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Approved Drugs

- The U.S. Food and Drug Administration (FDA) approved **Adcetris® (brentuximab vedotin)** (Seattle Genetics, Inc., seattlegenetics.com) to treat adult patients with previously untreated stage III or IV classical Hodgkin lymphoma in combination with chemotherapy.
- Amgen (amgen.com) announced that the FDA has approved the supplemental biologics license application (sBLA) for **Blincyto® (blinatumomab)** for the treatment of adults and children with B-cell precursor acute lymphoblastic leukemia in first or second complete remission with minimal residual disease greater than or equal to 0.1 percent. This indication is approved under accelerated approval based on minimal residual disease response rate and hematological relapse-free survival.
- The FDA has approved Janssen Pharmaceutical Companies of Johnson & Johnson's (janssen.com) **Erleada™ (apalutamide)**, a next-generation androgen receptor inhibitor, for the treatment of patients with non-metastatic castration-resistant prostate cancer. This approval is based on data from the Phase III SPARTAN study, which demonstrated a 72 percent reduction in risk of distant metastasis or death and an increase in median metastasis-free survival by more than two years (difference of 24.31 months) in patients with metastatic castration-resistant prostate cancer.
- The FDA announced the expanded approval of **Imfinzi® (durvalumab)** (AstraZeneca, astrazeneca.com), an immunotherapy treatment that is now available as a standard-of-care option for patients with stage III non–small cell lung cancer. Imfinzi is a monoclonal antibody delivered intravenously that helps increase T cell activation by blocking PD-L1.
- Novartis (novartis.com) announced that the FDA expanded the indication for **Tasigna® (nilotinib)** to include treatment of first- and second-line pediatric patients one year of age or older with Philadelphia chromosome–positive chronic myeloid leukemia in the chronic phase.
- The FDA has approved Eli Lilly and Company's (lilly.com) **Verzenio™ (abemaciclib)** in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor–positive (HR+), human epidermal growth factor receptor 2-negative (HER2–) advanced or metastatic breast cancer.
- Janssen Pharmaceutical Companies of Johnson & Johnson (janssen.com) announced that the FDA has approved a new indication for **Zytiga® (abiraterone acetate)** in combination with prednisone for the treatment of patients with metastatic high-risk castration-sensitive prostate cancer. The approval is based on Phase III data from the LATITUDE clinical trial, which found that in patients with metastatic high-risk castration-sensitive prostate cancer, Zytiga, in combination with prednisone, reduced the risk of death by 38 percent compared to placebos.

Approved Devices

- Hologic, Inc. (hologic.com), announced that **Clarity HD high-resolution 3D™ imaging and Intelligent 2D™ imaging technology** have received premarket approval from the FDA and are now available on the 3Dimensions breast tomosynthesis system. With these innovations, the system now provides higher resolution 3D images for radiologists, enhanced workflow for technologists, and a more comfortable mammography experience, with low-dose options, for patients.
- The FDA has granted Royal Philips (philips.com) 510(k) clearance to market **ProxiDiagnost N90**, a digital radiography–fluoroscopy system. With its ability to perform both fluoroscopy and digital X-rays through a single system, ProxiDiagnost N90 supports high room utilization and increased patient throughput.

Drugs in the News

- Agios Pharmaceuticals, Inc. (agios.com) announced that the FDA has accepted and given priority review to the company's new drug application (NDA) for **AG-120 (ivosidenib)** for the treatment of patients with relapsed or refractory acute myeloid leukemia with an isocitrate dehydrogenase 1 mutation.

- The FDA has granted final approval for the abbreviated NDA for **cyclophosphamide capsules**, 25 mg and 50 mg (Amerigen Pharmaceuticals Limited, amerigenpharma.com). Cyclophosphamide, an antineoplastic agent used in the treatment of various cancers, is expected to launch in the near future.
- Verastem, Inc. (verastem.com), has submitted an NDA to the FDA seeking full approval for its lead product candidate **duvelisib**, an oral dual inhibitor of phosphoinositide-3-kinase (PI3K)-delta and PI3K-gamma, for the treatment of relapsed or refractory chronic lymphocytic leukemia/small lymphocytic lymphoma and accelerated approval for the treatment of relapsed or refractory follicular lymphoma.
- The FDA has granted breakthrough therapy designation to **enfortumab vedotin (ASG-22ME)** (Astellas Pharma, Inc., astellas.com, and Seattle Genetics, Inc., seattlegenetics.com). The antibody–drug conjugate is for patients with locally advanced or metastatic urothelial cancer who were previously treated with checkpoint inhibitors.
- The Janssen Pharmaceutical Companies of Johnson & Johnson (janssen.com) announced that the FDA has granted breakthrough therapy designation for **erdafitinib** in the treatment of urothelial cancer.
- The FDA has granted breakthrough therapy designation to Galera Therapeutics, Inc.'s (galeratx.com) **GC4419**, a highly selective and potent small molecule dismutase mimetic, for the reduction of the duration, incidence, and severity of severe oral mucositis induced by radiation therapy with or without systemic therapy.
- Kazia Therapeutics Limited (kaziatherapeutics.com) announced that the FDA has granted orphan drug designation to Kazia's investigational new drug, **GDC-0084**, for the treatment of glioblastoma multiforme.
- The FDA has accepted a new supplemental biologics license application (sBLA) and granted priority review for Merck's (merck.com) **Keytruda® (pembrolizumab)**, the company's anti-PD-1 therapy. The application is seeking approval as a treatment for patients with advanced cervical cancer with disease progression on or after chemotherapy.
- Loxo Oncology, Inc. (loxooncology.com), announced that the company has completed the rolling submission of an NDA to the FDA for **larotrectinib (LOXO-101)** for the treatment of adult and pediatric patients with locally advanced or metastatic solid tumors harboring an NTRK gene fusion.
- AstraZeneca (astrazeneca.com) and MedImmune (medimmune.com) announced that the FDA has accepted and granted priority review status to the biologics license application (BLA) for **moxetumomab pasudotox**, an investigational anti-CD22 recombinant immunotoxin and a potential new medicine for the treatment of adult patients with hairy cell leukemia who have received at least two prior lines of therapy.
- The FDA has accepted Bristol-Myers Squibb Company's (bms.com) sBLA for **Opdivo® (nivolumab) in combination with Yervoy® (ipilimumab)** for the treatment of adults with microsatellite instability–high or mismatch repair deficient metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine, oxaliplatin, and irinotecan.
- FibroGen, Inc. (fibrogen.com), announced that the FDA has granted fast track designation for the company's anti-CTGF antibody, **pamrevlumab**, for the treatment of patients with locally advanced unresectable pancreatic cancer.
- Pfizer Inc. (pfizer.com) and Astellas Pharma Inc. (astellas.us) announced that a supplemental NDA for **Xtandi® (enzalutamide)** has been accepted for filing and granted priority review designation by the FDA. The approval would expand the indication of Xtandi to include men with nonmetastatic castration-resistant prostate cancer.
- The FDA has granted orphan drug designation to Yisheng Biopharma Co., Ltd.'s (yishengbio.com) lead immuno-oncology candidate, **YS-ON-001**, for the treatment of pancreatic cancer.

Genetic Tests and Assays in the News

- The FDA has granted premarket approval to Becton, Dickinson and Company's (bd.com) **BD Onclarity™ HPV Assay**, a test that can detect up to 14 types of high-risk human papillomavirus and provides information on women who are at risk for cervical cancer.
- Foundation Medicine, Inc. (foundationmedicine.com) announced that **FoundationOne CDx™**, the first FDA-approved comprehensive genomic profiling assay for all solid tumors incorporating multiple companion diagnostics, is now available in the United States. The test for individuals with advanced cancer is offered as a nationally covered benefit across all solid tumors for Medicare and Medicare Advantage beneficiaries who meet eligibility requirements.
- The FDA has granted expedited access pathway designation to the **Guardant360® Assay** (Guardant Health, guardanthealth.com). If approved, the assay could be the first FDA-approved comprehensive liquid biopsy.
- Genomic Health, Inc. (genomichealth.com) announced the U.S. commercial launch of the **Oncotype DX® AR-V7 Nucleus Detect™** test. A liquid biopsy test, the Oncotype DX AR-V7 Nucleus Detect test was developed by Epic Sciences to help prolong the lives of men with metastatic castration-resistant prostate cancer by accurately detecting a splice variant of the androgen receptor protein (AR-V7) in the nucleus of circulating tumor cells. Knowledge of a patient's AR-V7 status enables physicians to confidently decide whether men treated with an androgen receptor–signaling inhibitor therapy, such as enzalutamide and abiraterone, need to start another type of androgen receptor–signaling inhibitor or switch to chemotherapy. OI