tools

Approved Drugs

- The Food and Drug Administration (FDA) has approved Celgene Corporation's (*www.celgene.com*) **Revlimid®** (lenalidomide capsules) for the treatment of patients with mantle cell lymphoma whose disease has relapsed or progressed after two prior therapies, one of which included bortezomib. This approval is the first approval of an oral therapy for the treatment of non-Hodgkin's lymphoma, enabling patients to treat their disease with minimal disruption to their lives.

- The FDA has approved **Tarceva® (erlotinib)** (Genentech, *www.gene.com*) for the first-line treatment of metastatic non-small cell lung cancer (NSCLC) patients whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations. This indication for Tarceva is being approved concurrently with the cobas® EGFR Mutation Test, a companion diagnostic test for patient selection.

- The FDA approved **Xgeva®** (denosumab) (Amgen Inc., *www.amgen.com*) for the treatment of adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity.

Expanded Coverage for Oncotype DX®

Effective May 8, 2013, Palmetto GBA has expanded its coverage policy for all qualified Medicare patients to include patients with ductal carcinoma *in situ* (DCIS) following the recent publication of the breast cancer test's DCIS Score in the peer-reviewed *Journal of the National Cancer Institute*.

- Bayer HealthCare Pharmaceuticals Inc. (*www.bayer.com*) announced that the FDA has approved **Xofigo Injection® (radium Ra 223 dichloride)** for the treatment of patients with castration-resistant prostate cancer, symptomatic bone metastases, and no known visceral metastatic disease.

- GlaxoSmithKline (*www.gsk.com*) announced that the FDA has approved both **Tafinlar® (dabrafenib)** and **Mekinist™ (trametinib)**. Tafinlar is indicated as a single-agent oral treatment for unresectable melanoma or metastatic melanoma in adult patients with BRAF V600E mutation. Tafinlar is not indicated for the treatment of patients with wild-type BRAF melanoma.

  Mekinist is indicated as a single-agent oral treatment for unresectable or metastatic melanoma in adult patients with BRAF V600E or V600K mutations. Mekinist is not indicated for the treatment of patients who have received a prior BRAF inhibitor therapy. These mutations must be detected by an FDA-approved test.

Drugs in the News

- The FDA has granted breakthrough therapy designation for **daratumumab** (Janssen Research & Development, LLC, *www.janssenrnd.com*) for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent (IMiD), or who are double refractory to a PI and IMiD.

New Clinical Trial Matching Service

CureLauncher (*www.CureLauncher.com*) is a clinical trial matching service that helps determine the clinical trials that are best aligned with a person's unique goals and conditions. The personalized service is free to users and matches people to any of the 10,000 enrolling trials in the U.S. CureLauncher provides easy-to-understand information and supports people throughout the entire process—from considering a clinical trial to scheduling an appointment to meet the trial staff.

Approved Devices

- Hologic, Inc. (*www.hologic.com*), announced that the FDA has approved the use of its **C-View 2D imaging software**. C-View 2D images may now be used in place of the conventional 2D exposure previously required as part of a Hologic 3D mammography screening exam.

Devices in the News

- Olympus (*www.olympusamerica.com*) announced the commercial availability of its 510(k) cleared **BF-190 bronchoscopes**. The new BF-190 bronchoscopes offer maneuverability and flexibility through the combination of their rotary function and wider tip angulation, which will potentially allow physicians to access areas of the lung that may not be easily reached with current generation bronchoscopes. OI