tools

Approved Drugs

- On Sept. 2, the U.S. Food and Drug Administration (FDA) approved **Brukinsa® (zanubrutinib)** (BeiGene, beigene.com) for adult patients with Waldenström's macroglobulinemia. On Sept. 14, the FDA granted accelerated approval to Brukinsa for adult patients with relapsed or refractory marginal zone lymphoma who have received at least one anti-CD20-based regimen.
- On Sept. 17, the FDA approved **Cabometyx® (cabozantinib)** (Exelixis, Inc., exelixis.com) for adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer that has progressed following prior vascular endothelial growth factor receptor (EGFR)-targeted therapy and who are ineligible or refractory to radioactive iodine.
- On Sept. 15, the FDA granted accelerated approval to **Exkivity™ (mobocertinib)** (Takeda Pharmaceuticals, Inc., takeda.com) for adult patients with locally advanced or metastatic non-small cell lung cancer with EGFR exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.
- On Sept. 28, the FDA granted approval of a new indication for **Erbitux® (cetuximab)** (Eli Lilly and Company, lilly.com) **in combination with Braftovi® (encorafenib)** (Pfizer, pfizer.com) for the treatment of adult patients with metastatic colorectal cancer with a BRAF V600E mutation, as detected by an FDA-approved test, after prior therapy.
- On Sept. 22, the FDA approved **Jakafi® (ruxolitinib)** (Incyte Corp., incyte.com) for chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.
- On Aug. 18, the FDA granted accelerated approval to **Jemperli (dostarlimab-gxly)** (GlaxoSmithKline LLC, gsk.com/en-gb/) for adult patients with mismatch repair deficient recurrent or advanced solid tumors, as determined by an FDA-approved test, who have progressed on or following prior treatment and who have no satisfactory alternative treatment options.
- On Aug. 31, Merck (merck.com) announced that the FDA converted the indication for **Keytruda® (pembrolizumab)** from accelerated to a full approval for the treatment of first-line advanced urothelial carcinoma.
- On Aug. 10, the FDA approved the combination of **Lenvima® (lenvatinib)** (Eisai, us.eisai.com) plus **Keytruda** for first-line treatment of adult patients with advanced renal cell carcinoma.
- On Aug. 19, the FDA approved **Opdivo® (nivolumab)** (Bristol Myers Squibb, bms.com) for the adjuvant treatment of patients with urothelial carcinoma who are at high risk of recurrence after undergoing radical resection.
- On Oct. 1, the FDA approved **Tecartus® (brexucabtagene autoleucel)** (Kite Pharma, kitepharma.com) for adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia.
- On Aug. 25, the FDA approved **Tibsovo® (ivosidenib)** (Servier Pharmaceuticals, servier.us) for adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 mutation as detected by an FDA-approved test.
- On Sept. 20, the FDA granted accelerated approval to **Tivdak™ (tisotumab vedotin-tftv)** (Seagen Inc., seagen.com) for adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
- On Aug. 13, the FDA approved **Welireg™ (belzutifan)** (Merck, merck.com) for adult patients with von Hippel-Lindau disease who require therapy for associated renal cell carcinoma, central nervous system hemangioblastomas, or pancreatic neuroendocrine tumors, not requiring immediate surgery.

Drugs in the News

- NuCana Plc (nucana.com) announced that the FDA granted fast track designation to **Acelarin (NUC-1031)** for the first-line treatment of patients with advanced biliary tract cancer.
- Bluebird bio (bluebirdbio.com) announced it has completed the rolling submission of its biologics license application (BLA) to the FDA for **betibeglogene autotemcel (beti-cel) gene therapy** in adult, adolescent, and pediatric patients with β-thalassemia who require regular red blood cell transfusions, across all genotypes.
- The FDA has granted **Enhertu® (trastuzumab deruxtecan)** (AstraZeneca, astrazeneca.com) breakthrough therapy designation for the treatment of adult

patients with unresectable or metastatic human epidermal growth factor receptor 2-positive breast cancer who have received one or more prior anti-human epidermal growth factor receptor 2-based regimens.

- Merck (merck.com) announced that the FDA accepted and granted priority review for a new supplemental BLA for **Keytruda® (pembrolizumab)** for the adjuvant treatment of patients with renal cell carcinoma at intermediate-high or high risk of recurrence following nephrectomy (surgical removal of a kidney) or following nephrectomy and resection of metastatic lesions. Merck also announced that the FDA accepted for review a new supplemental BLA seeking approval for Keytruda as a single agent for the treatment of patients with advanced endometrial carcinoma that is microsatellite instability-high or mismatch repair deficient who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.
- Regeneron Pharmaceuticals, Inc. (regeneron.com) announced that the FDA accepted for priority review the supplemental BLA for **Libtayo® (cemiplimab-rwlc)** to treat patients with recurrent or metastatic cervical cancer whose disease progressed on or after chemotherapy.
- Lantern Pharma (lanternpharma.com) announced that the FDA granted orphan drug designation to **LP-184** for the treatment of glioblastoma multiforme and other malignant gliomas.
- Novartis (novartis.con) announced that the FDA accepted and granted priority review to the new drug application for **Lu-PSMA-617** for the treatment of metastatic castration-resistant prostate cancer in the post-androgen receptor pathway inhibition, post-taxane-based chemotherapy setting.
- Bristol Myers Squibb (bms.com) announced that the FDA accepted the supplemental BLA for both **Opdivo® (nivolumab) in combination with Yervoy® (ipilimumab)** and **Opdivo in combination with fluoropyrimidine- and platinum-containing chemotherapy** as first-line treatments for adult patients with unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma.
- Bristol Myers Squibb (bms.com) announced that the FDA accepted its supplemental BLA for **Orencia® (abatacept)** for the prevention of moderate to severe acute graft-versus-host disease in patients six years of age and older receiving unrelated donor hematopoietic stem cell transplantation.
- Bristol Myers Squibb (bms.com) announced that the FDA accepted for priority review the BLA for the **relatlimab and nivolumab fixed-dose combination**, administered as a single infusion, for the treatment of adult and pediatric patients (12 years and older and weighing at least 40 kg) with unresectable or metastatic melanoma.
- Sutro Biopharma Inc. (sutrobio.com) announced that the FDA granted fast track designation to **STRO-002** in certain patients with advanced ovarian cancer.
- BeiGene (beigene.com) announced that the FDA accepted for review a BLA for **tislelizumab** as a treatment for patients with unresectable recurrent locally advanced or metastatic esophageal squamous cell carcinoma after prior systemic therapy.
- Shanghai Junshi Biosciences Co., Ltd. (junshipharma.com/en/Index.html) and Coherus BioSciences, Inc. (coherus.com) announced that the FDA granted breakthrough therapy designation to **toripalimab in combination with chemotherapy (gemcitabine and cisplatin)** for the first-line treatment of metastatic nasopharyngeal carcinoma (NPC). The companies also announced completion of the rolling submission for their BLA to the FDA for **toripalimab in combination with gemcitabine and cisplatin** for first-line treatment for patients with advanced recurrent or metastatic NPC and toripalimab monotherapy for second-line or above treatment of recurrent or metastatic NPC after platinum-containing chemotherapy.
- Kite Pharma (kitepharma.com) announced that it has submitted a supplemental BLA to the FDA for **Yescarta® (axicabtagene ciloleucel)** to expand its current indication to include the treatment of adults with relapsed or refractory large B-cell lymphoma in the second-line setting.

Devices and Assays in the News

- Novocure (novocure.com) announced that the FDA granted breakthrough designation to the **NovoTTF-200T™ System**, a Tumor Treating Fields delivery system intended for use together with atezolizumab and bevacizumab for the first-line treatment of patients with unresectable or metastatic liver cancer.
- Thermo Fisher Scientific (corporate.thermofisher.com/us/en/index.html) announced that the FDA granted pre-market approval to **Oncomine Dx Target Test** as a companion diagnostic to identify patients with isocitrate dehydrogenase-1 mutated cholangiocarcinoma who may be candidates for Tibsovo. The FDA also granted premarket approval to Oncomine Dx Target Test as a companion diagnostic to identify patients with EGFR exon 20 insertion mutation-positive non-small cell lung cancer who are candidates for Exkivity.
- The FDA authorized the marketing of **Paige Prostate** (Paige, paige.ai), a software used to assist medical professionals who examine body tissues in the detection of areas that are suspicious of cancer as an adjunct to the review of digitally scanned slide images from prostate biopsies.
- Roche (roche.com) announced the FDA approval of the **VENTANA MMR RxDx Panel**, a companion diagnostic test to aid in identifying patients whose solid tumors are deficient in DNA mismatch repair and who may be eligible for Jemperli monotherapy. OI