tools

Approved Drugs

- On April 18, the US Food and Drug Administration (FDA) approved **Alecensa® (alectinib)** (Genentech, Inc, gene.com) for adjuvant treatment following tumor resection in patients with anaplastic lymphoma kinase-positive non-small cell lung cancer, as detected by an FDA-approved test.
- On April 22, the FDA approved **Anktiva® (nogapendekin alfa inbakicept-pmln)** (Altor Bioscience, LLC) in combination with **Bacillus Calmette-Guérin (BCG)** for adult patients with BCG-unresponsive non-muscle invasive bladder cancer with carcinoma in situ with or without papillary tumors.
- On May 15, the FDA granted accelerated approval to **Breyanzi® (lisocabtagene maraleucel)** (Juno Therapeutics, Inc, bms.com) for adults with relapsed or refractory follicular lymphoma who have received 2 or more prior lines of systemic therapy.
- On March 22, the FDA approved **Elahere® (mirvetuximab soravtansine-gynx)** (ImmunoGen, Inc [now a part of AbbVie], immunogen.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. Patients are selected based on an FDA-approved test.
- On April 5, the FDA granted accelerated approval to **Enhertu® (fam-trastuzumab deruxtecan-nxki)** (Daiichi Sankyo, Inc, daiichisankyo.com) for adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options.
- On May 16, the FDA granted accelerated approval to **Imdelltra® (tarlatamab-dlle)** (Amgen, Inc, amgen.com) for extensive stage small cell lung cancer with disease progression on or after platinum-based chemotherapy.
- On April 23, the FDA approved **Lutathera® (lutetium Lu 177 dotatate)** (Advanced Accelerator Applications USA, Inc, novartis.com) for pediatric patients aged 12 years or older with somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors, including foregut, midgut, and hindgut neuroendocrine tumors.
- On April 29, the FDA approved **Tivdak® (tisotumab vedotin-tftv)** (Seagen, Inc [now a part of Pfizer, Inc], seagen.com) for recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Tisotumab vedotin-tftv previously received accelerated approval for this indication.

Drugs In the News

- Candel Therapeutics, Inc (candeltx.com) announced that the FDA has granted orphan drug designation to **CAN-2409**, a multimodal biological immunotherapy candidate, for the treatment of pancreatic cancer.
- Context Therapeutics, Inc (contexttherapeutics.com) announced that the company submitted an investigational new drug (IND) application to the FDA to begin a first-in-human clinical study of **CTIM-76**. The IND supports the initiation of a phase 1 dose escalation and expansion clinical trial of **CTIM-76** in patients with Claudin 6-positive gynecologic and testicular cancers.
- Compass Therapeutics, Inc (compassthera-peutics.com) announced that the FDA has granted fast-track designation to **CTX-009 in combination with paclitaxel** for the treatment of patients with metastatic or locally advanced biliary tract cancer that has been previously treated.
- GSK, PLC (gsk.com) announced the FDA accepted the supplemental biologics license application (BLA) for **Jemperli® (dostarlimab) in combination with carboplatin and paclitaxel** to expand treatment to all adult patients with primary advanced or recurrent endometrial cancer.
- Lisata Therapeutics, Inc (lisata.com) announced that the FDA has granted orphan drug designation to **LSTA1** for the treatment of osteosarcoma, a rare cancer that can develop in children, adolescents, and young adults.
- PureTech Health, PLC (puretechhealth.com) announced that the FDA has granted fast-track designation for **LYT-200 in combination with anti-PD1 therapy** for the treatment of recurrent/metastatic head and neck squamous cell carcinomas.
- Bristol Myers Squibb (bms.com) announced that the FDA has accepted its BLA for the subcutaneous formulation of **Opdivo® (nivolumab)**, which was co-formulated with Halozyme's (halozyme.com) proprietary recombinant human hyaluronidase, across all previously approved adult, solid tumor **Opdivo** indications as monotherapy, monotherapy maintenance following completion of **Opdivo** plus **Yervoy® (ipilimumab)** combination therapy, or in **combination with chemo-therapy or cabozantinib**.
- Syndax Pharmaceuticals, Inc (syndax.com) announced that the FDA has granted priority review for its new drug application (NDA) for **revumenib**, the company's menin inhibitor,

for the treatment of adult and pediatric relapsed or refractory KMT2A-rearranged (KMT2Ar) acute leukemia.

- Shorla Oncology (shorlaoncology.com) announced that the FDA has accepted for review the company's NDA for **SH-201**, an oral liquid of the related chemotherapeutic agent to treat certain forms of leukemia and other cancers.
- SN Bioscience Co, Ltd (snbioscience.com) announced that the FDA has granted fast track designation for small cell lung cancer for **SNB-101 (API: SN-38)**, a new drug for polymer nanoparticle anticancer under clinical trial.
- Dizal Pharma (dizalpharma.com) announced that the FDA has granted breakthrough therapy designation to **sunvozertinib** as the first-line treatment for patients with locally advanced or metastatic non-small cell lung cancer harboring epidermal growth factor receptor exon 20 insertion (Exon20ins) mutations.
- Syros Pharmaceuticals (syros.com) announced that the FDA granted FTD to **tamibarotene in combination with azacitidine and venetoclax** for the treatment of newly diagnosed acute myeloid leukemia with RARA gene overexpression.
- Biostar Pharmaceuticals, Inc (biostar-pharm.com) announced that their core pipeline product **utidelone injectable** has been granted orphan drug designation by the FDA for the treatment of breast cancer brain metastasis.
- Jazz Pharmaceuticals, PLC (jazzpharma.com) announced that the FDA has granted priority review to the company's BLA for the its HER2-targeted bispecific antibody **zanidatamab** as a treatment for previously-treated, unresectable, locally advanced, or metastatic HER2-positive biliary tract cancer.
- Kura Oncology, Inc (kuraoncology.com) announced that its investigational drug, **ziftomenib**, has been granted breakthrough therapy designation by the FDA for the treatment of patients with relapsed/refractory NPM1-mutated acute myeloid leukemia.