tools

Approved Drugs

- On April 18, the U.S. Food and Drug Administration (FDA) approved **Alymsys® (bevacizumab-maly)** (Brand Institute and mAbxience, brandinstitute.com and mabxience.com)—a biosimilar to Avastin® (bevacizumab). Alymsys's approved indications include: 1) metastatic colorectal cancer in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment and 2) metastatic colorectal cancer in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen.
- On May 4, the FDA approved **Enhertu® (fam-trastuzumab deruxtecan-nxki)** (AstraZeneca and Daiichi Sankyo, Inc., astrazeneca.com and daiichisankyo.com) for adult patients with unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have received a prior anti-HER2-based regimen either in the metastatic setting or in the neoadjuvant or adjuvant setting and who have developed disease recurrence during or within 6 months of completing therapy.
- On May 27, the FDA granted accelerated approval to **Kymriah® (tisagenlecleucel)** (Novartis Pharmaceuticals Corporation, novartis.com) for adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy.
- On May 27, the FDA approved **Opdivo® (nivolumab)** (Bristol Myers Squibb, bms.com**) in combination with fluoropyrimidine- and platinum-based chemotherapy** and **Yervoy® (nivolumab)** (Bristol Myers Squibb, bms.com) **in combination with ipilimumab** for the first-line treatment of patients with advanced or metastatic esophageal squamous cell carcinoma.
- On May 25, the FDA approved **Tibsovo® (ivosidenib)** (Servier Pharmaceuticals LLC, servier.us) **in combination with azacitidine** for newly diagnosed acute myeloid leukemia with a susceptible IDH1 mutation, as detected by an FDA-approved test, in adults 75 years or older or who have comorbidities that preclude use of intensive induction chemotherapy.
- On May 20, the FDA approved **Vidaza® (azacytidine)** (Bristol Myers Squibb, bms.com) for pediatric patients with newly diagnosed juvenile myelomonocytic leukemia.

Drugs in the News

- BriaCell Therapeutics Corp. (briacell.com) announced that the FDA granted fast track status to **Bria-IMT™** for the treatment of metastatic breast cancer.
- AstraZeneca (astrazeneca.com) and Daiichi Sankyo (daiichisankyo.com) announced that the FDA accepted and granted priority review to the supplemental biologics license application (BLA) of **Enhertu** for the treatment of adult patients with unresectable or metastatic non-small cell lung cancer whose tumors have an HER2 mutation and who have received a prior systemic therapy. The companies also announced that Enhertu was granted breakthrough therapy designation for the treatment of adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-negative) breast cancer who have received a prior systemic therapy in the metastatic setting or developed disease recurrence during or within six months of completing adjuvant chemotherapy.
- Spectrum Pharmaceuticals (sppirx.com) announced that it resubmitted a BLA for **eflapegrastim**, which has been accepted by the FDA, seeking an indication to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.
- Gamida Cell Ltd. (gamida-cell.com) announced that the FDA cleared its investigational new drug application (NDA) and removed the clinical hold for a cryopreserved formulation of **GDA-201**—an off-the-shelf cell therapy candidate for the treatment of patients with follicular and diffuse large B-cell lymphomas.
- AstraZeneca (astrazeneca.com) announced that the supplemental BLA for **Imfinzi® (durvalumab) in combination with standard-of-care chemotherapy** was accepted and granted priority review by the FDA for patients with locally advanced or metastatic biliary tract cancer.
- ImmunoGen, Inc. (immunogen.com) announced that the FDA accepted and

granted priority review to the BLA for **mirvetuximab soravtansine monotherapy** for patients with folate receptor alpha-high platinum-resistant ovarian cancer who have been previously treated with one to three prior systemic treatments.

- Bayer (bayer.com) announced that the FDA accepted a supplemental NDA and granted priority review to **Nubeqa® (darolutamide) in combination with docetaxel** for the treatment of metastatic hormone-sensitive prostate cancer.
- ImmunityBio, Inc. (immunitybio.com) announced it has submitted a BLA to the FDA for **N-803 plus Bacillus Calmette-Guérin** (BCG) for the treatment of BCG-unresponsive non-muscle invasive bladder cancer carcinoma in situ with or without Ta or T1 disease.
- VBL Therapeutics (vblrx.com) announced that the FDA granted fast track designation to **ofra-vec (ofranergene obadenovec or VB-111) in combination with paclitaxel** for the treatment of platinum-resistant ovarian cancer.
- Gamida Cell Ltd. (gamida-cell.com) reported that it has submitted a rolling BLA to the FDA for **omidubicel** for the treatment of patients who have blood cancer and need allogenic hematopoietic stem cell transplant.
- Fennec Pharmaceuticals Inc. (fennecpharma.com) announced that the FDA accepted for filing the company's resubmitted NDA for **Pedmark™ (a formulation of sodium thiosulfate)** for the prevention of platinum-induced ototoxicity in pediatric patients one month to less than 18 years of age with localized, non-metastatic, solid tumors.
- Elevation Oncology, Inc. (elevationoncology.com) announced that the FDA granted fast track designation to **seribantumab** for the tumor-agnostic treatment of advanced solid tumors that harbor NRG1 gene fusions.
- SQZ Biotechnologies (sqzbiotech.com) announced that the FDA granted fast track designation to **SQZ-PBMC-HPV** for the treatment of HPV16+ advanced or metastatic solid tumors.
- AstraZeneca (astrazeneca.com) announced its BLA for **tremelimumab** has been accepted for priority review by the FDA, supporting the indication of a single priming dose of the anti-CTLA4 antibody added to Imfinzi® (durvalumab) for the treatment of patients with unresectable hepatocellular carcinoma.
- Mersana Therapeutics, Inc. (mersana.com) announced that the FDA granted orphan drug designation to **XMT-2056** for the treatment of gastric cancer.

Devices and Assays in the News

- Guardant Health, Inc. (guardanthealth.com) announced the availability of **Shield™**, a blood-based test for the detection of early-stage colorectal cancer.
- On June 9, the FDA approved **FoundationOne®CDx** (Foundation Medicine, foundationmedicine.com) as a companion diagnostic for two Rozlytrek® (entrectinib) (Genentech, Genentech.com) indications: 1) to identify patients with ROS1-positive non-small cell lung cancer and 2) to identify patients with neurotrophic tyrosine receptor kinase fusion-positive solid tumors.

Updated ASCO Guidelines

The American Society of Clinical Oncology (ASCO) has updated its 2022 Biomarkers for Adjuvant Endocrine and Chemotherapy in Early-Stage Breast Cancer guidelines to include **Oncotype DX Breast Recurrence Score®** test (Exact Sciences, exactsciences.com) in early-stage breast cancer.