tools

Approved Drugs

- Bayer HealthCare Pharmaceuticals, Inc. (bayer.com) announced that the U.S. Food and Drug Administration (FDA) has approved **Aliqopa™ (copanlisib)** for the treatment of adult patients with relapsed follicular lymphoma who have received at least two prior treatments known as systemic therapies.

- The FDA has approved AstraZeneca's (astrazeneca.com) **Faslodex® (fulvestrant)** 500 mg as monotherapy for expanded use in women with hormone-receptor positive (HR+), human epidermal growth factor receptor 2 negative (HER2-) advanced breast cancer who have gone through menopause and have not received previous endocrine therapy.

- The FDA approved a lower dose of **Jevtana® (cabazitaxel)** (Sanofi-Aventis, sanofi.us) (20 mg/m2 every 3 weeks) in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen.

- Merck (merck.com) announced that the FDA has approved **Keytruda® (pembrolizumab)**, the company's anti-PD-1 (programmed death receptor-1) therapy, for the treatment of patients with recurrent locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by an FDA-approved test, with disease progression on or after two or more prior lines of therapy including fluoropyrimidine- and platinum-containing chemotherapy and, if appropriate, HER2/neu-targeted therapy.

- The FDA approved **Kymriah™ (tisagenlecleucel)** (Novartis Pharmaceuticals Corp., novartis.com) for certain pediatric and young adult patients with a form of acute lymphoblastic leukemia. Kymriah, a cell-based gene therapy, is approved in the United States for the treatment of patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia that is refractory or in second or later relapse.

- The FDA approved **Mvasi™ (bevacizumab-awwb)** (Amgen, Inc., amgen.com) as a biosimilar to Avastin® (bevacizumab) for the treatment of multiple types of cancer. Mvasi is the first biosimilar approved in the U.S. for the treatment of cancer. Mvasi is approved for the treatment of adult patients with certain colorectal, lung, brain, kidney, and cervical cancers.

- The FDA approved **Mylotarg® (gemtuzumab ozogamicin)** (Pfizer, Inc., pfizer.com) for the treatment of adults with newly diagnosed acute myeloid leukemia whose tumors express the CD33 antigen (CD33-positive AML). The FDA also approved Mylotarg for the treatment of patients aged 2 years and older with CD33-positive acute myeloid leukemia who have experienced a relapse or who have not responded to initial treatment.

- Bristol-Myers Squibb (bms.com) announced that the FDA has approved **Opdivo® (nivolumab)**, injection for intravenous use for the treatment of patients with hepatocellular carcinoma who have been previously treated with sorafenib.

- Tesaro, Inc. (tesarobio.com) announced that the FDA has approved **Varubi® (rolapitant) IV** in combination with other antiemetic agents in adults for the prevention of delayed nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including, but not limited to, highly emetogenic chemotherapy.

- The FDA announced the approval of **Verzenio™ (abemaciclib)** (Eli Lilly and Company, lilly.com) to treat adult patients who have HR-positive, HER2-negative advanced or metastatic breast cancer that has progressed after taking therapy that alters a patient's hormones. Verzenio is approved to be given in combination with an endocrine therapy, called fulvestrant, after the cancer had grown on endocrine therapy. It is also approved to be given on its own, if patients were previously treated with endocrine therapy and chemotherapy after the cancer had spread.

- The FDA approved **Yescarta™ (axicabtagene ciloleucel)** (Kite Pharma, kitepharma.com), a cell-based gene therapy, to treat adult patients with certain types of large B-cell lymphoma who have not responded to or who have relapsed after at least two other kinds of treatment.

Yescarta, a chimeric antigen receptor (CAR) T cell therapy, is the second gene therapy approved by the FDA and the first for certain types of non-Hodgkin lymphoma.

Approved Devices

- The FDA cleared the first 2D digital mammography system that allows patients to increase or decrease the amount of compression applied to their own breast before the mammogram X-ray is taken. The **Senographe Pristina with Self-Compression** is a digital mammography system designed to give the patient an active role in the application of compression.

- Sapheneia (sapheneia.com) and Scannerside (scannerside.com) received FDA 510(k) clearance to market their **XR-29 DoseCheck** solution. Scannerside DoseCheck is a third-party vendor-neutral CT product that makes it affordable to update existing CT scanners and allows compliance with current MITA standards.

Drugs in the News

- Seattle Genetics, Inc. (seattlegenetics.com) announced that the FDA has granted breakthrough therapy designation to **Adcetris® (brentuximab vedotin)** in combination with chemotherapy for the frontline treatment of patients with advanced classical Hodgkin lymphoma.

- Janssen Biotech, Inc. (janssen.com) announced that it has submitted a new drug application (NDA) to the FDA for **Apalutamide (ARN-509)**, an investigational, next-generation oral androgen receptor inhibitor for men with non-metastatic castration-resistant prostate cancer.

- Sanofi (sanofi.com) and Regeneron Pharmaceuticals (regeneron.com) announced that the FDA has granted breakthrough therapy designation status to **Cemiplimab (REGN2810)** for the treatment of adults with metastatic cutaneous squamous cell carcinoma and adults with locally advanced and unresectable cutaneous squamous cell carcinoma.

- The FDA has granted orphan drug designation to **CK-101 (also known as RX518)** Checkpoint Therapeutics' (checkpointtx.com) third-generation epidermal growth-factor receptor (EGFR) inhibitor, for the treatment of EGFR mutation-positive non-small cell lung cancer (NSCLC).

- Boston Biomedical, Inc. (bostonbiomedical.com) announced that the FDA has granted orphan drug designation for **DSP-7888**, an investigational cancer peptide vaccine, for the treatment of brain cancer.

- Astellas Pharma Inc. (astellas.com) announced that the FDA has granted fast-track designation for the development of **gilteritinib** for adult patients with FLT3 mutation-positive (FLT3+) relapsed or refractory acute myeloid leukemia.

- The FDA accepted for review a supplemental new drug application (sNDA) for Eisai's (eisai.com) **Lenvima® (lenvatinib)** for the potential use in the first-line treatment of patients with hepatocellular carcinoma.

- Trovagene, Inc. (trovagene.com) announced that the FDA granted orphan drug designation to **PCM-075** for the treatment of patients with acute myeloid leukemia.

- The FDA has accepted Roche's (roche.com) supplemental biologics license application (sBLA) and granted priority review for **Perjeta® (pertuzumab)**, in combination with **Herceptin® (trastuzumab)** and chemotherapy (the Perjeta-based regimen), for adjuvant (after surgery) treatment of HER2-positive early breast cancer.

- Sandoz (sandoz.com) announced that the FDA has accepted its biologics license application (BLA) under the 351 (k) pathway for a proposed biosimilar to the reference medicine, **Rituxan® (rituximab)**.

- The FDA has granted breakthrough therapy designation to Novartis' (novartis.com) **Tafinlar® (dabrafenib)** in combination with **Mekinist® (trametinib)** for the adjuvant treatment of patients with stage III melanoma with a BRAF V600 mutation following complete resection.

- AstraZeneca (astrazeneca.com) announced that the FDA has granted breakthrough therapy designation for **Tagrisso® (osimertinib)** for the first-line treatment of patients with metastatic EGFR mutation-positive NSCLC.

- Janssen Biotech, Inc. (janssen.com) submitted an sNDA to the FDA seeking to expand the indication of **Zytiga® (abiraterone acetate)** in combination with prednisone and ADT to include treatment of patients with high-risk metastatic hormone-naïve prostate cancer or newly diagnosed, high-risk metastatic hormone-sensitive prostate cancer. OI

Palmetto GBA Issues a Positive LCD to Expand Coverage of Oncotype DX® Genomic Prostate Score™

Genomic Health, Inc. (genomichealth.com) announced that Palmetto GBA, a Medicare Administrative Contractor (MAC), has issued a positive final local coverage determination (LCD) to expand Medicare coverage of the Oncotype DX® Genomic Prostate Score™ (GPS™) test. The final LCD, recommending Medicare coverage for use of the test in qualified patients with favorable intermediate-risk prostate cancer throughout the United States, took effect on Oct. 9, 2017.

Generic Version of Gleevec Launched

Mylan N.V. (mylan.com) announced the U.S. launch of Imatinib Mesylate Tablets, 100 mg and 400 mg, a generic version of Novartis's Gleevec® Tablets. Mylan received final approval from the FDA for its abbreviated new drug application (aNDA) for this product, which has multiple indications, including for several blood cancers.