tools

Approved Drugs

- On Feb. 12, G1 Therapeutics, Inc. (g1therapeutics.com) announced that the U.S. Food and Drug Administration (FDA) approved **Cosela™ (trilaciclib)** to decrease the incidence of chemotherapy-induced myelosuppression in adult patients when administered prior to a platinum/etoposide-containing regimen or topotecan-containing regimen for extensive-stage small cell lung cancer.
- On March 10, the FDA approved **Fotivda® (tivozanib)** (AVEO Pharmaceuticals, aveooncology.com) for adult patients with relapsed or refractory advanced renal cell carcinoma following two or more prior systemic therapies.
- On March 22, the FDA approved **Keytruda® (pembrolizumab)** (Merck, Merck.com) in combination with platinum- and fluoropyrimidine-based chemotherapy for patients with metastatic or locally advanced esophageal or gastroesophageal carcinoma who are not candidates for surgical resection or definitive chemoradiation.
- On Feb. 22, the FDA approved **Libtayo® (cemiplimab-rwlc)** (Regeneron Pharmaceuticals, regeneron.com) for the first-line treatment of patients with advanced non-small cell lung cancer (NSCLC; locally advanced who are not candidates for surgical resection or definitive chemoradiation or metastatic) whose tumors have high programmed death ligand 1 expression as determined by an FDA-approved test, with no epidermal growth factor receptor (EGFR), anaplastic lymphoma kinase (ALK), or C-ros oncogene-1 (ROS-1) aberrations.
- On March 3, the FDA granted regular approval to **Lorbrena® (lorlatinib)** (Pfizer, pfizer.com) for patients with metastatic NSCLC whose tumors are anaplastic lymphoma kinase ALK-positive, detected by an FDA-approved test.
- On Feb. 26, the FDA granted accelerated approval to **Pepaxto® (melphalan flufenamide)** (Oncopeptides, oncopeptides-us.com/en) in combination with dexamethasone for adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD38-directed monoclonal antibody.
- On March 5, the FDA granted accelerated approval to **Yescarta® (axicabtagene ciloleucel)** (Kite Pharma, kitepharma.com) for adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.

Drugs in the News

- Novartis (novartis.com) announced that **asciminib (ABL001)** has been granted breakthrough therapy designation by the FDA for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase, previously treated with two or more tyrosine kinase inhibitors and for the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase harboring the T315I mutation.
- Merck (merck.com) announced that the FDA accepted and granted priority review for a new drug application (NDA) for the hypoxia-inducible factor-2 alpha inhibitor **belzutifan (MK-6482)** for the potential treatment of patients with von Hippel-Lindau disease-associated renal cell carcinoma not requiring immediate surgery.
- BeiGene (beigene.com) announced that the FDA has accepted a supplemental NDA for **Brukinsa® (zanubrutinib)** for the treatment of adult patients with Waldenström's macroglobulinemia.
- Exelixis (exelixis.com) announced that the FDA granted breakthrough therapy designation to **Cabometyx® (cabozantinib)** as a potential treatment for patients with differentiated thyroid cancer that has progressed following prior therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).
- Celsion Corporation (celsion.com) announced that it has received FDA fast track designation for **GEN-1** for the treatment of advanced ovarian cancer.
- Incyte (incyte.com) announced that the FDA accepted for priority review the supplemental NDA for **Jakafi® (ruxolitinib)** for treatment of steroid-refractory chronic graft-versus-host disease in adult and pediatric patients 12 years and older.
- Merck (merck.com) has voluntarily withdrawn the U.S. indication for its checkpoint inhibitor **Keytruda® (pembrolizumab)** in metastatic small cell lung cancer.
- Seagen (seagen.com) and Astellas Pharma (astellas.com) announced the

completion of two supplemental biologics license application (BLA) submissions to the FDA for **Padcev® (enfortumab vedotin-ejfv)**. One submission seeks to convert Padcev's accelerated approval to regular approval, and the second submission requests an expansion of the current label to include patients with locally advanced or metastatic urothelial cancer who have been previously treated with a programmed cell death protein 1/programmed death ligand 1 inhibitor and are ineligible for cisplatin.

- Steba Biotech announced that the FDA granted orphan drug designation to **padeliporfin** for the treatment of adult patients with upper tract urothelial cancer.
- On Target Laboratories (ontargetlabs.com) announced that the FDA accepted its NDA for priority review for **pafolacianine sodium injection** as an adjunct for identifying ovarian cancer during surgery.
- Spectrum Pharmaceuticals (sppirx.com) announced that the FDA granted fast track designation for **poziotinib** for the treatment of NSCLC in previously treated patients with human epidermal growth factor receptor 2 (HER2) exon 20 mutations.
- Amgen (amgen.com) announced that the FDA has granted priority review for **sotorasib (AMG 510)** for the treatment of patients with KRAS G12C-mutated locally advanced or metastatic NSCLC, following at least one prior systemic therapy.
- Roche (roche.com) announced that the company is voluntarily withdrawing the U.S. indication for **Tecentriq® (atezolizumab)** in prior platinum-treated metastatic urothelial carcinoma.
- Seagen (seagen.com) and Genmab (genmab.com) announced the submission of a BLA to the FDA seeking accelerated approval for **tisotumab vedotin** for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
- Shanghai Junshi Biosciences Co., Ltd. (junshipharma.com/en/AboutUs.html) and Coherus Biosciences (coherus.com) announced the initiation of the rolling submission of the BLA for **toripalimab** to the FDA for the treatment of recurrent or metastatic nasopharyngeal carcinoma.
- Sesen Bio (sesenbio.com) announced that the FDA accepted for filing and granted priority review its BLA for **Vicineum** for the treatment of high-risk, bacillus calmette-guerin (BCG)-unresponsive non-muscle invasive bladder cancer.

Devices, Genetic Tests, and Assays in the News

- Agilent Technologies (agilent.com) announced that the FDA approved the company's **PD-L1 IHC 22C3 pharmDx** assay for expanded use in patients with NSCLC.
- Natera, Inc. (natera.com) announced that the FDA granted two breakthrough device designations covering new intended uses of the **Signatera™** molecular residual disease test. Its performance has been clinically validated in multiple cancer types including colorectal, NSCLC, breast, and bladder cancers.
- Roche (roche.com) announced FDA approval of the **Ventana ALK (D5F3) CDx Assay** as a companion diagnostic to identify patients with ALK-positive NSCLC eligible for treatment with Lorbrena® (lorlatinib).

Other Oncology-Related Products in the News

- Boston Scientific Corporation (bostonscientific.com) announced it has received FDA approval of the **TheraSphere™ Y-90 Glass Microspheres** for the treatment of patients with hepatocellular carcinoma.
- Optellum (optellum.com) announced it received FDA 510(k) clearance for its **Virtual Nodule Clinic**, an artificial intelligence-powered clinical decision support software for pulmonologists and radiologists managing patients with small lesions in the lungs (nodules) that could represent early-stage lung cancer.