tools

Approved Drugs

- Janssen Biotech, Inc. (*www.janssenbiotech.com*) announced that the U.S. Food and Drug Administration (FDA) has approved an expanded indication for **Zytiga® (abiraterone acetate)** in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer. The approval was based on a trial randomizing patients with metastatic castration-resistant prostate cancer who had not received cytotoxic chemotherapy to either abiraterone acetate plus prednisone or placebo plus prednisone. Treatment with abiraterone acetate improved radiographic progression-free survival.

- The FDA approved **Cometriq (cabozantinib)** (Exelixis, *www.exelixis.com*) to treat meduallary thyroid cancer that has spread to other parts of the body. The approval is based on a clinical study involving 330 patients with medullary thyroid cancer. Treatment with Cometriq increased the length of time a patient lived without cancer progressing (progression-free survival) and, in some patients, reduced the size of tumors (response rate).

- The FDA approved **Iclusig (ponatinib)** (Ariad Pharmaceuticals, *www.ariad.com*) to treat adults with chronic myeloid leukemia (CML) and Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL). Iclusig blocks certain proteins that promote the development of cancerous cells. The drug is taken once a day to treat patients with chronic, accelerated, and blast phases of CML and Ph+ ALL whose leukemia is resistant or intolerant to a class of drugs called tyrosine kinase inhibitors (TKIs). Iclusig targets CML cells that have a particular mutation, known as T315I, which makes these cells resistant to currently approved TKIs.

- The FDA granted accelerated approval to **Synribo (omacetaxine mepesuccinate) for Injection** (Teva Pharmaceutical Industries Ltd., *www.tevapharm.com*) for the treatment of adult patients with chronic or accelerated phase CML with resistance and/or intolerance to two or more TKIs. The accelerated approval is based on combined data from two open label single-arm trials enrolling patients with CML in chronic phase or in accelerated phase.

- Genentech Inc. (*www.gene.com*) has received FDA approval of a 90-minute infusion for **Rituxan (rituximab) Injection**, starting at Cycle 2 for patients with non-Hodgkin's lymphoma (NHL) who did not experience a grade 3 or 4 infusion-related adverse reaction during Cycle 1. Patients with clinically significant cardiovascular disease and high circulating lymphocyte counts (>5000/mcL) are not recommended to receive the faster infusion.

Drugs in the News

- The FDA has granted Cell Therapeutics, Inc. *(www.celltherapeutics.com)* orphan drug designation for **Opaxio™ (paclitaxel poliglumex, CT-2103)** for the treatment of glioblastoma multiforme, a malignant brain cancer. The designation was granted based on preliminary activity seen from Phase II results of Opaxio when added to standard therapy (temozolamide [TMZ] plus radiation).

- OXiGENE, Inc. *(www.oxigene.com)* announced that its product candidate **OXi4503** has been granted orphan drug designation by the FDA for the treatment of acute myelogenous leukemia (AML). A Phase I study of OXi4503 for the treatment of patients with AML or myelodysplastic syndrome (MDS) is currently underway.

- The FDA has expanded labeling to include the results of an additional trial evaluating the safety and efficacy of **pemetrexed** (Alimta, Eli Lilly and Company, *www.lilly.com*) for the initial treatment of patients with locally advanced or metastatic, non-squamous, non-small cell lung cancer (NSCLC) followed by pemetrexed maintenance in patients whose disease has not progressed after four cycles of platinum and pemetrexed as first-line chemotherapy.

- Bayer HealthCare *(www.bayer.com)* and Onyx Pharmaceuticals *(www.onyx.com)* announced that the FDA granted priority review to the New Drug Application (NDA) for **Stivarga® (regorafenib) tablets** to treat patients with metstatic and/or unresectable gastrointestinal stromal tumors whose disease has progressed despite prior treatment with two kinase inhibitors. The submission was based on data from the Phase III GRID study.

- Astellas Pharma US, Inc. *(www.astellas.us)* has submitted a supplemental NDA to the FDA seeking approval for **Tarceva® (erlotinib) tablets** for first-line treatment of patients with locally advanced or metastatic NSCLC whose tumors have epidermal growth factor receptor (EGFR) activating mutations as detected by an approved test. The sNDA submission is based on results of the international EURTAC trial, a prospective, randomized, controlled Phase III trial evaluating the first-line use of Tarceva versus platinum-based chemotherapy in patients with EGFR activating mutation-positive advanced NSCLC.

- XBiotech *(www.xbiotech.com)* announced that the FDA has granted Fast Track Designation for its anti-cachexia drug **Xilonix™**. The therapeutic antibody was shown in a previous clinical study to stop or reverse cachexia in about a third of all advanced cancer patients treated. Under the Fast Track program, XBiotech will now launch a Phase III study to treat advanced colorectal cancer patients suffering from cachexia.

Assays and Genetic Tests in the News

- Hologic, Inc. *(www.hologic.com)* announced that the FDA approved the **APTIMA HPV 16 18/45 Genotype Assay** for use on its TIGRIS instrument system. The test is intended to test specimens from women with APTIMA HPV Assay positive results and is approved for two uses: adjunctively with the APTIMA HPV Assay in women 30 years and older in combination with cervical cytology to assess the presence or absence of specific high-risk genotypes 16, 18, and/or 45; adjunctively with the test in women 21 years or older with atypical squamous cells of undetermined significance cervical oncology results to assess the presence of genotypes 16, 18, and/or 45. The results of this test are not intended to prevent women from proceeding to colposcopy.

- Phenogen Sciences, Inc. *(www.phenogensciences.com)* announced the immediate availability of **BREVAGen™**, a predictive risk test for women for sporadic, hormone-dependent breast cancer. The risk assessment test examines a woman's clinical risk factors, such as her lifetime exposure to estrogen, combined with scientifically-validated genetic markers to determine each patient's personalized five-year and lifetime risk of developing breast cancer, regardless of family history.

- Quest Diagnostics *(www.questdiagnostics.com)* announced the availability of a new laboratory test that identifies molecular changes to cervical cells that increase the likelihood a woman may develop cervical cancer. The **Cervical Cancer *TERC* Test** is designed to help physicians identify women who are at increased risk of developing malignancy, unless treated, after receiving unclear results for cervical cancer from standard screening tests. The new test is designed as an adjunct to conventional Pap and human papillomavirus (HPV) tests. It detects abnormal changes to the TERC gene and chromosome 3 to provide a risk assessment of progression to cervical cancer in women who receive indeterminate Pap and/or HPV test results.

- Cytocell Ltd. *(www.cytocell.com)* announced the availability of a new molecular cytogenetic test designed to identify the presence of gene rearrangements associated with a specific form of non-small cell lung cancer. The **Cytocell ROS1 Breakapart FISH probe** uses Fluorescence *In Situ* Hybridization (FISH) technology to detect rearrangements of the ROS1 gene on chromosome 6 in band 6q22 in tumors.

- Roche *(www.roche.com)* announced the U.S. market availability of the **Elecsys HE4 assay**, an FDA-approved test used in monitoring patients with ovarian cancer. The HE4 test is used as an aid in monitoring the recurrence of progressive disease in patients with epithelial ovarian cancer.

Approved Devices

- The FDA has approved **ExAblate® MRI-guided Focused Ultrasound** (InSightec Ltd., *www.insightec.com*) as a therapy to treat pain from bone metastases in patients who do not respond or cannot undergo radiation treatment for their pain. ExAblate was also approved by the FDA in 2004 as a non-invasive, outpatient therapy for uterine fibroids. This second approval was based on results from an international, multi-center, randomized clinical study in which patients who underwent ExAblate therapy reported clinically significant pain relief and improvement of quality-of-life during follow-up three months after treatment.

Devices in the News

- Life Technologies Corporation *(www.lifetechnologies.com)* announced it has received FDA 510 (k) clearance for its **OpTmizer™ CTS™ T-Cell Expansion Tissue Culture Medium,** a reagent that is now cleared as a Class 2 medical device and offers cost and time-saving advantages for transitioning studies from the research bench to clinical trials. It is currently being used in multiple clinical trials in the United States.

- DFINE, Inc. *(www.dfineinc.com)* announced the launch of the **STAR™ Tumor Ablation System** which, along with targeted Radiofrequency Ablation™ (t-RFA) therapy, allows physicians to provide patients with rapid pain relief from metastatic spinal tumors in a single, minimally invasive treatment. The STAR system was developed specifically for the palliative treatment of metastatic vertebral body tumors. t-RFA therapy is typically an outpatient procedure and can be performed using local anesthesia through a small incision.

New C-Code for Perjeta™ (pertuzumab)

The code: C9292 (injection, pertuzumab, 10 mg) is for infusions administered to Medicare patients in hospital outpatient facilities. The C-code went into effect on Oct. 1, 2012 and can be used until a permanent J-code is assigned in 2013.