Approved Drugs

• On Nov. 14, the U.S. Food and Drug Administration (FDA) granted accelerated approval to Brukinsa™ (zanubrutinib) (BeiGene, beigene.com) for the treatment of adult patients with mantle cell lymphoma who have received at least one prior therapy.
• On Nov. 21, the FDA approved Calquence® (acalabrutinib) (AstraZeneca, astrazeneca.com) for adults with chronic lymphocytic leukemia or small lymphocytic lymphoma.
• On Nov. 20, the FDA approved Givlaari™ (givosiran) injection for subcutaneous use for the treatment of adults with acute hepatic porphyria.
• On Nov. 8, the FDA approved Reblozyl® (luspatercept-aamt) (Celgene Corp., Celgene.com) for treatment of anemia in adult patients with beta thalassemia who require regular red blood cell transfusions.
• On Dec. 4, Roche (roche.com) announced that the FDA has granted orphan drug designation to APVO436, a bispecific antibody candidate intended for the treatment of acute myelogenous leukemia.
• Aptevo Therapeutics Inc. (aptevotherapeutics.com) announced that the FDA has granted orphan drug designation to APVO436, a bispecific antibody candidate intended for the treatment of acute myelogenous leukemia.

Drugs in the News

• Aptevo Therapeutics Inc. (aptevotherapeutics.com) announced that the FDA has granted orphan drug designation to APVO436, a bispecific antibody candidate intended for the treatment of acute myelogenous leukemia.
• Heron Therapeutics, Inc. (herontx.com) announced that the FDA has approved a supplemental new drug application (sNDA) for Cinvanti® (aprepitant) injectable emulsion for intravenous use. The sNDA requested FDA approval to expand the recommended dosage to include the 130-mg single-dose regimen for patients receiving moderately emetogenic chemotherapy.
• The Janssen Pharmaceutical Companies of Johnson & Johnson announced the submission of an sNDA to the FDA seeking approval to expand the Imbruvica® (ibrutinib) label to include the combination with rituximab for the first-line treatment of patients with chronic lymphocytic leukemia or small lymphocytic lymphoma.
• AstraZeneca (astrazeneca.com) announced that the FDA has accepted a supplemental biologics license application (sBLA) and granted priority review for Imfinzi® (durvalumab) for the treatment of patients with previously untreated extensive-stage small cell lung cancer.
• The Janssen Pharmaceutical Companies of Johnson & Johnson announced today that the FDA has granted breakthrough therapy designation for JNJ-68284528 (JNJ-4528), an investigational B cell maturation antigen-directed chimeric antigen receptor T cell therapy in previously treated patients with multiple myeloma.
• Merck (merk.com) announced that the FDA has granted priority review for a new sBLA for Keytruda® (pembrolizumab) for the treatment of patients with bacillus Calmette-Guerin-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 (removal of bladder).
• Bristol-Myers Squibb Company (bms.com) announced that the FDA has accepted its sBLA and granted breakthrough therapy designation for Opdivo® (nivolumab) in combination with Yervoy® (ipilimumab) for the treatment of patients with advanced hepatocellular carcinoma previously treated with sorafenib.
• Bristol-Myers Squibb Company (bms.com) announced that the FDA has granted breakthrough therapy designation for Orencia® (abatacept) for the prevention of moderate to severe acute graft versus host disease in hematopoietic stem cell transplants from unrelated donors.

• Incyte (incyte.com) announced that the FDA accepted for priority review its new drug application for pemigatinib, a selective fibroblast growth factor receptor inhibitor, as a treatment for patients with previously treated, locally advanced, or metastatic cholangiocarcinoma with FGFR2 fusions or rearrangements.

• Spectrum Pharmaceuticals, Inc. (spprx.com) announced that the company submitted an updated BLA to the FDA for Rolontis® (eflapegrastim), a novel, long-acting granulocyte colony-stimulating factor, seeking an indication for the treatment of neutropenia in patients receiving myelosuppressive anticancer drugs.

• Immunomedics, Inc. (immunomedics.com) announced the resubmission of its BLA to the FDA seeking accelerated approval of sacituzumab govitecan for the treatment of patients with metastatic triple-negative breast cancer who have received at least two prior therapies for metastatic disease.

• Samsung Bioepis Co., Ltd. (samsungbioepis.com/en/index.do) announced that the FDA has accepted a BLA under the 351(k) pathway for SB8, a biosimilar candidate referencing Avastin® (bevacizumab).

• AstraZeneca (astrazeneca.com) and Daiichi Sankyo Company, Ltd. (daiichisankyo.com) announced that the FDA has accepted for review the BLA for trastuzumab deruxtecan (DS-8201), a human epidermal growth factor receptor 2 (HER2)-targeting antibody drug conjugate and potential new medicine for the treatment of HER2-positive metastatic breast cancer.

• Adastra Pharmaceuticals, Inc. (adastrarx.com) announced that the FDA has granted orphan drug designation to zotiraciclib for the treatment of glioma.

Approved Genetic Tests and Assays

• Myriad Genetics, Inc. (myriad.com) announced that the FDA approved myChoice® CDx for use as a companion diagnostic by healthcare professionals to identify women with advanced ovarian cancer who are candidates for Zejula® (niraparib) in the late-line treatment setting.

• Foundation Medicine, Inc. (foundation-medicine.com) announced FDA approval for FoundationOne® CDx to be used as a companion diagnostic for Piqray® (alpelisib) in combination with fulvestrant for postmenopausal women, and men, with hormone receptor-positive, HER2-negative, PIK3CA-mutated advanced or metastatic breast cancer following progression on or after an endocrine-based regimen.

Learn more at ecgmc.com/cancer