THE TOOLS

[Approved Drugs]

■ Eisai Inc. (Woodcliff Lake, N.J.) announced that the Food and Drug Administration (FDA) has approved a five-day dosing regimen for **Dacogen® (decitabine) for Injection** to treat patients with myelodysplastic syndromes (MDS). The new outpatient dosing option provides physicians and patients with the flexibility of a dosing regimen with a reduced infusion time.

Dacogen is the only hypomethylating agent approved for a five-day dosing regimen. The new regimen will be administered at a dose of 20 mg/m² continuous intravenous (IV) infusion over one hour repeated daily for five days per cycle. The cycle is repeated every four weeks. The previously approved Dacogen three-day regimen is administered in an inpatient setting at a dose of 15 mg/m² continuous IV infusion over three hours repeated every eight hours for three days per cycle and repeated every six weeks.

■ OSI Pharmaceuticals, Inc. (Melville, N.Y.) announced the FDA has approved the daily pill **Tarceva® (erlotinib)** as a maintenance treatment for patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) whose disease has not progressed after four cycles of platinum-based first-line chemotherapy. The new approval for Tarceva was based on data from the pivotal Phase III SATURN study. SATURN showed that Tarceva given as a maintenance therapy immediately after first-line chemotherapy significantly extended overall survival and significantly improved the time people with advanced NSCLC lived without the disease getting worse (progression-free survival) in a broad patient population, including squamous and non-squamous histology, compared with placebo.

Tarceva is already FDA-approved for people with advanced NSCLC whose cancer has grown or spread after receiving at least one course of chemotherapy. Tarceva is not meant to be used at the same time as certain types of chemotherapy for NSCLC.

■ Watson Pharmaceuticals Inc. (Morristown, N.J.) announced that the FDA has approved a six-month dose of the prostate cancer drug **Trelstar®**. The drug is already available in one- and three-month doses. Trelstar is developed by Debiopharm Group of Switzerland and is marketed by Watson. Watson plans to launch the six-month dose in May.

Fast Facts

Healthcare Reform—5 Reasons it Matters for Cancer Survivors

1. "Pre-existing" conditions are history
2. You can't lose your insurance when you need it most
3. An end to "lifetime caps" on your benefits
4. More coverage for young adults
5. Support for clinical trials.

Source: Doug Ulman, President and CEO, and the LIVESTRONG Action Team

New C-Codes Available

Effective April 1, 2010, for the Hospital Outpatient Prospective Payment System (HOPPS) only, new HCPCS codes are available for:

- Folotyn (pralatrexate injection), 1 mg, C9259
- Arzerra (ofatumumab injection), 10 mg, C9260
- Fludarabine phosphate, oral, 1 mg, C9262.

[Drugs in the News]

■ The FDA has granted orphan drug designation to Ariad Pharmaceuticals, Inc.'s (Cambridge, Mass.) investigational pan-BCR-ABL inhibitor, **AP24534** for the treatment of chronic myeloid leukemia (CML) and Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL). Ariad is currently completing a Phase I clinical trial of oral AP24534 in patients with advanced hematological cancers and plans to begin a pivotal registration trial of AP24534 later this year.

■ Caraco Pharmaceutical Laboratories Ltd. (Detroit, Mich.) announced plans to launch a generic version of **Exolatin (oxaliplatin injection)**. Caraco said it is launching the 50 mg and 100 mg generic doses of the drug after the FDA approved Sun Pharma's application. Caraco is a subsidiary of Sun Pharma.

■ The FDA has granted orphan drug designation to BioSante Pharmaceuticals, Inc.'s (Lincolnshire, Ill.) **GVAX Pancreas Cancer Vaccine** in the treatment of pancreatic cancer. BioSante also announced receipt of orphan drug designation from the FDA for the **GVAX AML Vaccine** in the treatment of acute myeloid leukemia (AML).

■ AEterna Zentaris Inc. (Quebec City) announced that its partner, Keryx Biopharmaceuticals, was granted fast track designation

by the FDA for **perifosine (KRX-0401)**, the company's novel, potentially first-in-class, oral anti-cancer agent that inhibits the phosphoinositide 3-kinase (PI3K)/Akt pathway, for the treatment of refractory advanced colorectal cancer. Keryx is AEterna Zentaris' partner and licensee for perifosine in the United States, Canada, and Mexico.

A randomized, double-blind Phase III trial investigating perifosine in combination with capecitabine (Xeloda®) versus placebo in combination with capecitabine (Xeloda®) in patients with refractory metastatic colorectal cancer is expected to commence this quarter under a Special Protocal Assessment (SPA) with the FDA.

■ Novartis (East Hanover, N.J.) announced that **Tasigna® (nilotinib) 200 mg capsules** has been granted priority review by the FDA for the treatment of adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase. Tasigna is a potent and selective inhibitor of the BCR-ABL protein that causes production of cancer cells in Ph+ CML.

Eprocrates Update

Epocrates, Inc. (San Mateo, Calif.) announced availability of a beta version of its software for Google's Android™. With this new offering Epocrates® software is now available across all major platforms, including iPhone, BlackBerry, Palm, Windows Mobile, and Android. The new Epocrates application for the Android is available for free download at: *www.epocrates.com/products/android*.

[Genetic Tests and Assays in the News]

■ Myriad Genetics, Inc. (Salt Lake City, Utah) announced the launch of **Prolaris™**, a 46-gene prognostic test that quantitatively determines the risk of recurrence in patients who have undergone prostatectomy surgery. Prolaris is a molecular diagnostic assay that offers urologists a more accurate way of determining a prostate cancer patient's risk of recurrence. The new molecular diagnostic test is based on cell growth and tumor biology and provides rigorous, quantitative measures of the expression level of multiple genes related to progression of the cell cycle.

■ **OVA1™**, the first blood test cleared by the FDA for aiding in the pre-surgical evaluation of a woman's ovarian mass for cancer, is now available nationally through Quest Diagnostics, Inc. (Madison, N.J.). With the availability of OVA1, physicians can assess, prior to a planned surgery, the likelihood that a woman's ovarian mass is malignant in order to direct her to the most appropriate surgeon. Vemillion, Inc., a molecular diagnostic company, developed the test in cooperation with Quest Diagnostics.

OVA1 is indicated for women who meet the following criteria: over age 18, ovarian adnexal mass present for which surgery is planned, and not yet referred to an oncologist. It is an aid to further assess the likelihood that malignancy is present when the physician's independent clinical and radiological evaluation does not indicate malignancy. The test should not be used without an independent clinical/radiological evaluation and is not intended to be a screening test or to determine whether a patient should proceed to surgery. Incorrect use of the OVA1 Test carries the risk of unnecessary testing, surgery, and/or delayed diagnosis.

PHOTOGRAPH/ISTOCKPHOTO