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Approved Drugs

- On May 19, the US Food and Drug Administration (FDA) granted accelerated approval to **Epkinly® (epcoritamab-bysp)** (Genmab, genmab.com) for relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy.

- On May 31, 2023, the FDA approved **Lynparza® (olaparib)** (AstraZeneca, astrazeneca.com) **in combination with abiraterone and prednisone (or prednisolone)** for adult patients with deleterious or suspected deleterious BRCA-mutated metastatic castration-resistant prostate cancer, as determined by an FDA-approved companion diagnostic test.

- On April 17, the FDA approved **Omisirge® (omidubicel-onlv)** (Gamida Cell, gamida-cell.com) for use in adult and pediatric patients with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning.

- On April 19, 2023, the FDA approved **Polivy® (polatuzumab vedotin-piiq)** (Genentech, gene.com) **in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone** for adult patients who have previously untreated DLBCL, not otherwise specified, or high-grade B-cell lymphoma and who have an International Prognostic Index score of 2 or greater.

Drugs In the News

- Bristol Myers Squibb (bms.com) and 2seventy bio (2seventybio.com) announced that the FDA accepted a supplemental biologics license application (BLA) for **Abecma® (idecabtagene vicleucel)** for the treatment of adult patients with relapsed and refractory multiple myeloma who have received an immunomodulatory agent, proteasome inhibitor, and anti-CD38 monoclonal antibody.

- Agenus (agenusbio.com) announced that the FDA granted fast track designation to the **AGEN2034 (balstilimab)** and **AGEN1181 (botensilimab)** combination.

- Takeda (Takeda.com) and Hutchmed (hutch-med.com) announced that the FDA accepted a new drug application (NDA) for **fruquintinib** for the treatment of adult patients with previously treated metastatic colorectal cancer.

- Janssen (janssen.com) announced that it submitted a supplemental BLA to the FDA for **Carvykti® (ciltacabtagene autoleucel)** for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy, including a proteasome inhibitor, immunomodulatory agent, and are refractory to lenalidomide.

- Accord BioPharma (accordbiopharma.com) announced that the FDA accepted the BLA for **HLX02**—a proposed biosimilar to Herceptin® (trastuzumab) (Genentech, gene.com)—for the adjuvant treatment of HER2-overexpressing and overexpressing metastatic breast cancer, as well as HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.

- GSK (gsk.com) announced that the FDA accepted a supplemental BLA for **Jemperli® (dostarlimab)** in combination with chemotherapy for the treatment of adult patients with mismatch repair deficient, primary advanced, or recurrent endometrial cancer.

- Merck (merck.com) announced that the FDA accepted for review a supplemental BLA for **Keytruda® (pembrolizumab) in combination with standard-of-care chemotherapy (gemcitabine and cisplatin)** for the treatment of patients with locally advanced unresectable or metastatic biliary tract cancer.

- Iovance Biotherapeutics (Iovance.com) announced that the FDA accepted a BLA for **lifileucel** for the treatment of patients with advanced melanoma.

- Taiho Oncology (taihooncology.com) announced that the FDA accepted for priority review the supplemental NDA for **Lonsurf® (trifluridine and tipiracil) as a monotherapy or in combination with bevacizumab** for the treatment of adult patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

- Lumicell, Inc. (lumicell.com) announced that the FDA has accepted and granted priority review to the NDA for **Lumisight™** (an optical imaging agent). The company also announced that the FDA accepted a premarket approval application for the **Lumicell™ direct visualization system**.

- Lantheus Holdings (lantheus.com) announced that the FDA granted fast track designation to **177Lu-PNT2002** for the treatment of metastatic castration resistant prostate cancer.

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

- Bristol Myers Squibb (bms.com) announced that the FDA accepted the supplemental BLA for **Reblozyl® (luspatercept-aamt)** to expand its current indication to include treatment of anemia without previous use of erythropoiesis-stimulating agents (ESA-naïve) in adult patients with very low- to intermediate-risk myelodysplastic syndromes who may require red blood cell transfusions.

- Bristol Myers Squibb (bms.com) announced that the FDA accepted the NDA for **repotrectinib** for the treatment of patients with ROS1-positive locally advanced or metastatic non-small cell lung cancer (NSCLC).

- Galera Therapeutics (galeratx.com) announced that the FDA granted orphan drug designation to **rucosopasem manganese** for the treatment of pancreatic cancer.

Devices and Assays in the News

- On May 4, the FDA approved the **FoundationOne®Liquid CDx** (Foundation Medicine, foundationmedicine.com) as a companion diagnostic for **Exkivity® (mobocertinib)** (Takeda, takedaoncology.com), which is approved for the treatment of adult patients with locally advanced or metastatic NSCLC with epidermal growth factor receptor exon 20 insertion mutations, as detected by an FDA-approved test, and whose disease has progressed on or after platinum-based chemotherapy.

- On June 9, the FDA also approved the **FoundationOne Liquid CDx** as a companion diagnostic for **Braftovi® (encorafenib)** (Pfizer, Pfizer.com) in combination with cetuximab, which is approved for adult patients with previously treated metastatic colorectal cancer harboring a BRAF V600E alteration.