Tools

Drugs

- Eli Lilly and Company (Indianapolis, Ind.) has received FDA approval for its drug **Alimta®** (pemetrexed) for use with cisplatin for the treatment of malignant pleural mesothelioma in patients who are not candidates for surgery.

- ImClone Systems Inc., (New York, N.Y.) and Bristol-Myers Squibb (New York, N.Y.) received FDA approval for **Erbitux™** cetuximab) **Injection** for use in combination with irinotecan in the treatment of patients with EGFR-expressing, metastatic colorectal cancer who are refractory to irinotecan-based chemotherapy and for use as a single agent in the treatment of patients with EGFR-expressing, metastatic colorectal cancer who are intolerant to irinotecan-based chemotherapy.

Erbitux binds specifically to epidermal growth factor (EGF) receptors (EGFR, HER1, c-ErbB-1) on both normal and tumor cells, and competitively inhibits the binding of EGF and other ligands, such as transforming growth factor-alpha. The effectiveness of Erbitux is based on objective response rates. Currently, no data are available that demonstrate an improvement in disease- related symptoms or increased survival with Erbitux.

- **Eloxatin™** (oxaliplatin for injection) in combination with 5FU/LV (Sanofi-Synthélabo of Paris, France) has been approved by the FDA for the first-line treatment of advanced colorectal cancer. Eloxatin was approved in August 2002 for second-line treatment of patients with metastatic carcinoma of the colon or rectum.

- The FDA has granted **Gleevec®** (imatinib mesylate) (Novartis Pharmaceuticals Corp., East Hanover, N.J.) regular approval as a second-line treatment for refractory chronic myeloid leukemia (CML), a rare life-threatening form of cancer affecting about 40,000 people in the U.S. Regular approval means that the FDA has determined that Gleevec has demonstrated a long-term clinical benefit for refractory CML patients.

Since May 2001 Gleevec has been approved for use in the first-line treatment CML, for use in pediatric leukemia, and for gastrointestinal stromal cancer.

- Praecis Pharmaceuticals (Waltham, Mass.) has received FDA approval to market **Plenaxis™** (abarelix for injectable suspension) for men with advanced prostate cancer who do not benefit from other treatments. Plenaxis will be restricted to only 5 percent to 10 percent of prostate cancer patients—those who cannot tolerate other hormone therapies and who have refused surgical castration.

- Telik, Inc., (Palo Alto, Calif.) has been granted FDA fast track designation for **TELCYTA™** (TLK286) for third-line therapy for locally advanced or metastatic non-small cell lung cancer. The FDA previously granted fast track designation for TELCYTA for third-line therapy in patients with platinum refractory or resistant ovarian cancer.

- Pharmacyclics, Inc., (Sunnyvale, Calif.) has been granted fast track designation by the FDA for its investigational drug **Xcytrin®** (motexafin gadolinium) Injection for the treatment of brain metastases in patients suffering from non-small cell lung cancer.

- The FDA has granted fast track designation to **MLN2704** (Millennium Pharmaceuticals, Inc., Cambridge, Mass.), which is currently being evaluated in a Phase 1/2 clinical trial for the treatment of patients with metastatic androgen-independent prostate cancer.

- Pharmion Corporation (Boulder, Colo.) has submitted a new drug application to the FDA for approval to

market **Vidaza** (azacitidine for injectable suspension) as a treatment for myelodysplastic syndromes (MDS). Vidaza has been granted fast track status by the FDA based on its potential to treat a serious, lifethreatening condition and address an unmet medical need. Vidaza has also been granted orphan product designation by the FDA for the MDS indication, which, if approved, entitles the drug to seven years of market exclusivity for the indication in the U.S.

New Products

- Ethicon Endo-Surgery, Inc., (Cincinnati, Ohio) received FDA approval to expand the use of its **Mammotome® Breast Biopsy System** for management of fibroadenomas (palpable non-cancerous breast lumps).

- BioMosaics Inc., (Burlington, Vt.) has licensed **a novel diagnostic test for hepatocellular carcinoma (HCC)**. The diagnostic test system detects primary liver cancer using a unique monoclonal antibody to glypican 3 (GPC3), known to have increased expression in HCC, and shown to be detectable in tissue specimens and serum.

- The FDA granted 510(k) premarket clearance to the **Elekta Synergy™** System, a new radiotherapy treatment platform by Elekta, Inc., (Norcross, Ga.). Using X-ray volume imaging technology integrated directly onto the treatment system, routine pre-treatment imaging of a tumor can be performed immediately prior to treatment, decreasing the risk that a tumor or internal organs will change position. According to the company, since the patient does not have to be moved from an imaging device (e.g., MRI, CT) to the radiotherapy treatment machine, Elekta Synergy eliminates the problem of errors from patient re-setup.

- Varian Medical Systems, Inc., (Palo Alto, Calif.) has received FDA 510(k) clearance for its **3-D conebeam computed tomography imaging system** on a radiation therapy simulation and verification device. The cone-beam CT option on Varian's Acuity™ simulator for Dynamic Targeting™ image-guided radiation therapy (IGRT) provides 3-D digital images for verifying and enhancing radiation therapy treatment plans. Cone-beam CT generates 3-D images of tumors and surrounding anatomy. The Acuity system's 3-D cone-beam imaging is also used for brachytherapy treatment planning and to guide the placement of catheters and seeds.

- **The Trilogy™ System**, a comprehensive linear accelerator for stereotatic, as well as advanced forms of radiotherapy, by Varian Medical Systems, Inc., (Palo Alto, Calif.) has received FDA 510(k) clearance. The Trilogy system can be used to deliver stereotactic radiosurgery, fractionated stereotactic radiation therapy, and intensity modulated radiosurgery, as well as 3-D conformal radiotherapy, SmartBeam IMRT, and Dynamic Targeting IGRT.

- BSD Medical Corp. (Salt Lake City, Utah) has received FDA approval for a new operating system **(BSD-500i-4, BSD-500c-4, BSD-500i-8, and BSD-500c-8)** for the treatment of cancer patients using superficial and interstitial hyperthermia therapy. These new products are intended to be companion systems to the more than 1,500 installed brachytherapy systems used for interstitial radiotherapy.

A high-resolution graphic touchscreen display drives the new systems. The more than 20,000 lines of code in the new systems software are supported by new high-performance hardware, which the FDA also approved as part of the configuration of the new operating system.

- **The CRystalView desk-top computed radiography system** (Alara, Inc., Hayward, Calif.) has received 510(k) clearance from the FDA. The CrystalView system uses storage phosphor technology to replace film in conventional medical X-ray systems and provides high-quality digital images at an affordable price.

- iCAD, Inc., (Nashua, N.H.) has been granted FDA approval to market its new **iCAD iQ Computer Aided Detection System**. The iQ system is designed specifically for women's health centers and breast clinics that perform less than 20 mammography procedures per day. The product has been designed to allow lower-volume

clinics to provide CAD services to women on a cost-effective basis.