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Approved Drugs

- On Mar. 26, the U.S. Food and Drug Administration (FDA) approved **Abecma® (idecabtagene vicleucel)** (Bristol Myers Squibb and bluebird bio, bms.com and bluebirdbio.com) for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.
- On Apr. 6, the FDA approved a new dosage regimen of 500 mg/m^2 as a 120-minute intravenous infusion every two weeks for **Erbitux® (cetuximab)** (Eli Lilly, lilly.com) for patients with K-Ras wild-type, epidermal growth factor receptor (EGFR)-expressing colorectal cancer or squamous cell carcinoma of the head and neck.
- On Apr. 22, the FDA granted accelerated approval to **Jemperli (dostarlimab-gxly)** (GlaxoSmithKline, us.gsk.com/en-us) for patients with recurrent or advanced endometrial cancer that has progressed on or following prior treatment with a platinum-containing chemotherapy and whose cancers have a specific genetic feature known as dMMR, as determined by an FDA-approved test.
- On May 5, the FDA granted accelerated approval to **Keytruda® (pembrolizumab)** (Merck, merck.com) in combination with trastuzumab and fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma.
- On May 28, the FDA granted accelerated approval to **Lumakras™ (sotorasib)** (Amgen, amgen.com) for adult patients with KRAS G12C mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA-approved test, who have received at least one prior systemic therapy.
- On Apr. 16, the FDA approved **Opdivo® (nivolumab)** (Bristol Myers Squibb, bms.com) in combination with certain types of chemotherapy for the initial treatment of patients with advanced or metastatic gastric cancer, GEJ cancer, and esophageal adenocarcinoma. On May 20, the FDA approved Opdivo for patients with completely resected esophageal or GEJ cancer with residual pathologic disease who have received neoadjuvant chemoradiotherapy.
- On May 21, the FDA approved **Rybrevant™ (amivantamab-vmjw)** (The Janssen Pharmaceutical Companies of Johnson & Johnson, janssen.com) for adult patients with NSCLC whose tumors have specific types of genetic mutations: EGFR exon 20 insertion mutations.
- On Mar. 31, the FDA approved **Sarclisa® (isatuximab-irfc)** (Sanofi Genzyme, sanofi.com/en) in combination with carfilzomib and dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.
- On Apr. 7, the FDA granted regular approval to **Trodelvy® (sacituzumab govitecan-hziy)** (Gilead, gilead.com) for patients with unresectable locally advanced or metastatic triple-negative breast cancer who have received two or more prior systemic therapies, at least one of them for metastatic disease. On Apr. 13, the FDA granted accelerated approval to **Trodelvy** for use in adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and either a programmed death receptor-1 or a programmed death-ligand 1 inhibitor.
- On May 28, the FDA granted accelerated approval to **Truseltiq (infigratinib)** (QED Therapeutics, Inc., qedtx.com) for adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 fusion or other rearrangement as detected by an FDA-approved test.
- Jazz Pharmaceuticals (jazzpharma.com) announced that the FDA approved a revised label for **Vyxeos® (daunorubicin and cytarabine)** to include a new indication to treat newly diagnosed therapy-related acute myeloid leukemia or acute myeloid leukemia with myelodysplasia-related changes in pediatric patients aged one year and older.

- On Apr. 23, ACD Therapeutics (ir.adctherapeutics.com) announced FDA approval of **Zynlonta™ (loncastuximab tesirine-lpyl)** for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma not otherwise specified, diffuse large B-cell lymphoma arising from low grade lymphoma, and high-grade B-cell lymphoma.
- On May 13, Heron Therapeutics, Inc. (herontx.com) announced that the FDA approved **Zynrelef™ (bupivacaine and meloxicam)** extended-release solution for use in adults for soft tissue or periarticular instillation to produce post-surgical analgesia for up to 72 hours after bunionectomy, open inguinal herniorrhaphy, and total knee arthroplasty.

Drugs in the News

- AffyImmune Therapeutics, Inc. (affyimmune.com) announced that the FDA granted fast track designation to **AIC100** for the treatment of anaplastic thyroid cancer and refractory poorly differentiated thyroid cancer.
- Agenus Inc. (agenusbio.com) announced the submission of a biologics license agreement (BLA) to the FDA for the accelerated approval of **balstilimab (AGEN2034)** for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
- Amgen (amgen.com) announced that the FDA granted breakthrough therapy designation to **bemarituzumab (anti-FGFR2b)** as first-line treatment for patients with fibroblast growth factor receptor 2b (FGFR2b) overexpressing and human epidermal growth factor receptor 2-negative metastatic and locally advanced GEJ adenocarcinoma in combination with modified FOLFOX6 (fluoropyrimidine, leucovorin, and oxaliplatin), based on an FDA-approved companion diagnostic assay showing at least 10 percent of tumor cells overexpressing FGFR2b.
- BeiGene, Ltd. (beigene.com) announced that the FDA accepted a supplemental new drug application (NDA) and granted priority review to **Brukinsa® (zanubrutinib)** for the treatment of adult patients with marginal zone lymphoma who have received at least one prior anti-CD20-based therapy.
- Foresee Pharmaceuticals (foreseepharma.com/en-us/index) announced that the FDA approved the NDA for **Camcevi® (leuprolide)** as a treatment for advanced prostate cancer.
- Legend Biotech Corporation (legendbiotech.com) announced that the FDA accepted for priority review the BLA submitted by the Janssen Pharmaceutical Companies of Johnson & Johnson (janssen.com) for **ciltacabtagene autoleucel (cilta-cel)**, an investigational B-cell maturation antigen-directed chimeric antigen receptor T-cell therapy.
- Immutep Limited (immutep.com) announced that it received FDA fast track designation for **eftilagimod alpha (IMP321)** for first-line recurrent or metastatic head and neck squamous cell carcinoma.
- Taiho Oncology, Inc. (taihooncology.com) announced that the FDA granted breakthrough therapy designation for **futibatinib (TAS-120)** for the treatment of patients with previously treated locally advanced or metastatic cholangiocarcinoma harboring FGFR2 gene rearrangements, including gene fusions.
- Merck (merck.com) and Eisai Inc. (eisai.com/index.html) announced that the FDA has accepted and granted priority review for applications seeking two new approvals for the combination of **Keytruda® (pembrolizumab) plus Lenvima® (lenvatinib)** for the first-line treatment of patients with advanced renal cell carcinoma.
- Takeda Pharmaceutical Company Limited (takeda.com) announced that the FDA accepted an NDA and granted priority review to **maribavir** for the treatment of post-transplant cytomegalovirus infection in those that are refractory, with or without resistance, in solid organ transplant or hematopoietic cell transplant recipients.
- Mustang Bio, Inc. (mustangbio.com) announced that the FDA accepted its investigational NDA for **MB-106**, a CD20-targeted chimeric antigen receptor T-cell therapy for relapsed or refractory CD20+ B-cell non-Hodgkin's lymphoma and chronic lymphocytic leukemia.
- Takeda Pharmaceutical Company Limited (takeda.com) announced that that the FDA granted priority review to the NDA for **mobocertinib (TAK-788)** for the treatment of adult patients with epidermal growth factor receptor Exon20 insertion mutation-positive (insertion+) metastatic NSCLC, as detected by an FDA-approved test, who have received prior platinum-based chemotherapy.
- Bristol Myers Squibb (bms.com) announced that the FDA accepted the supplemental BLA for **Opdivo® (nivolumab)** for the adjuvant treatment of patients with surgically resected, high-risk muscle-invasive urothelial carcinoma.
- Astellas Pharma Inc. (astellas.com) and Seagen Inc. (seagen.com) announced FDA acceptance and priority review for two supplemental BLAs for **Padcev® (enfortumab vedotin-ejfv)** in locally advanced or metastatic urothelial cancer.
- CTI BioPharma Corp. (ctibiopharma.com) announced that it has completed a rolling NDA submission to the FDA seeking approval of **pacritinib** as a treatment for myelofibrosis in patients with severe thrombocytopenia. The NDA has been accepted by the FDA for priority review.

- Fennec Pharmaceuticals Inc. (fennecpharma.com) announced the resubmission of an NDA to the FDA for **Pedmark™ (sodium thiosulfate)** for the prevention of ototoxicity induced by cisplatin chemotherapy in patients one month to less than 18 years of age with localized non-metastatic solid tumors.
- BeyondSpring Inc. (beyondspringpharma.com) announced that the FDA accepted for priority review the NDA seeking approval for use of **plinabulin in combination with granulocyte colony-stimulating factor** for the prevention of chemotherapy-induced neutropenia.
- Innovent Biologics, Inc. (innoventbio.com/en) and Eli Lilly (lilly.com) jointly announced that the FDA accepted for review a BLA for **Tyvyt® (sintilimab)** in combination with pemetrexed and platinum chemotherapy for the first-line treatment of people with non-squamous NSCLC.
- Hutchmed (hutch-med.com) announced that it completed the rolling submission of an NDA to the FDA for **surufatinib** for the treatment of pancreatic and extra-pancreatic (non-pancreatic) neuroendocrine tumors.
- Kite (kitepharma.com) announced that it has submitted a supplemental BLA to the FDA for **Tecartus® (brexucabtagene autoleucel)** for the treatment of adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia.
- The Janssen Pharmaceutical Companies of Johnson & Johnson (janssen.com) announced that the FDA granted breakthrough therapy designation to **teclistamab** for the treatment of relapsed or refractory multiple myeloma.
- Servier Pharmaceuticals (servier.us) announced that the FDA accepted the supplemental NDA for **Tibsovo® (ivosidenib tablets)** as a potential treatment for patients with previously treated IDH1-mutated cholangiocarcinoma.
- Seagen Inc. (seagen.com) and Genmab A/S (genmab.com) announced that the FDA accepted for priority review the BLA seeking accelerated approval for **tisotumab vedotin** for the treatment of patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.
- TG Therapeutics, Inc. (tgtherapeutics.com) announced that the FDA accepted the BLA for **ublituximab (TG-1101) in combination with Ukoniq® (umbralisib)** as treatment for patients with chronic lymphocytic leukemia and small lymphocytic lymphoma.
- Verastem, Inc. (verastem.com) announced that the FDA granted breakthrough therapy designation for the combination of its investigational RAF/MEK inhibitor, **VS-6766**, with **defactinib**, its FAK inhibitor, for the treatment of all patients with recurrent low-grade serous ovarian cancer regardless of KRAS status after one or more prior lines of therapy, including platinum-based chemotherapy.
- Exelixis, Inc. (exelixis.com) announced that the FDA accepted its investigational NDA for **XB002** in patients with advanced solid tumors.

Devices and Assays in the News

- Avenda Health (avendahealth.com) announced that the FDA has awarded breakthrough device designation to the **Avenda Health Focal Therapy System** for treating prostate cancer in-office while preserving patients' quality of life.
- Guardant Health, Inc. (guardanthealth.com) announced that the FDA approved the **Guardant360® CDx liquid biopsy test** to identify patients with locally advanced or metastatic NSCLC who harbor the EGFR exon 20 insertion mutation and may benefit from targeted treatment with Rybrevant™ (amivantamab-vmjw) after progressing on or after platinum-based chemotherapy. The test has also received FDA approval as a liquid biopsy companion diagnostic for Lumakras™ (sotorasib) in advanced NSCLC.
- IceCure Medical Ltd. (icecure-medical.com) announced that it has been granted FDA designation as a breakthrough device for **ProSense™** for use in the treatment of patients with T1 invasive breast cancer and/or patients not suitable for surgical alternatives for the treatment of breast cancer.
- Roche (roche.com) announced FDA approval of the **Ventana MMR RxDx Panel** for patients with advanced or recurrent endometrial cancer patients. Testing can identify patients eligible for treatment with Jemperli (dostarlimab-gxly) monotherapy.
- QIAGEN (qiagen.com/us/) announced the launch of an expanded scope of companion diagnostic claims for the ***therascreen*® KRAS RGQ PCR Kit** after it received U.S. regulatory approval as a companion diagnostic to aid in the identification of patients with NSCLC who may be eligible for treatment with Lumakras™ (sotorasib). OI

- The FDA announced that it has authorized marketing of the **GI Genius™** (Cosmo Pharmaceuticals, cosmopharma.com), a device that uses artificial intelligence-based machine learning to assist clinicians in detecting lesions in the colon in real time during a colonoscopy.
- Vysioneer (vysioneer.com) announced that the company received FDA clearance for **VBrain**, an artificial intelligence-powered tumor auto-contouring solution in radiation therapy.