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Approved Drugs

• The U.S. Food and Drug Administration (FDA) has approved Eli Lilly and Company's (www.lilly.com) **Cyramza® (ramucirumab)** for use in combination with FOLFIRI for the treatment of patients with metastatic colorectal cancer (mCRC) whose disease has progressed on a first line bevacizumab-, oxaliplatin-, and fluoropyrimidine-containing regimen.

• Amgen (www.amgen.com) announced that the FDA has approved use of **Neupogen® (filgrastim)** to treat adult and pediatric patients acutely exposed to myelo-suppressive doses of radiation (Hemato-poietic Syndrome of Acute Radiation Syndrome, or H-ARS).

Drugs in the News

• Aptose Biosciences Inc. (www.aptose.com) announced that the FDA has granted the company orphan drug designation for **APTO-253** for the treatment of acute myeloid leukemia (AML). APTO-253, a first-in-class inducer of the KLF4 gene, is the company's lead product candidate in a Phase Ib clinical trial in patients with AML, high-risk myelodysplastic syndrome (MDS), and other hematologic malignancies in which KLF4 silencing is reported as operative.

• Novogen (www.novogen.com) announced that its subsidiary joint venture company with Yale University, CanTx, Inc., has received notification from the FDA that its chemotherapy candidate drug, **Cantrixil**, has been granted orphan drug designation for ovarian cancer.

Cantrixil is a cyclodextrin envelope containing the active ingredient, TRXE-002. It is designed as an intra-cavity chemother-apy to be injected directly into the peritoneal and pleural cavities without causing local irritation or toxicity. Its purpose is to achieve high drug levels in the environment in which the cancer is spreading through the migration of the cancer stem cell.

• Janssen Research & Development, LLC (www.janssenrnd.com) has initiated the rolling submission of its biologic license application (BLA) for **daratumumab** to the FDA 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 immuno-modulatory agent (IMiD), or who are double refractory to a PI and an IMiD. Daratumumab —an investigational human anti-CD38 monoclonal antibody—received FDA breakthrough therapy designation for this set of patients in May 2013.

• The FDA has granted fast track designation for the development of Merck's (www.merck.com) **evofosfamide (previously known as TH-302)** administered in combination with gemcitabine, for the treatment of previously untreated patients with metastatic or locally advanced unresectable pancreatic cancer.

Evofosfamide is an investigational hypoxia-activated pro-drug thought to be activated under severe tumor hypoxic conditions, a feature of many solid tumors. The compound, currently in Phase III trials, is being developed in collaboration with Threshold Pharmaceuticals, Inc.

• The FDA has granted orphan drug designation to **GMI-1271** (GlycoMimetics, Inc., www.glycomimetics.com) for the treatment of patients with acute myeloid leukemia (AML). GMI-1271 is a novel and proprietary E-selectin antagonist. GlycoMi-metics is currently recruiting patients in a Phase I/II, open-label multicenter study designed to evaluate the safety, pharmaco-kinetics, and efficacy of GMI-1271 in combination with chemotherapy in adult patients with AML.

• Bristol-Myers Squibb Company (www.bms.com) announced that the FDA has accepted for filing and review the supplemental biologics license application (sBLA) for **Opdivo® (nivolumab)** for the treatment of previously untreated patients with unresectable or metastatic melanoma. The FDA also granted priority review for this application.

• The FDA has accepted Aspyrian Thera-peutics' (www.aspyriantherapeutics.com) investigational new drug (IND) application to begin clinical studies of **RM-1929** for the treatment of patients with recurrent head and neck cancer. This therapy uses an antibody conjugate to precisely target cancer cells after which it is locally activated to elicit rapid anticancer responses.

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• AbbVie (oncology.abbvie.com) announced its investigational medicine **venetoclax**, an inhibitor of the B-cell lymphoma-2 (BCL-2) protein, which is being developed in partnership with Genentech and Roche, has been granted breakthrough therapy designation by the FDA for the treatment of chronic lymphocytic leukemia (CLL) in previously treated (relapsed/refractory) patients with the 17p deletion genetic mutation.

Devices in the News

• SurgiQuest, Inc. (www.surgiquest.com) announced that its **AirSeal® System** recently received 510(k) clearance from the FDA for transanal endoscopic surgery (TES). The category of transanal endoscopic surgery includes both transanal minimally invasive surgery and transanal total mesorectal excision, a surgical technique that has been shown to significantly improve patient outcomes in colorectal cancer procedures.

Genetic Tests and Assays in the News

• Roche (www.roche.com) announced that the FDA has approved the **Cobas® KRAS Mutation Test** for diagnostic use. The real-time PCR (polymerase chain reaction) test is designed to identify KRAS mutations in tumor samples from mCRC patients and aid clinicians in determining a therapeutic path for them.

• Biodesix, Inc. (www.biodesix.com) announced that its **VeriStrat® test** received a positive coverage decision from United Healthcare. VeriStrat, included in the standard of care guidelines, is a blood-based proteomic test that provides physicians with prognostic and predictive information that helps guide treatment of advanced NSCLC.

• Personal Genome Diagnostics, Inc. (www.personalgenome.com) announced the launch of its **LungSelect™** product that identifies the most common, clinically actionable genetic alterations in the plasma of non-small cell lung cancer (NSCLC) patients. The plasma-based LungSelect test enables testing of all NSCLC patients for relevant sequence mutations, insertions and deletions, and genomic rearrangements, including those patients who may have acquired new mutations post-treatment and those with multiple tumor sites. LungSelect simultaneously identifies somatic sequence mutations and translocations that can be treated with agents already approved by the FDA or that are in clinical trials, including most defined in the NCCN Guidelines.

• NeoGenomics, Inc. (www.neogenomics.org) announced the launch of its **NeoLAB™** assays, which use next generation sequencing and other advanced molecular technologies. These 12 tests use cell-free circulating DNA and RNA found in blood plasma to identify molecular abnormalities in the bone marrow without the need for a bone marrow biopsy. Physicians can use the new liquid biopsy tests to: 1) screen patients to determine if a bone marrow biopsy is necessary, especially when myelodysplastic syndrome or acute leukemia is suspected; 2) monitor disease status, response to therapy and predict early relapse; and 3) complete testing when a bone marrow sample is inadequate or is technically difficult to obtain.