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Approved Drugs

• Janssen Biotech, Inc. (www.janssenbiotech.com) announced that the Food and Drug Administration (FDA) expanded the approved use of **Imbruvica (ibrutinib)** for chronic lymphocytic leukemia (CLL) patients who have received at least one previous therapy. Imbruvica works by blocking the enzyme that allows cancer cells to grow and divide. In November 2013, the FDA granted Imbruvica accelerated approval to treat patients with mantle cell lymphoma, a rare and aggressive type of blood cancer, if those patients received at least one prior therapy.

• The FDA has approved GlaxoSmithKline's (www.gsk.com) **Mekinist® (trametinib)** for use in combination with Tafinlar® (dabrafenib) for the treatment of patients with unresectable melanoma or metastatic melanoma with BRAF V600E or V600K mutations. These mutations must be detected by an FDA-approved test. Tafinlar is not indicated for treatment of patients with wild-type BRAF melanoma. The FDA approved the combination of Mekinist and Tafinlar under the agency's accelerated approval program.

Drugs in the News

• Spectrum Pharmaceuticals (www.sppirx.com) announced that its new drug application (NDA) for **Beleodaq**, a novel pan-histone deacetylase (HDAC) inhibitor, has been accepted for filing by the FDA and granted priority review. The FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date of August 9, 2014. Spectrum is seeking approval of Beleodaq for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (R/R PTCL).

• The FDA has granted orphan drug designation to **BL-8040** (BioLineRx, www.biolinerx.com) as a treatment for stem-cell mobilization. The orphan drug designation was granted for use of BL-8040, in combination with granulocyte colony-stimulating factor (G-CSF), to mobilize human stem cells from the bone marrow to the peripheral blood for collection for autologous or allogeneic (donor-based) transplantation. It is in addition to the orphan drug designation previously granted to BL-8040 as a treatment for acute myeloid leukemia (AML).

Approved Devices

• Miltenyi Biotec (www.miltenyibiotic.com) announced that the FDA has approved the company's **CliniMACS CD34 Reagent System** as a humanitarian use device for the prevention of graft-versus-host disease (GVHD) in patients with AML in first complete remission undergoing allogeneic stem cell transplantation (SCT) from a matched related donor. The FDA approval was based on data from a Phase II, single-arm, multi-center study (BMT CTN 0303) conducted by the Blood and Marrow Transplant Clinical Trials Network.

• **ProBeam™ proton therapy system** (Varian Medical Systems, www.varian.com) has received FDA 510 (k) clearance. The system's scanning beam technology enables intensity-modulated proton therapy (IMPT) by modulating dose levels on a spot-by-spot basis throughout the treatment area. Irradiations from multiple angles are combined in an optimal manner to improve control of dose distributions. Scanning beam technology also eliminates the time-consuming need to manually insert separate shaping accessories for each beam angle in order to match the beam to the shape of the tumor.

• IMRIS Inc. (www.imris.com) announced it has received FDA clearance for the newest generation **VISIUS® Surgical Theatre**, which integrates Siemens' latest high-field MRI scanners. The new core imaging technology based on Siemens Aera 1.5T (tesla) and Skyra 3.0T technology helps IMRIS deliver better image quality with higher signal-to-noise ratio, faster 3D image acquisition, and improved ease-of-use and workflow during neurosurgical procedures using intraoperative MRI.

Genetic Tests and Assays in the News

• **Ventana HER2/neu (4B5) Rabbit Monoclonal Primary Antibody Assay** (Ventana Medical Systems, Inc., http://ventana.com) can be used as a companion diagnostic for detecting HER2 protein expression for patients who, in countries where they are approved, may be appropriate candidates for Perjeta® (pertuzumab) and Kadcycla™ (ado-trastuzumab emtansine). OI