using imaging technology such as CT or ultrasound. Radio waves create energy at the needle tip to heat and destroy the tumor from the inside out. Because the ablation is minimally invasive, the procedure can be repeated until the entire liver tumor is ablated.