tools

Approved Drugs

- The U.S. Food and Drug Administration (FDA) has approved **Avastin® (bevacizumab solution for intravenous infusion)** (Genentech, Inc., www.gene.com) in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for the treatment of patients with platinum-resistant, recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

- The FDA has granted accelerated approval for **Blincyto (blinatumomab)** (Amgen Inc., www.amgen.com) for the treatment of Philadelphia chromosome-negative relapsed or refractory B-cell precursor acute lymphoblastic leukemia (R/R ALL).

- The FDA has approved **Cyramza® (ramucirumab)** (Eli Lilly and Company, www.lilly.com) for use in combination with paclitaxel for the treatment of patients with advanced gastric or gastroesophageal junction (GEJ) adenocarcinoma whose cancer has progressed on or after prior fluoropyrimidine- or platinum-containing chemotherapy. In April 2014, Cyramza was approved as a single agent for the treatment of patients with advanced gastric or GEJ adenocarcinoma refractory to or progressive following first-line therapy with platinum or fluoropyrimidine chemotherapy.

  The FDA has also approved Cyramza for use in combination with docetaxel for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) with disease progression on or after platinum-based chemotherapy.

- Merck (www.merck.com) announced that the FDA has approved **Gardasil® 9 (Human Papillomavirus 9-valent Vaccine, Recombinant)** for the prevention of certain diseases caused by nine types of Human Papillomavirus (HPV). Gardasil 9 now has the potential to prevent approximately 90 percent of cervical, vulvar, vaginal, and anal cancers.

- AstraZeneca Pharmaceuticals (www.astrazeneca.com) announced that the FDA has granted accelerated approval to **Lynparza™ (olaparib)** for women with advanced ovarian cancer associated with defective *BRCA* genes, as detected by an FDA-approved test. Lynparza is a poly ADP-ribose polymerase (PARP) inhibitor that blocks enzymes involved in repairing damaged DNA. It is intended for women with heavily pretreated ovarian cancer that is associated with defective *BRCA* genes.

- Ipsen Biopharmaceuticals, Inc. (www.ipsen.com), an affiliate of Ipsen, announced that **Somatuline® Depot® (lanreotide) Injection**, 120 mg, was approved by the FDA for the treatment of gastroenteropancreatic neuroendocrine tumors (GEP-NETs) in adult patients with unresectable, well, or moderately differentiated, locally advanced or metastatic disease to improve progression-free survival.

Drugs in the News

- Advaxis, Inc. (www.advaxis.com), announced that the FDA has cleared its Investigational New Drug (IND) application to conduct a Phase 1/2 clinical study of **ADXS-HPV (ADXS11-001)** alone or in combination with MedImmune's investigational anti-PD-L1 immune checkpoint inhibitor, MEDI4736, for the treatment of advanced, recurrent or refractory HPV-associated cervical cancer and HPV-associated head and neck cancer. The trial is expected to begin patient enrollment in early 2015.

  The company also announced that it has submitted an IND to the FDA to conduct the first-in-human study of **ADXS31-142** for the treatment of metastatic castration resistant prostate cancer (mCRPC). ADXS31-142 is the company's lead Lm-LLO immunotherapy designed to specifically target prostate-specific antigen (PSA). Pending FDA acceptance of the IND submission, the proposed Phase 1/2 protocol is designed to evaluate the safety and efficacy of ADXS31-142 as monotherapy and in combination with Keytruda® (pembrolizumab).

- The FDA has granted orphan drug designation to BerGenBio's (www.bergenbio.com) **BGB324** for the treatment of acute myeloid leukemia (AML). BGB324 is a first-in-class, highly selective small molecule inhibitor of the Axl receptor tyrosine kinase. It blocks the epithelial-mesenchymal transition (EMT), which is a key driver in drug-resistance and metastasis.

• Genentech (www.gene.com) announced the company has submitted a new drug application (NDA) to the FDA for **cobimetinib** for treatment, in combination with Zelboraf® (vemurafenib), for people with BRAF V600 mutation-positive advanced melanoma.

• Cellectar Biosciences, Inc. (www.cellectar.com) announced that the FDA has granted orphan drug designation to **I-131-CLR1404** for the treatment of multiple myeloma.

• The FDA has granted orphan drug designation to Juno Therapeutics, Inc.'s (www.junotherapeutics.com) **JCAR015**, a chimeric antigen receptor product candidate. The designation was granted for treatment of acute lymphoblastic leukemia. JCAR015 Phase I trials are currently underway at Juno's collaboration partner, Memorial Sloan Kettering Cancer Center.

• Merrimack Pharmaceuticals, Inc. (www.merrimackpharma.com) announced that the FDA has granted fast track designation to **MM-398 (nanoliposomal irinotecan injection)**, also known as "nal-IRI," for the treatment of patients with metastatic adenocarcinoma of the pancreas who have been previously treated with gemcitabine-based therapy.

• The FDA has granted fast track designation Momenta Pharmaceuticals, Inc.'s (www.momentapharma.com) **necuparanib**, as a first-line treatment in combination with Abraxane® and gemcitabine in patients with metastatic pancreatic cancer. Momenta recently announced the successful completion of Part A of the Phase I/II study and has initiated the Part B (Phase II proof-of-concept) study.

• Radius Health, Inc. (www.radiuspharm.com) announced that the FDA has accepted the Company's IND application for its investigational drug **RAD1901**, a tissue-selective estrogen receptor degrader (SERD) being developed for potential use in metastatic breast cancer. The Phase I study that is the subject of the IND is a multi-center, open-label, two-part, dose-escalation study of RAD1901 in postmenopausal women with advanced estrogen receptor positive and *HER2*-negative breast cancer, designed to determine the recommended Phase II dose and include a preliminary evaluation of the potential anti-tumor effect of RAD1901.

Devices in the News

• GI View Ltd. (www.giview.com), announced that it has received FDA 510(k) clearance for the **Aer-O-Scope™ Colonoscope System** for colorectal cancer screening. Market introduction is expected in the U.S. in early 2016.

• **Narrow Band Imaging® (NBI)** (Olympus, www.medical.olympusamerica.com), has received FDA 510(k) clearance for targeting of biopsies not seen under white light and improved visualization of tumor boundaries in non-muscle-invasive bladder cancer patients.

• RaySearch Laboratories AB (www.raysearchlabs.com) has received 510(k) clearance from the FDA for version 4.5 of its treatment planning system **RayStation®**. The new version includes a wide range of new features that will help cancer centers improve their treatment planning process and also enable them to take adaptive planning a step further, including ultrafast and robust optimization for proton and photon treatments, boosted dose calculation, automated breast planning, and biomechanical deformable registration using the unique MORFEUS technology.

• **SoftVue™** (Delphinus Medical Technologies, Inc., www.delphinusmt.com) has received another 510(k) clearance from the FDA. This additional regulatory clearance was granted less than a year after obtaining the first 510(k). Powered with circular, volumetric transducer technology, SoftVue is engineered with a proprietary process of ultrafast 360 electronic sequencing, enabling transducer elements to both send and receive signals. SoftVue captures reflection echoes from all directions around the breast and gathers transmitted signals coming through the breast.

Genetic Tests and Assays in the News

• Myriad Genetics, Inc. (www.myriad.com) announced that it has received approval from the FDA for **BRACAnalysis CDx** to be used as the only companion diagnostic in conjunction with AstraZeneca's drug Lynparza™ (olaparib). Lynparza is a poly ADP-ribose polymerase (PARP) inhibitor for patients with germline mutations in *BRCA*1/2 advanced ovarian cancer who have had three or more lines of chemotherapy. BRACAnalysis CDx is a highly accurate molecular companion diagnostic test that identifies deleterious or suspected deleterious mutations in the *BRCA*1 and *BRCA*2 genes, using DNA obtained from a blood sample. OI