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Approved Drugs

• The U.S. Food and Drug Administration (FDA) granted approval to **Adcetris® (brentuximab vedotin)** (Seattle Genetics, Inc., seattlegenetics.com) for the treatment of adult patients with primary cutaneous anaplastic large cell lymphoma or CD30-expressing mycosis fungoides who have received prior systemic therapy.

• The FDA has approved **Alecensa® (alectinib)** (Hoffmann-La Roche, Inc., roche.com, Genentech, Inc., gene.com) for the treatment of patients with anaplastic lymphoma kinase (ALK)-positive metastatic non–small cell lung cancer (NSCLC), as detected by an FDA-approved test.

• The U.S. FDA granted accelerated approval to **Calquence® (acalabrutinib)** (AstraZeneca Pharmaceuticals, astrazeneca.com) for the treatment of adults with mantle cell lymphoma who have received at least one prior therapy.

• AstraZeneca (astrazeneca.com) announced that the FDA has approved a new indication for **Faslodex® (fulvestrant)**, expanding the indication to include use with abemaciclib, a CDK4/6 inhibitor, for the treatment of hormone receptor–positive, human epidermal growth factor receptor 2–negative (HER2–) advanced or metastatic breast cancer in women with disease progression after endocrine therapy.

• The FDA has approved **Gazyva® (obinutuzumab)** (Genentech, gene.com) in combination with chemotherapy, followed by Gazyva alone, for the first-line treatment of patients with advanced follicular lymphoma.

• Bristol-Myers Squibb (bms.com) announced that the FDA has expanded the indication for **Sprycel® (dasatinib)** tablets to include the treatment of children with Philadelphia chromosome–positive (Ph+) chronic myeloid leukemia in chronic phase. This approval for Sprycel in pediatric patients with Ph+ chronic myeloid leukemia in chronic phase was granted under priority review, and the indication received orphan drug designation from the FDA.

• The FDA has approved **Sutent® (sunitinib malate)** (Pfizer, Inc., pfizer.com) for the adjuvant treatment of adult patients who are at a high risk of kidney cancer (renal cell carcinoma) returning after a kidney has been removed (nephrectomy). Adjuvant treatment is a form of therapy that is taken after an initial surgical removal to lower the risk of the cancer coming back.

• Tesaro, Inc. (tesarobio.com) announced that the FDA has approved **Varubi® (rolapitant)** intravenous 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 expanded the approval of **Zelboraf® (vemurafenib)** (Hoffman-LaRoche, Inc., roche.com) to include the treatment of certain adult patients with Erdheim-Chester Disease, a rare cancer of the blood. Zelboraf is indicated to treat patients whose cancer cells have a specific genetic mutation known as BRAF V600. This is the first FDA-approved treatment for this disease.

Drugs in the News

• BriaCell Therapeutics Corp. (briacell.com) announced that the FDA has approved the rollover combination study of **BriaVax™** with **Keytruda® (embrolizumab)** or **Yervoy® (ipilimumab)** for patients previously treated with BriaVax™ from the ongoing Phase I/IIA clinical trial in advanced breast cancer.

• Janssen Biotech, Inc. (janssen.com) announced that it has submitted a supplemental biologics license application to the FDA for **Darzalex® (daratumumab)**. This application seeks to expand the current indication, using Darzalex in combination with bortezomib (a proteasome inhibitor), melphalan, and prednisone, for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplantation.

• The FDA has approved Eureka Therapeutics' (eurekainc.com) investigational new drug application and authorized the company to commence a Phase I clinical trial for **ET190L1-ARTEMIS™** T cells in relapsed and refractory CD19+ non-Hodgkin lymphoma (NHL), including chronic lymphocytic leukemia. Eureka expects to enroll the first patient in this trial in the first quarter of 2018.

• Novartis (novartis.com) announced that the company has submitted a supplemental biologics license application to the FDA for **Kymriah™ (tisagenlecleucel)** suspension for intravenous infusion, formerly CTL019, for the treatment of adult patients with relapsed or refractory (r/r) diffuse large B-cell lymphoma who are ineligible for autologous stem cell transplant.

• The FDA has granted RedHill Biopharma (redhillbio.com) orphan drug designation **Mesupron® (upamostat)** for the adjuvant treatment of pancreatic cancer.

• Merrimack Pharmaceuticals, Inc. (merrimack.com) announced that the FDA has granted orphan drug designation to **MM-121** for the treatment of heregulin-positive NSCLC. MM-121 is a fully human monoclonal antibody designed to block tumor survival signals and enhance the antitumor effect of combination therapies by targeting the cell surface receptor human epidermal growth factor receptor 3 (ErbB3) in patients with high expression of the biomarker heregulin.

• The FDA has approved Collegium Pharmaceutical's (collegiumpharma.com) supplemental new drug application to enhance the label for **Xtampza® ER (oxycodone extended-release)**, an abuse-deterrent, extended-release opioid, for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate.

Approved Devices

• Hologic, Inc. (hologic.com) announced that it has received 510(k) clearance from the FDA for its **Quantra™ 2.2 Breast Density Assessment Software**, which enables clinicians to provide women with consistent breast density assessments during routine breast cancer screenings.

• The FDA has approved Roche's (roche.com) **Ventana ALK (D5F3) CDx Assay** as a companion diagnostic to identify ALK-positive NSCLC patients eligible for treatment with the Roche medicine **Alecensa® (alectinib)**. The Ventana ALK (D5F3) CDx Assay is the only test FDA-approved as a companion diagnostic for Alecensa.

• MIM Software Inc. (mimsoftware.com), a leading global provider of medical imaging software, announced that it has received 510(k) clearance from the FDA for posttreatment dosimetry of **Yttrium-90 (Y90) microspheres.**