# tools

## Approved Drugs

• The Food and Drug Administration (FDA) has granted regular approval for Pfizer's (*www.pfizer.com*) **Xalkori® (crizotinib) capsules** for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test. The approval was based on demonstration of superior progression-free survival and overall response rate for crizotinib-treated patients compared to chemotherapy in patients with ALK-positive NSCLC with disease progression after platinum-based doublet chemotherapy.

• Pharmacyclics, Inc. (*www.pharmacyclics.com*) announced that the FDA approved **Imbruvica™ (ibrutinib)** as a single agent for the treatment of patients with mantle cell lymphoma (MCL) who have received at least one prior therapy. This indication is based on overall response rate. An improvement in survival or disease-related symptoms has not been established. Imbruvica inhibits the function of Bruton's tyrosine kinase (BTK). BTK is a key signaling molecule of the B-cell receptor signaling complex that plays an important role in the survival of malignant B cells. Imbruvica blocks signals that stimulate malignant B cells to grow and divide uncontrollably.

• The FDA approved Genentech's (*www.gene.com*) **Gazyva™ (obinutuzumab)** for use in combination with chlorambucil for the treatment of patients with previously untreated chronic lymphocytic leukemia (CLL). Obinutuzumab is approved with a Boxed Warning regarding Hepatitis B virus reactivation and progressive multifocal leukoencephalopathy. Patients should be advised of these risks and assessed for Hepatitis B virus and reactivation risk. Infusion reactions are included in the Warning and Precautions section of the label.

• Bayer Healthcare (*www.bayer.com*) announced that the FDA expanded the approved uses of **Nexavar® (sorafenib)** to treat late-stage (metastatic) differentiated thyroid cancer. Nexavar works by inhibiting multiple proteins in cancer cells, limiting cancer cell growth and division. The drug's new use is intended for patients with locally recurrent or metastatic, progressive differentiated thyroid cancer that no longer responds to radioactive iodine treatment.

## Drugs in the News

• **Busulipo™** (Pharmalink AB, *www.pharmalink.se*) has received orphan drug designation from the FDA. Busulipo, a conditioning agent for use in cancer patients prior to hematopoietic stem cell transplantation (HSCT), was developed by Pharmalink as a liposome/lipid complex formulation that improves the safety and stability of the chemotherapy agent busulfan. An early Busulipo formulation has successfully undergone clinical trials with more than 90 patients treated.

• Eli Lilly and Company (*www.lilly.com*) announced that the FDA has assigned priority review to the regulatory submission for **ramucirumab (IMC-1121B)** as a single-agent treatment for advanced gastric cancer following disease progression after initial chemotherapy. The application was based on data from REGARD, a global, randomized, double-blind Phase III study of ramucirumab plus best supportive care compared to placebo plus best supportive care as a treatment in patients with advanced gastric cancer (including adenocarcinomas of the gastro-esophageal junction) following progression after initial chemotherapy.

### New Safety Measures for Iclusig®

The FDA is requiring several new safety measures for **Iclusig (ponatinib)** to address the risk of life-threatening blood clots and severe narrowing of blood vessels. Once these new safety measures are in place, the drug manufacturer of Iclusig (Ariad Pharmaceuticals, *www.ariad.com*) is expected to resume marketing to appropriate patients. Healthcare professionals should review these additional safety measures and carefully consider them when evaluating the risks and benefits of Iclusig for each patient.

## Approved Devices

• Ventana Medical Systems, Inc. (*www.ventana.com*) announced that it has received 510(k) clearance from the FDA for the **Companion Algorithm ER (SP1) Image Analysis Algorithm** used with the VENTANA iScan Coreo scanner running Virtuoso software. There are two intended uses obtained with the 510(k) clearance: first, clinical use of the software algorithm to semi-quantify the ER biomarker, and second,

digital read, or clearance to manually read and score the ER biomarker using a computer monitor, in lieu of a microscope.

• **Monaco® 5** (Elekta, *www.elekta.com*) has received 510(k) clearance from the FDA. With this latest version of Elekta's Monaco treatment planning system, Monaco now supports the full spectrum of radiotherapy techniques, including VMAT, IMRT and 3D conformal radiation therapy. The system is especially well equipped for sophisticated stereotactic therapies, such as SRS and SRT, with added planning support for specialized beam shaping solutions, including circular cones.

• Novocure (*www.novocure.com*) announced that the FDA has approved its **NovoTAL (Transducer Array Layout) System** through a premarket approval (PMA) supplement. The NovoTAL System allows certified physicians to use the individual MRI data of recurrent glioblastoma multiforme (GBM) patients to optimize the field distribution and intensity of Tumor Treating Fields (TTFields) therapy. The system consists of a dedicated workstation and specialized, PMA supplement-approved software that enables physicians to determine optimal transducer array layouts based on morphological measurements of the head, tumor size and location, and the distribution of TTFields within the brain. OI

## New HCPCS Codes for NovoTTF-100A System

The Centers for Medicare & Medicaid Services (CMS) has established new therapy-specific Healthcare Common Procedure Coding System (HCPCS) codes (E0766 and A4555) to describe treatment with the **NovoTTF-100A System** (Novocure, *www.novocure.com*). The new codes were effective Jan. 1, 2014. CMS also designated the product as a frequently serviced item, and as a result all necessary accessories are included in the E0766 code. The designation of a single HCPCS code, as opposed to separate codes for the device and monthly supplies, will enable a straightforward payment structure for payers, replacing the need to use separate codes for the device and standard monthly supplies. CMS issued a separate HCPCS code (A4555) to describe replacement supplies, if provided separately from the bundled accessories.

## USPSTF Releases Final Recommendations on Lung Cancer Screening and Genetic Testing for BRCA-related Cancer

On Dec. 30, 2013, the U.S. Preventive Services Task Force (USPSTF) released its final recommendation on screening those at high risk of lung cancer, grading annual low-dose CT screening for individuals at high risk for lung cancer with a B grade. The USPSTF recommends annual screening for lung cancer with low-dose computed tomography in adults aged 55 to 80 years who have a 30 pack-year smoking history and currently smoke or have quit within the past 15 years. Screening should be discontinued once a person has not smoked for 15 years or develops a health problem that substantially limits life expectancy or the ability or willingness to have curative lung surgery. Read the full recommendation online at: *www.uspreventiveservicestaskforce.org/uspstf13/lungcan/lungcanfinalrs.htm*.

On Dec. 24, 2013, the USPSTF issued its final recommendation on risk assessment, genetic counseling, and genetic testing for BRCA-related cancer in women. The USPSTF recommends that women with family members who have had breast, ovarian, tubal, or peritoneal cancer talk with a healthcare professional to learn if their history might put them at risk for carrying a BRCA mutation. Women who screen positive should receive genetic counseling and, if indicated after counseling, BRCA testing. Additionally, for the vast majority of American women (90 percent), who do not have a family history associated with an increased risk for the inherited mutations, the USPSTF continues to recommend against genetic counseling and testing. Read the full recommendation online at: *www.uspreventiveservicestaskforce.org/uspstf/uspsbrgen.htm*.