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Approved Drugs

- On February 9, the U.S. Food and Drug Administration (FDA) approved **Jemperli® (dostarlimab-gxly)** (GSK, gsk.com) for adult patients with mismatch repair deficient recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following a prior platinum-containing regimen in any setting and who are not candidates for curative surgery or radiation.
- On March 30, the FDA granted full approval to **Keytruda® (pembrolizumab)** (Merck, merck.com) for treating adult and pediatric patients with unresectable or metastatic microsatellite instability-high or mismatch repair deficient solid tumors, as determined by an FDA-approved test, that have progressed after treatment, leaving patients no good alternative treatment options.
- On April 3, the FDA granted accelerated approval to **Padcev® (enfortumab vedotin-ejfv)** (Astellas Pharma, astellas.com) **in combination with Keytruda** (Merck, merck.com) for patients, with locally advanced or metastatic urothelial carcinoma, who are ineligible for cisplatin-containing chemotherapy.
- On March 16, the FDA approved **Tafinlar® (dabrafenib) in combination with Mekinist® (trametinib)** (Novartis, novartis.com) for pediatric patients 1 year of age and older with low-grade glioma, a BRAF V600E mutation, and who require systemic therapy.
- On March 6, Coherus BioSciences (coherus.com) announced that the FDA approved the single-dose, prefilled autoinjector presentation of **Udenyca® (pegfilgrastim-cbqv)**, a biosimilar of **Neulasta® (pegfilgrastim)** (Amgen, amgen.com).
- On March 3, the FDA approved **Verzenio® (abemaciclib)** (Eli Lilly and Company, lilly.com) **in combination with endocrine therapy (tamoxifen or an aromatase inhibitor)** for the adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence.
- On March 22, the FDA granted accelerated approval to **Zynyz® (retifanlimab-dlwr)** (Incyte Corporation, incyte.com) for adult patients with metastatic or recurrent locally advanced Merkel cell carcinoma.

Drugs In the News

- Pfizer Inc. (pfizer.com) announced that the FDA accepted for review its supplemental new drug applications (NDAs) for **Braftovi® (encorafenib) and Mektovi® (binimetinib)** for patients with metastatic non-small cell lung cancer with a BRAF V600E mutation, as detected by an FDA-approved test.
- Pfizer (pfizer.com) announced that the FDA granted priority review to its biologics license application (BLA) for **elranatamab** for the treatment of patients with relapsed or refractory multiple myeloma.
- Fore Biotherapeutics (fore.bio) announced that the FDA granted orphan drug designation to **FORE8394** for the treatment of primary brain and central nervous system malignancies.
- Hutchmed Limited (hutch-med.com) announced that it completed the rolling submission of an NDA to the FDA for **fruquintinib** for the treatment of refractory metastatic colorectal cancer.
- Accord BioPharma (accordbiopharma.com) announced that the FDA accepted its BLA for **HLX02** (a proposed trastuzumab biosimilar) for the adjuvant treatment of HER2-overexpressing breast cancer, HER2-overexpressing metastatic breast cancer, HER2-overexpressing metastatic gastric, or gastroesophageal junction adenocarcinoma.
- Telix Pharmaceuticals (telixpharma.com) announced that the FDA approved its supplementary NDA for **Illuccix®** (kit for the preparation of gallium Ga 68 gozetotide injection) for the selection of patients with metastatic prostate cancer for whom lutetium-177 (177Lu) PSMA-directed therapy is indicated.
- Lumicell (lumicell.com) announced it submitted an NDA to the FDA for **Lumsight™** for intraoperative breast cancer detection and removal.
- SpringWorks Therapeutics, Inc. (springworkstx.com) announced that the FDA accepted its NDA for **nirogacestat** for the treatment of adults with desmoid tumors.
- Bristol Myers Squibb (bms.com) announced that the FDA accepted its supplemental BLA for **Opdivo® (nivolumab)** as a monotherapy in the adjuvant setting for the treatment of patients with completely resected Stage IIB or IIC melanoma.
- Deciphera Pharmaceuticals, Inc. (deciphera.com) announced that the FDA

granted breakthrough therapy designation to **Qinlock® (ripretinib)** for the treatment of adult patients with unresectable or metastatic second-line gastrointestinal stromal tumor, who received prior treatment with imatinib and harbor a KIT exon 11 mutation and co-occurring KIT exon 17 and/or 18 mutations (KIT exon 11 + 17/18 mutations).

- Mesoblast Limited (mesoblast.com) announced that the FDA accepted its BLA resubmission for **remestemcel-L** for the treatment of children with steroid-refractory acute graft versus host disease.
- Ymmunobio (ymmunobio.com) announced that the FDA granted orphan drug designation to **YB-200** for the treatment of hepatocellular carcinoma.
- Janssen (janssen.com) announced the submission of its NDA to the FDA, seeking approval of **Zejula® (niraparib)** (GSK, us.gsk.com/en-us/) **in combination with Zytiga® abiraterone acetate** (Janssen) **plus prednisone** for the treatment of patients with BRCA-positive metastatic castration-resistant prostate cancer.

Devices and Assays in the News

- Roche (roche.com) announced that the FDA approved its **VENTANA PD-L1 (SP263) Assay** as a companion diagnostic to identify patients with non-small cell lung cancer, who are eligible for treatment with Libtayo® (cemiplimab) (Regeneron, regeneron.com). OI