# tools

## Approved Drugs

• Eli Lilly and Company (www.lilly.com) announced today that the U.S. Food and Drug Administration (FDA) has approved **Cyramza™ (ramucirumab)** as a single-agent treatment for patients with advanced or metastatic gastric cancer or gastroesophageal junction (GEJ) adenocarcinoma with disease progression on or after prior fluoropyrimidine- or platinum-containing chemotherapy. With this approval, Cyramza becomes the first FDA-approved treatment for patients in this setting.

• Guerbet (www.guerbet.com) announced that **Lipiodol® (ethiodized oil) Injection** was approved by the FDA pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act indicated for selective hepatic intra-arterial use for imaging tumors in adults with known hepatocellular carcinoma (HCC). As previously announced in October 2013, Lipiodol has received an orphan-drug designation for management of patients with known HCC.

• The FDA has approved GlaxoSmithKline's (www.gsk.com) **Arzerra Injection (ofatumumab, for intravenous infusion)** in combination with chlorambucil, for the treatment of previously untreated patients with chronic lymphocytic leukemia (CLL), for whom fludarabine-based therapy is considered inappropriate. The approval was based on the results of a multi-center, randomized, open-label trial comparing ofatumumab in combination with chlorambucil to single agent chlorambucil.

• Novartis (www.novartis.com) announced that the FDA has approved **Zykadia™ (ceritinib)** for the treatment of patients with anaplastic lymphoma kinase-positive (ALK+) metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib. Zykadia is an oral, selective inhibitor of ALK, an important therapeutic target in lung cancer. ALK is a gene that can fuse with other genes to form an aberrant "fusion protein" that promotes the development and growth of cancer cells.

## Drugs in the News

• Advanced Accelerator Applications (www.adacap.com) announced that the FDA has granted orphan drug designation status to their radiopharmaceutical **Gallium-68 Dotatate**. The orphan drug designation has been granted for use of Gallium-68 Dotatate as a diagnostic agent for the management of gastro-entero-pancreatic neuroendocrine tumors (GEP-NETs). Gallium-68 Dotatate is a radiopharmaceutical used in PET/CT imaging of GEP-NETs.

• Janssen Research & Development, LLC (www.janssenrnd.com) announced the submission of a supplemental new drug application for **Imbruvica™ (ibrutinib)** to the FDA by its collaboration partner Pharmacyclics, Inc. (www.pharmacyclics.com). This regulatory submission is based on data from the Phase III RESONATE™ study in relapsed or refractory chronic lymphocytic leukemia (CLL). Imbruvica is being jointly developed and commercialized by Janssen and Pharmacyclics. In February 2014, Imbruvica received FDA approval to treat patients with CLL who have received at least one prior therapy.

• The FDA has granted orphan drug designation to MEI Pharma, Inc.'s (www.meipharma.com) investigational drug **Pracinostat** for the treatment of acute myeloid leukemia (AML). Pracinostat is an orally available histone deacetylase (HDAC) inhibitor that has been tested in a number of Phase I and Phase II clinical trials in advanced hematologic disorders and solid tumor indications in both adult and pediatric patients.

• Boehringer Ingelheim Pharmaceuticals, Inc. (www.boehringer-ingelheim.com) announced the FDA has granted orphan drug designation to **volasertib** for acute myeloid leukemia (AML). Volasertib is currently being evaluated in a Phase III clinical trial for the treatment of certain patients with AML. Volasertib has not been approved by the FDA; its safety and efficacy have not been established.

## Genetic Tests and Assays in the News

• Roche (www.roche.com) announced that the FDA Microbiology Devices Panel of the Medical Devices Advisory Committee recommended unanimously that the benefits of the **cobas HPV (Human Papillomavirus) Test** as a first-line, primary screening tool in women 25 years and older to assess their risk of cervical cancer based on the presence of clinically relevant high-risk HPV DNA outweigh the risks.