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Approved Drugs

- On Feb. 5, 2021, the U.S. Food and Drug Administration (FDA) approved Bristol Myers Squibb's (bms.com) **Breyanzi® (lisocabtagene maraleucel)**, a CD19-directed chimeric antigen receptor T-cell therapy for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma not otherwise specified (including diffuse large B-cell lymphoma arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B.
- On Jan. 15, 2021, the FDA granted accelerated approval to **Darzalex Faspro™ (daratumumab and hyaluronidase-fihj)** (The Janssen Pharmaceutical Companies of Johnson & Johnson, janssen.com) in combination with bortezomib, cyclophosphamide, and dexamethasone for newly diagnosed light chain amyloidosis.
- On Jan. 15, 2021, the FDA approved **Enhertu® (fam-trastuzumab deruxtecan-nxki)** (Daiichi Sankyo, daiichisankyo.com) for adult patients with locally advanced or metastatic human epidermal growth factor receptor 2 (HER2)-positive gastric or gastro-esophageal adenocarcinoma who have received a prior trastuzumab-based regimen.
- On Feb. 9, 2021, the FDA granted regular approval to Regeneron Pharmaceuticals' (regeneron.com) **Libtayo® (cemiplimab-rwlc)** for patients with locally advanced basal cell carcinoma previously treated with a hedgehog pathway inhibitor (HHI) or for whom an HHI is not appropriate and accelerated approval to Libtayo for patients with metastatic basal cell carcinoma previously treated with an HHI or for whom an HHI is not appropriate.
- On Dec. 16, 2020, the FDA approved **Margenza™ (margetuximab-cmkb)** (MacroGenics, macrogenics.com) in combination with chemotherapy for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.
- On Jan. 22, 2021, the FDA approved the combination of **Opdivo® (nivolumab)** (Bristol Myers Squibb, bms.com) and **Cabometyx® (cabozantinib)** (Exelixis, exelixis.com) as first-line treatment for patients with advanced renal cell carcinoma.
- On Dec. 18, 2020, the FDA approved the first oral gonadotropin-releasing hormone receptor antagonist **Orgovyx™ (relugolix)** (Myovant Sciences, Inc., myovant.com) for adult patients with advanced prostate cancer.
- On Dec. 17, 2020, the FDA approved **Riabni™ (rituximab-arrx)** (Amgen, amgen.com), a biosimilar to Rituxan® (rituximab), for the treatment of adult patients with non-Hodgkin's lymphoma, chronic lymphocytic leukemia, granulomatosis with polyangiitis (Wegener's granulomatosis), and microscopic polyangiitis.
- On Dec. 18, 2020, the FDA approved **Tagrisso® (osimertinib)** (AstraZeneca, astrazeneca.com) for adjuvant therapy after tumor resection in patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- On Feb. 3, 2021, the FDA granted accelerated approval to **Tepmetko® (tepotinib)** (EMD Serono, emdserono.com/us-en) for adult patients with metastatic NSCLC harboring mesenchymal-epithelial transition exon 14 skipping alterations.
- On Feb. 5, 2021, TG Therapeutics (tgtherapeutics.com) announced the FDA has approved **Ukoniq™ (umbralisib)** for the treatment of adult patients with relapsed or refractory marginal zone lymphoma who have received at least one prior anti-CD20 based regimen and adult patients with relapsed or refractory follicular lymphoma who have received at least three prior lines of systemic therapy.
- On Jan. 14, 2021, the FDA approved **Xalkori® (crizotinib)** (Pfizer, pfizer.com) for pediatric patients one year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma that is ALK-positive. The safety and efficacy of crizotinib have not been established in older adults with relapsed or refractory, systemic ALK-positive anaplastic large cell lymphoma.
- On Dec. 18, 2020, the FDA approved **Xpovio® (selinexor)** (Karyopharm Therapeutics Inc., karyopharm.com) in

combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.

Drugs in the News

- Moleculin Biotech, Inc. (moleculin.com) announced that the FDA granted orphan drug designation to **annamycin** for the treatment of soft tissue sarcomas.
- Ambrx (ambrx.com) announced that the FDA granted **ARX788** fast track designation as monotherapy for the treatment of advanced or metastatic HER2-positive breast cancer for patients who have received one or more prior anti-HER2-based regimens in the metastatic setting.
- Bio-Thera Solutions (bio-thera.com/en) announced that the FDA has accepted its biologics license application (BLA) for **BAT1706**, a proposed biosimilar to Avastin® (bevacizumab).
- CNS Pharmaceuticals, Inc. (cnspharma.com) announced that the investigational new drug application (NDA) for **berubicin** for the treatment of glioblastoma multiforme is now approved and in effect as filed with the FDA.
- The Janssen Pharmaceutical Companies of Johnson & Johnson (janssen.com) announced the initiation of a rolling submission of its BLA to the FDA for **ciltacabtagene autoleucel (cilta-cel)** for the treatment of adults with relapsed and/or refractory multiple myeloma.
- Rafael Pharmaceuticals, Inc. (rafaelpharma.com) announced that the FDA has granted fast track designation to **CPI-613® (devimistat)** for the treatment of acute myeloid leukemia.
- Immunicum (immunicum.se) announced that it has received orphan drug designation from the FDA for **ilixadencel** for the treatment of soft tissue sarcoma.
- Takeda Pharmaceutical Company (takeda.com/en-us) announced that the FDA has approved the supplemental NDA for **Iclusig® (ponatinib)** for adult patients with chronic-phase chronic myeloid leukemia with resistance or intolerance to at least two prior kinase inhibitors.
- Jazz Pharmaceuticals (jazzpharma.com) announced that it has initiated the submission of a BLA to the FDA seeking marketing approval for **JZP-458** for use as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia or lymphoblastic lymphoma in adult and pediatric patients who have developed hypersensitivity or silent inactivation to *Escherichia coli*-derived asparaginase.
- Steba biotech (stebabiotech.com) announced that the FDA has granted fast track designation for **padeliporfin ImPACT (Immune Photo Activated Cancer Therapy)** for the treatment of adult patients with low-grade and unifocal high-grade upper tract urothelial cancer.
- Merck (merck.com) announced that the FDA has accepted and granted priority review for a new supplemental BLA for **Keytruda® (pembrolizumab)** in combination with platinum- and fluoropyrimidine-based chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the esophagus and gastroesophageal junction.
- Pfizer Inc. (pfizer.com) announced that the FDA has accepted for priority review the supplemental NDA for **Lorbrena® (lorlatinib)** as a first-line treatment for people with anaplastic lymphoma kinase-positive metastatic NSCLC.
- Bayer (bayer.com/en) announced that the FDA approved a supplemental NDA to add overall survival and other secondary endpoint data from the Phase III ARAMIS trial to the **Nubeqa® (darolutamide)** prescribing information.
- Bristol Myers Squibb (bms.com) announced that the FDA has accepted its supplemental BLA and granted priority review for **Opdivo® (nivolumab)** in combination with fluoropyrimidine- and platinum-containing chemotherapy for the treatment of patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma. The FDA also accepted the company's supplemental BLA and granted priority review for Opdivo for the treatment of patients with resected esophageal or gastroesophageal junction cancer in the adjuvant setting after neoadjuvant chemoradiation therapy.
- Avelas Biosciences, Inc. (avelasbio.com) announced that the company has received breakthrough therapy designation from the FDA for **pegloprastide (AVB-620)** for the intraoperative detection and visualization of positive margins during breast cancer surgery.
- Istari Oncology (istarioncology.com) announced that the FDA granted orphan drug designation for **PVSRIPO** for the treatment of advanced melanoma.
- Incyte (incyte.com) announced that the FDA has accepted for priority review its BLA for **retifanlimab** as a potential treatment for adult patients with locally advanced or metastatic squamous cell carcinoma of the anal canal who have progressed on, or who are intolerant of, platinum-based chemotherapy.
- Amgen (amgen.com) announced submission of an NDA to the FDA for **sotorasib** for the treatment of patients with KRAS G12C-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, following at least one prior systemic therapy.
- Roche (roche.com) announced that **tiragolumab** has been granted breakthrough therapy designation by the FDA in combination with Tecentriq® (atezolizumab) for the first-line treatment of people with metastatic NSCLC whose tumors have high PD-L1 expression with no EGFR or ALK genomic tumor aberrations.
- Junshi Biosciences (junshipharma.com/en/AboutUs.html) announced that FDA has granted **toripalimab** fast track designation for the first-line treatment of mucosal melanoma.
- Merus (merus.nl) announced that the FDA granted fast track designation to **zenocutuzumab (Zeno)** for the treatment of patients with metastatic solid tumors harboring NRG1 gene fusions that have progressed on standard of care therapy. OI