THE TOOLS

[Approved Drugs]

■ The U.S. Food and Drug Administration (FDA) has granted Bristol-Myers Squibb (New York, N.Y.) approval of a **Sprycel 100 mg tablet**. The new tablet supports the recently FDA-approved Sprycel 100 mg starting dose for chronic phase chronic myeloid leukemia. The new tablet was available in July.

■ Millennium Pharmaceuticals, the Takeda Oncology Company, and Takeda Pharmaceutical Company Limited (Cambridge, Mass. and Osaka, Japan) announced the FDA has approved **Velcade® (bortezomib) for injection** for patients with previously untreated multiple myeloma.

[Drugs in the News]

■ The FDA has granted priority review to GE Healthcare's (Princeton, N.J.) new drug application (NDA) for **AdreView (iobenguane I 123 injection)**. AdreView is a molecular imaging agent for the detection of neuroendocrine tumors in pediatric and adult patients. The FDA also encouraged GE to establish an expanded access program for the agent, which was granted orphan drug designation by the FDA in December 2006.

■ Clavis Pharma (Oslo, Norway) announced that the FDA has granted orphan drug designation to **Elacyt™** for the treatment of acute myeloid leukemia.

■ The FDA has granted orphan drug designation to **Marqibo® (vincristine sulfate injection, Optisome™)** for the treatment of adult patients with metastatic uveal melanoma. Marqibo (Hana Biosciences, South San Francisco, Calif.) is a novel, targeted, Optisomal formulation of vincristine.

■ Genzyme Corporation (Cambridge, Mass.) announced submission of marketing applications in both the United States and the European Union for **Mozobil™ (plerixafor)**, a product candidate intended to enhance mobilization of hematopoietic stem cells for collection and subsequent autologous transplantation in patients with lymphoma and multiple myeloma. Mozobil has been granted orphan drug status in the United States and the European Union.

■ Polyphenon Pharma (New York, N.Y.) announced that the FDA has granted orphan drug designation to its botanical drug, **Polyphenon E®**, for the treatment of chronic lymphocytic leukemia (CLL). A Phase II Study is currently underway at the Mayo Clinic in Rochester, Minn., where researchers are studying the effects of an oral daily dose of Polyphenon E in CLL patients. Polyphenon E contains highly characterized catechins that are extracted from green tea leaves through a proprietary process. The primary catechin in Polyphenon E, epigallocatechin gallate (EGCG), has been shown to affect many processes in the body related to abnormal cellular activity that can lead to cancer.

■ The FDA has granted orphan drug designation to Epeius Biotechnologies Corporation's (San Marino, Calif.) **Rexin-G** for the treatment of all soft tissue sarcomas.

■ SGX Pharmaceuticals (San Diego, Calif.) announced submission of an investigational new drug (IND) application to the FDA for **SGX393**. This compound is an internally developed, selective, orally bioavailable small molecule for the treatment of relapsed and refractory chronic myelogenous leukemia. SGX393 inhibits both wild-type BCR-ABL and many drug resistant mutant forms of

Fast Facts

Going Digital

- 73 percent of Americans believe the benefits of electronic records, such as better care in emergencies and reduction in medical errors, outweigh any potential privacy risks.
- 72 percent of Americans believe that a computer system is more efficient than a paper system when it comes to managing medical records.
- 51 percent of American adults favor providers who use electronic medical records over those who do not (17 percent).
- While only 12 percent of Americans currently review their personal medical records on their health insurance company's website, 56 percent said they would like to be able to check claims and coverage and 51 percent said they would like to be able to access personal records electronically in the future.

Source: StrategyOne, an independent public opinion research company, on behalf of Kaiser Permanente.

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THE TOOLS

BCR-ABL, including the T3151 mutation.

■ Sound Pharmaceuticals (Seattle, Wash.) has filed an IND application with the FDA for the clinical testing of a proprietary formulation of ebselen for the prevention of chemotherapy-induced hearing loss or ototoxicity. The oral capsule containing ebselen, **SPI-3005**, will be tested in advanced stage lung cancer and head and neck cancer patients receiving platinum-based chemotherapy.

[Approved Devices]

■ Bayer HealthCare Pharmaceuticals Inc. (Wayne, N.J.) announced that the FDA has approved **Eovist® (Gadoxetate Disodium) Injection**, a gadolinium-based contrast agent, for intravenous use in T1-weighted magnetic resonance imaging (MRI) of the liver to detect and characterize lesions in adults with known or suspected focal liver disease. Eovist is a paramagnetic MRI contrast agent that combines features of both an extracellular contrast agent and a hepatocyte-specific agent. The agent is administered via an intravenous, bolus injection and has a dual route of excretion with approximately 50 percent eliminated through the liver and 50 percent eliminated through the kidney. Detection and characterization of malignant and benign focal liver lesions with Eovist may help enhance diagnostic accuracy and increase diagnostic confidence. Eovist provides useful diagnostic information at the time immediately after contrast administration (dynamic imaging) and, thus, also supports lesion characterization (i.e., distinction of malignant and benign types of liver lesions).

No Medicare Expansion of Colorectal Cancer Screening with PreGen-Plus

CMS will not expand the colorectal cancer screening benefit to include coverage of PreGen-Plus™, a commercially available screening DNA stool test as an alternative to a screening colonoscopy or a screening flexible sigmoidoscopy. The FDA determined that PreGen-Plus™ is a medical device that requires pre-market review and approval prior to marketing, which, to date, has not been obtained. A subsequent request for reconsideration will be considered once FDA approval is obtained. In the absence of an FDA determination, CMS believes that there may be unresolved questions regarding the safety and effectiveness of the stool DNA test.

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[Genetic Tests and Assays in the News]

■ AMDL (Tustin, Calif.) announced that the FDA has issued a letter of substantial equivalence to an existing predicate device and granted clearance to market the **AMDL-ELISA DR-70® (FDP)** as a safe and effective blood test for monitoring patients who have been previously diagnosed with colorectal cancer. The FDA clearance to market was based on data showing DR-70(FDP) has the ability to monitor the progression of colorectal cancer post-surgery in patients who are biopsy confirmed with this disease.

■ The Pathwork Diagnostics, Inc., (Sunnyvale, Calif.) product, **Pathwork® Tissue of Origin Test**, has received FDA clearance for use in determining the origin of uncertain tumors. The test analyzes a tumor's gene expression pattern to help pinpoint the source of hard-to-identify tumors and is the first test of its kind to receive FDA clearance. Up to an estimated 200,000 newly diagnosed cancer patients annually in the U.S. may have a tumor for which the site of origin is uncertain after the initial diagnostic workup. The Pathwork Tissue of Origin Test uses a microarray to measure the expression pattern, comprising more than 1,500 genes, in the uncertain tumor and compares it to expression patterns of a panel of 15 known tumor types, representing 60 morphologies overall, to help determine the tumor's origin.

■ Invitrogen Corporation (Carlsbad, Calif.) announced FDA premarket approval for its **SPOT-Light® HER2 CISH Kit**, indicated as an aid in the assessment of breast cancer patients for whom trastuzumab (Herceptin) treatment is being considered. The kit is based on a technology called chromogenic in situ hybridization (CISH). The test uses a DNA probe for the HER2 gene, which is amplified in 18 to 30 percent of breast cancers and predicts whether a breast cancer patient is a candidate for trastuzumab treatment. CISH test results are visualized under a standard bright-field microscope, as opposed to fluorescent in situ hybridization tests, in which the results must be visualized using a fluorescent microscope. This specialized microscope frequently requires that the analysis is done at a reference lab. In addition, HER2 CISH test results are quantifiable; removing the subjectivity inherent in tests based on immunhistochemistry (IHC) interpretation schemes.