Oncology (Cancer)/Hematologic Malignancies Approval Notifications

FDA does not issue approval announcements for every approval or drug label update that occurs in oncology and hematology. Please refer to Drugs@FDA (https://www.accessdata.fda.gov/scripts/cder/daf/) for the latest approvals and prescribing information for specific products.

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Webpage	Description	Date
FDA approves cabozantinib for adults and pediatric patients 12 years of age and older with pNET and epNET (/drugs/resources-information-approved-drugs/fda-approves-cabozantinib-adults-and-pediatric-patients-12-years-age-and-older-pnet-and-epnet)	On March 26, 2025, the Food and Drug Administration approved cabozantinib (Cabometyx, Exelixis, Inc.) for adult and pediatric patients 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors (pNET) and well-differentiated extra-pancreatic neuroendocrine tumors (epNET).	3/26/2025
FDA approves pembrolizumab for HER2 positive gastric or gastroesophageal junction adenocarcinoma expressing PD-L1 (CPS ≥1) (/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-her2-positive-gastric-or-gastroesophageal-junction-adenocarcinoma)	On March 19, 2025, the Food and Drug Administration granted traditional approval to pembrolizumab (Keytruda, Merck) with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma whose tumors express PD-L1 (CPS ≥1).	3/19/2025
FDA approves vimseltinib for symptomatic tenosynovial giant cell tumor (/drugs/resources-information-approved-drugs/fda-approves-vimseltinib-symptomatic-tenosynovial-giant-cell-tumor)	On February 14, 2025, the Food and Drug Administration approved vimseltinib (Romvimza, Deciphera Pharmaceuticals, LLC), a kinase inhibitor, for adult patients with symptomatic tenosynovial giant cell tumor (TGCT) for which surgical resection will potentially cause worsening functional limitation or severe morbidity.	2/14/2025
FDA approves brentuximab vedotin with lenalidomide and rituximab for relapsed or refractory large B-cell lymphoma (/drugs/resources-information-approved-drugs/fda-approves-brentuximab-vedotin-lenalidomide-and-rituximab-relapsed-or-refractory-large-b-cell)	On February 11, 2025, the Food and Drug Administration approved brentuximab vedotin (Adcetris, Seagen Inc., a subsidiary of Pfizer) in combination with lenalidomide and a rituximab product for adult patients with relapsed or refractory large B-cell lymphoma (LBCL), including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (NOS), DLBCL arising from indolent lymphoma, or high-grade B-cell lymphoma (HGBL), after two or more lines of systemic therapy who are ineligible for autologous hematopoietic stem cell transplantation (auto-HSCT) or CAR T-cell therapy.	2/12/2025

Webpage	Description	Date
FDA approves mirdametinib for adult and pediatric patients with neurofibromatosis type 1 who have symptomatic plexiform neurofibromas not amenable to complete resection (/drugs/resources-information-approved-drugs/fda-approves-mirdametinib-adult-and-pediatric-patients-neurofibromatosis-type-1-who-have-symptomatic)	On February 11, 2025, the Food and Drug Administration approved mirdametinib (Gomekli, SpringWorks Therapeutics, Inc.), a kinase inhibitor, for adult and pediatric patients 2 years of age and older with neurofibromatosis type 1 (NF1) who have symptomatic plexiform neurofibromas (PN) not amenable to complete resection.	2/11/2025
FDA approves treosulfan with fludarabine as a preparative regimen for alloHSCT in adult and pediatric patients with AML or MDS (/drugs/resources-information-approved-drugs/fda-approves-treosulfan-fludarabine-preparative-regimen-allohsct-adult-and-pediatric-patients-aml-or)	On January 21, 2025, the Food and Drug Administration approved treosulfan (Grafapex, medac GmbH), an alkylating agent, with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (alloHSCT) in adult and pediatric patients 1 year of age and older with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS).	2/06/2025
FDA approves fam-trastuzumab deruxtecan-nxki for unresectable or metastatic HR-positive, HER2-low or HER2-ultralow breast cancer (/drugs/resources-information-approved-drugs/fda-approves-fam-trastuzumab-deruxtecan-nxki-unresectable-or-metastatic-hr-positive-her2-low-or-her2)	On January 27, 2025, the Food and Drug Administration approved fam-trastuzumab deruxtecan-nxki (Enhertu, Daiichi Sankyo, Inc.) for unresectable or metastatic hormone receptor (HR)-positive, HER2-low (IHC 1+ or IHC 2+/ISH-) or HER2-ultralow (IHC 0 with membrane staining) breast cancer, as determined by an FDA-approved test, that has progressed on one or more endocrine therapies in the metastatic setting.	1/27/2025
Safety announcement: FDA highlights importance of DPD deficiency discussions with patients prior to capecitabine or 5FU treatment (/drugs/resources-information-approved-drugs/safety-announcement-fda-highlights-importance-dpd-deficiency-discussions-patients-prior-capecitabine)	The U.S. Food and Drug Administration (FDA) is providing this communication to increase awareness of recent updates to the product labeling of capecitabine and fluorouracil (5-FU) related to risks associated with dihydropyrimidine dehydrogenase (DPD) deficiency. All healthcare providers should be aware of the risks of DPD deficiency, inform patients prior to treatment about the potential for serious and life-threatening toxicities due to DPD deficiency, and discuss testing options for DPD deficiency with their patients.	1/24/2025
FDA approves datopotamab deruxtecan-dlnk for unresectable or metastatic, HR-positive, HER2-negative breast cancer (/drugs/resources-information-approved-drugs/fda-approves-datopotamab-deruxtecan-dlnk-unresectable-or-metastatic-hr-positive-her2-negative-breast)	On January 17, 2025, the Food and Drug Administration approved datopotamab deruxtecan-dlnk (Datroway, Daiichi Sankyo, Inc.), a Trop-2-directed antibody and topoisomerase inhibitor conjugate, for adult patients with unresectable or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC1+ or IHC2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease.	1/17/2025
FDA approves sotorasib with panitumumab for KRAS G12C-mutated colorectal cancer (/drugs/resources-information-approved-drugs/fda-approves-sotorasib-panitumumab-kras-g12c-mutated-colorectal-cancer)	On January 16, 2025, the Food and Drug Administration approved sotorasib (Lumakras, Amgen Inc.) with panitumumab (Vectibix, Amgen Inc.) for adult patients with KRAS G12C-mutated metastatic colorectal cancer (mCRC), as determined by an FDA-approved test, who have received prior fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.	1/16/2025

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Previous Notifications

- 2017-2020 (https://wayback.archive-it.org/7993/20201219232235/https://www.fda.gov/drugs/resources-information-approved-drugs/hematologyoncology-cancer-approvals-safety-notifications) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)
- 2006-2016 (http://wayback.archive-it.org/7993/20170111064250/http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm) (http://www.fda.gov/about-fda/website-policies/website-disclaimer)