# tools

## Approved Drugs

- On Dec. 3, 2021, the U.S. Food and Drug Administration (FDA) approved **Keytruda® (pembrolizumab)** (Merck, merck.com) for the adjuvant treatment of adult and pediatric (less than or equal to 12 years of age) patients with Stage IIB or IIC melanoma following complete resection.
- On Jan. 25, 2022, the FDA approved **Kimmtrak® (tebentafusp-tebn)** (Immunocore Limited, immunocore.com) for HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.
- On Dec. 15, 2021, the FDA approved **Orencia® (abatacept)** (Bristol Myers Squibb, bms.com) for the prophylaxis of acute graft versus host disease **in combination with a calcineurin inhibitor and methotrexate** in adults and pediatric patients two years of age and older undergoing hematopoietic stem cell transplantation from a matched or one allele-mismatched unrelated donor.
- On Dec. 2, 2021, the FDA approved **Rituxan® (rituximab)** (Genentech, Inc., gene.com) **in combination with chemotherapy** for pediatric patients (less than or equal to 6 months old to less than 18 years old) with previously untreated, advanced stage CD20-positive diffuse large B-cell lymphoma, Burkitt's lymphoma, Burkitt's-like lymphoma, or mature B-cell acute leukemia.

## Drugs in the News

- Arch Oncology, Inc. (archoncology.com) announced that the FDA granted orphan drug designation to **AO-176** for the treatment of relapsed or refractory multiple myeloma.
- Cullinan Oncology, Inc. (cullinanoncology.com) announced that the FDA has granted breakthrough therapy designation for **CLN-081** for the treatment of patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) harboring EGFR exon 20 insertion mutations who have previously received platinum-based systemic chemotherapy.
- Secura Bio, Inc. (securabio.com) voluntarily withdrew the United States **Copiktra® (duvelisib)** indication for the treatment of patients with relapsed or refractory follicular lymphoma after at least two prior systemic therapies.
- Allarity Therapeutics, Inc. (allarity.com) announced the submission of a new drug application (NDA) to the FDA seeking marketing approval for **dovitinib** for the third-line treatment of patients with renal cell carcinoma.
- Karyopharm Therapeutics Inc. (karyopharm.com) announced that the FDA granted orphan drug designation to **eltanexor** for the treatment of myelodysplastic syndromes.
- AstraZeneca (astrazeneca.com) and Daiichi Sankyo (daiichisankyo.com) announced that its supplemental biologics license application (BLA) for **Enhertu® (trastuzumab deruxtecan)** for the treatment of adult patients with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen was granted priority review by the FDA.
- Celcuity Inc. (celcuity.com) announced that the FDA granted fast track designation to **gedatolisib** for the treatment of patients with hormone receptor (HR)+/HER2– metastatic breast cancer after progression on CDK4/6 therapy.
- Immix Biopharma, Inc. (immixbio.com) announced that the FDA granted rare pediatric disease designation to **IMX-110** for the treatment of rhabdomyosarcoma.
- Regeneron Pharmaceuticals, Inc. (regeneron.com) announced that the FDA accepted for review the supplemental BLA for **Libtayo® (cemiplimab-rwlc) in combination with chemotherapy** as first-line treatment in advanced NSCLC.
- Nkarta, Inc. (nkartatx.com) announced that the FDA granted orphan drug designation to **NKX101** for treatment of acute myeloid leukemia.
- Daiichi Sankyo Company, Ltd. (daiichisankyo.com) announced that the FDA granted breakthrough therapy designation to **patritumab deruxtecan (HER3-DXd)** for the treatment of patients with metastatic or locally advanced EGFR-mutated NSCLC with disease progression on or after

treatment with a third-generation tyrosine kinase inhibitor and platinum-based therapies.

- Senhwa Biosciences, Inc. (senhwabio.com/en) announced that the FDA granted fast track designation to **pidnarulex** for the treatment of patients with breast and ovarian cancers with BRCA1/2, PALB2, or other homologous recombination deficiency (HRD) mutations.
- Spectrum Pharmaceuticals (sppirx.com) announced that it has submitted an NDA for **poziotinib** to the FDA for use in patients with previously treated locally advanced or metastatic NSCLC with HER2 exon 20 insertion mutations.
- Genprex, Inc. (genprex.com) announced that the FDA has granted fast track designation to **Reqorsa™ (quaratusugene ozeplasmid) in combination with Keytruda** (Merck, merck.com) in patients with histologically confirmed unresectable Stage III or IV NSCLC whose disease progressed after treatment with Keytruda.
- Rakuten Medical, Inc. (rakuten-med.com/us) announced that the FDA accepted the investigational NDA to begin clinical studies of **RM-1995** photoimmunotherapy in patients with advanced cutaneous squamous cell carcinoma or with head and neck squamous cell carcinoma.
- Jazz Pharmaceuticals (jazzpharma.com) announced the completed submission of a supplemental BLA to the FDA seeking approval for a Monday/Wednesday/Friday intramuscular dosing schedule for **Rylaze™ (asparaginase erwinia chrysanthemi [recombinant]-rywn)** for use as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia and lymphoblastic lymphoma in adult and pediatric patients one month and older who have developed hypersensitivity to *Escherichia coli*-derived asparaginase.
- Senhwa Biosciences, Inc. (senhwabio.com/en) announced that the FDA granted orphan drug designation to **silmitasertib** to treat patients with biliary tract cancer.
- The Janssen Biotech, Inc. (janssen.com) announced submission of a BLA to the FDA seeking approval of **teclistamab** for the treatment of patients with relapsed or refractory multiple myeloma.
- AbbVie (abbvie.com) announced that the FDA granted breakthrough therapy designation to investigational **Teliso-V telisotuzumab vedotin** for the treatment of patients with advanced/metastatic EGFR wild type, nonsquamous NSCLC with high levels of c-mesenchymal epithelial transition (MET)< overexpression whose disease has progressed on or after platinum-based therapy.
- Sandoz (sandoz.com) announced the submission of its BLA to the FDA for a proposed biosimilar to trastuzumab (150 mg, for intravenous use) developed by EirGenix, Inc.
- Kite (kitepharma.com) announced the FDA has approved an update to the prescribing information for **Yescarta® (axicabtagene ciloleucel)** to include use of prophylactic corticosteroids across all approved indications.

## Devices and Assays in the News

- Blue Note Therapeutics (bluenotetherapeutics.com) announced that the FDA granted breakthrough device designation to **BNT200**, a digital therapeutic to treat anxiety and depressive symptoms in adults with acute myeloid leukemia who are hospitalized for a regimen of high-intensity induction chemotherapy.
- Foundation Medicine, Inc. (foundationmedicine.com) announced that it has received approval from the FDA for **FoundationOne®CDx** to be used as a companion diagnostic for two groups of current and future FDA-approved therapeutics in melanoma, which includes BRAF inhibitor monotherapies targeting BRAFV600E and BRAF/MEK inhibitor combination therapies targeting BRAFV600E or V600K mutations.
- Telix Pharmaceuticals (telixpharma.com) announced that the FDA approved **Illuccix® (TLX591-CDx)**, a kit for the preparation of gallium-68 (68Ga) gozetotide (also known as PSMA-11) injection—a radioactive diagnostic agent indicated for positron emission tomography of prostate-specific membrane antigen-positive lesions in patients with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or suspected recurrence based on elevated serum prostate-specific antigen level.
- The FDA granted premarket approval to Thermo Fisher Scientific's (corporate.thermofisher.com/us/en/index.html) **Oncomine Dx Target Test** as a companion diagnostic to help identify patients with NSCLC whose tumors carry EGFR exon 20 insertion mutations for potential treatment with Rybrevant® (amivantamab-vmjw) (Janssen Biotech, Inc., janssen.com). OI