THE TOOLS

Fast Facts

Fast Facts about Breast Cancer

- Despite medical advancements, just over 40,000 people—roughly the population of Grand Rapids, Mich.—will die of the disease in the U.S. this year.
- African American women have a 35 percent higher breast cancer death rate than Caucasian women even though they are less likely to get breast cancer.
- Only 38 percent of Hispanic women age 40 or older have regular mammograms.
- For uninsured women, the risk of dying from breast cancer increases by 30 to 50 percent.
- Washington, D.C. has the highest breast cancer death rate of any city in the country, due in part to healthcare access challenges and long waits for screening and follow-up care.

Source: Susan G. Komen for the Cure. *State of Breast Cancer Report, 2007.*

[Approved Drugs]

- Bayer HealthCare Pharmaceuticals and Onyx Pharmaceuticals, Inc., (Wayne, N.J., and Emeryville, Calif.) announced that the FDA has approved a supplemental new drug application (sNDA) for **Nexavar® (sorafenib)** tablets for the treatment of patients with unresectable hepatocellular carcinoma (HCC). Nexavar, an oral anticancer drug, is the first approved systemic therapy for liver cancer and the only one shown to significantly improve overall survival in patients with the disease.

- The FDA has approved new labeling for **Sprycel® (dasatinib)** (Bristol-Myers Squibb Company, New York, N.Y.) to include a lower recommended starting dose of 100 mg once daily and safety and efficacy data in a greater number of patients with chronic-phase chronic myeloid leukemia (CML) resistant or intolerant to prior therapy including Gleevec. The product labeling now also includes data from the first randomized trial of Sprycel and Gleevec. Sprycel is indicated for the treatment of adults with chronic-, accelerated-, or myeloid or lymphoid blast-phase CML with resistance or intolerance to prior therapy including Gleevec. The effectiveness of Sprycel is based on hematologic and cytogenetic response rates. There are no controlled trials demonstrating a clinical benefit, such as improvement in disease-related symptoms or increased survival.

- Novartis Pharmaceuticals Corporation's (East Hanover, N.J.) **Tasigna (nilotinib)** capsules have been approved by the FDA for treatment of Philadelphia chromosome positive CML in adult patients whose disease has progressed on or who cannot tolerate other therapies that included imatinib. Imatinib (Gleevec) is approved for the treatment of newly diagnosed patients with Philadelphia chromosome positive CML.

[Drugs in the News]

- The FDA has granted orphan drug designation for **CDX-110** (Celldex Therapeutics, Phillipsburg, N.J.) for the treatment of EGFRvIII expressing glioblastoma multiforme (GBM), the most common and aggressive form of brain cancer. CDX-110 is an immunotherapy that targets the tumor-specific growth promoter EGFRvIII.

- SGX Pharmaceuticals, Inc., (San Diego, Calif.) announced submission of an investigational new drug (IND) application to the FDA for **SGX523**. This compound is a small molecule inhibitor of the cMET receptor tyrosine kinase. Phase I clinical trials of SGX523 for solid tumor cancer patients are expected to begin in early 2008.

- The FDA has cleared Supratek Pharma Inc.'s (Montreal) IND application for **SP1049C** for the treatment of metastatic adenocarcinoma of the upper gastrointestinal tract. The IND proposes a randomized Phase III clinical trial that will compare SP1049C plus best supportive care (BSC) versus BSC alone for the treatment of patients with advanced adenocarcinoma of the esophagus, gastroesophageal junction, and stomach who have failed adjuvant or first- or second-line chemotherapy.

- Cephalon, Inc. (Frazer, Pa.) announced that the FDA has accepted and granted priority review designation to the **Treanda® (bendamustine HCl)** NDA for the first-line treatment of patients with chronic lymphocytic leukemia (CLL). Treanda is a rationally designed purine analog/alkylator hybrid. Preclinical data demonstrate that Treanda acts in two ways to kill cancer cells. It damages the DNA in cancer cells, which leads to the normal path of cell death. It also stops cancer cells from dividing to create new cancer cells. The FDA granted orphan drug status for Treanda for CLL in August 2007.

[Devices in the News]

- Varian Medical Systems, Inc. (Palo Alto, Calif.) has received FDA 510(k) clearance for a new high-definition multileaf collimator (MLC), an ultra-fine beam shaping device for radiosurgery. The

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2008 Lilly Oncology On Canvas

On Nov. 15, 2007, Eli Lilly and Company kicked off the 2008 Lilly Oncology on Canvas™ Expressions of a Cancer Journey International Art Competition and Exhibition.

All entries for the 2008 competition must be received by the U.S. Art Director no later than June 30, 2008. Entries can be from any of six different art media: oil; watercolor; acrylic; photography; pastel; and mixed media (any other type of one-dimensional art). Submitted artwork must be at least 12" x 12" and no larger than 17" x 26". There are three participant categories from which people can enter the competition: person diagnosed with cancer; healthcare professional; and family member, friend, or caregiver.

For more information about the Lilly Oncology on Canvas International Art Competition and Exhibition or to obtain an entry form and contest criteria please call 800. 734.4131.

new **HD120 MLC multileaf collimator** enables clinicians to deliver extremely precise radiosurgical treatments, including intensity-modulated radiosurgery (IMRS), and will be included with the new Novalis Tx® radiosurgery system.

■ Accuray Incorporated (Sunnyvale, Calif.) announced that its **Monte Carlo Dose Calculation** algorithm has received 510(k) clearance from the FDA and is now commercially available worldwide. The Monte Carlo Dose Calculation capability will be available for purchase as a software upgrade for customers with the MultiPlan® 2.0 Treatment Planning System.

■ Vidacare Corp., (San Antonio, Tex.) has received FDA approval for its **OnControl Biopsy System**, a bone-marrow biopsy system for hematology and oncology. The new technology is designed to increase control, improve core capture rates, and reduce patient discomfort during bone-marrow biopsy procedures.

■ Baxa Corporation announced the launch of its **Repeater™ Pump II with P2™ Technology** no-calibration pharmacy pump. The positive displacement nature of the Repeater Pump II eliminates the need for calibration or adjustment, providing accurate liquid delivery regardless of source container, final container, tubing diameter, and fluid viscosity.

The company also announced the launch of the **MedBoard™ Medication™ Tracking System.** The system complements existing Baxa pharmacy preparation and automation products. MedBoard tracks the 20 to 50 percent of pharmacy orders that are not stocked in automated dispensing cabinets (ADCs), such as first fills, stat orders, compounded items, and irregular-size items. With the MedBoard Medication Tracking System, pharmacies can manage workflows using barcode technology, improving efficiency and patient safety, by providing tracking for doses that are not part of pharmacy ADCs.

■ Varian Medical Systems (Palo Alto, Calif.) has received FDA 510(k) clearance for its **Smart Segmentation™** feature, which has been added to Varian's Eclipse™ treatment planning product. It is the first fully automatic tool that uses intelligent software to identify and outline organs and other structures within diagnostic images of the thorax and male pelvis. According to the company, the Smart Segmentation tool can automatically identify all of the structures of interest in less than 45 seconds.

■ Deep Breeze (Or-Akiva, Israel) announced that the FDA has granted 510(k) marketing clearance for the **VRIXP™**, a non-invasive, radiation-free pulmonary imaging system that uses lung sounds to create dynamic images of the lungs. The lung imaging system records lung sounds from sensors applied to a patient's back while he or she breathes. The system then uses an algorithm to convert these data into images. Changes in tissue composition or alteration in airflow impact how sounds within the lungs vibrate, and subsequently how the VRIXP images appear on the system's computer screen.

[Assays and Genetic Tests in the News]

■ Immunicon Corporation (Huntingdon Valley, Pa.) announced FDA clearance for the **CellSearch™ Circulating TumorCell Kit** as an aid in the monitoring of patients with metastatic colorectal cancer. The CellSearch test was originally cleared for *in vitro* diagnostic use in patients with metastatic breast cancer. Serial testing of circulating tumor cell (CTC) count should be used in conjunction with other clinical methods for monitoring colorectal or breast cancer. Evaluation of CTC count at any time during the course of disease allows assessment of patient prognosis and is predictive of progression free survival and overall survival. The CellSearch Circulating Tumor Cell Kit, developed by Immunicon, is exclusively marketed by Veridex, LLC, in the cancer field.

■ The Molecular Profiling Institute, Inc. (Phoenix, Ariz.) has launched **Mammostrat™**, a molecular-targeted, prognostic test for breast cancer patients. The Mammostrat prognostic test uses five immunohistochemical (IHC) biomarkers to classify patients into high-, moderate-, or low-risk categories for disease recurrence.