tools

Approved Drugs

- On February 16, the U.S. Food and Drug Administration (FDA) granted accelerated approval to **Amtagvi® (lifileucel)** (Iovance Biotherapeutics, Inc., iovance.com) for adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 positive, a BRAF inhibitor with or without a MEK inhibitor.
- On January 19, the FDA approved **Balversa® (erdafitinib)** (Janssen Biotech, janssen.com) for adult patients with locally advanced or metastatic urothelial carcinoma with susceptible FGFR3 genetic alterations, as determined by an FDA-approved companion diagnostic test, whose disease has progressed on or after at least 1 line of prior systemic therapy.
- On March 6, the FDA approved **Besponsa® (inotuzumab ozogamicin)** (Pfizer, pfizer.com) for pediatric patients 1 year and older with relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia.
- On March 7, the FDA granted accelerated approval to **Brukinsa® (zanubrutinib)** (BeiGene, Inc., beigene.com) **in combination with obinutuzumab** for relapsed or refractory follicular lymphoma after 2 or more lines of systemic therapy.
- On March 22, the FDA approved **Elahere® (mirvetuximab soravtansine-gynx)** (AbbVie, abbvie.com) for adult patients with FRα positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received 1 to 3 prior systemic treatment regimens.
- On March 19, the FDA granted accelerated approval to **Iclusig® (ponatinib)** (Takeda Pharmaceuticals Inc., takeda.com) in combination with chemotherapy for adult patients with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia.
- On March 6, the FDA approved **Opdivo® (nivolumab)** (Bristol Myers Squibb, bms.com) **in combination with cisplatin and gemcitabine** for first-line treatment of adult patients with unresectable or metastatic urothelial carcinoma.
- On February 13, the FDA approved **Onivyde® (irinotecan liposome)** (Ipsen Biopharmaceuticals, Inc., ipsen.com) **in combination with oxaliplatin, fluorouracil, and leucovorin**, for the first-line treatment of metastatic pancreatic adenocarcinoma.
- On March 1, the FDA approved **Rybrevant® (amivantamab-vmjw)** (Janssen Biotech, janssen.com) **in combination with carboplatin and pemetrexed** for the first-line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor exon 20 insertion mutations, as detected by an FDA-approved test.
- On February 16, the FDA approved **Tagrisso® (osimertinib)** (AstraZeneca Pharmaceuticals LP, astrazeneca.com) in combination with platinum-based chemotherapy for patients with locally advanced or metastatic NSCLC whose tumors have EGFR exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
- On February 15, the FDA approved **Tepmetko® (tepotinib)** (EMD Serono, Inc., emdsereno.com) for adult patients with metastatic NSCLC harboring mesenchymal-epithelial transition exon 14 skipping alterations.

Drugs In the News

- A2 Biotherapeutics, Inc. (A2bio.com) announced that the FDA has granted orphan drug designation to **A2B530** for the treatment of germline heterozygous HLA-A*02(+) patients with colorectal cancer that expresses carcinoembryonic antigen and has lost HLA-A*02 expression.
- Adaptimmune Therapeutics plc (adaptimmune.com) announced that the FDA has accepted for priority review its biologics license application (BLA) for **afami-cel**, an investigational engineered T-cell therapy, for advanced synovial sarcoma.
- RadioMedix, Inc. (radiomedix.com) and Orano Med (oranomed.com) announced that the FDA has granted breakthrough therapy designation to **AlphaMedix™ (212Pb-DOTAMTATE)** for the treatment of adult patients with unresectable or metastatic, progressive somatostatin receptor expressing gastroenteropancreatic neuroendocrine tumors who are naïve to peptide receptor radionuclide therapy.
- Bristol Myers Squibb (bms.com) announced that the FDA has accepted the supplemental new drug application (NDA) for **Augtyro™ (repotrectinib)** for the treatment of adult and pediatric patients 12 years of age and older with solid tumors that have a neurotrophic tyrosine receptor kinase gene fusion and are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity.

- Verastem Oncology (verastem.com) announced that the FDA granted orphan drug designation to **avutometinib**, alone or **in combination with defactinib** for the treatment of all patients with recurrent low-grade serous ovarian cancer. The company also announced that the FDA granted fast track designation to **avutometinib** in combination with Amgen's (amgen.com) **Lumarkas® (sotorasib)** for the treatment of NSCLC.
- BioNTech SE (biontech.com) announced that the FDA granted fast track designation to **BNT325/DB-1305** for the treatment of patients with platinum-resistant ovarian epithelial cancer, fallopian tube cancer, or primary peritoneal cancer who have received 1 to 3 prior systemic treatment regimens.
- Biosyngen (biosyngen.com) announced that the FDA granted fast track designation to **BST02** for the treatment of various liver cancers, including hepatocellular carcinoma and cholangiocarcinoma.
- AstraZeneca Pharmaceuticals LP (astrazeneca.com) and Daiichi Sankyo (daiichisankyo.com) announced that the FDA has accepted their BLA for **datopotamab deruxtecan** for the treatment of adult patients with locally advanced or metastatic nonsquamous NSCLC who have received prior systemic therapy.
- AstraZeneca Pharmaceuticals LP (astrazeneca.com) and Daiichi Sankyo (daiichisankyo.com) announced that the FDA has accepted and granted priority review to their supplemental BLA for **Enhertu® (trastuzumab deruxtecan)** for the treatment of adult patients with unresectable or metastatic HER2-positive (immunohistochemistry [IHC] 3+) solid tumors who have received prior treatment or who have no satisfactory alternative treatment options.
- Xcovery Holdings, Inc. (xcovery.com) announced that the FDA has accepted the NDA for **ensartinib**, an anaplastic lymphoma kinase inhibitor (ALK) for the treatment of adult patients with metastatic ALK-positive NSCLC.
- Indapta Therapeutics, Inc. (indapta.com) announced that the FDA has granted fast track designation for **IDP-023** for the treatment of patients with non-Hodgkin's lymphoma and multiple myeloma.
- Immune-Onc Therapeutics Inc. (immune-onc.com) announced that the FDA has granted orphan drug designation to **IO-202** for the treatment of chronic myelomonocytic leukemia.
- Bristol Myers Squibb (bms.com) announced that the FDA has accepted for priority review the supplemental NDA for **Krazati® (adagrasib) in combination with cetuximab** for the treatment of patients with previously treated KRASG12C-mutated locally advanced or metastatic colorectal cancer.
- Citius Pharmaceuticals, Inc. (citiuspharma.com) announced that the FDA has accepted the resubmission of the company's BLA for **Lymphir™ (denileukin diftitox)** an IL-2-based immunotherapy for the treatment of patients with relapsed or refractory cutaneous T-cell lymphoma after at least 1 prior systemic therapy.
- PureTech Health plc (purehealth.com) announced that the FDA has granted orphan drug designation to **LYT-200** for the treatment of acute myeloid leukemia.
- Nuvalent, Inc. (nuvalent.com) announced that the FDA has granted breakthrough therapy designation to **NVL-520** for the treatment of patients with ROS1-positive metastatic NSCLC who have been previously treated with 2 or more ROS1 tyrosine kinase inhibitors.
- Autolus Therapeutics plc (autoplus.com) announced that the FDA has accepted its BLA for **obecabtagene autoleucel** for patients with relapsed/refractory adult b-Cell acute lymphoblastic leukemia.
- Bristol Myers Squibb (bms.com) announced that the FDA accepted its supplemental BLA for neoadjuvant **Opdivo® (nivolumab)** with chemotherapy followed by surgery and adjuvant Opdivo for the perioperative treatment of resectable stage IIA to IIIB NSCLC.
- Poseida Therapeutics, Inc. (posieda.com) announced that the FDA has granted orphan drug designation to **P-BCMA-ALLO1**, a novel BCMA-targeted allogeneic, T stem cell memory-rich chimeric antigen receptor-T therapy candidate, for the treatment of multiple myeloma.
- Terns Pharmaceuticals, Inc. (ternspharma.com) announced that the FDA granted orphan drug designation for **TERN-701** for the treatment of chronic myeloid leukemia.
- BeiGene, Ltd. (beigene.com) announced that the FDA has accepted a BLA for **Tevimbra® (tislelizumab) in combination with fluoropyrimidine** and platinum-containing chemotherapy, for the treatment of patients with locally advanced unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma.

Device and Assays

- DermaSensor Inc. (dermasensor.com) announced that the FDA approved **DermaSensor**, a handheld device that uses artificial intelligence to non-invasively detect skin cancer.
- Amadix (amadix.com) a Spanish biotech company, announced that **PreveCol®**, its colorectal cancer screening blood test, has received breakthrough device designation from the FDA.