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.

Search:

Show 10 entries

Webpage	Description	Date
FDA approves selpercatinib for *RET* fusion-positive thyroid cancer (/drugs/resources-information-approved-drugs/fda-approves-selpercatinib-ret-fusion-positive-thyroid-cancer)	On June 12, 2024, the Food and Drug Administration granted traditional approval to selpercatinib (Retevmo, Eli Lilly and Company) for adult and pediatric patients 2 years of age and older with advanced or metastatic *RET* fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).	6/12/2024
FDA approves imetelstat for low- to intermediate-1 risk myelodysplastic syndromes with transfusion-dependent anemia (/drugs/resources-information-approved-drugs/fda-approves-imetelstat-low-intermediate-1-risk-myelodysplastic-syndromes-transfusion-dependent)	On June 6, 2024, the Food and Drug Administration approved imetelstat (Rytelo, Geron Corporation), an oligonucleotide telomerase inhibitor, for adults with low- to intermediate-1 risk myelodysplastic syndromes (MDS) with transfusion-dependent anemia requiring four or more red blood cell units over 8 weeks who have not responded to or have lost response to or are ineligible for erythropoiesis-stimulating agents (ESAs).	6/6/2024
FDA approves lisocabtagene maraleucel for relapsed or refractory mantle cell lymphoma (/drugs/resources-information-approved-drugs/fda-approves-lisocabtagene-maraleucel-relapsed-or-refractory-mantle-cell-lymphoma)	On May 30, 2024, the Food and Drug Administration approved lisocabtagene maraleucel (Breyanzi, Juno Therapeutics, Inc.) for adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least two prior lines of systemic therapy, including a Bruton tyrosine kinase inhibitor (BTKi).	5/30/2024
FDA grants accelerated approval to selpercatinib for pediatric patients two years and older with RET-altered metastatic thyroid cancer or solid tumors (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-selpercatinib-pediatric-patients-two-years-and-older-ret-altered)	On May 29, 2024, the Food and Drug Administration granted accelerated approval to selpercatinib (Retevmo, Eli Lilly and Company) for pediatric patients two years of age and older.	5/29/2024
FDA grants accelerated approval to tarlatamab-dlle for extensive stage small cell lung cancer (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-tarlatamab-dlle-extensive-stage-small-cell-lung-cancer)	On May 16, 2024, the Food and Drug Administration granted accelerated approval to tarlatamab-dlle (Imdelltra, Amgen, Inc.) for extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.	5/16/2024

Webpage	Description	Date
FDA grants accelerated approval to lisocabtagene maraleucel for follicular lymphoma (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-lisocabtagene-maraleucel-follicular-lymphoma)	On May 15, 2024, the Food and Drug Administration granted accelerated approval to lisocabtagene maraleucel (Breyanzi, Juno Therapeutics, Inc.) for adults with relapsed or refractory follicular lymphoma (FL) who have received two or more prior lines of systemic therapy.	5/15/2024
FDA approves tisotumab vedotin-tftv for recurrent or metastatic cervical cancer (/drugs/resources-information-approved-drugs/fda-approves-tisotumab-vedotin-tftv-recurrent-or-metastatic-cervical-cancer)	On April 29, 2024, the Food and Drug Administration granted traditional approval to tisotumab vedotin-tftv (Tivdak, Seagen Inc. [now a part of Pfizer Inc.]) for recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Tisotumab vedotin-tftv previously received accelerated approval for this indication.	4/29/2024
FDA grants accelerated approval to tovorafenib for patients with relapsed or refractory BRAF-altered pediatric low-grade glioma (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-tovorafenib-patients-relapsed-or-refractory-braf-altered-pediatric)	On April 23, 2024, the Food and Drug Administration granted accelerated approval to tovorafenib (Ojemda, Day One Biopharmaceuticals, Inc.) for patients 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.	4/23/2024
FDA approves lutetium Lu 177 dotatate for pediatric patients 12 years and older with GEP-NETS (/drugs/resources-information-approved-drugs/fda-approves-lutetium-lu-177-dotatate-pediatric-patients-12-years-and-older-gep-nets)	On April 23, 2024, the Food and Drug Administration approved lutetium Lu 177 dotatate (Lutathera, Advanced Accelerator Applications USA, Inc., a Novartis company) for pediatric patients 12 years and older with somatostatin receptor (SSTR)-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors. Lutetium Lu 177 dotatate received approval for this indication for adults in 2018.	4/23/2024
FDA approves nogapendekin alfa inbakicept-pmln for BCG-unresponsive non-muscle invasive bladder cancer (/drugs/resources-information-approved-drugs/fda-approves-nogapendekin-alfa-inbakicept-pmln-bcg-unresponsive-non-muscle-invasive-bladder-cancer)	On April 22, 2024, the Food and Drug Administration approved nogapendekin alfa inbakicept-pmln (Anktiva, Altor BioScience, LLC) with Bacillus Calmette-Guérin (BCG) for adult patients with BCG-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.	4/22/2024

Showing 11 to 20 of 243 entries

Previous 1 2 3 4 5 … 25 Next

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)