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 vorasidenib for Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation (/drugs/resources-information-approved-drugs/fda-approves-vorasidenib-grade-2-astrocytoma-or-oligodendroglioma-susceptible-idh1-or-idh2-mutation)	On August 6, 2024, the Food and Drug Administration approved vorasidenib (Voranigo, Servier Pharmaceuticals LLC), an isocitrate dehydrogenase-1 (IDH1) and isocitrate dehydrogenase-2 (IDH2) inhibitor, for adult and pediatric patients 12 years and older with Grade 2 astrocytoma or oligodendroglioma with a susceptible IDH1 or IDH2 mutation, following surgery including biopsy, sub-total resection, or gross total resection.	8/6/2024
FDA grants accelerated approval to afamitresgene autoleucel for unresectable or metastatic synovial sarcoma (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-afamitresgene-autoleucel-unresectable-or-metastatic-synovial-sarcoma)	On August 2, 2024, the Food and Drug Administration granted accelerated approval to afamitresgene autoleucel (TECELRA, Adaptimmune, LLC), a melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy, for adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices.	8/2/2024
FDA expands endometrial cancer indication for dostarlimab-gxly with chemotherapy (/drugs/resources-information-approved-drugs/fda-expands-endometrial-cancer-indication-dostarlimab-gxly-chemotherapy)	On August 1, 2024, the Food and Drug Administration approved dostarlimab-gxly (Jemperli, GSK) with carboplatin and paclitaxel, followed by single-agent dostarlimab-gxly, for adult patients with primary advanced or recurrent endometrial cancer (EC).	8/1/2024
FDA approves daratumumab and hyaluronidase-fihj with bortezomib, lenalidomide, and dexamethasone for multiple myeloma (/drugs/resources-information-approved-drugs/fda-approves-daratumumab-and-hyaluronidase-fihj-bortezomib-lenalidomide-and-dexamethasone-multiple)	On July 30, 2024, the Food and Drug Administration approved daratumumab and hyaluronidase-fihj (Darzalex Faspro, Janssen Research & Development, LLC) in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in patients with newly diagnosed multiple myeloma who are eligible for autologous stem cell transplant (ASCT).	7/30/2024

Webpage	Description	Date
FDA grants accelerated approval to epcoritamab-bysp for relapsed or refractory follicular lymphoma (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-epcoritamab-bysp-relapsed-or-refractory-follicular-lymphoma)	On June 26, 2024, the Food and Drug Administration granted accelerated approval to epcoritamab-bysp (Epkinly, Genmab US, Inc.), a bispecific CD20-directed CD3 T-cell engager, for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.	6/26/2024
FDA grants accelerated approval to adagrasib with cetuximab for KRAS G12C-mutated colorectal cancer (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-adagrasib-cetuximab-kras-g12c-mutated-colorectal-cancer)	On June 21, 2024, the Food and Drug Administration granted accelerated approval to adagrasib (Krazati; Mirati Therapeutics, Inc.) plus cetuximab for adults with KRAS G12C-mutated locally advanced or metastatic colorectal cancer (CRC), as determined by an FDA-approved test, who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.	6/21/2024
FDA approves pembrolizumab with chemotherapy for primary advanced or recurrent endometrial carcinoma (/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-chemotherapy-primary-advanced-or-recurrent-endometrial-carcinoma)	On June 17, 2024, the Food and Drug Administration approved pembrolizumab (Keytruda, Merck) with carboplatin and paclitaxel, followed by single-agent pembrolizumab, for adult patients with primary advanced or recurrent endometrial carcinoma.	6/17/2024
FDA approves blinatumomab as consolidation for CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (/drugs/resources-information-approved-drugs/fda-approves-blinatumomab-consolidation-cd19-positive-philadelphia-chromosome-negative-b-cell)	On June 14, 2024, the Food and Drug Administration approved blinatumomab (Blincyto, Amgen Inc.) for adult and pediatric patients one month and older with CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (Ph-negative BCP ALL) in the consolidation phase of multiphase chemotherapy.	6/14/2024
FDA approves durvalumab with chemotherapy for mismatch repair deficient primary advanced or recurrent endometrial cancer (/drugs/resources-information-approved-drugs/fda-approves-durvalumab-chemotherapy-mismatch-repair-deficient-primary-advanced-or-recurrent)	On June 14, 2024, the Food and Drug Administration approved durvalumab (Imfinzi, AstraZeneca UK Limited) with carboplatin plus paclitaxel followed by single-agent durvalumab for adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).	6/14/2024
FDA grants accelerated approval to repotrectinib for adult and pediatric patients with NTRK gene fusion-positive solid tumors (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-repotrectinib-adult-and-pediatric-patients-ntrk-gene-fusion-positive)	On June 13, 2024, the Food and Drug Administration granted accelerated approval to repotrectinib (AUGTYRO, Bristol-Myers Squibb Company) for adult and pediatric patients 12 years and older with solid tumors that have a neurotrophic tyrosine receptor kinase (*NTRK*) gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity, and that have progressed following treatment or have no satisfactory alternative therapy.	6/13/2024

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