THE TOOLS

Fast Facts

Leading Causes of Death by Race/Ethnicity, 2003

White, Non-Hispanic
1. Heart Disease
2. Cancer
3. Cerebrovascular Disease
4. Chronic Lung Disease
5. Accidents

Hispanic
1. Heart Disease
2. Cancer
3. Accidents
4. Cerebrovascular Disease
5. Diabetes

African-American
1. Heart Disease
2. Cancer
3. Cerebrovascular Disease
4. Diabetes
5. Accidents

Asian and Pacific Islander
1. Cancer
2. Heart Disease
3. Cerebrovascular Disease
4. Accidents
5. Diabetes

American Indian and Native Alaskan
1. Heart Disease
2. Cancer
3. Accidents
4. Diabetes
5. Liver Disease

Source: National Center for Health Statistics, National Vital Statistics System

Approved Drugs

■ Bristol-Myers Squibb Company (New York, N.Y.) announced that the FDA has approved a new 200 mg vial for **Erbitux® (cetuximab)**. The 200 mg vial will reduce preparation time and effort, requiring the use of only 3 vials where previously 5 vials would have been required. The 200 mg vial also requires less storage space than the space required for the equivalent milligram quantity of the 100 mg vial. The 100 mg vial will continue to be available to provide convenience and minimization of waste. The new Erbitux vial will be priced on an equivalent basis to the 100 mg vial price.

■ **Nexavar® (sorafenib) tablets** (Bayer HealthCare Pharmaceuticals, Inc., Wayne, N.J., and Onyx Pharmaceuticals, Inc., Emeryville, Calif.) have received a new indication from the USP DI compendium for the treatment of advanced hepatocellular carcinoma.

Drugs in the News

■ The FDA has cleared YM BioSciences Inc.'s (Mississauga, Ontario) investigational new drug application (INDA) for **AeroLEF™**. AeroLEF is an inhaled-delivery composition of free and liposome-encapsulated fentanyl in development for the treatment of moderate to severe pain, including cancer pain. In contrast to fixed-dose approaches to opioid delivery, where a significant titration period is often required to determine the suitable dose for the patient, AeroLEF is being developed as a non-invasive delivery system designed to enable patients to self-titrate.

■ ImClone Systems Incorporated and Bristol-Myers Squibb Company's (New York, N.Y.) supplemental biologics license (sBLA) for **Erbitux® (cetuximab)** for overall survival in patients with advanced colorectal cancer has been granted priority review by the FDA. The companies seek to include evidence of improved overall survival in the product labeling for Erbitux in the third-line treatment of patients with metastatic colorectal cancer.

■ The FDA has granted CEL-SCI Corporation (Vienna, Va.) orphan drug designation for **Multikine®** as neoadjuvant therapy in patients with squamous cell carcinoma of the head and neck. Multikine is a mixture of naturally occurring cytokines, substances that regulate the immune system. Multikine is currently cleared for a Phase III clinical trial in the U.S. and Canada in advanced primary head and neck cancer patients.

■ GlaxoSmithKline (Philadelphia, Pa.) announced that its new drug application (NDA) for **oral Hycamtin® (topotecan) capsules**, a treatment for relapsed small cell lung cancer (SCLC), has been granted priority review by the FDA. The company's application was based on results from a Phase III study comparing oral Hycamtin plus best supportive care (BSC) to BSC alone in patients with relapsed SCLC, in addition to two Phase II and Phase III supporting studies.

Unlike IV Hycamtin, which requires five consecutive days of intravenous therapy every three weeks, oral Hycamtin will allow patients to be treated at home. Oral Hycamtin is not currently approved for patients with SCLC in any country.

■ The FDA has granted priority review to Bristol-Myers Squibb's (New York, N.Y.) NDA for the investigational compound **ixabepilone**, an epothilone B analog. The proposed indications for ixabepilone are as a monotherapy to treat patients with metastatic or locally advanced breast cancer after failure with an anthracycline, a taxane, and capecitabine, and in combination with capecitabine to treat patients with metastatic or locally advanced breast cancer after failure of an anthracycline and a taxane. Ixabepilone is a semisynthetic analog of epothilone B, designed to inhibit or prevent the growth or development of cancer cells. Epothilones and their analogs are a potential new class of antineoplastic, chemotherapy agents.

■ Bayer HealthCare Pharmaceuticals Inc., and Onyx Pharmaceuticals, Inc., (Wayne, N.J. and Emeryville,

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Calif.) announced submission of a supplemental new drug application (sNDA) to the FDA for **Nexavar® (sorafenib) tablets** for the treatment of patients with hepatocellular carcinoma (HCC). The companies are planning a company-sponsored Phase III study of Nexavar in the adjuvant treatment of HCC following the complete removal of early stage liver cancer. The sNDA submission is based on positive data from the international, Phase III, placebo-controlled Sorfenib HCC Assessment Randomized Protocol (SHARP) trial, which demonstrated that Nexavar extended overall survival by 44 percent in patients with HCC (HR=0.69; p=0.0006) versus placebo. Nexavar targets both the tumor cell and tumor vasculature.

■ The FDA granted priority review status to the sNDA filed by sanofi-aventis (Bridgewater, N.J.) for **Taxotere® (docetaxel) Injection Concentrate** in combination with cisplatin and fluorouracil for the neo-adjuvant therapy of patients with locally advanced squamous cell carcinoma of the head and neck (SCCHN) prior to chemoradiotherapy and surgery. The sNDA submission is based on the results of TAX 324, a randomized, open-label, international Phase III trial, which showed that a Taxotere-based regimen, versus standard chemotherapy, improved overall survival as a part of a sequential treatment plan for locally advanced SCCHN.

Devices in the News

■ Mindray Medical International Limited (Shenzhen, China) has received FDA 510(k) clearance for its **BC-3200**, an automatic three-part differential hematology analyzer, and **Hypervisor VI**, a central monitoring system. The BC-3200 is designed to provide reliable, efficient, and safe closed-tube sampling with a throughput rate of up to 60 samples per hour. The Hypervisor VI central monitoring system can connect up to 32 bedside patient monitors and allows healthcare professionals to view and manage data from each connected monitor and the hospital's record system at a central monitoring station. Hypervisor VI increases the functionality of three of Mindray's existing patient monitoring devices including the VS-800, PM-8000 Express, and PM-9000 Express.

Diagnostic and Genetic Tests in the News

■ Veridex, LLC, (Warren, N.J.) a Johnson & Johnson company, announced FDA approval of the **GeneSearch™ Breast Lymph Node (BLN) Assay**, an in vitro diagnostic test approved for the rapid detection of metastases greater than 0.2 mm in sentinel lymph node tissue removed from breast cancer patients. In clinical trials with more than 300 patients that compared the performance of GeneSearch with commonly performed intraoperative procedures, GeneSearch correctly identified 95.6 percent of patients who had metastases in their lymph nodes.

The test allows for the analysis of 50 percent of the sentinel node, versus five percent of tissue typically examined under a microscope for evidence of cancer cells. Test results can be produced in 35 to 40 minutes during the initial surgical procedure versus two to three days with tissue pathology. Veridex will initiate two post-approval studies on the GeneSearch BLN Assay. The first study will further substantiate the turnaround time of the test when used intraoperatively. An additional study, which will involve more than 1,000 patients, will further validate the accuracy of the GeneSearch BLN Assay.

■ Panacea Pharmaceuticals, Inc., (Gaithersburg, Md.) announced that **LC Detect**, a serum-based lung cancer diagnostic test, is now available from Panacea Laboratories. LC Detect is a simple blood test that should facilitate the identification of lung cancer, even among individuals with early-stage disease. The test measures levels of human aspartyl (asparaginyl) Beta-hydroxylase (HAAH), a cancer molecular marker, in blood. Panacea has found increased levels of HAAH in the serum of 99 percent of patients with lung cancer (n=160), including those with early-stage disease. In individuals not known to have cancer, HAAH was essentially undetectable in serum (n=93, specificity = 91 percent).

Panacea Laboratories, a division of Panacea Pharmaceuticals, is certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA).

New CPT Code for Electronic Brachytherapy for Treatment of Early Breast Cancer

The American Medical Association (AMA) Common Procedural Terminology (CPT) Editorial Panel recently approved a CPT code for the use of electronic brachytherapy, a novel form of high-dose-rate radiation therapy for the treatment of early stage breast cancer. The Category III CPT code 0182T for electronic brachytherapy became effective July 1, 2007, and will be included in the upcoming AMA CPT 2008 codebook. High-dose-rate electronic brachytherapy, per fraction, has also been assigned a new technology ambulatory payment classification (APC), which includes the high-dose-rate electronic brachytherapy radiation treatment and the cost of the X-ray source.

According to Xoft, Inc., developer of the **Axxent® Electronic Brachytherapy System**, a proprietary cancer treatment platform, this decision is an important step in accelerating the adoption of the new treatment option that is designed to deliver targeted radiation therapy directly to cancer sites with minimal radiation exposure to surrounding healthy tissue. The FDA approved the Axxent Electronic Brachytherapy System for the treatment of breast cancer in January 2006.