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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)** (Alnylam Pharmaceuticals, Inc., alnylam.com) **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 approved **Tecentriq® (atezolizumab)** in combination with chemotherapy (Abraxane® [paclitaxel protein-bound; nab-paclitaxel] and carboplatin) for the first-line treatment of adults with metastatic non-squamous non-small cell lung cancer with no epidermal growth factor receptor or anaplastic lymphoma kinase genomic tumor aberrations.
- On Oct. 23, the FDA approved an expanded indication of **Zejula® (niraparib)** (Tesaro, Inc., tesarobio.com) for patients with advanced ovarian, fallopian tube, or primary peritoneal cancer treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency-positive status.
- On Nov. 5, the FDA approved **Ziextenzo™ (pegfilgrastimbmez)** (Sandoz, sandoz.com), a long-acting oncology supportive care biosimilar, indicated to decrease the incidence of infection, as manifested by febrile neutropenia (low white blood cell count with a fever), in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia.

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. (sppirx.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. (foundationmedicine.com) announced FDA approval for **FoundationOne®CDx** to be used as a companion diagnostic for Piqray® (alpelisib) in combination with fulvestrant for the treatment of 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. OI