tools

Approved Drugs

• On September 11, the US Food and Drug Administration (FDA) approved **Aphexda® (motixafortide)** in **combination with Neupogen® (filgrastim)** (BioLineRx Ltd., biolinerx.com) to mobilize hematopoietic stem cells to the peripheral blood in patients with multiple myeloma for collection and subsequent autologous transplantation.

• On September 26, the FDA approved **Bosulif® (bosutinib)** (Pfizer Inc., pfizer.com) for pediatric patients 1 year of age and older with chronic phase Ph+ chronic myelogenous leukemia that is newly diagnosed or resistant or intolerant to prior therapy.

• On October 11, the FDA approved **Braftovi® (encorafenib) in combination with Mektovi® (binimetinib)** (Pfizer, pfizer.com) for adult patients with metastatic non-small cell lung cancer (NSCLC) with a BRAF V600E mutation, as detected by an FDA-approved test.

• On October 16, the FDA approved **Keytruda® (pembrolizumab)** (Merck, merck.com) with platinum-containing chemotherapy as neoadjuvant treatment, and with continuation of single-agent **pembrolizumab** as post-surgical adjuvant treatment for resectable NSCLC.

• On October 27, the FDA approved **Loqtroz® (toripalimab-tpzi) in combination with cisplatin and gemcitabine** (Coherus BioSciences, coherus.com) for the first-line treatment of adults with metastatic or recurrent, locally advanced nasopharyngeal carcinoma. The FDA also Loqtroz as a single agent for adults with recurrent unresectable or metastatic nasopharyngeal carcinoma with disease progression on or after a platinum-containing chemotherapy.

• On October 13, the FDA approved **Opdivo® (nivolumab)** (Bristol Myers Squibb, bms.com) for the adjuvant treatment of completely resected Stage IIB/C melanoma in patients 12 years of age and older.

• On August 28, the FDA approved **Reblozyl® (luspatercept-aamt)** (Bristol Myers Squibb, bms.com) as a first-line treatment for anemia in adults with low to intermediate risk myelodysplastic syndromes who have not previously received erythropoiesis-stimulating agents and may require regular red blood cell transfusions.

• On October 20, the FDA granted accelerated approval to **Rozlytrek® (entrectinib)** (Genentech Inc., gene.com) for pediatric patients older than 1 month with solid tumors that have a neurotrophic tyrosine receptor kinase gene fusion without a known acquired resistance mutation, are metastatic or where surgical resection is likely to result in severe morbidity and have progressed following treatment or have no satisfactory standard therapy.

• On September 14, the FDA approved updated labeling for **Temodar® (temozolomide)** (Merck, merck.com) under Project Renewal, an Oncology Center of Excellence initiative aimed at updating labeling information for older oncology drugs.

• On October 24, the FDA approved **Tibsovo® (ivosidenib)** (Servier, servier.us) for adult patients with relapsed or refractory myelodysplastic syndromes with a susceptible isocitrate dehydrogenase-1 mutation, as detected by an FDA-approved test.

Drugs In the News

• Daiichi Sankyo (daiichisankyo.com) announced that the FDA has granted two additional breakthrough therapy designations for **Enhertu® (fam-trastuzumab deruxtecan-nxki)** for the treatment of adult patients with unresectable or metastatic HER+ solid tumors that have progressed following prior treatment and who have no satisfactory alternative treatment options, and for the treatment of patients with HER2+ metastatic colorectal cancer who have received 2 or more prior regimens.

• Geron Corporation (geron.com) announced that the FDA has assigned a standard review and a prescription drug user fee act action date of June 16, 2024, for Geron's new drug application (NDA) for **imetelstat** for the treatment of transfusion-dependent anemia in patients with lower risk myelodysplastic syndromes.

• Merck (merck.com) announced the FDA has accepted for priority review a new supplemental biologics license application (BLA) seeking approval for **Keytruda®** in combination with external beam radiotherapy and concurrent chemotherapy, followed by brachytherapy for newly diagnosed patients with high-risk locally advanced cervical cancer.

• Regeneron Pharmaceuticals (regeneron.com) announced that the FDA has accepted for priority review, the BLA for **odronextamab** to treat adult patients with relapsed/refractory follicular lymphoma or relapsed/refractory diffuse large B-cell lymphoma, who have progressed after at least two prior systemic therapies.

• AstraZeneca (astrazeneca.com) announced that the FDA approved a supplemental NDA for **Tagrisso® (osimertinib)** in combination with chemotherapy for the treatment of adult patients with locally advanced or metastatic epidermal growth factor receptor-mutated NSCLC.

• Servier (servier.us) announced the FDA has accepted a sNDA and granted Priority Review for **Tibsovo® (ivosidenib tablets)** in the treatment of patients with isocitrate dehydrogenase 1-mutated relapsed or refractory MDS.

• Day One Biopharmaceuticals (dayonebio.com) announced the FDA accepted a NDA for **tovorafenib** as a monotherapy in relapsed or progressive pediatric low-grade glioma.

• Merck (merck.com) announced the FDA has accepted and granted priority review for a supplemental NDA seeking approval for **welireg**, the company's oral hypoxia-inducible factor-2 alpha inhibitor, for the treatment of adult patients with advanced renal cell carcinoma following immune checkpoint and anti-angiogenic therapies.

• Pfizer Inc. (pfizer.com) and Astellas Pharma Inc. (astellas.com) announced that the FDA has accepted and granted priority review for the companies's NDA for **Xtandi® (enzalutamide)** for the treatment of patients with non-metastatic castration-sensitive prostate cancer with high-risk biochemical recurrence.

Approved Diagnostic Tests and Assays

• On October 24, the FDA approved the **Abbott RealTime IDH1 Assay** as a companion diagnostic device to select patients for Tibsovo® (ivosidenib) (Servier, servier.us).

• On October 26, the FDA granted breakthrough device designation for **Paige Lymph Node** (Paige, paige.ai) an artificial intelligence application used to detect breast cancer metastases in lymph node tissue.