New FDA-Approved Oncology Drugs (2021–2022)

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Over the past year (May 2021–May 2022), the U.S. Food and Drug Administration (FDA) approved and expanded indications for many drugs related to the treatment of different types of cancers and adverse events. The new approvals and accelerated approvals are listed below.

FAM-TRASTUZUMAB DERUXTECAN-NXKI (ENHERTU) was approved for 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. May 4, 2022.

ALPELISIB (VIJOICE) was approved for adult and pediatric patients two years of age and older with severe manifestations of *PIK3CA*-related overgrowth spectrum who require systemic therapy.

AXICABTAGENE CILOLEUCEL (YESCARTA) was approved for adult patients with large B-cell lymphoma who are refractory to first-line chemoimmunotherapy or who experienced relapse within 12 months of first-line chemoimmunotherapy. April 1, 2022.

LUTETIUM (LU-177) VIPIVOTIDE TETRAXETAN (PLUVICTO) was approved for prostate-specific membrane antigen-positive metastatic castration-resistant prostate cancer after other therapies. March 23, 2022.

PEMBROLIZUMAB (KEYTRUDA) was approved as a single agent for patients with advanced endometrial carcinoma that is microsatellite instability–high or mismatch repair–deficient. Eligible patients have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation. March 21, 2022.

NIVOLUMAB AND RELATLIMAB-RMBW (OPDUALAG) was approved for unresectable or metastatic melanoma. March 18, 2022.

OLAPARIB (LYNPARZA) was approved for the adjuvant treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated, 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. March 11, 2022.

NIVOLUMAB (OPDIVO) was approved in combination with platinum-doublet chemotherapy for the neoadjuvant treatment of early-stage non–small cell lung cancer (NSCLC). March 4, 2022.

PACRITINIB (VONJO) was approved for adults with intermediate- or high-risk primary or secondary (post–polycythemia vera or post–essential thrombocythemia) myelofibrosis with a platelet count below 50×10^9/L. February 28, 2022.

CILTACABTAGENE AUTOLEUCEL (CARVYKTI) was approved for the treatment of adults with relapsed or refractory multiple myeloma after four or more prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody.

TEBENTAFUSP-TEBN (KIMMTRAK) was approved for HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma. January 25, 2022.

PEMBROLIZUMAB (KEYTRUDA) was approved for the adjuvant treatment of adult and pediatric (≥ 12 years of age) patients with stage IIB or IIC melanoma following complete resection. December 3, 2021.

RITUXIMAB (RITUXAN) was approved in combination with chemotherapy for pediatric patients with previously untreated, advanced-stage, CD20-positive diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, or mature B-cell acute leukemia. December 2, 2021.

DARATUMUMAB PLUS HYALURONIDASE-FIHJ (DARZALEX FASPRO) was approved for adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy. December 1, 2021.

CARFILZOMIB (KYPROLIS) was approved combined with dexamethasone for adult patients with relapsed/refractory multiple myeloma who have received one to three prior lines of therapy. December 1, 2021.

PAFOLACIANINE (CYTALUX), an imaging drug, received approval for use in adult patients with ovarian cancer to help identify cancerous lesions during surgery. November 29, 2021.

SIROLIMUS PROTEIN-BOUND PARTICLES FOR INJECTABLE SUSPENSION (FYARRO) was approved for treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor. November 22, 2021.

PEMBROLIZUMAB (KEYTRUDA) was approved for the adjuvant treatment of patients with renal cell carcinoma at intermediate-high or high risk of disease recurrence following nephrectomy or nephrectomy and resection of metastatic lesions. November 17, 2021.

ASCIMINIB (SCEMBLIX) received accelerated approval for Philadelphia chromosome–positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, previously treated with two or more tyrosine kinase inhibitors, and was approved for adult patients with Ph+ CML in chronic phase with the T315I mutation. October 29, 2021.

ATEZOLIZUMAB (TECENTRIQ) was approved for adjuvant treatment following resection and platinum-based chemotherapy in patients with stage II to IIIA NSCLC whose tumors have PD-L1 expression on ≥1% of tumor cells. October 15, 2021.

PEMBROLIZUMAB (KEYTRUDA) combined with chemotherapy, with or without bevacizumab (Avastin), was approved for patients with persistent, recurrent, or metastatic cervical cancer whose tumors express PD-L1 (combined positive score ≥ 1). October 13, 2021.

ABEMACICLIB (VERZENIO) combined with endocrine therapy was approved for adjuvant treatment of patients with hormone receptor–positive, HER2-negative, node-positive early breast cancer who are at high risk of disease recurrence and who have a Ki67 score ≥ 20%. October 12, 2021.

BREXUCABTAGENE AUTOLEUCEL (TECARTUS) received approval for adult patients with relapsed or refractory B-cell precursor acute lymphoblastic leukemia (ALL). October 1, 2021.

CETUXIMAB (ERBITUX) was approved combined with encorafenib (Braftovi) for the treatment of adults with metastatic colorectal cancer and a *BRAF* V600E mutation after prior therapy. September 28, 2021.

RUXOLITINIB (JAKAFI) was approved for the treatment of chronic graft-vs-host disease (GVHD) after failure of one or two lines of systemic therapy in adult and pediatric patients aged 12 years and older. September 22, 2021.

TISOTUMAB VEDOTIN-TFTV (TIVDAK) was approved to treat adult patients with recurrent or metastatic cervical cancer who experienced disease progression on or after chemotherapy. September 20, 2021.

CABOZANTINIB (CABOMETYX) was approved to treat adult and pediatric patients aged 12 years and older with locally advanced or metastatic differentiated thyroid cancer that has progressed following prior VEGFR-targeted therapy and who are radioactive iodine–refractory or ineligible. September 17, 2021.

MOBOCERTINIB (EXKIVITY) was granted accelerated approval to treat adults with locally advanced or metastatic NSCLC and epidermal growth factor receptor exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. September 15, 2021.

ZANUBRUTINIB (BRUKINSA) received accelerated approval for the treatment of adult patients with relapsed or refractory marginal zone lymphoma who have received at least one anti–CD20-based regimen. September 15, 2021.

ZANUBRUTINIB (BRUKINSA) was approved for the treatment of adult patients with Waldenström's macroglobulinemia. August 31, 2021.

IVOSIDENIB (TIBSOVO) was granted approval for previously treated locally advanced or metastatic cholangiocarcinoma with an isocitrate dehydrogenase-1 *(IDH1)* mutation. August 25, 2021.

NIVOLUMAB (OPDIVO) was approved for the adjuvant treatment of patients with urothelial carcinoma who are at high risk of disease recurrence after undergoing radical resection. August 19, 2021.

DOSTARLIMAB-GXLY (JEMPERLI), an anti–PD-1 antibody, received accelerated approval for adult patients with mismatch repair–deficient (dMMR) recurrent or advanced solid tumors who have had disease progression on or following prior treatment and who have no satisfactory alternative treatment options. August 17, 2021.

LENVATINIB (LENVIMA) PLUS PEMBROLIZUMAB (KEYTRUDA) received approval for the first-line treatment of adult patients with advanced renal cell carcinoma. August 10, 2021.

PEMBROLIZUMAB (KEYTRUDA) was approved for high-risk, early-stage triple-negative breast cancer in combination with chemotherapy as a neoadjuvant treatment and then continued as a single agent as adjuvant treatment after surgery. July 26, 2021.

PEMBROLIZUMAB (KEYTRUDA) PLUS LENVATINIB (LENVIMA) was granted approval for treatment of patients with advanced endometrial carcinoma that is not microsatellite instability–high or dMMR. July 21, 2021.

BELUMOSUDIL (REZUROCK) was approved for adult and pediatric patients aged 12 years and older with chronic GVHD after failure of at least two prior lines of systemic therapy. July 16, 2021.

ENFORTUMAB VEDOTIN-EJFV (PADCEV) was approved for adults with locally advanced or metastatic urothelial cancer who have previously received a PD-1 or PD-L1 inhibitor and platinum-containing chemotherapy. It also was approved for patients who are ineligible for cisplatin-containing chemotherapy and have received one or more prior lines of therapy. July 9, 2021.

DARATUMUMAB AND HYALURONIDASE-FIHJ (DARZALEX FASPRO) combined with pomalidomide and dexamethasone was approved to treat adult patients with multiple myeloma who have received at least one prior line of therapy including lenalidomide and a proteasome inhibitor. July 9, 2021.

ASPARAGINASE ERWINIA -CHRYSANTHEMI (RECOMBINANT)-RYWN (RYLAZE) was approved for ALL and lymphoblastic lymphoma in patients allergic to *Escherichi coli*–derived asparaginase products, as a component of a chemotherapy regimen. June 30, 2021.

AVAPRITINIB (AYVAKIT) was approved to treat adult patients with advanced systemic mastocytosis, including those with aggressive systemic mastocytosis, systemic mastocytosis with an associated hematologic neoplasm, and mast cell leukemia. June 16, 2021.

INFIGRATINIB (TRUSELTIQ) received accelerated approval for adults with previously treated, unresectable, locally advanced, or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 fusion or other rearrangement. May 28, 2021.

SOTORASIB (LUMAKRAS) was approved as the first treatment for adult patients with NSCLC whose tumors have a *KRAS* G12C genetic mutation and who have received at least one prior systemic therapy. May 28, 2021.

PIFLUFOLASTAT F-18 INJECTION (PYLARIFY) was approved for the identification of suspected metastasis or recurrence of prostate cancer. May 27, 2021.

AMIVANTAMAB-VMJW (RYBREVANT) received accelerated approval for adult patients with locally advanced or metastatic NSCLC and *EGFR* exon 20 insertion mutations whose disease has progressed on or after platinum-based chemotherapy. May 21, 2021.

NIVOLUMAB (OPDIVO) was approved for patients with completely resected esophageal or gastroesophageal junction cancer with residual pathologic disease who have received neoadjuvant chemoradiotherapy. May 20, 2021.

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TODAY IN ONCOLOGY

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T-DXd in HER2-Expressing Advanced or Recurrent Uterine Carcinosarcoma

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