tools

Approved Drugs

- On Jan. 31, the Food and Drug Administration (FDA) approved **Alimta® (pemetrexed for injection)** (Eli Lilly and Company, lilly.com) in combination with pembrolizumab and platinum chemotherapy for the first-line treatment of patients with metastatic non-squamous non-small cell lung cancer with no EGFR or ALK genomic tumor aberrations.
- On Dec. 20, the FDA approved **Asparlas™ (calaspargase pegol-mknl)** (Servier Pharmaceuticals LLC, servier.com) as a component of a multi-agent chemotherapeutic regimen for acute lymphoblastic leukemia in pediatric and young adult patients aged one month to 21 years.
- On Jan. 14, Exelixis, Inc. (exelixis.com) announced that the FDA has approved **Cabometyx® (cabozantinib)** for patients with hepatocellular carcinoma who have been previously treated with sorafenib.
- On Dec. 21, the FDA approved **Elzonris™ (tagraxofusp-erzs)** (Stemline Therapeutics, stemline.com) for blastic plasmacytoid dendritic cell neoplasm in adults and in pediatric patients two years and older.
- On Dec. 14, Celltrion, Inc. (celltrion.com) and Teva Pharmaceutical Industries Ltd. (tevapharm.com) announced that the FDA has approved **Herzuma® (trastuzumab-pkrb)**, a biosimilar to Herceptin®, for the treatment of HER2-overexpressing breast cancer for certain indications.
- On Jan. 28, the FDA approved **Imbruvica® (ibrutinib)** (Janssen Biotech, Inc., janssen.com; Pharmacyclics LLC, pharmacyclics.com) in combination with obinutuzumab for treatment-naïve patients with chronic lymphocytic leukemia/small lymphocytic lymphoma.
- On Dec. 19, the FDA granted accelerated approval to **Keytruda® (pembrolizumab)** (Merck & Co., Inc., merck.com) for adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma.
- On Dec. 19, the FDA approved **Lynparza® (olaparib)** (AstraZeneca, astrazeneca.com) for the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy.
- The FDA has approved **Ontruzant® (trastuzumab-dttb)** (Samsung Bioepis Co., Ltd., samsungbioepis.com), a biosimilar to Herceptin®, for the adjuvant treatment of HER2-overexpressing breast cancer, metastatic breast cancer, and metastatic gastric cancer or gastro-esophageal junction adenocarcinoma in patients who have not received prior treatment for metastatic disease.
- The FDA has approved **Sprycel® (dasatinib)** (Bristol-Myers Squibb Co., bms.com) to include the treatment of pediatric patients one year of age and older with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia in combination with chemotherapy.

Drugs in the News

- ASLAN Pharmaceuticals (aslanpharma.com) announced that the FDA has accepted its investigational new drug application for **ASLAN003**, a potential first-in-class treatment for acute myeloid leukemia.
- EMD Serono (emd-serono.com) and Pfizer Inc. (pfizer.com) announced that the FDA has accepted its supplemental biologics license application (BLA) and granted priority review to **Bavencio® (avelumab)** in combination with axitinib for patients with advanced renal cell carcinoma.
- BioLineRx Ltd. (biolinerx.com) announced that the FDA has granted orphan drug designation to its lead oncology candidate, **BL-8040**, for the treatment of pancreatic cancer.
- Janssen Biotech, Inc. (janssen.com) announced that the FDA has approved a split-dosing regimen for **Darzalex® (daratumumab)** for the treatment of patients with multiple myeloma, allowing healthcare providers to split the dosing into two days.
- Equillium (equilliumbio.com) announced that the FDA has granted orphan drug designations for **EQ001 (itolizumab)** for the prevention and treatment of acute graft-versus-host disease.
- Gritstone Oncology (gritstoneoncology.com) announced that the FDA has granted fast track designation to **GRANITE-001** for the treatment of colorectal cancer.
- Merck & Co. (merck.com) announced that the FDA has accepted a new supplemental BLA for **Keytruda® (pembrolizumab)**

as monotherapy or in combination with platinum and 5-fluorouracil chemotherapy for the first-line treatment of patients with recurrent or metastatic head and neck squamous cell carcinoma.

- Roche (roche.com) announced that it had submitted a supplemental BLA to the FDA for **Kadcycla® (trastuzumab emtansine)** for adjuvant treatment of people with HER2-positive early breast cancer with residual disease after neoadjuvant treatment.
- Merus N.V. (merus.nl) announced that the FDA has accepted the investigational new drug application for **MCLA-145** for the treatment of solid tumors.
- Mustang Bio, Inc. (mustangbio.com) announced that the FDA has granted orphan drug designation to **MB-102 (CD123 CAR T)** for the treatment of blastic plasmacytoid dendritic cell neoplasm, a rare and incurable blood cancer.
- Daiichi Sankyo (daiichisankyo.com) announced that the FDA has accepted a new drug application and granted priority review for **pexidartinib** for the treatment of adult patients with symptomatic tenosynovial giant cell tumor.
- Roche (roche.com) announced that the FDA has accepted the company's supplemental BLA for **Tecentriq® (atezolizumab)** in combination with Abraxane® (albumin-bound paclitaxel; nab-paclitaxel) and carboplatin for the first-line treatment of people with metastatic non-squamous non-small cell lung cancer who do not have EGFR or ALK genomic tumor aberrations.
- Samumed, LLC (samumed.com) announced that the FDA has granted orphan drug designation to **SM08502** for the treatment of pancreatic cancer.
- TG Therapeutics, Inc. (tgtherapeutics.com) announced that the FDA has granted breakthrough therapy designation to **Umbralisib (TGR-1202)** for the treatment of adult patients with marginal zone lymphoma who have received at least one prior anti-CD20 regimen.

Devices in the News

- ArcherDX, Inc. (archerdx.com) announced that the FDA has granted breakthrough device designation to the **ArcherDX companion diagnostic assay**, a sequencing-based test intended for detection of somatic alterations in circulating tumor DNA present in plasma and in RNA or DNA derived from formalin-fixed paraffin-embedded cancer tissue.

Genetic Tests and Assays in the News

- Myriad Genetics, Inc. (myriad.com) announced that the FDA has approved **BRACAnalysis CDx®** to identify patients with advanced ovarian cancer who have a germline BRCA mutation and are eligible for first-line maintenance therapy with Lynparza® (olaparib) following response to platinum-based chemotherapy.
- 23andMe, Inc. (23andme.com) announced that the FDA has authorized the use without prescription of their **MUTYH-Associated Polyposis report** for genetic health risk report of the rare condition associated with increased risk of colorectal cancer.
- Illumina, Inc. (illumina.com) announced that the FDA has granted breakthrough device designation for **TruSight™ Oncology Comprehensive**, a pan-cancer assay currently in development that is designed to detect known and emerging solid tumor biomarkers.