THE TOOLS

[Approved Drugs]

■ The Food and Drug Administration (FDA) has approved GE Healthcare's (Princeton, N.J.) **Cysview (hexaminolevulinate HCl)** for the detection of non-muscle-invasive papillary cancer of the bladder in patients with known or suspected bladder cancer. Cysview is an optical imaging agent indicated for use in the cystoscopic detection of non-muscle-invasive papillary cancer of the bladder among patients suspected or known to have lesion(s) on the basis of a prior cystoscopy.

■ Sagent Pharmaceuticals, Inc. (Schaumburg, Ill.) announced FDA approval of the company's two abbreviated new drug applications (ANDAs) to market **granisetron hydrochloride injection, USP (granisetron)**, an antiemetic used to prevent nausea and vomiting caused by chemotherapy. Granisetron will be available in 0.1 mg per mL and 1.0 mg per mL single-dose vials, and 4.0 mg per 4mL multi-dose vials.

Sagent expects to begin marketing granisetron in the third quarter of 2010. Granisetron is the generic equivalent of Kyril®.

■ The FDA has approved **Jevtana® (cabazitaxel) Injection**, a chemotherapy drug used in combination with the steroid prednisone to treat men with prostate cancer. Marketed by sanofi-aventis (Bridgewater, N.J.), Jevtana is the first treatment for advanced, hormone-refractory, prostate cancer that has worsened during or after treatment with docetaxel.

■ Novartis (East Hanover, N.J.) announced FDA approval of **Tasigna® (nilotinib) 150 mg capsules** for the treatment of adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Tasigna has been approved in more than 80 countries for the treatment of chronic phase and accelerated phase Ph+ CML in adult patients resistant or intolerant to at least one prior therapy, including Gleevec (imatinib).

[Drugs in the News]

■ Aeterna Zentaris Inc. (Quebec City) announced that the FDA has approved the company's investigational new drug application (IND) for its doxorubicin targeted conjugate compound, **AEZS-108**, in luteinizing hormone releasing hormone (LHRH) receptor positive urothelial (bladder) cancer. Following this FDA approval, the company expects to initiate a Phase II clinical trial in this indication in the second half of this year.

The company also announced that AEZS-108 has received orphan drug designation for the treatment of ovarian cancer.

■ The FDA recently approved the addition of new supplementary data to the label of **Femara® (letrozole tablets)**, which shows updated results from the Breast International Group (BIG) 1-98 trial supporting superiority of Femara over tamoxifen on disease-free survival and time to distant metastasis. Femara is a product of Novartis, Inc. (New York, N.Y.)

■ Allos Therapeutics, Inc. (Westminster, Colo.) announced that the FDA has granted orphan drug designation to **pralatrexate** for the treatment of advanced or metastatic transitional cell carcinoma (TCC) of the urinary bladder, a form of bladder cancer. The company is currently investigating pralatrexate in a Phase II clinical study in patients with

Fast Facts

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Financial Burdens of Cancer Care Hard on Patients and Families

- 81% of patients and 72% of caregivers experienced "moderate to severe" stress levels from the monetary burdens associated with care
- 23% of patients used pharmaceutical assistance programs to pay for unexpected costs
- 46% of the patients who received patient assistance reported that the programs were difficult to use
- 45% of patients were not aware of pharmaceutical assistance programs
- To reduce expenses, nearly 50% of patients delayed seeking psychological support

Source: *Understanding Challenges and Barriers to Financial Support for Cancer Treatment*. A national pilot survey conducted by the Research and Training Institute at the Cancer Support Community, *www.thewellnesscommunity.org*.

Pfizer Withdraws Mylotarg from U.S. Market

Pfizer Inc. announced on June 21, 2010, the voluntary withdrawal from the U.S. market of the drug Mylotarg (gemtuzumab ozogamicin) for patients with acute myeloid leukemia (AML). The company took the action at the request of the FDA after results from a recent clinical trial raised new concerns about the product's safety and the drug failed to demonstrate clinical benefit to patients enrolled in trials. As a result of the withdrawal, Mylotarg will not be commercially available to new patients. Patients who are currently receiving the drug may complete their therapy following consultation with their health care professional. Health care professionals should inform all patients receiving Mylotarg of the product's potential safety risks.

advanced or metastatic relapsed TCC of the urinary bladder.

■ The FDA has granted **Prostvac™** (Bavarian Nordic A/S, Kvistgaard, Denmark) fast track designation for its proposed use in the treatment of men with asymptomatic or minimally symptomatic metastatic castration-resistant prostate cancer (mCRPC).

Prostvac is a therapeutic vaccine moving into late-stage clinical development that has the potential to extend the lives of people with advanced prostate cancer. Administered subcutaneously, it induces a specific, targeted immune response that attacks prostate cancer cells.

[Devices in the News]

■ Hybridyne Imaging Technologies, Inc. (Toronto, Ontario) announced FDA clearance of **ProxiScan™**, a high-resolution gamma camera for the detection of cancer and other abnormalities in the body. ProxiScan, which is powered by cadmium zinc telluride detectors, produces higher resolution images than current nuclear imaging methods and may greatly improve the accuracy of diagnosing malignant tumors and provide the detailed information needed for early treatment.

FDA Approves Provenge for Advanced Prostate Cancer

The FDA approved Provenge (sipuleucel-T), a new therapy for certain men with advanced prostate cancer that uses their own immune system to fight the disease. Provenge is indicated for the treatment of asymptomatic or minimally symptomatic prostate cancer that has spread to other parts of the body and is resistant to standard hormone treatment. Provenge is manufacturered by Seattle-based Dendreon Corp.

Provenge is an autologous cellular immunotherapy, designed to stimulate a patient's own immune system to respond against the cancer. Each dose of Provenge is manufactured by obtaining a patient's immune cells from the blood, using a machine in a process known as leukapheresis. To enhance their response against the cancer, the immune cells are then exposed to a protein that is found in most prostate cancers, linked to an immune stimulating substance. After this process, the patient's own cells are returned to the patient to treat the prostate cancer. Provenge is administered intravenously in a three-dose schedule given at about two-week intervals.

Update to NCCN Guidelines™ and NCCN Compendium™ for Prostate Cancer

The NCCN Prostate Panel added sipuleucel-T as a category 1 treatment recommendation for patients with castration-recurrent prostate cancer. Sipuleucel-T is appropriate for asymptomatic or minimally symptomatic patients with ECOG performance status 0-1. It is not recommended for patients with visceral disease and a life expectancy of less than six months.

Recently, NCCN published updates to the *NCCN Clinical Practice Guidelines in Oncology* for antiemesis, neuroendocrine tumors, and soft tissue sarcoma. For the complete updated versions of the *NCCN Clinical Practice Guidelines in Oncology* and the *NCCN Drugs & Biologics Compendium*, go to *www.NCCN.org*.

[Genetic Tests and Assays in the News]

■ Abbott Diagnostics (Abbott Park, Ill.) announced that the FDA has cleared the company's new diagnostic test to monitor ovarian cancer. **Architect HE4 (human epididymis protein 4) assay** uses a simple blood test to aid in monitoring for the recurrence or progression of this disease. The assay is designed to be used as an aid in monitoring recurrence or progressive disease in patients with epithelial ovarian cancer, and should be used in conjunction with other clinical data. The Architect HE4 assay should not be used as a cancer screening test. In addition, certain types of cancer (e.g., mucinous or germ cell tumors) rarely express HE4, and the use of Architect HE4 assay is not recommended for monitoring patients with those types of cancer.

■ IRIS International, Inc. (Chatsworth, Calif.) announced that its IRIS Molecular Diagnostics subsidiary has submitted a 510(k) pre-market notification application to the FDA requesting regulatory clearance for **NADiA® ProsVue™**, a prostate cancer prognostic test. The test is designed to help physicians identify patients at low risk of cancer recurrence post radical prostatectomy.

■ Myriad Genetics, Inc. (Salt Lake City) announced a significant improvement in the sample collection kit for **OnDose™**, the company's 5-Fluorouracil (5-FU) dose optimization product. Patient sample handling can now be conducted at room temperature, eliminating the need for frozen product sample handling. The new OnDose sample handling protocol employs a chemical stabilizer that is injected into the blood collection test tube immediately following the patient's blood draw. The stabilizer effectively inhibits any enzyme degradation of the 5-FU in the patient's blood sample.

OnDose is a simple blood test that provides oncologists with a practical means to optimize infusional 5-FU therapy for colon cancer patients by measuring a patient's actual exposure to the chemotherapeutic drug, 5-FU.