tools

Approved Drugs

- On Nov. 12, the U.S. Food and Drug Administration (FDA) approved **Besremi® (ropeginterferon alfa-2b-njft)** (PharmaEssentia Corporation, us.pharmaessentia.com) for the treatment of adults with polycythemia vera.
- On Nov. 29, the FDA approved **Cytalux™ (pafolacianine)** (On Target Laboratories, Inc., ontargetlabs.com) as an imaging drug intended to assist surgeons in identifying ovarian cancer lesions.
- On Nov. 30, the FDA approved **Darzalex Faspro® (daratumumab and hyaluronidase-fihj)** (Janssen, janssen.com) **in combination with Kyprolis® (carfilzomib)** (Amgen, amgen.com) **and dexamethasone** for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy.
- On Nov. 23, the FDA approved **Fyarro™ (sirolimus protein-bound particles for injectable suspension) (albumin-bound)** (Aadi Bioscience, Inc., aadibio.com) for intravenous use for the treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor.
- On Oct. 13, the FDA approved **Keytruda® (pembrolizumab)** (Merck, merck.com) **in combination with chemotherapy, with or without bevacizumab**, for patients with persistent, recurrent, or metastatic cervical cancer whose tumors express programmed death ligand 1 (PD-L1), as determined by an FDA-approved test. On Nov. 18, the FDA also approved Keytruda for the adjuvant treatment of patients with renal cell carcinoma at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.
- On Oct. 29, the FDA approved **Scemblix® (asciminib)** (Novartis, novartis.com) for the treatment of chronic myeloid leukemia (CML) in two distinct indications: the FDA granted Scemblix 1) accelerated approval for adult patients with Philadelphia chromosome-positive CML in chronic phase (Ph+ CML-CP) previously treated with two or more tyrosine kinase inhibitors, based on major molecular response rate at 24 weeks, and 2) full approval for adult patients with Ph+ CML-CP with the T315I mutation.
- On Oct. 15, the FDA approved **Tecentriq® (atezolizumab)** (Genentech, Inc., gene.com) for adjuvant treatment following resection and platinum-based chemotherapy in patients with stage II to IIIA non-small cell lung cancer whose tumors have PD-L1 expression on greater than or equal to 1 percent of tumor cells, as determined by an FDA-approved test.
- On Oct. 12, the FDA approved **Verzenio® (abemaciclib)** (Eli Lilly and Company, lilly.com) **with endocrine therapy (tamoxifen or an aromatase inhibitor)** for the adjuvant treatment of adult patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative, node-positive early breast cancer at high risk of recurrence and a Ki-67 score greater than or equal to 20 percent, as determined by an FDA-approved test.

Drugs in the News

- Isofol Medical AB (isofolmedical.com) announced that the FDA granted fast track designation to **arfolitixorin** for the treatment of patients with metastatic colorectal cancer.
- Bluebird bio, Inc. (bluebirdbio.com) announced that the FDA accepted the biologics license application (BLA) and granted priority review for **betibeglogene autotemcel (beti-cel)**—a gene therapy for adult, adolescent, and pediatric patients with β-thalassemia across all genotypes who require regular red blood cell transfusions.
- CRISPR Therapeutics (crisprtx.com) announced that the FDA granted regenerative medicine advanced therapy designation to **CTX110™** for the treatment of relapsed or refractory CD19+ B-cell malignancies.
- Epizyme, Inc. (epizyme.com) announced that the FDA granted fast track designation to **EZM0414** as an investigational agent for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma.
- Novartis (novartis.com) announced that the FDA accepted the supplemental BLA

and granted priority review for **Kymriah® (tisagenlecleucel)** in adult patients with relapsed or refractory follicular lymphoma after two prior lines of treatment.

- AstraZeneca (astrazeneca.com) announced that the FDA accepted and granted priority review to the supplemental new drug application (NDA) for **Lynparza® (olaparib)** for the adjuvant treatment of patients with BRCA-mutated human epidermal growth factor receptor 2-negative high-risk early breast cancer who have already been treated with chemotherapy either before or after surgery.
- Alkermes plc (alkermes.com) announced the FDA granted fast track designation to **nemvaleukin alfa (nemvaleukin) in combination with pembrolizumab** for the treatment of platinum-resistant ovarian cancer.
- CTI BioPharma Corp. (ctibiopharma.com) announced that the FDA extended the review period for its NDA for **pacritinib** for the treatment of adult patients with intermediate or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis with a baseline platelet count of $<50 \times 10^9$/L.
- Incyte (incyte.com) announced that the FDA accepted its NDA for **parsaclisib** for the treatment of patients with relapsed or refractory follicular lymphoma, marginal zone lymphoma, and mantle cell lymphoma.
- Coherus BioSciences, Inc. (coherus.com) and Shanghai Junshi Biosciences Co., Ltd. (junshipharma.com/en/Index.html) announced that the FDA accepted and granted priority review to the BLA for **toripalimab in combination with gemcitabine and cisplatin** as the first-line treatment for patients with advanced recurrent or metastatic nasopharyngeal carcinoma and toripalimab monotherapy for the second-line or above treatment of recurrent or metastatic nasopharyngeal carcinoma after platinum-containing chemotherapy. Both companies also announced that the FDA granted orphan drug designation for toripalimab for the treatment of esophageal cancer.
- Ultimovacs ASA (ultimovacs.com) announced that the FDA granted fast track designation to its **universal cancer vaccine (UV1) in combination with checkpoint inhibitors** for the treatment of unresectable or metastatic melanoma—as add-on therapy to either pembrolizumab or ipilimumab.
- Y-mAbs Therapeutics, Inc. (ymabs.com) announced that the FDA granted rare pediatric disease designation to **177lu-omburtamab-DTPA** for the treatment of medulloblastoma.

Devices and Assays in the News

- Agilent Technologies Inc. (agilent.com) announced that the FDA approved **Ki-67 IHC MIB-1 pharmDx (Dako Omnis)** as an aid in identifying patients with early breast cancer.
- Delphinus Medical Technologies (delphinusmt.com) announced that the FDA gave pre-market approval to **SoftVue 3D Whole Breast Ultrasound Tomography System** to be used in addition to digital mammograms for screening patients with breast cancer with dense breast tissue.
- Datar Cancer Genetics Inc. (datarpgx.com) announced that the FDA granted breakthrough device designation to its **TriNetra™** blood test to detect early-stage breast cancer.
- Roche (roche.com) announced FDA approval of the **VENTANA PD-L1 (SP263) Assay** in non-small cell lung cancer as a companion diagnostic test for Tecentriq.
- Zetagen Therapeutics (zetagen.com) announced that it has received breakthrough device designation from the FDA for **ZetaMet™**, a synthetic, small-molecule, and inductive biologic technology that is being developed to target and resolve metastatic bone lesions while inhibiting future tumor growth and regenerating bone.