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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FDA approves crizotinib for ALK-positive inflammatory myofibroblastic tumor (/drugs/resources-information-approved-drugs/fda-approves-crizotinib-alk-positive-inflammatory-myofibroblastic-tumor)	On July 14, 2022, the Food and Drug Administration approved crizotinib (Xalkori, Pfizer Inc.) for adult and pediatric patients 1 year of age and older with unresectable, recurrent, or refractory inflammatory anaplastic lymphoma kinase (ALK)-positive myofibroblastic tumors (IMT).	7/14/2022
FDA approves lisocabtagene maraleucel for second-line treatment of large B-cell lymphoma (/drugs/resources-information-approved-drugs/fda-approves-lisocabtagene-maraleucel-second-line-treatment-large-b-cell-lymphoma)	On June 24, 2022, the Food and Drug Administration approved lisocabtagene maraleucel (Breyanzi, Juno Therapeutics, Inc.) for adult patients with large B-cell lymphoma (LBCL) who have refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age. It is not indicated for the treatment of patients with primary central nervous system lymphoma.	6/24/2022
FDA grants accelerated approval to dabrafenib in combination with trametinib for unresectable or metastatic solid tumors with BRAF V600E mutation (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-dabrafenib-combination-trametinib-unresectable-or-metastatic-solid)	On June 22, 2022, the Food and Drug Administration granted accelerated approval to dabrafenib (Tafinlar, Novartis) in combination with trametinib (Mekinist, Novartis) for the treatment of adult and pediatric patients ≥ 6 years of age with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options.	6/22/2022
FDA approves tisagenlecleucel for relapsed or refractory follicular lymphoma (/drugs/resources-information-approved-drugs/fda-approves-tisagenlecleucel-relapsed-or-refractory-follicular-lymphoma)	On May 27, 2022, the Food and Drug Administration granted accelerated approval to tisagenlecleucel (Kymriah, Novartis Pharmaceuticals Corporation) for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.	5/27/2022

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FDA approves Opdivo in combination with chemotherapy and Opdivo in combination with Yervoy for first-line esophageal squamous cell carcinoma indications (/drugs/resources-information-approved-drugs/fda-approves-opdivo-combination-chemotherapy-and-opdivo-combination-yervoy-first-line-esophageal)	On May 27, 2022, the Food and Drug Administration approved the following for the first-line treatment of patients with advanced or metastatic esophageal squamous cell carcinoma (ESCC): • nivolumab (Opdivo, Bristol-Myers Squibb Company) in combination with fluoropyrimidine- and platinum-based chemotherapy • nivolumab in combination with ipilimumab (Yervoy, Bristol-Myers Squibb Company)	5/27/2022
FDA approves ivosidenib in combination with azacitidine for newly diagnosed acute myeloid leukemia (/drugs/resources-information-approved-drugs/fda-approves-ivosidenib-combination-azacitidine-newly-diagnosed-acute-myeloid-leukemia)	On May 25, 2022, the Food and Drug Administration approved ivosidenib (Tibsovo, Servier Pharmaceuticals LLC) in combination with azacitidine for newly diagnosed acute myeloid leukemia (AML) with a susceptible IDH1 mutation, as detected by an FDA-approved test in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.	5/25/2022
FDA approves azacitidine for newly diagnosed juvenile myelomonocytic leukemia (/drugs/resources-information-approved-drugs/fda-approves-azacitidine-newly-diagnosed-juvenile-myelomonocytic-leukemia)	On May 20, 2022, the Food and Drug Administration approved azacitidine (Vidaza, Celgene Corp.) for pediatric patients with newly diagnosed juvenile myelomonocytic leukemia (JMML).	5/20/2022
FDA grants regular approval to fam-trastuzumab deruxtecan-nxki for breast cancer (/drugs/resources-information-approved-drugs/fda-grants-regular-approval-fam-trastuzumab-deruxtecan-nxki-breast-cancer)	On May 4, 2022, the Food and Drug Administration approved fam-trastuzumab deruxtecan-nxki (Enhertu, Daiichi Sankyo, Inc.) for adult patients with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen either in the metastatic setting, or in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within 6 months of completing therapy.	5/4/2022
FDA approves alpelisib for PIK3CA-related overgrowth spectrum (/drugs/resources-information-approved-drugs/fda-approves-alpelisib-pik3ca-related-overgrowth-spectrum)	On April 5, 2022, the Food and Drug Administration granted accelerated approval to alpelisib (Vijoice, Novartis Pharmaceuticals) for adult and pediatric patients two years of age and older with severe manifestations of PIK3CA-related overgrowth spectrum (PROS) who require systemic therapy.	4/6/2022

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FDA approves axicabtagene ciloleucel for second-line treatment of large B-cell lymphoma (/drugs/resources-information-approved-drugs/fda-approves-axicabtagene-ciloleucel-second-line-treatment-large-b-cell-lymphoma)	On April 1, 2022, the Food and Drug Administration approved axicabtagene ciloleucel (Yescarta, Kite Pharma, Inc.) for adult patients with large B-cell lymphoma (LBCL) that is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy. It is not indicated for the treatment of patients with primary central nervous system lymphoma.	4/1/2022
FDA approves Pluvicto for metastatic castration-resistant prostate cancer (/drugs/resources-information-approved-drugs/fda-approves-pluvicto-metastatic-castration-resistant-prostate-cancer)	On March 23, 2022, the Food and Drug Administration approved Pluvicto (lutetium Lu 177 vipivotide tetraxetan, Advanced Accelerator Applications USA, Inc., a Novartis company) for the treatment of adult patients with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.	3/23/2022
FDA approves pembrolizumab for advanced endometrial carcinoma (/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-advanced-endometrial-carcinoma)	On March 21, 2022, the Food and Drug Administration approved pembrolizumab (Keytruda, Merck), as a single agent, for patients with advanced endometrial carcinoma that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), as determined by an FDA-approved test, who have disease progression following prior systemic therapy in any setting and who are not candidates for curative surgery or radiation.	3/21/2022
FDA approves Opdualag for unresectable or metastatic melanoma (/drugs/resources-information-approved-drugs/fda-approves-opdualag-unresectable-or-metastatic-melanoma)	On March 18, 2022, the Food and Drug Administration approved nivolumab and relatlimab-rmbw (Opdualag, Bristol-Myers Squibb Company) for adult and pediatric patients 12 years of age or older with unresectable or metastatic melanoma. Opdualag is a fixed-dose combination of the LAG-3-blocking antibody relatlimab and the programmed death receptor-1 blocking antibody nivolumab	3/18/2022
FDA approves olaparib for adjuvant treatment of high-risk early breast cancer (/drugs/resources-information-approved-drugs/fda-approves-olaparib-adjuvant-treatment-high-risk-early-breast-cancer)	On March 11, 2022, the Food and Drug Administration approved olaparib (Lynparza, AstraZeneca Pharmaceuticals, LP) for the adjuvant treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative high-risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy. Patients must be selected for therapy based on an FDA-approved companion diagnostic for olaparib	3/11/2022

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FDA approves neoadjuvant nivolumab and platinum-doublet chemotherapy for early-stage non-small cell lung cancer (/drugs/resources-information-approved-drugs/fda-approves-neoadjuvant-nivolumab-and-platinum-doublet-chemotherapy-early-stage-non-small-cell-lung)	On March 4, 2022, the Food and Drug Administration approved nivolumab (Opdivo, Bristol-Myers Squibb Company) with platinum-doublet chemotherapy for adult patients with resectable non-small cell lung cancer (NSCLC) in the neoadjuvant setting.	3/4/2022
FDA approves ciltacabtagene autoleucel for relapsed or refractory multiple myeloma (/drugs/resources-information-approved-drugs/fda-approves-ciltacabtagene-autoleucel-relapsed-or-refractory-multiple-myeloma)	On February 28, 2022, the Food and Drug Administration approved ciltacabtagene autoleucel (CARVYKTI, Janssen Biotech, Inc.) for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 monoclonal antibody.	2/28/2022
FDA approves tebentafusp-tebn for unresectable or metastatic uveal melanoma (/drugs/resources-information-approved-drugs/fda-approves-tebentafusp-tebn-unresectable-or-metastatic-uveal-melanoma)	On January 25, 2022, the Food and Drug Administration approved tebentafusp-tebn (Kimmtrak, Immunocore Limited), a bispecific gp100 peptide-HLA-directed CD3 T cell engager, for HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma.	1/25/2022
FDA approves abatacept for prophylaxis of acute graft versus host disease (/drugs/resources-information-approved-drugs/fda-approves-abatacept-prophylaxis-acute-graft-versus-host-disease)	On December 15, 2021, the Food and Drug Administration approved abatacept (Orencia, Bristol-Myers Squibb Company) for the prophylaxis of acute graft versus host disease (aGVHD), in combination with a calcineurin inhibitor (CNI) and methotrexate (MTX), in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation (HSCT) from a matched or 1 allele-mismatched unrelated donor.	12/15/2021
FDA approves pembrolizumab for adjuvant treatment of Stage IIB or IIC melanoma (/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-adjuvant-treatment-stage-iib-or-iic-melanoma)	On December 3,2021, the Food and Drug Administration approved pembrolizumab (Keytruda, Merck) for the adjuvant treatment of adult and pediatric (≥12 years of age) patients with stage IIB or IIC melanoma following complete resection.	12/3/2021
FDA approves rituximab plus chemotherapy for pediatric cancer indications (/drugs/resources-information-approved-drugs/fda-approves-rituximab-plus-chemotherapy-pediatric-cancer-indications)	On December 2, 2021, the Food and Drug Administration approved rituximab (Rituxan, Genentech, Inc.) in combination with chemotherapy for pediatric patients (≥6 months to <18 years) with previously untreated, advanced stage, CD20-positive diffuse large B-cell lymphoma (DLBCL), Burkitt lymphoma (BL), Burkitt-like lymphoma (BLL), or mature B-cell acute leukemia (B-AL).	12/2/2021

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FDA approves Darzalex Faspro, Kyprolis, and Dexamethasone for Multiple Myeloma (/drugs/resources-information-approved-drugs/fda-approves-darzalex-faspro-kyprolis-and-dexamethasone-multiple-myeloma)	On November 30, 2021, the Food and Drug Administration approved daratumumab + hyaluronidase-fihj (Darzalex Faspro, Janssen Biotech, Inc.) and carfilzomib (Kyprolis, Amgen, Inc.) plus dexamethasone foradult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy.	12/01/2021
FDA approves pafolacianine for identifying malignant ovarian cancer lesions (/drugs/resources-information-approved-drugs/fda-approves-pafolacianine-identifying-malignant-ovarian-cancer-lesions)	On November 29, 2021, the Food and Drug Administration approved pafolacianine (Cytalux, On Target Laboratories, LLC), an optical imaging agent, for adult patients with ovarian cancer as an adjunct for interoperative identification of malignant lesions. Pafolacianine is a fluorescent drug that targets folate receptor which may be overexpressed in ovarian cancer. It is used with a Near-Infrared (NIR) fluorescence imaging system cleared by the FDA for specific use with pafolacianine.	11/29/2021
FDA approves sirolimus protein-bound particles for malignant perivascular epithelioid cell tumor (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	On November 22, 2021, the Food and Drug Administration approved sirolimus protein-bound particles for injectable suspension (albumin-bound) (Fyarro, Aadi Bioscience, Inc.) for adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor (PEComa).	11/23/2021
FDA approves pembrolizumab for adjuvant treatment of renal cell carcinoma (/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-adjuvant-treatment-renal-cell-carcinoma)	On November 17, 2021, the Food and Drug Administration approved pembrolizumab (Keytruda, Merck) for the adjuvant treatment of patients with renal cell carcinoma (RCC) at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions.	11/17/2021
FDA approves asciminib for Philadelphia chromosome-positive chronic myeloid leukemia (/drugs/resources-information-approved-drugs/fda-approves-asciminib-philadelphia-chromosome-positive-chronic-myeloid-leukemia)	On October 29, 2021, the Food and Drug Administration granted accelerated approval to asciminib (Scemblix, Novartis AG) for patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP), previously treated with two or more tyrosine kinase inhibitors (TKIs), and approved asciminib for adult patients with Ph+ CML in CP with the T315I mutation.	10/29/2021

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FDA approves atezolizumab as adjuvant treatment for non-small cell lung cancer (/drugs/resources-information-approved-drugs/fda-approves-atezolizumab-adjuvant-treatment-non-small-cell-lung-cancer)	On October 15, 2021, the Food and Drug Administration approved atezolizumab (Tecentriq, Genentech, Inc.) for adjuvant treatment following resection and platinum-based chemotherapy in patients with stage II to IIIA non-small cell lung cancer (NSCLC) whose tumors have PD-L1 expression on ≥ 1% of tumor cells, as determined by an FDA-approved test.	10/15/2021
FDA approves pembrolizumab combination for the first-line treatment of cervical cancer (/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-combination-first-line-treatment-cervical-cancer)	On October 13, 2021, the Food and Drug Administration approved pembrolizumab (Keytruda, Merck) in combination with chemotherapy, with or without bevacizumab, for patients with persistent, recurrent or metastatic cervical cancer whose tumors express PD-L1 (CPS ≥1), as determined by an FDA-approved test.	10/13/2021
FDA approves abemaciclib with endocrine therapy for early breast cancer (/drugs/resources-information-approved-drugs/fda-approves-abemaciclib-endocrine-therapy-early-breast-cancer)	On October 12, 2021, the Food and Drug Administration approved abemaciclib (Verzenio, Eli Lilly and Company) with endocrine therapy (tamoxifen or an aromatase inhibitor) for adjuvant treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive, early breast cancer at high risk of recurrence and a Ki-67 score ≥20%, as determined by an FDA approved test. This is the first CDK 4/6 inhibitor approved for adjuvant treatment of breast cancer.	10/12/2021
FDA recognizes Memorial Sloan-Kettering database of molecular tumor marker information (/drugs/resources-information-approved-drugs/fda-recognizes-memorial-sloan-kettering-database-molecular-tumor-marker-information)	On October 7, 2021, the Food and Drug Administration granted recognition to a partial listing of the Memorial Sloan Kettering Cancer Center's Oncology Knowledge Base (OncoKB) as the first tumor mutation database to be included in the Public Human Genetic Variant Databases (/media/99200/download).	10/7/2021
FDA approves brexucabtagene autoleucel for relapsed or refractory B-cell precursor acute lymphoblastic leukemia (/drugs/resources-information-approved-drugs/fda-approves-brexucabtagene-autoleucel-relapsed-or-refractory-b-cell-precursor-acute-lymphoblastic)	On October 1, 2021, the Food and Drug Administration approved brexucabtagene autoleucel (Tecartus, Kite Pharma, Inc.) for adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL).	10/1/2021
FDA approves ruxolitinib for chronic graft-versus-host disease (/drugs/resources-information-approved-drugs/fda-approves-ruxolitinib-chronic-graft-versus-host-disease)	On September 22, 2021, the Food and Drug Administration approved ruxolitinib (Jakafi, Incyte Corp.) for chronic graft-versus-host disease (cGVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older.	9/22/2021

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FDA grants accelerated approval to tisotumab vedotin-tftv for recurrent or metastatic cervical cancer (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-tisotumab-vedotin-tftv-recurrent-or-metastatic-cervical-cancer)	On September 20, 2021, the Food and Drug Administration granted accelerated approval to tisotumab vedotin-tftv (Tivdak, Seagen Inc.), a tissue factor-directed antibody and microtubule inhibitor conjugate, for adult patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy.	9/20/2021
FDA approves cabozantinib for differentiated thyroid cancer (/drugs/resources-information-approved-drugs/fda-approves-cabozantinib-differentiated-thyroid-cancer)	On September 17, 2021, the Food and Drug Administration approved cabozantinib (Cabometyx, Exelixis, Inc.) for adult and pediatric patients 12 years of age and older with locally advanced or metastatic differentiated thyroid cancer (DTC) that has progressed following prior VEGFR-targeted therapy and who are ineligible or refractory to radioactive iodine.	9/17/2021
FDA grants accelerated approval to mobocertinib for metastatic non-small cell lung cancer with EGFR exon 20 insertion mutations (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-mobocertinib-metastatic-non-small-cell-lung-cancer-egfr-exon-20)	Food and Drug Administration granted accelerated approval to mobocertinib (Exkivity, Takeda Pharmaceuticals, Inc.) for adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.	9/15/2021
FDA grants accelerated approval to zanubrutinib for marginal zone lymphoma (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-zanubrutinib-marginal-zone-lymphoma)	Food and Drug Administration granted accelerated approval to zanubrutinib (Brukinsa, BeiGene) for adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen.	9/14/2021
FDA approves zanubrutinib for Waldenström's macroglobulinemia (/drugs/resources-information-approved-drugs/fda-approves-zanubrutinib-waldenstroms-macroglobulinemia)	Food and Drug Administration approved zanubrutinib (Brukinsa, BeiGene) for adult patients with Waldenström's macroglobulinemia (WM).	9/1/2021
FDA approves ivosidenib for advanced or metastatic cholangiocarcinoma (/drugs/resources-information-approved-drugs/fda-approves-ivosidenib-advanced-or-metastatic-cholangiocarcinoma)	Food and Drug Administration approved ivosidenib (Tibsovo, Servier Pharmaceuticals LLC) for adult patients with previously treated, locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test.	8/25/2021
FDA approves nivolumab for adjuvant treatment of urothelial carcinoma (/drugs/resources-information-approved-drugs/fda-approves-nivolumab-adjuvant-treatment-urothelial-carcinoma)	Food and Drug Administration approved nivolumab (Opdivo, Bristol-Myers Squibb Co.) for the adjuvant treatment of patients with urothelial carcinoma (UC) who are at high risk of recurrence after undergoing radical resection.	8/19/2021

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FDA grants accelerated approval to dostarlimab-gxly for dMMR advanced solid tumors (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-dostarlimab-gxly-dmmr-advanced-solid-tumors)	Food and Drug Administration granted accelerated approval to dostarlimab-gxly (Jemperli, GlaxoSmithKline LLC) for adult patients with mismatch repair deficient (dMMR) recurrent or advanced solid tumors, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options.	8/18/2021
FDA approves belzutifan for cancers associated with von Hippel-Lindau disease (/drugs/resources-information-approved-drugs/fda-approves-belzutifan-cancers-associated-von-hippel-lindau-disease)	Food and Drug Administration approved belzutifan (Welireg, Merck), a hypoxia-inducible factor inhibitor for adult patients with von Hippel-Lindau (VHL) disease who require therapy for associated renal cell carcinoma (RCC), central nervous system (CNS) hemangioblastomas, or pancreatic neuroendocrine tumors (pNET), not requiring immediate surgery	8/13/2021
FDA approves lenvatinib plus pembrolizumab for advanced renal cell carcinoma (/drugs/resources-information-approved-drugs/fda-approves-lenvatinib-plus-pembrolizumab-advanced-renal-cell-carcinoma)	Food and Drug Administration approved the combination of lenvatinib (Lenvima, Eisai) plus pembrolizumab (Keytruda, Merck) for first-line treatment of adult patients with advanced renal cell carcinoma (RCC).	8/10/2021
FDA approves pembrolizumab for high-risk early-stage triple-negative breast cancer (/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-high-risk-early-stage-triple-negative-breast-cancer)	Food and Drug Administration approved pembrolizumab (Keytruda, Merck) for high-risk, early-stage, triple-negative breast cancer (TNBC) in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery.	7/26/2021
FDA grants regular approval to pembrolizumab and lenvatinib for advanced endometrial carcinoma (/drugs/resources-information-approved-drugs/fda-grants-regular-approval-pembrolizumab-and-lenvatinib-advanced-endometrial-carcinoma)	Food and Drug Administration approved pembrolizumab (Keytruda, Merck) in combination with lenvatinib (Lenvima, Eisai) for patients with advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation.	7/21/2021
FDA approves belumosudil for chronic graft-versus-host disease (/drugs/resources-information-approved-drugs/fda-approves-belumosudil-chronic-graft-versus-host-disease)	Food and Drug Administration approved belumosudil (Rezurock, Kadmon Pharmaceuticals, LLC), a kinase inhibitor, for adult and pediatric patients 12 years and older with chronic graft-versus-host disease (chronic GVHD) after failure of at least two prior lines of systemic therapy.	7/16/2021

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FDA approves daratumumab and hyaluronidase-fihj with pomalidomide and dexamethasone for multiple myeloma (/drugs/resources-information-approved-drugs/fda-approves-daratumumab-and-hyaluronidase-fihj-pomalidomide-and-dexamethasone-multiple-myeloma)	Food and Drug Administration approved daratumumab and hyaluronidase-fihj (Darzalex Faspro, Janssen Biotech, Inc.) in combination with pomalidomide and dexamethasone for adult patients with multiple myeloma who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor.	7/9/2021
FDA grants regular approval to enfortumab vedotin-ejfv for locally advanced or metastatic urothelial cancer (/drugs/resources-information-approved-drugs/fda-grants-regular-approval-enfortumab-vedotin-ejfv-locally-advanced-or-metastatic-urothelial-cancer)	Food and Drug Administration approved enfortumab vedotin-ejfv (Padcev, Astellas Pharma US, Inc.), a Nectin-4-directed antibody and microtubule inhibitor conjugate, for adult patients with locally advanced or metastatic urothelial cancer who • have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand (PD-L1) inhibitor and platinum-containing chemotherapy, or • are ineligible for cisplatin-containing chemotherapy and have previously received one or more prior lines of therapy.	7/9/2021
FDA approves asparaginase erwinia chrysanthemi (recombinant) for leukemia and lymphoma (/drugs/resources-information-approved-drugs/fda-approves-asparaginase-erwinia-chrysanthemi-recombinant-leukemia-and-lymphoma)	Food and Drug Administration approved asparaginase erwinia chrysanthemi (recombinant)-rywn) (Rylaze, Jazz Pharmaceuticals, Inc.) as a component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month or older who have developed hypersensitivity to E. coli-derived asparaginase. .	7/1/2021
FDA approves avapritinib for advanced systemic mastocytosis (/drugs/resources-information-approved-drugs/fda-approves-avapritinib-advanced-systemic-mastocytosis)	Food and Drug Administration approved avapritinib (Ayvakit™, Blueprint Medicines Corp.) for adult patients with advanced systemic mastocytosis (AdvSM), including patients with aggressive systemic mastocytosis (ASM), systemic mastocytosis with an associated hematological neoplasm (SM-AHN), and mast cell leukemia (MCL).	6/16/2021
FDA grants accelerated approval to infigratinib for metastatic cholangiocarcinoma (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-infigratinib-metastatic-cholangiocarcinoma)	Food and Drug Administration granted accelerated approval to infigratinib (Truseltiq, QED Therapeutics, Inc.), a kinase inhibitor for adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test	5/28/2021

Webpage (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Description (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Date (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)
FDA grants accelerated approval to sotorasib for KRAS G12C mutated NSCLC (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-sotorasib-kras-g12c-mutated-nsclc)	Food and Drug Administration granted accelerated approval to sotorasib (Lumakras™, Amgen, Inc.), a RAS GTPase family inhibitor, for adult patients with KRAS G12C mutated locally advanced or metastatic non-small cell lung cancer (NSCLC), as determined by an FDA approved test, who have received at least one prior systemic therapy.	5/28/2021
FDA grants accelerated approval to amivantamab-vmjw for metastatic non-small cell lung cancer (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-amivantamab-vmjw-metastatic-non-small-cell-lung-cancer)	FDA granted accelerated approval to amivantamab-vmjw (Rybrevant, Janssen Biotech, Inc.) for adult patients with locally advanced or metastatic non-small cell lung cancer with EGFR exon 20 insertion mutations that progressed on or after platinum-based chemotherapy.	5/21/2021
FDA approves nivolumab for resected esophageal or GEJ cancer (/drugs/resources-information-approved-drugs/fda-approves-nivolumab-resected-esophageal-or-gej-cancer)	Food and Drug Administration approved nivolumab (Opdivo, Bristol-Myers Squibb Company) for patients with completely resected esophageal or gastroesophageal junction (GEJ) cancer with residual pathologic disease who have received neoadjuvant chemoradiotherapy.	5/20/2021
FDA grants accelerated approval to pembrolizumab for HER2-positive gastric cancer (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-pembrolizumab-her2-positive-gastric-cancer)	Food and Drug Administration granted accelerated approval to pembrolizumab (Keytruda, Merck & Co.) in combination with trastuzumab, fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic HER2 positive gastric or gastroesophageal junction (GEJ) adenocarcinoma.	5/5/2021
FDA grants accelerated approval to loncastuximab tesirine-lpyl for large B-cell lymphoma (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-loncastuximab-tesirine-lpyl-large-b-cell-lymphoma)	On April 23, 2021, the Food and Drug Administration granted accelerated approval to loncastuximab tesirine-lpyl (Zynlonta, ADC Therapeutics SA), a CD19-directed antibody and alkylating agent conjugate, for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma.	4/23/2021
FDA grants accelerated approval to dostarlimab-gxly for dMMR endometrial cancer (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-dostarlimab-gxly-dmmr-endometrial-cancer)	Food and Drug Administration granted accelerated approval to dostarlimab-gxly (Jemperli, GlaxoSmithKline LLC) for adult patients with mismatch repair deficient (dMMR) recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following a prior platinum-containing regimen.	4/22/2021

Webpage (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Description (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Date (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)
FDA approves nivolumab in combination with chemotherapy for metastatic gastric cancer and esophageal adenocarcinoma (/drugs/resources-information-approved-drugs/fda-approves-nivolumab-combination-chemotherapy-metastatic-gastric-cancer-and-esophageal)	Food and Drug Administration approved nivolumab (Opdivo, Bristol-Myers Squibb Company) in combination with fluoropyrimidine- and platinum-containing chemotherapy for advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.	4/16/2021
FDA grants accelerated approval to sacituzumab govitecan for advanced urothelial cancer (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-sacituzumab-govitecan-advanced-urothelial-cancer)	FDA grants accelerated approval to sacituzumab govitecan for advanced urothelial cancer.	4/13/2021
FDA grants regular approval to sacituzumab govitecan for triple-negative breast cancer (/drugs/resources-information-approved-drugs/fda-grants-regular-approval-sacituzumab-govitecan-triple-negative-breast-cancer)	Food and Drug Administration granted regular approval to sacituzumab govitecan (Trodelvy, Immunomedics Inc.) for patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.	4/7/2021
FDA approves new dosing regimen for cetuximab (/drugs/resources-information-approved-drugs/fda-approves-new-dosing-regimen-cetuximab)	Food and Drug Administration approved a new dosage regimen of 500 mg/m2 as a 120-minute intravenous infusion every two weeks (Q2W) for cetuximab (Erbitux, ImClone LLC) for patients with K-Ras wild-type, EGFR-expressing colorectal cancer (mCRC) or squamous cell carcinoma of the head and neck (SCCHN).	4/6/2021
FDA approves isatuximab-irfc for multiple myeloma (/drugs/resources-information-approved-drugs/fda-approves-isatuximab-irfc-multiple-myeloma)	Food and Drug Administration approved isatuximab-irfc (Sarclisa, sanofi-aventis U.S. LLC) in combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. March 31, 2021	3/31/2021
FDA approves idecabtagene vicleucel for multiple myeloma (/drugs/resources-information-approved-drugs/fda-approves-idecabtagene-vicleucel-multiple-myeloma)	Food and Drug Administration approved idecabtagene vicleucel (Abecma, Bristol Myers Squibb) for the treatment of adult patients with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. This is the first FDA-approved cell-based gene therapy for multiple myeloma. March 26, 2021	3/26/2021

Webpage (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Description (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Date (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)
FDA approves pembrolizumab for esophageal or GEJ carcinoma (/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-esophageal-or-gej-carcinoma)	Food and Drug Administration approved pembrolizumab (Keytruda, Merck Sharp & Dohme Corp.) in combination with platinum and fluoropyrimidine-based chemotherapy for patients with metastatic or locally advanced esophageal or gastroesophageal (GEJ) (tumors with epicenter 1 to 5 centimeters above the gastroesophageal junction) carcinoma who are not candidates for surgical resection or definitive chemoradiation. March 22, 2021.	3/22/2021
FDA approves tivozanib for relapsed or refractory advanced renal cell carcinoma (/drugs/resources-information-approved-drugs/fda-approves-tivozanib-relapsed-or-refractory-advanced-renal-cell-carcinoma)	Food and Drug Administration approved tivozanib (Fotivda, AVEO Pharmaceuticals, Inc.), a kinase inhibitor, for adult patients with relapsed or refractory advanced renal cell carcinoma (RCC) following two or more prior systemic therapies. March 10, 2021	3/10/2021
FDA grants accelerated approval to axicabtagene ciloleucel for relapsed or refractory follicular lymphoma (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-axicabtagene-ciloleucel-relapsed-or-refractory-follicular-lymphoma)	Food and Drug Administration granted accelerated approval to axicabtagene ciloleucel (Yescarta, Kite Pharma, Inc.) for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.	3/5/2021
FDA approves lorlatinib for metastatic ALK-positive NSCLC (/drugs/resources-information-approved-drugs/fda-approves-lorlatinib-metastatic-alk-positive-nsclc)	Food and Drug Administration granted regular approval to lorlatinib (Lorbrena, Pfizer Inc.) for patients with metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive, detected by an FDA-approved test. March 3, 2021	3/3/2021
FDA grants accelerated approval to melphalan flufenamide for relapsed or refractory multiple myeloma (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-melphalan-flufenamide-relapsed-or-refractory-multiple-myeloma)	Food and Drug Administration granted accelerated approval to melphalan flufenamide (Pepaxto, Oncopeptides AB) in combination with dexamethasone for adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and one CD-38 directed monoclonal antibody.Efficacy was evaluated in HORIZON (NCT02963493), a multicenter, single-arm trial. Eligible patients were required to have relapsed refractory multiple myeloma. Patients received melphalan flufenamide 40 mg intravenously on day 1 and dexamethasone 40 mg orally (20 mg for patients ≥75 years of age) on day 1, 8, 15 and 22 of each 28-day cycle until disease progression or unacceptable toxicity.	2/26/2021

Webpage (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Description (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Date (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)
FDA approves cemiplimab-rwlc for non-small cell lung cancer with high PD-L1 expression (/drugs/resources-information-approved-drugs/fda-approves-cemiplimab-rwlc-non-small-cell-lung-cancer-high-pd-l1-expression)	Food and Drug Administration approved cemiplimab-rwlc (Libtayo, Regeneron Pharmaceuticals, Inc.) for the first-line treatment of patients with advanced non-small cell lung cancer (NSCLC) (locally advanced who are not candidates for surgical resection or definitive chemoradiation or metastatic) whose tumors have high PD-L1 expression (Tumor Proportion Score [TPS] > 50%) as determined by an FDA-approved test, with no EGFR, ALK or ROS1 aberrations.	2/22/2021
FDA approves cemiplimab-rwlc for locally advanced and metastatic basal cell carcinoma (/drugs/resources-information-approved-drugs/fda-approves-cemiplimab-rwlc-locally-advanced-and-metastatic-basal-cell-carcinoma)	Food and Drug Administration approved cemiplimab-rwlc for locally advanced and metastatic basal cell carcinoma.	2/9/2021
FDA approves lisocabtagene maraleucel for relapsed or refractory large B-cell lymphoma (/drugs/resources-information-approved-drugs/fda-approves-lisocabtagene-maraleucel-relapsed-or-refractory-large-b-cell-lymphoma)	Food and Drug Administration approved lisocabtagene maraleucel (Breyanzi, Juno Therapeutics, Inc.) for the treatment of adult patients with relapsed or refractory (R/R) large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal large B-cell lymphoma, and follicular lymphoma grade 3B. February 5, 2021	2/5/2021
FDA grants accelerated approval to umbralisib for marginal zone lymphoma and follicular lymphoma (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-umbralisib-marginal-zone-lymphoma-and-follicular-lymphoma)	Food and Drug Administration granted accelerated approval to umbralisib (Ukoniq, TG Therapeutics), a kinase inhibitor including PI3K-delta and casein kinase CK1-epsilon, for the following indications: Adult patients with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one prior anti-CD20-based regimen; Adult patients with relapsed or refractory follicular lymphoma (FL) who have received at least three prior lines of systemic therapy.	2/5/2021
FDA grants accelerated approval to tepotinib for metastatic non-small cell lung cancer (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-tepotinib-metastatic-non-small-cell-lung-cancer)	Food and Drug Administration granted accelerated approval to tepotinib (Tepmetko, EMD Serono Inc.) for adult patients with metastatic non-small cell lung cancer (NSCLC) harboring mesenchymal-epithelial transition (MET) exon 14 skipping alterations.	2/3/2021
FDA approves nivolumab plus cabozantinib for advanced renal cell carcinoma (/drugs/resources-information-approved-drugs/fda-approves-nivolumab-plus-cabozantinib-advanced-renal-cell-carcinoma)	Food and Drug Administration approved the combination of nivolumab (Opdivo, Bristol-Myers Squibb Co.) and cabozantinib (Cabometyx, Exelixis) as first-line treatment for patients with advanced renal cell carcinoma (RCC).	1/22/2021

Webpage (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Description (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Date (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)
FDA grants accelerated approval to Darzalex Faspro for newly diagnosed light chain amyloidosis (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-darzalex-faspro-newly-diagnosed-light-chain-amyloidosis)	Food and Drug Administration granted accelerated approval to daratumumab plus hyaluronidase (Darzalex Faspro, Janssen Biotech Inc.) in combination with bortezomib, cyclophosphamide and dexamethasone for newly diagnosed light chain (AL) amyloidosis.	1/15/2021
FDA approves fam-trastuzumab deruxtecan-nxki for HER2-positive gastric adenocarcinomas (/drugs/resources-information-approved-drugs/fda-approves-fam-trastuzumab-deruxtecan-nxki-her2-positive-gastric-adenocarcinomas)	Food and Drug Administration approved fam-trastuzumab deruxtecan-nxki (Enhertu, Daiichi Sankyo) for adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal (GEJ) adenocarcinoma who have received a prior trastuzumab-based regimen.	1/15/2021
FDA approves crizotinib for children and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (/drugs/resources-information-approved-drugs/fda-approves-crizotinib-children-and-young-adults-relapsed-or-refractory-systemic-anaplastic-large)	Food and Drug Administration approved crizotinib (Xalkori, Pfizer Inc.) for pediatric patients 1 year of age and older and young adults with relapsed or refractory, systemic anaplastic large cell lymphoma (ALCL) that is ALK-positive. The safety and efficacy of crizotinib have not been established in older adults with relapsed or refractory, systemic ALK-positive ALCL.	1/14/2021
FDA approves osimertinib as adjuvant therapy for non-small cell lung cancer with EGFR mutations (/drugs/resources-information-approved-drugs/fda-approves-osimertinib-adjuvant-therapy-non-small-cell-lung-cancer-egfr-mutations)	Food and Drug Administration approved osimertinib (TAGRISSO, AstraZeneca Pharmaceuticals LP) for adjuvant therapy after tumor resection in patients with non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.	12/18/2020
FDA approves relugolix for advanced prostate cancer (/drugs/resources-information-approved-drugs/fda-approves-relugolix-advanced-prostate-cancer)	Food and Drug Administration approved the first oral gonadotropin-releasing hormone (GnRH) receptor antagonist, relugolix, (ORGOVYX, Myovant Sciences, Inc.) for adult patients with advanced prostate cancer.	12/18/2020
FDA approves selinexor for refractory or relapsed multiple myeloma (/drugs/resources-information-approved-drugs/fda-approves-selinexor-refractory-or-relapsed-multiple-myeloma)	Food and Drug Administration approved selinexor (XPOVIO, Karyopharm Therapeutics Inc.) in combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least one prior therapy.	12/18/2020
FDA approves margetuximab for metastatic HER2-positive breast cancer (/drugs/resources-information-approved-drugs/fda-approves-margetuximab-metastatic-her2-positive-breast-cancer)	Food and Drug Administration approved margetuximab-cmkb (MARGENZA, MacroGenics) in combination with chemotherapy, for the treatment of adult patients with metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 regimens, at least one of which was for metastatic disease.	12/16/2020

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FDA approves pralsetinib for RET-altered thyroid cancers (/drugs/resources-information-approved-drugs/fda-approves-pralsetinib-ret-altered-thyroid-cancers)	Food and Drug Administration approved pralsetinib (GAVRETO, Blueprint Medicines Corporation) for adult and pediatric patients 12 years of age and older with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy or RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).	12/1/2020
FDA approves device for treatment of osteoid osteoma in the extremities (/drugs/resources-information-approved-drugs/fda-approves-device-treatment-osteoid-osteoma-extremities)	Food and Drug Administration approved the Sonalleve MR-HIFU system (Profound Medical Inc.) for the treatment of osteoid osteoma in the extremities.	11/27/2020
FDA grants accelerated approval to naxitamab for high-risk neuroblastoma in bone or bone marrow (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-naxitamab-high-risk-neuroblastoma-bone-or-bone-marrow)	Food and Drug Administration granted accelerated approval to naxitamab (DANYELZA, Y-mAbs Therapeutics, Inc.) in combination with granulocyte-macrophage colony-stimulating factor (GM-CSF) for pediatric patients one year of age and older and adult patients with relapsed or refractory high-risk neuroblastoma in the bone or bone marrow demonstrating a partial response, minor response, or stable disease to prior therapy.	11/25/2020
FDA grants accelerated approval to pembrolizumab for locally recurrent unresectable or metastatic triple negative breast cancer (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-pembrolizumab-locally-recurrent-unresectable-or-metastatic-triple)	Food and Drug Administration granted accelerated approval to pembrolizumab (KEYTRUDA, Merck & Co.) in combination with chemotherapy for the treatment of patients with locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (CPS ≥10) as determined by an FDA approved test.	11/13/2020
FDA approves liquid biopsy NGS companion diagnostic test for multiple cancers and biomarkers (/drugs/resources-information-approved-drugs/fda-approves-liquid-biopsy-ngs-companion-diagnostic-test-multiple-cancers-and-biomarkers)	Food and Drug Administration approved the liquid biopsy next-generation sequencing-based FoundationOne Liquid CDx test (Foundation Medicine, Inc.) as a companion diagnostic device for multiple additional biomarkers detected in cell free-DNA isolated from plasma specimens. October 26, 2020 and November 6, 2020.	10/26/2020
FDA Approves Companion Diagnostic to identify NTRK fusions in solid tumors for Vitrakvi (/drugs/resources-information-approved-drugs/fda-approves-companion-diagnostic-identify-ntrk-fusions-solid-tumors-vitrakvi)	Food and Drug Administration approved the next-generation sequencing (NGS)-based FoundationOne CDx test (Foundation Medicine, Inc.) as a companion diagnostic to identify fusions in neurotrophic receptor tyrosine kinase (NTRK) genes, NTRK1, NTRK2, and NTRK3, in DNA isolated from tumor tissue specimens from patients with solid tumors eligible for treatment with larotrectinib (VITRAKVI, Bayer Healthcare Pharmaceuticals, Inc.). October 26, 2020	10/26/2020

Webpage (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Description (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Date (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)
FDA grants regular approval to venetoclax in combination for untreated acute myeloid leukemia (/drugs/resources-information-approved-drugs/fda-grants-regular-approval-venetoclax-combination-untreated-acute-myeloid-leukemia)	Food and Drug Administration grants regular approval to venetoclax in combination for untreated acute myeloid leukemia.	10/16/2020
FDA extends approval of pembrolizumab for classical Hodgkin lymphoma (/drugs/resources-information-approved-drugs/fda-extends-approval-pembrolizumab-classical-hodgkin-lymphoma)	Food and Drug Administration extended the approval of pembrolizumab (KEYTRUDA®, Merck Sharp & Dohme Corp.) for the following indications: adult patients with relapsed or refractory classical Hodgkin lymphoma (cHL) and pediatric patients with refractory cHL, or cHL that has relapsed after 2 or more lines of therapy.	10/14/2020
FDA approves nivolumab and ipilimumab for unresectable malignant pleural mesothelioma (/drugs/resources-information-approved-drugs/fda-approves-nivolumab-and-ipilimumab-unresectable-malignant-pleural-mesothelioma)	Food and Drug Administration approved the combination of nivolumab (OPDIVO, Bristol-Myers Squibb Co.) plus ipilimumab (YERVOY, Bristol-Myers Squibb Co.) as first-line treatment for adult patients with unresectable malignant pleural mesothelioma.	10/2/2020
FDA issues alert about efficacy and potential safety concerns with atezolizumab in combination with paclitaxel for treatment of breast cancer (/drugs/resources-information-approved-drugs/fda-issues-alert-about-efficacy-and-potential-safety-concerns-atezolizumab-combination-paclitaxel)	Food and Drug Administration alerted health care professionals and oncology clinical investigators about efficacy and potential safety concerns with atezolizumab in combination with paclitaxel for treatment of breast cancer.	9/8/2020
FDA approves pralsetinib for lung cancer with RET gene fusions (/drugs/resources-information-approved-drugs/fda-approves-pralsetinib-lung-cancer-ret-gene-fusions)	Food and Drug Administration granted accelerated approval to pralsetinib (GAVRETO, Blueprint Medicines Corporation) for adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as detected by an FDA approved test.	9/4/2020
FDA approves Onureg (azacitidine tablets) for acute myeloid leukemia (/drugs/resources-information-approved-drugs/fda-approves-onureg-azacitidine-tablets-acute-myeloid-leukemia)	Food and Drug Administration approved azacitidine tablets (ONUREG, Celgene Corporation) for continued treatment of patients with acute myeloid leukemia who achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy and are not able to complete intensive curative therapy.	9/1/2020
FDA Approves Liquid Biopsy Next-Generation Sequencing Companion Diagnostic Test (/news-events/press-announcements/fda-approves-first-liquid-biopsy-next-generation-sequencing-companion-diagnostic-test)	Food and Drug Administration approved the liquid biopsy next-generation sequencing-based FoundationOne Liquid CDx test (Foundation Medicine, Inc.) as a companion diagnostic to identify mutations in BRCA1 and BRCA2 genes in cell free-DNA isolated from plasma specimens from patients with metastatic castration-resistant prostate cancer (mCRPC) eligible for treatment with rucaparib (RUBRACA, Clovis Oncology, Inc.).	8/26/2020

Webpage (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Description (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Date (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)
FDA approves carfilzomib and daratumumab with dexamethasone for multiple myeloma (/drugs/resources-information-approved-drugs/fda-approves-carfilzomib-and-daratumumab-dexamethasone-multiple-myeloma)	On August 20, 2020, the Food and Drug Administration approved carfilzomib (KYPROLIS, Onyx Pharmaceuticals, Inc.) and daratumumab (DARZALEX, Janssen Biotech, Inc.) in combination with dexamethasone for adult patients with relapsed or refractory multiple myeloma who have received one to three lines of therapy.	8/20/2020
FDA granted accelerated approval to belantamab mafodotin-blmf for multiple myeloma (/drugs/resources-information-approved-drugs/fda-granted-accelerated-approval-belantamab-mafodotin-blmf-multiple-myeloma)	Food and Drug Administration approved belantamab mafodotin-blmf (Blenrep, GlaxoSmithKline) for adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.	8/5/2020
FDA grants accelerated approval to tafasitamab-cxix for diffuse large B-cell lymphoma (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-tafasitamab-cxix-diffuse-large-b-cell-lymphoma)	FDA granted accelerated approval to tafasitamab-cxix (MONJUVI, MorphoSys US Inc.), a CD19-directed cytolytic antibody, indicated in combination with lenalidomide for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant.	7/31/2020
FDA approves atezolizumab for BRAF V600 unresectable or metastatic melanoma (/drugs/resources-information-approved-drugs/fda-approves-atezolizumab-braf-v600-unresectable-or-metastatic-melanoma)	Food and Drug Administration approved atezolizumab (Tecentriq, Genentech, Inc.) in combination with cobimetinib and vemurafenib for patients with BRAF V600 mutation-positive unresectable or metastatic melanoma.	7/30/2020
FDA approves brexucabtagene autoleucel for relapsed or refractory mantle cell lymphoma (/drugs/resources-information-approved-drugs/fda-approves-brexucabtagene-autoleucel-relapsed-or-refractory-mantle-cell-lymphoma)	Food and Drug Administration granted accelerated approval to brexucabtagene autoleucel (TECARTUS, Kite, a Gilead Company), a CD19-directed genetically modified autologous T cell immunotherapy, for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).	7/24/2020
FDA approves oral combination of decitabine and cedazuridine for myelodysplastic syndromes (/drugs/resources-information-approved-drugs/fda-approves-oral-combination-decitabine-and-cedazuridine-myelodysplastic-syndromes)	Food and Drug Administration approved an oral combination of decitabine and cedazuridine (INQOVI, Astex Pharmaceuticals, Inc.) for adult patients with myelodysplastic syndromes (MDS) including the following:	7/7/2020
FDA approves avelumab for urothelial carcinoma maintenance treatment (/drugs/drug-approvals-and-databases/fda-approves-avelumab-urothelial-carcinoma-maintenance-treatment)	Food and Drug Administration approved avelumab (BAVENCIO, EMD Serono, Inc.) for maintenance treatment of patients with locally advanced or metastatic urothelial carcinoma (UC) that has not progressed with first-line platinum-containing chemotherapy.	6/30/2020

Webpage (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Description (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Date (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)
FDA approves pembrolizumab for first-line treatment of MSI-H/dMMR colorectal cancer (/drugs/drug-approvals-and-databases/fda-approves-pembrolizumab-first-line-treatment-msi-hdmmr-colorectal-cancer)	Food and Drug Administration approved pembrolizumab (KEYTRUDA, Merck & Co.) for the first-line treatment of patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer. June 29, 2020	6/29/2020
FDA approves combination of pertuzumab, trastuzumab, and hyaluronidase-zzxf for HER2-positive breast cancer (/drugs/drug-approvals-and-databases/fda-approves-combination-pertuzumab-trastuzumab-and-hyaluronidase-zzxf-her2-positive-breast-cancer)	Food and Drug Administration approved a new fixed-dose combination of pertuzumab, trastuzumab, and hyaluronidase–zzxf (PHESGO, Genentech, Inc.) for subcutaneous injection	6/29/2020
FDA approves pembrolizumab for cutaneous squamous cell carcinoma (/drugs/drug-approvals-and-databases/fda-approves-pembrolizumab-cutaneous-squamous-cell-carcinoma)	Food and Drug Administration approved pembrolizumab (KEYTRUDA, Merck & Co., Inc.) for patients with recurrent or metastatic cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation	6/24/2020
FDA approves selinexor for relapsed/refractory diffuse large B-cell lymphoma (/drugs/resources-information-approved-drugs/fda-approves-selinexor-relapsedrefractory-diffuse-large-b-cell-lymphoma)	Food and Drug Administration granted accelerated approval to selinexor (XPOVIO, Karyopharm Therapeutics) for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma, after at least 2 lines of systemic therapy.	6/22/2020
FDA granted accelerated approval to tazemetostat for follicular lymphoma (/drugs/fda-granted-accelerated-approval-tazemetostat-follicular-lymphoma)	Food and Drug Administration granted accelerated approval to tazemetostat (TAZVERIK, Epizyme, Inc.), an EZH2 inhibitor, for adult patients with relapsed or refractory (R/R) follicular lymphoma (FL) whose tumors are positive for an EZH2 mutation as detected by an FDA-approved test and who have received at least 2 prior systemic therapies, and for adult patients with R/R FL who have no satisfactory alternative treatment options.	6/18/2020
FDA approves pembrolizumab for adults and children with TMB-H solid tumors (/drugs/drug-approvals-and-databases/fda-approves-pembrolizumab-adults-and-children-tmb-h-solid-tumors)	Food and Drug Administration granted accelerated approval to pembrolizumab (KEYTRUDA, Merck & Co., Inc.) for the treatment of adult and pediatric patients with unresectable or metastatic tumor mutational burden-high (TMB H) [≥10 mutations/megabase (mut/Mb)] solid tumors, as determined by an FDA-approved test, that have progressed following prior treatment and who have no satisfactory alternative treatment options.	6/16/2020

Webpage (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Description (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Date (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)
FDA approves gemtuzumab ozogamicin for CD33-positive AML in pediatric patients (/drugs/drug-approvals-and-databases/fda-approves-gemtuzumab-ozogamicin-cd33-positive-aml-pediatric-patients)	Food and Drug Administration extended the indication of gemtuzumab ozogamicin (MYLOTARG, Wyeth Pharmaceuticals LLC) for newly-diagnosed CD33-positive acute myeloid leukemia (AML) to include pediatric patients 1 month and older.	6/16/2020
FDA grants accelerated approval to lurbinectedin for metastatic small cell lung cancer (/drugs/drug-approvals-and-databases/fda-grants-accelerated-approval-lurbinectedin-metastatic-small-cell-lung-cancer)	Food and Drug Administration granted accelerated approval to lurbinectedin(ZEPZELCA, Pharma Mar S.A.) for adult patients with metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy. June 15, 2020	6/15/2020
FDA approves nivolumab for esophageal squamous cell carcinoma (/drugs/drug-approvals-and-databases/fda-approves-nivolumab-esophageal-squamous-cell-carcinoma)	Food and Drug Administration approved nivolumab (OPDIVO, Bristol-Myers Squibb Co.) for patients with unresectable advanced, recurrent or metastatic esophageal squamous cell carcinoma (ESCC) after prior fluoropyrimidine- and platinum-based chemotherapy.	6/10/2020
FDA approves ramucirumab plus erlotinib for first-line metastatic NSCLC (/drugs/resources-information-approved-drugs/fda-approves-ramucirumab-plus-erlotinib-first-line-metastatic-nsclc)	Food and Drug Administration approved ramucirumab (CYRAMZA, Eli Lilly and Company) in combination with erlotinib for first-line treatment of metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) mutations.	5/29/2020
FDA approves atezolizumab plus bevacizumab for unresectable hepatocellular carcinoma (/drugs/resources-information-approved-drugs/fda-approves-atezolizumab-plus-bevacizumab-unresectable-hepatocellular-carcinoma)	Food and Drug Administration approved atezolizumab in combination with bevacizumab (TECENTRIQ and AVASTIN, Genentech Inc.) for patients with unresectable or metastatic hepatocellular carcinoma who have not received prior systemic therapy.	5/29/2020
FDA approves nivolumab plus ipilimumab and chemotherapy for first-line treatment of metastatic NSCLC (/drugs/resources-information-approved-drugs/fda-approves-nivolumab-plus-ipilimumab-and-chemotherapy-first-line-treatment-metastatic-nsclc)	Food and Drug Administration approved the combination of nivolumab (OPDIVO, Bristol-Myers Squibb Co.) plus ipilimumab (YERVOY, Bristol-Myers Squibb Co.) and 2 cycles of platinum-doublet chemotherapy as first-line treatment for patients with metastatic or recurrent non-small cell lung cancer (NSCLC), with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.	5/26/2020
FDA approves brigatinib for ALK-positive metastatic NSCLC (/drugs/resources-information-approved-drugs/fda-approves-brigatinib-alk-positive-metastatic-nsclc)	Food and Drug Administration approved brigatinib (ALUNBRIG, ARIAD Pharmaceuticals Inc.) for adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.	5/22/2020

Webpage (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Description (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Date (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)
FDA approves olaparib for HRR gene-mutated metastatic castration-resistant prostate cancer (/drugs/resources-information-approved-drugs/fda-approves-olaparib-hrr-gene-mutated-metastatic-castration-resistant-prostate-cancer)	Food and Drug Administration approved olaparib (LYNPARZA, AstraZeneca Pharmaceuticals, LP) for adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC), who have progressed following prior treatment with enzalutamide or abiraterone.	5/19/2020
FDA approves atezolizumab for first-line treatment of metastatic NSCLC with high PD-L1 expression (/drugs/resources-information-approved-drugs/fda-approves-atezolizumab-first-line-treatment-metastatic-nsclc-high-pd-l1-expression)	Food and Drug Administration approved atezolizumab (TECENTRIQ®, Genentech Inc.) for the first-line treatment of adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (PD-L1 stained ≥ 50% of tumor cells [TC ≥ 50%] or PD-L1 stained tumor-infiltrating immune cells [IC] covering ≥ 10% of the tumor area [IC ≥ 10%]), with no EGFR or ALK genomic tumor aberrations. May 18, 2020	5/18/2020
FDA approves ripretinib for advanced gastrointestinal stromal tumor (/drugs/resources-information-approved-drugs/fda-approves-ripretinib-advanced-gastrointestinal-stromal-tumor)	Food and Drug Administration approved ripretinib (QINLOCK, Deciphera Pharmaceuticals, LLC.), for adult patients with advanced gastrointestinal stromal tumor (GIST) who have received prior treatment with 3 or more kinase inhibitors, including imatinib.	5/15/2020
FDA grants accelerated approval to rucaparib for BRCA-mutated metastatic castration-resistant prostate cancer (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-rucaparib-brca-mutated-metastatic-castration-resistant-prostate)	Food and Drug Administration granted accelerated approval to rucaparib (RUBRACA, Clovis Oncology, Inc.) for patients with deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.	5/15/2020
FDA approves nivolumab plus ipilimumab for first-line mNSCLC (PD-L1 tumor expression ≥1%) (/drugs/resources-information-approved-drugs/fda-approves-nivolumab-plus-ipilimumab-first-line-mnsclc-pd-l1-tumor-expression-1)	Food and Drug Administration approved the combination of nivolumab (OPDIVO, Bristol-Myers Squibb Co.) plus ipilimumab (YERVOY, Bristol-Myers Squibb Co.) as first-line treatment for patients with metastatic non-small cell lung cancer whose tumors express PD-L1(≥1%), as determined by an FDA-approved test, with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberrations.	5/15/2020
FDA grants accelerated approval to pomalidomide for Kaposi sarcoma (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-pomalidomide-kaposi-sarcoma)	Food and Drug Administration expanded the indication of pomalidomide (POMALYST, Celgene Corporation) to include treating adult patients with AIDS-related Kaposi sarcoma after failure of highly active antiretroviral therapy and Kaposi sarcoma in adult patients who are HIV-negative.	5/14/2020

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FDA approves olaparib plus bevacizumab as maintenance treatment for ovarian, fallopian tube, or primary peritoneal cancers (/drugs/resources-information-approved-drugs/fda-approves-olaparib-plus-bevacizumab-maintenance-treatment-ovarian-fallopian-tube-or-primary)	Food and Drug Administration expanded the indication of olaparib (LYNPARZA®, AstraZeneca Pharmaceuticals, LP) to include its combination with bevacizumab for first-line maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency positive status defined by either a deleterious or suspected deleterious BRCA mutation, and/or genomic instability.	5/8/2020
FDA approves selpercatinib for lung and thyroid cancers with RET gene mutations or fusions (/drugs/resources-information-approved-drugs/fda-approves-selpercatinib-lung-and-thyroid-cancers-ret-gene-mutations-or-fusions)	Food and Drug Administration granted accelerated approval to selpercatinib (RETEVMO, Eli Lilly and Company) for the following indications: Adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC); Adult and pediatric patients ≥12 years of age with advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who require systemic therapy; Adult and pediatric patients ≥12 years of age with advanced or metastatic RET fusion-positive thyroid cancer who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).	5/8/2020
FDA grants accelerated approval to capmatinib for metastatic non-small cell lung cancer (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-capmatinib-metastatic-non-small-cell-lung-cancer)	Food and Drug Administration granted accelerated approval to capmatinib (TABRECTA, Novartis) for adult patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have a mutation that leads to mesenchymal-epithelial transition (MET) exon 14 skipping as detected by an FDA-approved test.	5/6/2020
FDA approves daratumumab and hyaluronidase-fihj for multiple myeloma (/drugs/resources-information-approved-drugs/fda-approves-daratumumab-and-hyaluronidase-fihj-multiple-myeloma)	Food and Drug Administration approved daratumumab and hyaluronidase-fihj (DARZALEX FASPRO, Janssen Biotech, Inc.) for adult patients with newly diagnosed or relapsed/refractory multiple myeloma. This new product allows for subcutaneous dosing of daratumumab. May 1, 2020	5/1/2020
FDA approves niraparib for first-line maintenance of advanced ovarian cancer (/drugs/resources-information-approved-drugs/fda-approves-niraparib-first-line-maintenance-advanced-ovarian-cancer)	Food and Drug Administration approved niraparib (ZEJULA, GlaxoSmithKline) for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy.	4/29/2020

Webpage (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Description (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Date (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)
FDA approves new dosing regimen for pembrolizumab (/drugs/resources-information-approved-drugs/fda-approves-new-dosing-regimen-pembrolizumab)	Food and Drug Administration granted accelerated approval to a new dosing regimen of 400 mg every six weeks for pembrolizumab (KEYTRUDA, Merck) across all currently approved adult indications, in addition to the current 200 mg every three weeks dosing regimen.	4/28/2020
FDA grants accelerated approval to sacituzumab govitecan-hziy for metastatic triple negative breast cancer (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-sacituzumab-govitecan-hziy-metastatic-triple-negative-breast-cancer)	Food and Drug Administration granted accelerated approval to sacituzumab govitecan-hziy (TRODELVY, Immunomedics, Inc.) for adult patients with metastatic triple-negative breast cancer who received at least two prior therapies for metastatic disease.	4/22/2020
FDA approves ibrutinib plus rituximab for chronic lymphocytic leukemia (/drugs/resources-information-approved-drugs/fda-approves-ibrutinib-plus-rituximab-chronic-lymphocytic-leukemia)	Food and Drug Administration expanded the indication of ibrutinib (IMBRUVICA, Pharmacyclics LLC) to include its combination with rituximab for the initial treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).	4/21/2020
FDA grants accelerated approval to pemigatinib for cholangiocarcinoma with an FGFR2 rearrangement or fusion (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-pemigatinib-cholangiocarcinoma-fgfr2-rearrangement-or-fusion)	Food and Drug Administration granted accelerated approval to pemigatinib (PEMAZYRE, Incyte Corporation) for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.	4/20/2020
FDA approves tucatinib for patients with HER2-positive metastatic breast cancer (/drugs/resources-information-approved-drugs/fda-approves-tucatinib-patients-her2-positive-metastatic-breast-cancer)	Food and Drug Administration approved tucatinib (TUKYSA, Seattle Genetics, Inc.) in combination with trastuzumab and capecitabine, for adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.	4/17/2020
FDA approves mitomycin for low-grade upper tract urothelial cancer (/drugs/resources-information-approved-drugs/fda-approves-mitomycin-low-grade-upper-tract-urothelial-cancer)	Food and Drug Administration approved mitomycin (JELMYTO™, UroGen Pharma) for adult patients with low-grade upper tract urothelial cancer (LG-UTUC).	4/15/2020
FDA approves selumetinib for neurofibromatosis type 1 with symptomatic, inoperable plexiform neurofibromas (/drugs/resources-information-approved-drugs/fda-approves-selumetinib-neurofibromatosis-type-1-symptomatic-inoperable-plexiform-neurofibromas)	Food and Drug Administration approved selumetinib (KOSELUGO, AstraZeneca) for pediatric patients, 2 years of age and older, with neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).	4/10/2020

Webpage (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Description (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Date (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)
FDA approves encorafenib in combination with cetuximab for metastatic colorectal cancer with a BRAF V600E mutation (/drugs/resources-information-approved-drugs/fda-approves-encorafenib-combination-cetuximab-metastatic-colorectal-cancer-braf-v600e-mutation)	Food and Drug Administration approved encorafenib (BRAFTOVI, Array BioPharma Inc.) in combination with cetuximab for the treatment of adult patients with metastatic colorectal cancer (CRC) with a BRAF V600E mutation, detected by an FDA-approved test, after prior therapy.	4/8/2020
FDA approves luspatercept-aamt for anemia in adults with MDS (/drugs/resources-information-approved-drugs/fda-approves-luspatercept-aamt-anemia-adults-mds)	Food and Drug Administration approved luspatercept-aamt (REBLOZYL, Celgene Corporation) for the treatment of anemia failing an erythropoiesis stimulating agent and requiring 2 or more red blood cell (RBC) units over 8 weeks in adult patients with very low- to intermediate-risk myelodysplastic syndromes with ring sideroblasts (MDS-RS) or with myelodysplastic/myeloproliferative neoplasm with ring sideroblasts and thrombocytosis (MDS/MPN-RS-T).	4/3/2020
FDA approves durvalumab for extensive-stage small cell lung cancer (/drugs/resources-information-approved-drugs/fda-approves-durvalumab-extensive-stage-small-cell-lung-cancer)	Food and Drug Administration approved durvalumab (IMFINZI, AstraZeneca) in combination with etoposide and either carboplatin or cisplatin as first-line treatment of patients with extensive-stage small cell lung cancer (ES-SCLC).	3/30/2020
FDA grants accelerated approval to nivolumab and ipilimumab combination for hepatocellular carcinoma (/drugs/resources-information-approved-drugs/fda-grants-accelerated-approval-nivolumab-and-ipilimumab-combination-hepatocellular-carcinoma)	Food and Drug Administration granted accelerated approval to the combination of nivolumab and ipilimumab (OPDIVO and YERVOY, Bristol-Myers Squibb Co.) for patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.	3/10/2020
FDA approves isatuximab-irfc for multiple myeloma (/drugs/resources-information-approved-drugs/fda-approves-isatuximab-irfc-multiple-myeloma-0)	Food and Drug Administration approved isatuximab-irfc (SARCLISA, sanofi-aventis U.S. LLC) in combination with pomalidomide and dexamethasone for adult patients with multiple myeloma who have received at least two prior therapies including lenalidomide and a proteasome inhibitor.	3/2/2020
FDA approves neratinib for metastatic HER2-positive breast cancer (/drugs/resources-information-approved-drugs/fda-approves-neratinib-metastatic-her2-positive-breast-cancer)	Food and Drug Administration approved neratinib (NERLYNX, Puma Biotechnology, Inc.) in combination with capecitabine for adult patients with advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting.	2/25/2020
FDA approves tazemetostat for advanced epithelioid sarcoma (/drugs/resources-information-approved-drugs/fda-approves-tazemetostat-advanced-epithelioid-sarcoma)	Food and Drug Administration granted accelerated approval to tazemetostat (TAZVERIK, Epizyme, Inc.) for adults and pediatric patients aged 16 years and older with metastatic or locally advanced epithelioid sarcoma not eligible for complete resection.	1/23/2020

Webpage (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Description (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)	Date (/drugs/resources-information-approved-drugs/fda-approves-sirolimus-protein-bound-particles-malignant-perivascular-epithelioid-cell-tumor)
FDA approves avapritinib for gastrointestinal stromal tumor with a rare mutation (/drugs/resources-information-approved-drugs/fda-approves-avapritinib-gastrointestinal-stromal-tumor-rare-mutation)	Food and Drug Administration approved avapritinib (AYVAKIT, Blueprint Medicines Corporation) for adults with unresectable or metastatic gastrointestinal stromal tumor (GIST) harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation, including D842V mutations.	1/9/2020
FDA approves pembrolizumab for BCG-unresponsive, high-risk non-muscle invasive bladder cancer (/drugs/resources-information-approved-drugs/fda-approves-pembrolizumab-bcg-unresponsive-high-risk-non-muscle-invasive-bladder-cancer)	Food and Drug Administration approved pembrolizumab (KEYTRUDA, Merck & Co. Inc.) for the treatment of patients with Bacillus Calmette-Guerin (BCG)-unresponsive, high-risk, non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors who are ineligible for or have elected not to undergo cystectomy.	1/8/2020

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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)