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Approved Drugs

• On November 10, the U.S Food and Drug Administration (FDA) approved **Adcetris® (brentuximab vedotin)** (Seagen, seagen.com) **in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide** for pediatric patients 2 years of age and older with previously untreated high-risk classical Hodgkin's lymphoma.

• On November 14, the FDA granted accelerated approval to **Elahere® (mirvetuximab soravtansine-gynx)** (Immunogen, immunogen.com) for adult patients with folate receptor alpha (FRα) positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens.

• On October 21, the FDA approved **Imjudo® (tremelimumab)** (AstraZeneca, astrazeneca.com) **in combination with durvalumab** for adult patients with unresectable hepatocellular carcinoma. And on November 10, the FDA approved Imjudo in combination with Imfinzi® (durvalumab) (AstraZeneca, astrazeneca.com) and platinum-based chemotherapy for adult patients with metastatic NSCLC with no sensitizing epidermal growth factor receptor (EGFR) mutation or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.

• On Nov. 2, Amneal Pharmaceuticals, Inc. (amneal.com) announced that it received abbreviated new drug application (NDA) approval from the FDA for **leuprolide acetate** in the palliative treatment of ad-vanced prostatic cancer.

• On November 8, the FDA approved **Libtayo® Inc., (cemiplimab-rwlc)** (Regeneron Pharmaceuticals, Inc., regeneron.com) **in combination with platinum-based chemotherapy** for adult patients with advanced NSCLC with no EGFR, ALK, or c-ros oncogene 1 (ROS1) aberration.

• On December 1, the FDA approved **Rezlidhia® (olutasidenib)** (Rigel Pharmaceuticals Inc., rigel.com) capsules for adult patients with relapsed or refractory acute myeloid leukemia with a susceptible isocitrate dehydrogenase 1 (IDH1) mutation, as detected by an FDA-approved test.

• On November 18, the FDA approved a new dosing regimen for **Rylaze® (asparaginase erwinia chrysanthemi** (recombinant)-rywn) (Jazz Pharmaceuticals, jazzpharma.com). Under the new regimen, patients should receive 25 mg/m2 intramuscularly on Monday and Wednesday mornings, and 50 mg/m2 intramuscularly on Friday afternoon.

• On October 25, the FDA granted accelerated approval to **Tecvayli® (teclistamab-cqyv)** (Janssen, Janssen.com) for adult patients with relapsed or refractory multiple myeloma, who have received at least four prior lines of therapy, including a proteasome inhibitor, immunomodulatory agent, and anti-CD38 monoclonal antibody.

Drugs in the News

• Aravive Inc. (aravive.com) announced that the FDA granted fast track designation to **batiraxcept** for the treatment of patients with advanced or metastatic clear cell renal cell carcinoma, who have progressed after 1 or 2 prior lines of systemic therapy that include both immuno-oncology-based and vascular endothelial growth factor tyrosine kinase inhibitor-based therapies (either in combination or sequentially).

• Caribou Biosciences, Inc. (cariboubio.com) announced that the FDA granted regenerative medicine advanced therapy designation to **CB-010** for relapsed or refractory large B-cell lymphoma and fast track designation for relapsed or refractory B-cell non-Hodgkin's lymphoma.

• Citius Pharmaceuticals, Inc. (citiuspharma.com) announced that the FDA accepted its biologics license application (BLA) for **denileukin diftitox (E7777)** for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma.

• Pfizer Inc. (pfizer.com) announced that the FDA granted breakthrough therapy designation to **elranatamab** for the treatment of relapsed or refractory multiple myeloma.

• Myeloid Therapeutics, Inc. (myeloidtx.com) announced that the FDA granted fast track designation to **MT-101** for patients with refractory or relapsed CD5+ peripheral T-cell lymphoma.

• Ipsen (ipsen.com) announced its intent to file a supplemental NDA with the FDA for **Onivyde® (irinotecan liposome injection) in combination with oxaliplatin plus 5- fluorouracil/leucovorin** for the treatment of patients with previously untreated metastatic pancreatic ductal adenocarcinoma, following the fast track designation granted in 2020.

• Oncolytics Biotech Inc. (oncolyticsbiotech.com) announced that the FDA granted fast track designation to **pelareorep in combination with Tentriq® (atezolizumab)** (Genentech, gene.com), **Abraxane® (nab-paclitaxel)** (Bristol Myers Squibb, bms.com), **and nab-paclitaxel** for the treatment of advanced/metastatic pancreatic ductal adenocarcinoma.

• Gilead Sciences, Inc. (gilead.com) announced that the FDA accepted for priority review the supplemental BLA for **Trodelvy® (sacituzumab govitecan-hziy)** for the treatment of adult patients with unresectable, locally advanced, or metastatic hormone receptor positive (HR+), HER2- (IHC 0, IHC 1+, or IHC 2+/ISH–) breast cancer, who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting.

• Tvardi Therapeutics, Inc. (tvarditherapeutics.com) announced that the FDA granted fast track designation to **TTI-101** for the treatment of relapsed/refractory locally advanced, unresectable, or metastatic hepatocellular carcinoma.

• Daiichi Sankyo (daiichisankyo.com) announced that the FDA accepted and granted priority review to the NDA for **quizartinib in combination with standard cytarabine and anthracycline induction, as well as standard cytarabine consolidation chemotherapy**, as continuation monotherapy following consolidation, for the treatment of adult patients with newly diagnosed acute myeloid leukemia that is FLT3-ITD+.

Assays and Devices in the News

• Genmab A/S (genmab.com) announced that the FDA accepted and granted priority review to the BLA for **enporitamab (DuoBody®—CD3xCD20)** for the treatment of patients with relapsed/refractory large B-cell lymphoma after two or more lines of systemic therapy.

• Roche (roche.com) announced that the FDA approved the **VENTANA FOLR1 (FOLR1-2.1) RxDx Assay** to aid in identifying epithelial ovarian cancer in patients who are eligible for targeted treatment with Elahere. OI