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Approved Drugs

- On Jan. 9, 2020, the U.S. Food and Drug and Administration (FDA) approved **Ayvakit™ (avapritinib)** (Blueprint Medicines, blueprintmedicines.com) for the treatment of adults with unresectable or metastatic gastrointestinal stromal tumor harboring a platelet-derived growth factor receptor alpha exon 18 mutation, including PDGFRA D842V mutations.
- On Dec. 20, 2019, the FDA granted accelerated approval to **Enhertu® (fam-trastuzumab deruxtecan-nxki)** (Daiichi Sankyo, daiichisankyo.com) for patients with unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.
- On Jan. 8, 2020, the FDA approved **Keytruda® (pembrolizumab)** (Merck, merk.com) as a monotherapy for the treatment of patients with bacillus Calmette-Guérin unresponsive, high-risk, non-muscle-invasive bladder cancer with carcinoma *in situ* with or without papillary tumors, who are ineligible for or have elected not to undergo cystectomy.
- On Dec. 27, 2019, the FDA approved **Lynparza® (olaparib)** (AstraZeneca and Merck, astrazeneca.com, merck.com) for the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.
- On Dec. 18, 2019, the FDA granted accelerated approval to **Padcev™ (enfortumab vedotin-ejfv)** (Astellas Pharma Inc. and Seattle Genetics, Inc., astellas.com, seattlegenetics.com) for the treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a PD-1/L1 inhibitor and a platinum-containing chemotherapy before or after surgery or in a locally advanced or metastatic setting.
- On Jan. 23, 2020, the FDA granted accelerated approval to **Tazverik™ (tazemetostat)** (Epizyme, Inc., epizyme.com) for the treatment of adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.
- On Dec. 16, 2019, the FDA approved **Xtandi® (enzalutamide)** (Astellas Pharma Inc., astellas.com) for patients with metastatic castration-sensitive prostate cancer.

Drugs in the News

- The FDA has approved an investigational new drug application for a phase 1 trial of **ACE1702** (Acepodia, acepodia.com), a targeted cancer therapy created by a proprietary chemical process that directly links anti-tumor antibodies to the surface of natural killer cells. It will soon enter in-human clinical trials in HER2-positive solid tumors.
- Amgen (amgen.com) and Allergan plc. (allergan.com) announced the submission of a biologics license application (BLA) to the FDA for **ABP 798**, a biosimilar candidate to Rituxan® (rituximab).
- GlaxoSmithKline (gsk.com/en-gb) announced that the FDA has granted priority review for the company's BLA seeking approval of **belantamab mafodotin (GSK2857916)** for the treatment of patients with relapsed or refractory multiple myeloma whose prior therapy included an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody.
- AstraZeneca (astrazeneca.com) announced that the FDA has granted orphan drug designations to PD-L1 **Imfinzi® (durvalumab)** and anti-CTLA4 antibody **tremelimumab** for liver cancer.
- Kite (kitepharma.com) announced that it has submitted a BLA to the FDA for the investigational chimeric antigen receptor (CAR) T-cell therapy, **KTE-X19**, for the treatment of adult patients with relapsed or refractory mantle cell lymphoma.
- CytoDyn (cytodyn.com) filed for breakthrough therapy designation for its targeted therapy, **leronlimab (PRO 140)**, as an adjuvant therapy for the treatment of metastatic triple-negative breast cancer.
- Bristol-Myers Squibb (bms.com) submitted a BLA to the FDA for **Lisocabtagene Maraleucel (liso-cel)**, its autologous anti-CD19 CAR T-cell immunotherapy including individually formulated CD8+ and CD4+ CAR T-cells for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after at least two prior therapies.
- AstraZeneca (astrazeneca.com) and Merck (merck.com) announced that a supplemental new drug application for **Lynparza® (olaparib)** in combination with **bevacizumab** has been accepted and granted priority review by the FDA for the maintenance treatment of patients with advanced ovarian cancer who are in

complete or partial response to first-line platinum-based chemotherapy with bevacizumab. The FDA has accepted and granted priority review to a second supplemental new drug application for **Lynparza® (olaparib)** for patients with metastatic castration-resistant prostate cancer and deleterious or suspected deleterious germline or somatic homologous recombination repair gene mutations who have progressed following prior treatment with a new hormonal agent.

- MacroGenics, Inc. (macrogenics.com) announced that it has submitted a BLA for **margetuximab**, an investigational, Fc-engineered, monoclonal antibody that targets HER2, for the treatment of patients with metastatic HER2-positive breast cancer in combination with chemotherapy.
- OBI Pharma, Inc. (obipharma.com) announced that the FDA has granted orphan drug designation to **OBI-999** for the treatment of gastric cancer.
- Bristol-Myers Squibb (bms.com) announced that the FDA has accepted and granted priority review to its supplemental BLA for **Opdivo® (nivolumab)** in combination with **Yervoy® (ipilimumab)** for the first-line treatment of patients with metastatic or recurrent non-small cell lung cancer with no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations.
- Precigen, Inc. (precigen.com) announced that the FDA has granted orphan drug designation to **PRGN-3006**, an investigational therapy using Precigen's non-viral UltraCAR-T™ therapeutic platform for patients with relapsed or refractory acute myeloid leukemia.
- Eli Lilly (lilly.com) announced that the FDA granted priority review for an NDA for **selpercatinib (LOXO-292)** for the treatment of patients with advanced RET fusion-positive non-small cell lung cancer, RET-mutant medullary thyroid cancer, and RET fusion-positive thyroid cancer.
- Roche (roche.com) announced the submission of a supplemental BLA to the FDA for **Tecentriq® (atezolizumab)** in combination with **Avastin® (bevacizumab)** (Genentech, gene.com) for the treatment of patients with unresectable hepatocellular carcinoma who have not received prior systemic therapy.
- Kura Oncology, Inc. (kuraoncology.com) announced that the FDA has granted fast track designation to **tipifarnib** for the treatment of patients with HRAS-mutant head and neck squamous cell carcinomas after progression on platinum therapy.
- Seattle Genetics, Inc. (seattlegenetics.com) announced that it has submitted an NDA to the FDA for **tucatinib** in combination with **trastuzumab** and **capecitabine** for treatment of patients with locally advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received at least three prior HER2-directed agents separately or in combination in the neoadjuvant, adjuvant, or metastatic setting.
- Karyopharm Therapeutics Inc. (karyopharm.com) announced that it has submitted an NDA to the FDA seeking accelerated approval for **Xpovio® (selinexor)** as a new treatment for patients with relapsed or refractory diffuse large B-cell lymphoma after at least two prior multi-agent therapies and who are ineligible for stem cell transplantation, including CAR T-cell therapy.

Approved Genetic Tests and Assays

- Myriad Genetics, Inc. (myriad.com) announced that the FDA has approved **BRACAnalysis CDx®** for use as a companion diagnostic test by healthcare professionals to identify patients with metastatic pancreatic cancer who have a germline BRCA mutation and are candidates for treatment with PARP inhibitor Lynparza® (olaparib).
- IceCure Medical Ltd. (icecure-medical.com) announced that it received FDA clearance for expanded indications of **Cryoablation Technology**, a non-surgical liquid nitrogen cryoablation technology that destroys benign and cancerous tumors by freezing. The new FDA clearance will enable the company to market its solution for the treatment of cancerous and benign tumors of the kidney; liver; and ear, nose, and throat; and further neurology indications.
- Myriad Genetics, Inc. (myriad.com) announced submission of a supplementary premarket approval application to the FDA for its **myChoice® CDx test** to help predict outcomes of women with first-line platinum-responsive advanced ovarian cancer treated with PARP inhibitor Zejula® (niraparib). OI