tools

Approved Drugs

- The Food and Drug Administration (FDA) has approved **Afinitor® (everolimus)** (Novartis Pharmaceuticals Corporation, *www.novartis.com*) in combination with Aromasin (exemestane), after failure of treatment with letrozole or anastrozole. The approval was based on a randomized, double-blind, multicenter trial conducted in 724 postmenopausal women with estrogen receptor-positive, HER2-negative, advanced breast cancer with recurrence or progression following prior therapy with letrozole or anastrozole.

- The FDA approved **Erbitux (cetuximab)** (ImClone LLC, a wholly owned subsidiary of Eli Lilly and Co., *www.lilly.com*) for use in combination with FOLFIRI (irinotecan, 5-fluorouracil, leucovorin) for the first-line treatment of patients with KRAS mutation-negative (wild-type), EGFR-expressing metastatic colorectal cancer (mCRC) as determined by FDA-approved tests for this use. The FDA also approved the **therascreen® KRAS RGQ PCR Kit** (QIAGEN Manchester, Ltd., *www.qiagen.com*) concurrent with this cetuximab approval.

- Onyx Pharmaceuticals, Inc., (*www.onyx.com*) announced that the FDA has granted accelerated approval of **Kyprolis™ (carfilzomib)** for injection, a proteasome inhibitor indicated for the treatment of patients with multiple myeloma who have received at least two prior therapies, including bortezomib and an immunomodulatory agent, and have demonstrated disease progression on or within 60 days of completion of the last therapy. The indication for Kyprolis is based on response rate. Currently, no data are available for Kyprolis that demonstrate an improvement in progression-free survival or overall survival.

- Talon Therapeutics (*www.talontx.com*) announced that **Marqibo® (vincristine sulfate liposome injection)** has received accelerated approval from the FDA for the treatment of adult patients with Philadelphia chromosome negative (Ph-) acute lymphoblastic leukemia (ALL) in second or greater relapse or whose disease has progressed following two or more anti-leukemia therapies. This indication is based on overall response rate. Clinical benefit such as improvement in overall survival has not been verified.

- Sanofi (*www.sanofi.com*) announced that the FDA has approved **Zaltrap® (ziv-aflibercept) injection** for intravenous infusion in combination with 5-fluorouracil, leucovorin, irinotecan (FOLFIRI), for patients with metastatic colorectal cancer (mCRC) that is resistant to or has progressed following an oxaliplatin-containing regimen. Ziv-aflibercept (previously known as aflibercept) is a recombinant fusion protein consisting of vascular endothelial growth factor (VEGF)-binding portions from the extracellular domains of human VEGF receptors 1 and 2 that are fused to the Fc portion of the human IgG1 immunoglobulin. This approval is based on the results of a randomized, double-blind, placebo-controlled, global, multicenter trial enrolling patients with mCRC that progressed during or within 6 months of receiving oxaliplatin-based combination chemotherapy, with or without prior bevacizumab.

Drugs in the News

- The FDA has granted orphan drug designation to **BAY 94-9343** (Bayer HealthCare, *www.bayer.com*), a mesothelin-targeting antibody-drug conjugate (ADC), for the treatment of patients with mesothelioma. This investigational agent is currently in Phase I clinical development.

- Biokine Therapeutics Ltd. (*www.biokine.com*) announced the company has received orphan drug designation from the FDA for the mobilization of hematopoietic stem cells from bone marrow into peripheral blood for collection and subsequent transplantation in patients with hematological cancers. Earlier in 2012, Biokine received FDA approval to conduct a Phase II clinical study for stem cell mobilization in multiple myeloma and non-Hodgkin lymphoma patients utilizing **BKT140.**

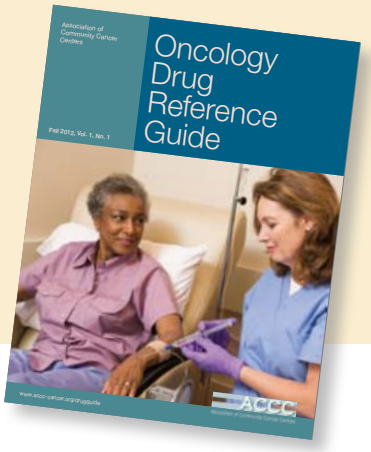
- The FDA has granted orphan drug designation to **CNDO-109—activated allogeneic natural killer cells** (Coronado Biosciences, Inc., *www.coronadobio.com*) for the treatment of acute myeloid leukemia.

Coming This Fall! ACCC's *Oncology Drug Reference Guide*

This practical publication will be published yearly to help oncologists, nurses, pharmacists, financial counselors, and other oncology support and administrative staff navigate the increasingly complex area of drug information. ACCC's *Oncology Drug Reference Guide* is a convenient source of information on the drugs commonly used to treat cancer.

Each drug is presented by HCPCS code, generic name, brand name, billing unit, and manufacturer contact information. The guide lists average sales prices for all currently marketed drugs that have Medicare billing codes in the oncology range (J8500 through J9600), or that have been approved by the Food and Drug Administration for treating cancer. Manufacturers are identified for each brand drug for which there is no generic equivalent. Contact information is included for both the reimbursement and medical affairs departments, so that readers may request copies of the latest evidence as well as compendia and journal reprints.

ACCC members will receive a copy of the Guide in the mail. Quarterly updates will be available on ACCC's website (*www.accc-cancer.org/drugguide*).



- Janssen Research & Development, LLC, (*www.janssenpharmaceuticalsinc.com*) announced that the company has submitted a supplemental New Drug Application (sNDA) to the FDA for **Zytiga® (abiraterone acetate)**. The application is intended to extend the use of Zytiga administered with prednisone to include the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) who are asymptomatic or mildly symptomatic after failure of androgen deprivation therapy and before chemotherapy.

- Bayer HealthCare (*www.bayer.com*) and Onyx Pharmaceuticals announced that the FDA has granted priority review designation to the company's new drug application (NDA) for the oral multikinase inhibitor **regorafenib**, for the treatment of patients with metastatic colorectal cancer whose disease has progressed after approved standard therapies.

- The FDA has completed review of Cellceutix Corporation's (*www.cellceutix.com*) investigational new drug application (INDA) for **Kevetrin™** and informed the company that it may proceed with a proposed Phase I clinical trial.

Assays and Genetic Tests in the News

- Beckman Coulter, Inc., (*www.beckmancoulter.com*) announced FDA premarket approval (PMA) for the **Prostate Health Index *(phi)***, a simple, non-invasive blood test that is 2.5 times more specific in detecting prostate cancer than PSA (prostate-specific antigen) in patients with PSA values in the 4-10 ng/mL range and is proven to reduce the number of prostate biopsies. *Phi* will be available in the U.S. in the third quarter of 2012 for use on the company's Access 2 and UniCel Dxl immunoassay systems.

- Caris Life Sciences (*www.carislifesciences.com*) announced the launch of **Caris Target Now™ Select**, an advanced, evidence-based molecular profiling service for patients with non-small cell lung cancer (NSCLC), melanoma, and cancers of the breast, colon, and ovary. Caris Target Now Select incorporates updated, evidence-based technology platforms to determine the genomic information unique to a patient's tumor based on the presence of relevant biomarkers.

Devices in the News

- Elekta's **Agility™*** multi-leaf collimator recently received 510(k) clearance from the FDA. Agility uses a combination of 160 high-resolution tungsten leaves and faster leaf movement, precisely sculpting delivered radiation to the unique contours of the tumor, while reducing the risk of exposure to healthy tissue. **Note: Agility is not licensed for sale in all markets. For details, contact a local representative.* OI