THE TOOLS

[APPROVED DRUGS]

■ The Food and Drug Administration (FDA) approved Genentech Inc.'s (South San Francisco, Calif.) anti-cancer drug **Rituxan® (rituximab)** to treat certain patients with chronic lymphocytic leukemia (CLL). Rituxan is intended for patients with CLL who are beginning chemotherapy for the first time and for those who have not responded to other cancer drugs for CLL. Rituxan is administered with two other chemotherapy drugs—fludarabine and cyclophosphamide.

Rituxan is a monoclonal antibody that is manufactured through biotechnology methods rather than by the human body's own immune system. The drug binds to the surface of cancer cells, making it easier for the patient's immune system to attack the cancer cell as if it were a foreign pathogen.

■ GlaxoSmithKline (Philadelphia, Pa.) announced that the FDA has granted accelerated approval for a new combination regimen using **Tykerb® (lapatinib)** as a first-line, all-oral treatment for women with metastatic breast cancer.

Tykerb is now indicated in combination with letrozole for the treatment of postmenopausal women with hormone receptor positive metastatic breast cancer that overexpresses the HER2 receptor for whom hormonal therapy is indicated. Tykerb in combination with an aromatase inhibitor has not been compared to a trastuzumab-containing chemotherapy regimen for the treatment of metastatic breast cancer.

PHOTOGRAPH/ISTOCKPHOTO

Fast Facts

10 Ways to Improve Cash Flow Position

1. Review and revise capital equipment policies.
2. Review revenue cycle processes for opportunities to accelerate cash collections.
3. Install a point-of-service cash collection process and make arrangements to be paid upon discharge.
4. Analyze the financial performance of high-cost, low-reimbursement procedures.
5. Renegotiate high-volume services vendor contracts to avoid undue interest charges and late fees.
6. Extend scheduling hours for high-demand outpatient services that are exceeding capacity such as imaging and surgery.
7. Evaluate salary expense adjustments.
8. Review and analyze changes to retirement benefits.
9. Assess current health-benefit contract terms.
10. Negotiate lease payments.

Source: The Camden Group, El Segundo, Calif.

[DRUGS IN THE NEWS]

■ The FDA has revised dosage and safety information for **Velcade® (bortezomib)**, the myeloma and mantle cell lymphoma drug, to reflect an increased toxicity risk. The new label includes a warning for patients with moderate-to-severe hepatic impairment and now recommends at-risk patients start at a lower dosage of 0.7 mg/m² for the first cycle of treatment and escalate to 1.0 mg/m², or reduce further to 0.5 mg/m², in subsequent cycles.

■ Cequent Pharmaceuticals, Inc., (Cambridge, Mass.) announced that the FDA approved Cequent's first investigational new drug application (IND). This action enables Cequent to initiate the first-ever clinical trial of an orally administered RNA interference drug in humans: **CEQ508**, the company's lead drug candidate based on its proprietary tkRNAi technology. CEQ508 targets beta-catenin, a key oncogene implicated in the formation of colonic polyps and in the progress of polyps to colorectal cancer.

■ EntreMed, Inc. (Rockville, Md.) announced that the FDA has granted orphan drug designation for **ENMD-2076** for the treatment of acute myeloid leukemia. ENMD-2076 is an orally-active, Aurora A/angiogenic kinase inhibitor with a unique kinase selectivity profile and multiple mechanisms of action. Preclinical studies with ENMD-2076 demonstrated significant antitumor activity, including tumor regression, in multiple solid and hematological malignancies.

■ The FDA granted orphan drug designation to **Graspa**, a new drug being developed by Erytech Pharma (Lyons, France) as a potential treatment for acute-lymphoblastic leukemia. Graspa is a new enzyme formulation of L-asparaginase—a chemical shown to damage cancer cells—that the company has encapsulated inside red blood cells

to make it safer and have a broader range of clinical uses, as compared to existing forms of L-asparaginase.

■ Sopherion Therapeutics, LLC, (Princeton, N.J.) announced that the FDA has granted fast track designation for **Myocet™ (nonpegylated liposomal doxorubicin)** for first-line therapy of HER2 positive metastatic breast cancer. Treatment with Myocet has already shown a reduced level of cardiotoxicity as compared to traditional doxorubicin. Myocet is a liposome-encapsulated doxorubicin-citrate complex.

■ Amgen (Thousand Oaks, Calif.) announced that the Centers for Medicare & Medicaid Services (CMS) established a product-specific Healthcare Common Procedures Coding System (HCPCS) J-code, or permanent code, for **Nplate® (romiplostim)**. Effective for dates of service on or after Jan. 1, 2010, the new J-code for Nplate is J2796.

The new J-code, J2796 for 10 mcg units of Nplate, should be used instead of the current miscellaneous J-code (J3590) as well as the current C-code (C9245) when used on a claims form starting on Jan. 1, 2010.

The new J2796 code is included in the 2010 version of coding manuals that providers rely on for coding information.

Epocrates Expands iPhone Offerings

Epocrates, Inc., (San Mateo, Calif.), developer of a medical application for iPhone and iPod touch devices has introduced a new premium software suite for the platform—Epocrates® Essentials Deluxe. Epocrates® Essentials Deluxe is an integrated software suite that combines the Epocrates Essentials premium drug, disease, and diagnostic information with a coding reference and an industry-standard medical dictionary. U.S. physicians who rely on Epocrates products on the iPhone and iPod touch devices can access reference, diagnosis, decision support, and billing information all in one application.

PHOTOGRAPHS COURTESY OF EPOCRATES, INC.

[DEVICES IN THE NEWS]

■ Veran Medical Technologies (St. Louis, Mo.) announced two FDA clearances to expand the company's indications for use of the **ig4 Navigation System** to use ultrasound and 3D fluoroscopic X-ray.

■ In its annual update to the Healthcare Common Procedure Coding System (HCPCS) for 2010, CMS has assigned a new HCPCS billing code and unit to **Taxotere® (docetaxel) Injection Concentrate** (J9171) for dates of service on or after Jan. 1, 2010. This change applies to all payers. Medicare contractors were required to accept this new code on Jan. 1, 2010; other payers, including private payers and Medicaid programs, may update their systems on an alternate schedule.

J9171 (docetaxel, injection, per 1 mg) should replace J9170 (docetaxel, injection, per 20 mg). The retired J9170 code and 20-mg billing unit should not be used on or after Jan. 1, 2010.

[GENETIC TESTS AND ASSAYS IN THE NEWS]

■ On Jan. 21, 2010, Genomic Health, Inc., (Redwood City, Calif.) announced worldwide commercial availability of its **Oncotype DX® colon cancer test**, the first multigene expression test developed for the assessment of risk of recurrence in patients with Stage II disease. The 12-gene advanced diagnostic test is clinically validated to predict individual recurrence risk in Stage II colon cancer patients following surgery, as reported at the 2009 American Society of Clinical Oncology (ASCO) meeting.

Availability in New York is pending review by the state, as is required for all laboratory developed tests.

■ Agendia (Huntington Beach, Calif., and Amsterdam, The Netherlands) announced that the FDA cleared its **MammaPrint®** breast cancer recurrence test for all ages. MammaPrint identifies patients with early metastasis risk—patients who are likely to develop metastases within five years following surgery. All MammaPrint tests are conducted in Agendia's CLIA-accredited service laboratory. FDA clearance under the *in vitro* diagnostic multivariate index assay guidelines requires clinical and analytical validation and reporting system to ensure patient safety issues are addressed.

■ Polymedco, Inc., (Cortlandt Manor, N.Y.) announced that the FDA has granted 510(k) clearance of the **OC-Sensor Diana**, a high throughput automated system for the immunoassay fecal occult blood test (FIT) used for detecting gastrointestinal bleeding associated with disorders such as colorectal cancer, polyps, and colitis. The new OC-Sensor Diana system measures 280 FIT samples per hour and ensures that quality data is consistently collected.