tools

Approved Drugs

- The U.S. Food and Drug Administration (FDA) has granted approval to **Cabometyx® (cabozantinib)** (Exelixis, Inc., exelixis.com) for the treatment of patients with advanced renal cell carcinoma.
- Boehringer Ingelheim Pharmaceuticals, Inc. (Boehringer-ingelheim.com) has announced that the FDA has granted approval to **Gilotrif® (afatinib)** for a broadened indication in first-line treatment of patients with metastatic non-small cell lung cancer whose tumors have nonresistant epidermal growth factor receptor mutations as detected by an FDA-approved test.
- The FDA has approved Advanced Accelerator Applications' (adacap.com) **Lutathera® (lutetium Lu 177 dotatate)** for the treatment of gastroenteropancreatic neuroendocrine tumors. Lutathera is indicated for adult patients with somatostatin receptor–positive gastroenteropancreatic neuroendocrine tumors.
- AstraZeneca Pharmaceuticals (astrazeneca.com) has announced that the FDA has expanded the approved use of **Lynparza® (olaparib tablets**) to include the treatment of patients with certain types of breast cancer that have metastasized and whose tumors have a specific inherited (germline) genetic mutation. Patients are selected for treatment with Lynparza based on an FDA-approved genetic test called the BRACAnalysis CDx.
- The FDA has approved **Ogivri™ (trastuzumab-dkst)** (Mylan GmbH, mylan.com) as a biosimilar to Herceptin® (trastuzumab) for the treatment of patients with breast or metastatic stomach cancer (gastric or gastroesophageal junction adenocarcinoma) whose tumors overexpress the HER2 gene (HER2+).
- Bristol-Myers Squibb Company (bms.com) announced that the FDA has approved **Opdivo® (nivolumab)** injection for intravenous use for the adjuvant treatment of patients with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection.
- The FDA has approved the use of Teva Pharmaceutical Industries' (tevapharm.com) **Trisenox® (arsenic trioxide)** injection in combination with tretinoin for the treatment of adults with newly diagnosed low-risk acute promyelocytic leukemia whose acute promyelocytic leukemia is characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression.

Drugs in the News

- Seattle Genetics, Inc. (seattlegenetics.com) announced that the FDA has accepted for filing a supplemental Biologics License Application (sBLA) for **Adcetris® (brentuximab vedotin)** in combination with chemotherapy for the frontline treatment of patients with advanced classical Hodgkin lymphoma.
- Agios Pharmaceuticals, Inc. (agios.com) has announced that it has submitted a new drug application to the FDA for **AG-120 (ivosidenib)**, an investigational oral treatment for patients with relapsed or refractory acute myeloid leukemia and an isocitrate dehydrogenase-1 mutation.
- Merck and Co., Inc. (merck.com) and Pfizer, Inc. (pfizer.com) announced that the FDA has granted breakthrough therapy designation for **Bavencio® (avelumab) in combination with Inlyta® (axitinib)** for treatment-naïve patients with advanced renal cell carcinoma.
- The FDA has cleared BioAtla's (bioatla.com) investigational new drug application for **BA3011,** a novel conditionally active AXL-targeted antibody–drug conjugate (CAB-AXL-ADC) in patients with solid tumors. Under this investigational new drug application, the company intends to initiate a first-in-human, open label, multicenter dose escalation and dose expansion study of CAB-AXL-ADC in patients with locally advanced or metastatic solid tumors.
- The FDA has approved a supplemental new drug application (sNDA) for Pfizer's (Pfizer.com) **Bosulif® (bosutinib)**. The approved sNDA expands the indication for Bosulif to include the treatment of adult patients with newly diagnosed chronic phase Philadelphia chromosome–positive chronic myelogenous leukemia.

- Aptose Biosciences Inc. (aptose.com) announced that the FDA has granted orphan drug designation to **CG'806**, a pan-FLT3/pan-BTK inhibitor, for the treatment of patients with acute myeloid leukemia.
- The FDA has granted fast track designation for Arog Pharmaceuticals' (arogpharma.com) **crenolanib** for the treatment of patients with FLT3 mutation-positive relapsed or refractory acute myeloid leukemia.
- Cantex Pharmaceuticals, Inc. (cantex.com) has announced that the FDA has granted orphan drug designation to **CX-01** for the treatment of acute myeloid leukemia. CX-01 is an investigational agent that has the potential to enhance the effectiveness of leukemia treatments by disrupting the adhesion of leukemia cells in the protective bone marrow environment.
- The FDA has granted priority review designation to **Darzalex® (daratumumab)** (Janssen Biotech, Inc., janssen.com) in combination with Velcade® (bortezomib), melphalan, and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.
- Idera Pharmaceuticals, Inc. (iderapharma.com) has announced that the FDA has granted fast track designation for the company's **IMO-2125 in combination with ipilimumab** for the treatment of anti-PD-1 refractory metastatic melanoma in combination with ipilimumab therapy.
- The FDA granted breakthrough therapy designation to Novartis (novartis.com) for **Kisqali® (ribociclib)**, an initial endocrine-based treatment of pre- or perimenopausal women with hormone receptor–positive, human epidermal growth factor receptor-2-negative (HR+/HER2–) advanced or metastatic breast cancer in combination with tamoxifen or an aromatase inhibitor.
- Novartis (novartis.com) announced that its sBLA for **Kymriah™ (tisagenlecleucel)** suspension for intravenous infusion, formerly CTL019, for the treatment of adult patients with relapsed or refractory (r/r) diffuse large B-cell lymphoma who are ineligible for or relapse after autologous stem cell transplant has been accepted by the FDA for priority review.
- The FDA has approved Amgen's (amgen.com) sNDA to add overall survival data from the Phase II head-to-head ENDEAVOR trial to the Prescribing Information for **Kyprolis® (carfilzomib)**.
- Eisai Co., Ltd. (eisai.com) and Merck (merck.com) have announced that they received FDA breakthrough therapy designation for **Lenvima® (lenvatinib) in combination with Keytruda® (pembrolizumab)** for the potential treatment of patients with advanced and/or metastatic renal cell carcinoma.
- The FDA has updated the product label for **Tasigna® (nilotinib)** (Novartis Pharmaceuticals Corporation, novartis.com) to include information for providers about how to discontinue the drug in certain patients.
- Amgen (amgen.com) has announced that the FDA has approved the sBLA for **Xgeva® (denosumab)** to expand the currently approved indication for the prevention of skeletal-related events in patients with bone metastases from solid tumors to include patients with multiple myeloma.

Approved Devices

- The FDA has cleared the **GammaPod™ system** (Xcision Medical Systems, LLC, xcision.com) for use in the noninvasive stereotactic delivery of a radiation dose to a portion of the breast in conjunction with breast conserving treatment.
- Bracco Diagnostics Inc. (imaging.bracco.com) announced that the labeling of its contrast agent **MultiHance®** has obtained FDA approval for an extension to include magnetic resonance imaging of the central nervous system in pediatric patients younger than 2 years of age to visualize lesions with an abnormal blood–brain barrier or abnormal vascularity of the brain, spine, and associated tissues.

Genetic Tests and Assays in the News

- Myriad Genetics, Inc. (myriad.com) announced that the FDA has approved **BRACAnalysis CDx®** for use as a companion diagnostic by healthcare professionals to identify patients with HER2-negative metastatic breast cancer who have a germline BRCA mutation and are candidates for treatment with the PARP inhibitor Lynparza (olaparib).
- The FDA has approved **FoundationOne CDx™ (F1CDx)** (Foundation Medicine, Inc., foundationmedicine.com), a next-generation sequencing–based *in vitro* diagnostic test that can detect genetic mutations in 324 genes and two genomic signatures in any solid tumor type. The Centers for Medicare & Medicaid Services (CMS) at the same time proposed coverage of the F1CDx.
- Sebia (sebia.com) has announced that it has received FDA 510(k) clearance for its **Hydrashift 2/4 daratumumab assay**, intended to be used with Hydragel IF, for the qualitative detection of monoclonal proteins in human serum by immunofixation electrophoresis. OI

CMS Proposes Coverage for the Oncomine Dx Target Test

The CMS has proposed coverage for the Oncomine Dx Target Test (Thermo Fisher Scientific, thermofisher.com) as part of a national coverage determination for next-generation sequencing in vitro diagnostic tests. Once implemented, the national coverage determination would provide Medicare beneficiaries with reimbursable testing using Thermo Fisher Scientific's multi-biomarker non-small cell lung cancer diagnostic.