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Approved Drugs

- On June 24 the U.S. Food and Drug Administration (FDA) approved **Breyanzi® (lisocabtagene maraleucel)** (Bristol Myers Squibb, bms.com) for adult patients with large B-cell lymphoma who have refractory disease to first-line chemo-immunotherapy or relapse within 12 months of first-line chemo-immunotherapy or who have refractory disease to first-line chemo-immunotherapy or relapse after first-line chemo-immunotherapy and are not eligible for hematopoietic stem cell transplantation due to comorbidities or age. It is not indicated for the treatment of patients with primary central nervous system lymphoma.
- On Aug. 5 the FDA approved the new tablet formulation of **Calquence® (acalabrutinib)** (AstraZeneca, astrazeneca.com) for all current indications, including chronic lymphocytic leukemia, small lymphocytic lymphoma, and relapsed or refractory mantle cell lymphoma.
- On Aug. 5 the FDA approved **Enhertu® (fam-trastuzumab deruxtecan-nxki)** (AstraZeneca and Daiichi Sankyo, Inc., astrazeneca.com and daiichisankyo.com) for adult patients with unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-low (IHC 1+ or IHC 2+/ISH–) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy. Enhertu was also approved by the FDA on Aug. 12 for the treatment of adult patients with unresectable or metastatic non-small cell lung cancer whose tumors have activating HER2 (ERBB2) mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy.
- On Aug. 5 the FDA approved **Nubeqa® (darolutamide)** (Bayer HealthCare Pharmaceuticals Inc., bayer.com) **in combination with docetaxel** for adult patients with metastatic hormone-sensitive prostate cancer.
- On Aug. 10, the FDA granted regular approval to **Tabrecta® (capmatinib)** (Novartis Pharmaceutical Corporation, novratis.com) for adult patients with metastatic non-small cell lung cancer whose tumors have a mutation leading to mesenchymal-epithelial transition exon 14 skipping, as detected by an FDA-approved test.
- On June 22 the FDA granted accelerated approval to **Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib)** (Novartis Pharmaceutical Corporation, novratis.com) for the treatment of adult and pediatric patients six years and older with unresectable or metastatic solid tumors with BRAF V600E mutation, who have progressed following prior treatment and have no satisfactory alternative treatment options.
- On July 14 the FDA approved **Xalkori® (crizotinib)** (Pfizer Inc., pfizer.com) for adult and pediatric patients one year of age and older with unresectable, recurrent, or refractory inflammatory anaplastic lymphoma kinase-positive myofibroblastic tumors.

Drugs in the News

- Genmab (genmab.com) announced its intent to submit a biologics license application (BLA) to the FDA for **DuoBody®-CD3xCD20 (epcoritamab)**, an investigational bispecific antibody for the treatment of patients with relapsed/refractory large B-cell lymphoma.
- The Menarini Group (menarini.com/en-us) and Stemline Therapeutics (stemline.com) announced that the FDA accepted and granted priority review to the new drug application (NDA) for **elacestrant** to treat patients with ER+/HER2– advanced or metastatic breast cancer.
- AstraZeneca (astrazeneca.com) and Daiichi Sankyo (daiichisankyo.com) have received notification of acceptance from the FDA and for its supplemental BLA, which was granted priority review, for **Enhertu® (trastuzumab deruxtecan)** for the treatment of adult patients unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-negative) breast cancer who have received a prior therapy in the metastatic setting.
- Roche (roche.com) announced that the FDA accepted and granted priority review to its BLA for **Lunsumio® (mosunetuzumab)** for the treatment of adults with relapsed or refractory follicular lymphoma who have received at least two prior systemic therapies.
- Mustang Bio, Inc. (mustangbio.com) announced that the FDA granted orphan drug designation to **MB-106**, an autologous chimeric antigen receptor

T-cell therapy for the treatment of Waldenström macroglobulinemia.

- Sierra Oncology, Inc. (sierraoncology.com) announced the submission of an NDA to the FDA for **momelotinib**, an ACVR1/ALK2, JAK1, and JAK2 inhibitor in development for the treatment of myelofibrosis.
- Immunity Bio, Inc. (immunitybio.com) announced that the FDA accepted for review the BLA for **N-803** for the treatment of patients with BCG-unresponsive non-muscle-invasive bladder cancer carcinoma *in situ* with or without Ta or T1 disease.
- Gamida Cell Ltd. (gamida-cell.com) announced that the FDA accepted for filling the company's BLA for **omidubicel** for the treatment of patients with blood cancers in need of an allogenic hematopoietic stem cell transplant.
- Kazia Therapeutics, Ltd. (kaziatherapeutics.com) announced that the FDA has awarded orphan drug designation to **paxalisib** for the treatment of atypical rhabdoid and teratoid tumors.
- Janssen (janssen.com) announced that the FDA has granted breakthrough therapy designation to **talquetamab** for the treatment of adult patients with relapsed or refractory multiple myeloma who have previously received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 antibody.
- Coherus BioSciences, Inc. (coherus.com) and Shanghai Junshi Biosciences Co., Ltd. (junshipharma.com/en/Index.html) announced that the FDA accepted for review the BLA resubmission for **toripalimab in combination with gemcitabine and cisplatin** as first-line treatment for patients with advanced recurrent or metastatic nasopharyngeal carcinoma and for **toripalimab monotherapy** for the second-line or later treatment of recurrent or metastatic nasopharyngeal carcinoma after platinum-containing chemotherapy.
- TG Therapeutics, Inc. (tgtherapeutics.com) announced their voluntary withdrawal of the pending BLA/supplemental NDA for the combination of **ublituximab and Ukoniq®** (**umbralisib**) for the treatment of adult patients with chronic lymphocytic leukemia and small lymphocytic lymphoma.
- Wugen, Inc. (wugen.com) announced that the FDA granted fast track designation and rare pediatric disease designation to **WU-CART-007** for the treatment of relapsed or refractory T-cell acute lymphoblastic leukemia/lymphoblastic lymphoma.
- VBI Vaccines Inc. (vbivaccines.com) announced that the FDA granted orphan drug designation to **VBI-1901** for the treatment of glioblastoma.
- Byondis (byondis.com) announced that the FDA accepted the company's BLA submission for **[vic-] trastuzumab duocarmazine (SYD985)** for patients with HER2-positive unresectable locally advanced or metastatic breast cancer.

Devices and Assays in the News

- Adaptive Biotechnologies (adaptivebiotech.com) announced that Palmetto GBA, a Medicare administrative contractor, has expanded coverage for the **clonoSEQ® Assay** to include monitoring minimal residual disease in Medicare beneficiaries with diffuse large B-cell lymphoma.
- Guardant Health, Inc. (guardanthealth.com) announced that the FDA approved the **Guardant360® CDx** as a companion diagnostic to select patients with unresectable or metastatic HER2-mutant non-small cell lung cancer whose tumors have activating ERBB2 mutations for treatment with Enhertu.
- Berry Oncology (en.berryoncology.com/index.html) announced the launch of its innovative, one-time precision product **HIFI Pan-Cancer Screening**, which is an early multi-cancer screening product developed based on the company's proprietary HIFI technology platform.
- Pillar Biosciences (pillarbiosci.com) announced that the FDA accepted for review the company's premarket approval supplement application to expand the label/indication of **oncoReveal™ Dx Lung & Colon Cancer Assay** to include actionable targets for eight additional cancer types.
- Roche (roche.com) announced that the FDA approved its VENTANA MMR RxDx Panel label expansion to aid in identifying patients whose solid tumors are deficient in DNA mismatch repair and who may be eligible for Keytruda® (pembrolizumab) (Merck, merck.com).

FDA Guidance on Inclusion of Patients with Incurable Cancers in Clinical Trials

On July 29 the FDA issued finalized guidance on the inclusion of patients with incurable cancers in clinical trials for investigational therapies. The agency recommends that sponsors include patients with incurable cancer—defined as unresectable, locally advanced, or metastatic disease in solid tumors and/or hematologic malignancies with unfavorable long-term overall survival—in oncology clinical trials even if patients met criteria that would otherwise exclude them, such as in situations where a patient had previously received an available therapy in a non-curative setting. The recommendation by the FDA emphasizes that sponsors still need to follow regulations around informed consent before enrolling patients with incurable cancers in clinical trials. OI