tools

Approved Drugs

- On June 27, the U.S. Food and Drug Administration (FDA) approved **Darzalex® (daratumumab)** (Janssen Biotech, Inc., Janssen.com) in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.
- On June 14, Amgen (amgen.com) and Allergan (allergan.com) announced FDA approval of the biosimilar **Kanjinti™ (trastuzumab-anns)** for all approved indications of the reference product Herceptin® (trastuzumab) for the treatment of human epidermal growth factor receptor 2-overexpressing adjuvant and metastatic breast cancer and human epidermal growth factor receptor 2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.
- On June 17, Merck (merck.com) announced that the FDA granted accelerated approval to **Keytruda® (pembrolizumab)** for patients with metastatic small cell lung cancer with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy. On July 31, Merck announced FDA approval for Keytruda as monotherapy for the treatment of patients with recurrent locally advanced or metastatic squamous cell carcinoma of the esophagus whose tumors express PD-L1 (combined positive score ≥10) as determined by an FDA-approved test, with disease progression after one or more prior lines of systemic therapy.
- On July 30, Bayer HealthCare Pharmaceuticals, Inc. (bayer.us) announced FDA approval of **Nubeqa® (darolutamide)**, an androgen receptor inhibitor, for the treatment of patients with non-metastatic castration-resistant prostate cancer. Nubeqa was approved under the FDA's Priority Review designation.
- On July 31, the FDA granted accelerated approval to **Polivy™ (polatuzumab vedotin-piiq)** (Genentech, Inc., gene.com) in combination with bendamustine plus rituximab for the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma who have received at least two prior therapies. The FDA's Accelerated Approval Program allows conditional approval of a medicine that fills an unmet medical need for a serious condition.
- On July 23, Pfizer, Inc. (pfizer.com) announced FDA approval of **Ruxience™ (rituximab-pvvr)**, a biosimilar to Rituxan® (rituximab), for the treatment of adult patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, and granulomatosis with polyangiitis and microscopic polyangiitis.
- On July 3, the FDA granted accelerated approval to **Xpovio™ (selinexor)** (Karyopharm Therapeutics, karyopharm.com) in combination with dexamethasone for adult patients with relapsed or refractory multiple myeloma who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.
- On June 28, Pfizer Inc. (pfizer.com) announced that the FDA has approved **Zirvabev™ (bevacizumab-bvzr)**, a biosimilar to Avastin® (bevacizumab), for the treatment of five types of cancer: metastatic colorectal cancer; unresectable, locally advanced, recurrent, or metastatic nonsquamous non-small cell lung cancer; recurrent glioblastoma; metastatic renal cell carcinoma; and persistent, recurrent, or metastatic cervical cancer.

Drugs in the News

- On August 1, Xynomic Pharmaceuticals Holdings, Inc. (xynomicpharma.com) announced filing an application with the FDA seeking fast track designation for its drug candidate **abexinostat** as a monotherapy for the treatment of relapsed or refractory follicular lymphoma.
- On August 7, Blueprint Medicines Corporation (blueprintmedicines.com) announced that the FDA has granted priority review to the company's new drug application for **avapritinib** as a treatment for adult patients with PDGFRA exon 18 mutant gastrointestinal stromal tumors (GIST), regardless of prior therapy, and in the fourth-line setting for GIST. Currently, no effective therapy exists for either population. Avapritinib is an investigational, potent, and highly selective KIT and PDGFRA inhibitor for patients with advanced GIST.
- On August 1, eNektar Therapeutics (nektar.com) and Bristol-Myers Squibb (bms.com) announced that the FDA granted breakthrough therapy designation for investigational agent **bempegaldesleukin (NKTR-214)** in combination with Bristol-Myers Squibb's **Opdivo® (nivolumab)** for the treatment of patients with previously untreated unresectable or metastatic melanoma.
- On July 9, Cellectar Biosciences, Inc. (cellectar.com) announced that the FDA

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has granted fast track designation for **CLR 131** in relapsed or refractory diffuse large B-cell lymphoma. CLR 131 is a small-molecule, cancer-targeting radio-therapeutic phospholipid drug conjugate designed to deliver cytotoxic radiation directly and selectively to cancer cells and cancer stem cells. It is currently being evaluated in Cellectar's ongoing Phase II CLOVER-1 clinical study in patients with relapsed or refractory select B-cell lymphomas.

- On June 19, CARsgen Therapeutics (carsgen.com) announced that one of its leading drug candidates, **CT053 fully human BCMA (B-cell maturation antigen)-CAR-T cell** for the treatment of patients suffering from relapsed/refractory multiple myeloma, has received investigational new drug (IND) clearance from the FDA.
- On July 12, the Janssen Pharmaceutical Companies of Johnson & Johnson announced the submission of a biologics license application (BLA) to the FDA seeking approval of a new subcutaneous formulation of **Darzalex® (daratumumab)**, an intravenous treatment approved for certain patients with multiple myeloma.
- On July 16, Astellas Pharma Inc. (astellas.com) and Seattle Genetics, Inc. (seattlegenetics.com) announced submission of a BLA for accelerated approval to the FDA for the investigational agent **enfortumab vedotin** for the treatment of patients with locally advanced or metastatic urothelial cancer who have received a PD-1/L1 inhibitor and who have received a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced, or metastatic setting.
- On July 9, Merck (merck.com) announced that the FDA has accepted for review six supplemental BLAs to update the dosing frequency for **Keytruda**, Merck's anti-PD-1 therapy, to include an every-six-weeks (Q6W) dosing schedule option. Merck is seeking FDA approval of a 400-mg Q6W dose infused over 30 minutes for Keytruda indications in melanoma, classical Hodgkin lymphoma, primary mediastinal large B-cell lymphoma, gastric cancer, hepatocellular carcinoma, and Merkel cell carcinoma. If approved by the FDA, the Q6W dose would be available for use in adults in addition to the currently approved dose of Keytruda 200 mg every three weeks (Q3W) infused over 30 minutes. The FDA has set a Prescription Drug User Fee Act date of Feb. 18, 2020.
- On July 24, Kura Oncology, Inc. (kuraoncology.com) announced that the FDA has granted orphan drug designation to the company's menin-mixed lineage leukemia inhibitor **KO-539** for the treatment of acute myeloid leukemia.
- On August 5, Mustang Bio, Inc. (mustangbio.com) announced that the FDA has approved the company's IND application to initiate a multicenter Phase I/II clinical trial of **MB-102 (CD123 CAR T)** in acute myeloid leukemia, blastic plasmacytoid dendritic cell neoplasm, and high-risk myelodysplastic syndrome. MB-102 is a chimeric antigen receptor (CAR) T-cell therapy that is produced by engineering patient T-cells to recognize and eliminate CD123-expressing tumors. CD123 is widely expressed on bone marrow cells of patients with myelodysplastic syndrome and hematologic malignancies.
- On July 29, Spring Bank Pharmaceuticals, Inc. (springbankpharma.com) announced that the company's IND application for a Phase I trial of **SB 11285**, the company's intravenously administered stimulator of interferon gene agonist development candidate, is now effective following clearance by the FDA. The Phase I trial aims to evaluate safety, tolerability, and initial antitumor activity of intravenous SB 11285 in patients with advanced solid tumors.
- On June 18, Torque (torquetx.com) announced that the FDA granted fast track designation for the company's first Deep-Primed™ T-cell immunotherapy program, **TRQ-1501 (Deep IL-15 Primed T cells)**. The designation is for the treatment of relapsed or refractory solid tumors and lymphomas that express any of five tumor-associated antigens (PRAME, WT-1, SSX2, Survivin, and NY-ESO-1). Torque is currently conducting a Phase I/II clinical trial of TRQ-1501 for this indication.

Devices in the News

- On June 17, Bio-Techne announced that the FDA has granted breakthrough device designation to its **ExoDx™ Prostate IntelliScore test**, making it the first exosome-based liquid biopsy test to receive this designation.
- On July 17, the Erchonia Corporation announced that the FDA granted marketing clearance for the company's **FX 635 low-level laser** as treatment for "whole-body" musculoskeletal pain. The 510(k) clearance will allow the marketing of the device to provide temporary relief from pain that is chronic and nociceptive in adult patients.

CMS Releases NCD for CAR-T Cell Therapy

On August 7, the Centers for Medicare & Medicaid Services (CMS) released the final National Coverage Determination for FDA-approved CAR T-cell therapy. FDA-approved CAR T-cell therapies are approved to treat some people with specific types of cancer—certain types of non-Hodgkin lymphoma and B-cell precursor acute lymphoblastic leukemia. Medicare will cover CAR T-cell therapies when they are provided in healthcare facilities enrolled in the FDA risk evaluation and mitigation strategies for FDA-approved indications (according to the FDA-approved label). In addition, Medicare will cover FDA-approved CAR T-cell therapies for off-label uses that are recommended by CMS-approved compendia. The NCD continues coverage for routine costs in clinical trials that use CAR T-cell therapy as an investigational agent that meet the requirements listed in NCD 310.1. In announcing the NCD, CMS notes that outcomes data for CAR T-cell therapy in the Medicare population are "relatively limited" and states that "CMS will leverage information obtained from the FDA's required post-approval safety studies for CAR T-cell therapies to the fullest extent possible." In finalizing the national coverage determination, however, CMS does not require hospitals that administer CAR-T therapy to participate in a clinical registry or study to assess whether real-world results are similar to those from clinical trials.

First Therapeutic Cancer Biosimilars Available in the United States

On July 19, Amgen and Allergan plc announced the launch of **Mvasi™ (bevacizumab-awwb)**, a biosimilar to Avastin® (bevacizumab), and **Kanjinti™ (trastuzumab-anns)**, a biosimilar to Herceptin® (trastuzumab), on the U.S. market.