

tools



Approved Drugs

- On Sept. 16, the U.S. Food and Drug Administration (FDA) approved **Aponvie™ (aprepitant)** (Heron Therapeutics, herontx.com/) for the prevention of postoperative nausea and vomiting in adults.
- On Aug. 11, the FDA granted accelerated approval to **Enhertu® (fam-trastuzumab deruxtecan-nxki)** (Daiichi Sankyo, Inc., daiichisankyo.com) for adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating human epidermal growth factor receptor 2 (HER2) mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy.
- On Aug. 24, the FDA approved **Imbruvica® (ibrutinib)** (PharmacyClics LLC, pharmacyclics.com) for pediatric patients one year and older with chronic graft-versus-host disease after failure of one or more lines of systemic therapy.
- On Sept. 2, the FDA approved **Imfinzi® (durvalumab)** (AstraZeneca, astrazeneca.com) **in combination with gemcitabine and cisplatin** for adult patients with locally advanced or metastatic biliary tract cancer.
- On Sept. 30, the FDA granted accelerated approval to **Lytgobi® (futibatinib)** (Taiho Oncology, Inc., taihooncology.com) for adult patients with previously treated, unresectable, locally advanced, or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 gene fusions or other rearrangements.
- On Aug. 26, the FDA approved **Pemazyre® (pemigatinib)** (Incyte Corporation, incyte.com) for adults with relapsed or

refractory myeloid/lymphoid neoplasms with fibroblast growth factor receptor 1 rearrangement.

- On Sept. 21, the FDA granted accelerated approval to **Retevmo® (selpercatinib)** (Eli Lilly and Company, lilly.com) for adult patients with locally advanced or metastatic solid tumors with a rearranged during transfection gene fusion who have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options. The FDA also approved Retevmo for adult patients with locally advanced or metastatic NSCLC with a rearranged during transfection gene fusion, as detected by an FDA-approved test.
- On Sept. 9, the FDA approved **Rolvedon™ (eflapragrastim-xnst)** (Spectrum Pharmaceuticals, sppirx.com/index.html) to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with clinically significant incidence of febrile neutropenia.
- On Sept. 6, the FDA approved **Stimufend® (pegfilgrastim-fpgk)** (Fresenius Kabi, fresenius-kabi.com), a biosimilar of Neulasta® (pegfilgrastim) (Amgen, amgen.com), which is indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.
- On Aug. 10, the FDA approved **Tabrecta® (capmatinib)** (Novartis Pharmaceutical Corporation, novartis.com) for adult patients with metastatic NSCLC whose tumors have a mutation leading to mesenchymal epithelial transition exon

14 skipping, as detected by an FDA-approved test.

- On Sept. 28, the FDA approved **Vegzelma® (bevacizumab-adcd)**, a biosimilar to Avastin® (bevacizumab) (Genentech, gene.com), for the treatment of metastatic colorectal cancer; recurrent or metastatic non-squamous NSCLC; recurrent glioblastoma; metastatic renal cell carcinoma; persistent, recurrent, or metastatic cervical cancer; and epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Drugs in the News

- Clovis Oncology, Inc. (clovisoncology.com) announced the submission of a supplemental new drug application to the FDA for approval of **Rubraca® (rucaparib)** as a first-line maintenance treatment for women with advanced ovarian cancer regardless of biomarker status who have responded to first-line platinum-based chemotherapy.
- Seagen (seagen.com) announced that the FDA accepted for priority review the supplemental new drug application seeking accelerated approval for **Tukysa® (tucatinib) in combination with trastuzumab** for adult patients with HER2+ colorectal cancer who have received at least one prior treatment regimen for unresectable or metastatic disease.
- GlaxoSmithKline (gsk.com) announced that it is planning to voluntarily withdraw the indication of **Zejula® (niraparib)** for the treatment of adult patients with advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency+ status.