tools

Approved Drugs

- On Aug. 5, the U.S. Food and Drug Administration (FDA) approved **Blenrep (belantamab mafodotin-blmf)** (GlaxoSmithKline, gsk.com) for adult patients with relapsed or refractory multiple myeloma who have received at least four prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.
- On May 29, the FDA approved **Cyramza® (ramucirumab)** (Eli Lilly and Company, lilly.com) in combination with erlotinib for first-line treatment of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) mutations.
- On June 12, Merck (merck.com) announced that the FDA has approved an expanded indication for **Gardasil®9 (Human Papillomavirus 9-valent Vaccine, Recombinant)** for the prevention of oropharyngeal and other head and neck cancers caused by HPV Types 16, 18, 31, 33, 45, 52, and 58.
- On July 7, the FDA approved **Inqovi® (decitabine and cedazuridine)** (Astex Pharmaceuticals, Inc., astx.com) for adult patients with myelodysplastic syndromes, including the following: (1) previously treated and untreated, *de novo* and secondary myelodysplastic syndromes with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia) and (2) intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups.
- On June 16, the FDA granted accelerated approval to **Keytruda® (pembrolizumab)** (Merck, merck.com) for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (≥10 mutations/megabase [mut/Mb]) solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options. On June 24, the FDA approved Keytruda for patients with recurrent or metastatic cutaneous squamous cell carcinoma that is not curable by surgery or radiation. On June 29, the FDA approved Keytruda for the first-line treatment of patients with unresectable or metastatic microsatellite instability-high or mismatch repair deficient colorectal cancer.
- On July 31, the FDA granted accelerated approval to **Monjuvi® (tafasitamab-cxix)** (MorphoSys US Inc., morphosys.com and Incyte, incyte.com), a CD19-directed cytolytic antibody, indicated in combination with lenalidomide for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant.
- On June 16, the FDA extended the indication of **Mylotarg™ (gemtuzumab ozogamicin)** (Pfizer Inc., Pfizer.com) for newly diagnosed CD33-positive acute myeloid leukemia to include pediatric patients one month and older.
- On June 11, Pfizer Inc. (pfizer.com) announced that the FDA has approved **Nyvepria™ (pegfilgrastim-apgf)**, a biosimilar to Neulasta® (pegfilgrastim).
- On June 10, the FDA approved **Opdivo® (nivolumab)** (Bristol Myers Squibb Co., bms.com) for patients with unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma after prior fluoropyrimidine- and platinum-based chemotherapy.
- On June 29, the FDA approved **Phesgo™ (pertuzumab, trastuzumab, and hyaluronidase-zzxf)** (Genentech, Inc., gene.com) for subcutaneous injection for the following indications. The first is use of the agent in combination with chemotherapy as: (1) neoadjuvant treatment of patients with human epidermal growth factor receptor 2 (HER2)-positive, locally advanced, inflammatory, or early stage breast cancer (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen for early breast cancer and (2) adjuvant treatment of patients with HER2-positive early breast cancer at high risk of recurrence. The second is use of the agent in combination with docetaxel for treatment of patients with HER2-positive

metastatic breast cancer who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease.

- On June 22, the FDA granted accelerated approval to **Xpovio® (selinexor)** (Karyopharm Therapeutics, karyopharm.com) for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least two lines of systemic therapy.
- On June 18, the FDA granted accelerated approval to **Tazverik™ (tazemetostat)** (Epizyme, Inc., epizyme.com), an enhancer of zeste homolog 2 (EZH2) inhibitor, for adult patients with relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least two prior systemic therapies and for adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options.
- On July 24, the FDA granted accelerated approval to **Tecartus™ (brexucabtagene autoleucel)** (Kite Pharma, kitepharma.com), a CD19-directed genetically modified autologous T-cell immunotherapy, for the treatment of adult patients with relapsed or refractory mantle cell lymphoma.
- On July 31, Roche (roche.com) announced that the FDA approved **Tecentriq® (atezolizumab) plus Cotellic® (cobimetinib) and Zelboraf® (vemurafenib)** for the treatment of BRAF V600 mutation-positive advanced melanoma patients.
- On June 15, Jazz Pharmaceuticals plc (jazzpharma.com) and its partner PharmaMar (pharmamar.com) announced that the FDA approved **Zepzelca™ (lurbinectedin)** for the treatment of adult patients with metastatic small cell lung cancer with disease progression on or after platinum-based chemotherapy.

Drugs in the News

- EMD Serono (emdserono.com/us-en) announced that the FDA has approved the supplemental biologics license application (BLA) for **Bavencio® (avelumab)** for the maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma that has not progressed with first-line platinum-containing chemotherapy.
- Black Diamond Therapeutics, Inc. (blackdiamondtherapeutics.com) announced that the FDA granted fast track designation to **BDTX-189** for the treatment of adult patients with solid tumors harboring an allosteric HER2 mutation or an EGFR or HER2 Exon 20 insertion mutation who have progressed following prior treatment and who have no satisfactory treatment options.
- CNS Pharmaceuticals, Inc. (cnspharma.com) announced that the FDA has granted orphan drug designation for its lead product **Berubicin** for the treatment of malignant gliomas.
- Checkmate Pharmaceuticals, Inc. (checkmatepharma.com) announced that the FDA granted fast track designation to its product candidate, **CMP-001**, in combination with a programmed cell death receptor 1 (PD-1) blocking antibody (nivolumab or pembrolizumab) for two development programs, including initial treatment of patients with unresectable Stage III or Stage IV melanoma to prolong the time to disease progression and treatment of patients with unresectable or metastatic melanoma refractory to prior anti-PD-1 blockade to improve the overall tumor response rate.
- Celyad Oncology SA (celyad.com) announced that the company's investigational new drug application (NDA) for **CYAD-211**, a short hairpin RNA (shRNA)-based allogeneic chimeric antigen receptor T candidate and second non-gene edited off-the-shelf program, is in effect with the FDA.
- Y-mAbs Therapeutics, Inc. (ymabs.com) announced that the BLA for **Danyelza™ (naxitamab)** for the treatment of patients with relapsed/refractory high-risk neuroblastoma has been accepted for priority review by the FDA.
- Leap Therapeutics, Inc. (leaptx.com) announced that the FDA has granted orphan drug designation for **DKN-01** for the treatment of gastric and gastro-esophageal junction cancer.
- AVEO Oncology (aveooncology.com) announced that the FDA accepted for filing its NDA seeking approval for **Fotivda® (tivozanib)**, a vascular endothelial growth factor receptor tyrosine kinase inhibitor as a treatment for relapsed or refractory renal cell carcinoma.
- Hutchison China MediTech Limited (chi-med.com) announced that the FDA has granted fast track designation for the development of **fruquintinib** for the treatment of patients with metastatic colorectal cancer who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy; an anti-vascular endothelial growth factor biological therapy; and, if RAS wild type, an anti-EGFR therapy.
- Bristol Myers Squibb (bms.com) and bluebird bio, Inc. (bluebirdbio.com) announced the submission of their BLA to the FDA for **idecabtagene vicleucel (ide-cel; bb2121)**, the companies' investigational B-cell maturation antigen-directed chimeric antigen receptor T-cell immunotherapy, for the treatment of adult patients with relapsed and refractory multiple myeloma.
- Merck (merck.com) announced that the FDA accepted and granted priority review for a new supplemental BLA for **Keytruda® (pembrolizumab)** as monotherapy for the treatment of adult patients with relapsed or refractory classical Hodgkin lymphoma. The company also announced that the FDA has accepted and granted priority review for a new supplemental BLA seeking accelerated

approval for Keytruda in combination with chemotherapy for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer whose tumors express PD-L1 (combined positive score ≥10), based on the Phase 3 KEYNOTE-355 trial.

- Oncopeptides AB (oncopeptides.se/en/) announced the submission of an NDA to the FDA for accelerated approval of **melflufen (melphalan flufenamide)** in combination with dexamethasone for the treatment of adult patients with multiple myeloma whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one anti-CD38 monoclonal antibody.
- Merck (merck.com) announced that the FDA has granted breakthrough therapy designation to the hypoxia-inducible factor-2 alpha inhibitor **MK-6482** for the treatment of patients with von Hippel-Lindau disease-associated renal cell carcinoma with nonmetastatic renal cell carcinoma tumors less than 3 cm in size, unless immediate surgery is required.
- Ipsen (ipsen.com) announced that the FDA has granted fast track designation for the investigational use of **Onivyde® (liposomal irinotecan)** in combination with 5-fluorouracil/leucovorin and oxaliplatin together, known as NALIRIFOX, for patients with previously untreated, unresectable, locally advanced, and metastatic pancreatic ductal adenocarcinoma.
- Blueprint Medicines Corporation (blueprintmedicines.com) announced the submission of an NDA to the FDA for **pralsetinib** for the treatment of patients with advanced or metastatic RET mutant medullary thyroid cancer and RET fusion-positive thyroid cancers.
- Myovant Sciences (myovant.com) announced that its NDA for once-daily, oral **relugolix** (120 mg) for the treatment of men with advanced prostate cancer has been accepted for priority review by the FDA.
- AstraZeneca (astrazeneca.com) announced that **Tagrisso® (osimertinib)** has been granted breakthrough therapy designation for the adjuvant treatment of patients with early-stage (IB, II and IIIA) EGFR-mutated NSCLC after complete tumor resection with curative intent.
- Karyopharm Therapeutics Inc. (karyopharm.com) announced that the FDA has accepted for filing its supplemental NDA seeking approval for **Xpovio® (selinexor)** as a new treatment for patients with multiple myeloma after at least one prior line of therapy.
- Merus N.V. (merus.nl/) announced that the FDA has granted orphan drug designation to **Zenocutuzumab (Zeno)** for the treatment of patients with pancreatic cancer.

Approved Genetic Tests and Assays

- Adaptive Biotechnologies (adaptivebiotech.com) received clearance from the FDA for its **clonoSEQ® Assay** to detect and monitor minimal residual disease in blood or bone marrow from patients with chronic lymphocytic leukemia.
- Roche (roche.com) announced FDA approval of the **cobas® EZH2 Mutation Test** as a companion diagnostic for Tazverik™ (tazemetostat) (Epizyme, Inc., epizyme.com). This molecular test detects abnormalities in the EZH2 gene in patients with follicular lymphoma, a type of non-Hodgkin lymphoma, who may be eligible for treatment with Tazverik, a cancer drug that acts as a selective EZH2 gene inhibitor.
- Zebra Medical Vision (zebra-med.com) said it received FDA clearance from the FDA for its **mammography technology** that uses artificial intelligence to prioritize and identify suspicious mammograms.
- Roche (roche.com) announced FDA approval of new **Ventana HER2 Dual ISH DNA Probe Cocktail** assay for the detection of the HER2 biomarker in breast cancer and as a companion diagnostic for Herceptin® (trastuzumab) therapy.
- The FDA has approved the **Guardant360 CDx assay** (Guardant Health), a liquid biopsy companion diagnostic that also uses next-generation sequencing technology to identify patients with specific types of mutations of the EGFR gene in metastatic NSCLC. Though the Guardant360CDx assay can provide information on multiple solid tumor biomarkers, today's approval is specific to its use in identifying EGFR mutations in patients who will benefit from treatment with Tagrisso® (osimertinib), an FDA-approved therapy for metastatic NSCLC. OI