# tools

## Approved Drugs

- The U.S. Food and Drug Administration (FDA) approved Boehringer Ingelheim's (http://us.boehringer-ingelheim.com) **Gilotrif (afatinib)** for patients with late stage non-small cell lung cancer (NSCLC) whose tumors express specific types of epidermal growth factor receptor (EGFR) gene mutations, as detected by an FDA-approved test. Gilotrif is being approved concurrently with Qiagen's therascreen® **EGFR RGQ PCR Kit**, a companion diagnostic that helps determine if a patient's lung cancer cells express the EGFR mutations.

## Drugs in the News

- GlaxoSmithKline (*www.gsk.com*) announced it will discontinue the manufacture and sale of the **Bexxar® therapeutic regimen (tositumomab and iodine I 131 tositumomab)** on February 20, 2014. Bexxar is currently approved in the U.S. and Canada for the treatment of certain types of non-Hodgkin's lymphoma. Providers with questions can call GSK Response Center at 1.888.825.5249

- The FDA has granted orphan drug designation to Eisai Inc.'s (*www.eisai.com/us*) investigational compound, **E7777**, for cutaneous T-cell lymphoma (CTCL). E7777 is designed to have an improved purity profile and manufacturing process.

- Janssen Research & Development (*www.janssenrnd.com*) announced the submission of a new drug application (NDA) for **ibrutinib** to the FDA for its use in the treatment of previously treated patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), and for its use in the treatment of previously treated patients with mantle cell lymphoma (MCL). Ibrutinib is a novel Bruton's tyrosine kinase (BTK) inhibitor being jointly developed by Janssen and Pharmacyclics, Inc. for the treatment of B-cell malignancies.

- Bayer HealthCare (*www.bayer.com*) and Onyx Pharmaceuticals (*www.onyx.com*) announced the submission of a supplemental NDA (sNDA) to the FDA for the oral multi-kinase inhibitor **Nexavar® (sorafenib) tablets** for the treatment of locally advanced or metastatic radioactive iodine (RAI)-refractory differentiated thyroid cancer.

## Approved Devices

- The FDA has granted 510(k) clearance to Royal Philips (*www.usa.philips.com*) to market its **AlluraClarity** live image guidance system in the US. ClarityIQ technology will also be available as an upgrade for the majority of Philips' installed base of monoplane and biplane interventional X-ray systems.

## Genomic Tests and Assays in the News

- Veracyte, Inc. (*www.veracyte.com*) announced that Aetna has issued a positive coverage policy for the company's **Afirma Gene Expression Classifier**. The policy now makes the company's genomic test available to the insurer's estimated 22 million medical members, effective June 2013, for use in assessing thyroid nodule fine needle aspiration (FNA) biopsies that are indeterminate—not clearly benign or malignant following traditional cytopathology review. OI

## Support for Required Cancer Patient Distress Screening

In July 2013 the American Psychosocial Oncology Society (APOS), the Association of Oncology Social Work (AOSW), and the Oncology Nursing Society (ONS) published a joint statement, identifying eight key issues that must be addressed before cancer centers can adhere to new CoC standards scheduled to go into effect in 2015. The joint statement emphasized that referrals for the assessment and management of distress should be considered part of a patient's routine medical care, and presented to the patient as such. To prepare for 2015 and the implementation of the screening program, APOS recommends the required psychosocial representative on the cancer committee who oversees the screening program should have training in the identification and management of distress in patients with cancer. Online training opportunities are available through APOS (www.apos-society.org), AOSW (www.aosw.org), and ONS (www.ons.org).