

APPENDIX

TABLE A1. FDA Approvals of Anticancer Therapies (November 2018 to October 2019)

New Approvals	Comments
New therapies or tests	
October 2019	
Niraparib (Zejula)	For patients with advanced ovarian, fallopian tube, or primary peritoneal cancer treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD)-positive status.
August 2019	
Fedratinib (Inrebic)	For adults with intermediate-2 or high-risk primary or secondary (post-polycythemia vera or post-essential thrombocythemia) myelofibrosis (MF).
Entrectinib (RoZlytrek)	For adult and pediatric patients (≥ 12 years of age) with iobenguane scan-positive, unresectable, locally advanced or metastatic pheochromocytoma or paraganglioma that requires systemic anticancer therapy.
July 2019	
Pembrolizumab (Keytruda)	For advanced esophageal squamous cell cancer.
Darolutamide (Nubeqa)	For nonmetastatic castration-resistant prostate cancer.
May 2019	
Gilteritinib (Xospata)	Indicated for adult patients who have relapsed or refractory acute myeloid leukemia (AML) with an FLT3 mutation as detected by an FDA-approved test.
Venetoclax (Venclexta)	For adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
Ado-trastuzumab emtansine (Kadcyla)	For the adjuvant treatment of patients with HER2-positive early breast cancer who have residual invasive disease after neoadjuvant taxane and trastuzumab-based treatment.
Ivosidenib (Tibsovo)	For newly diagnosed acute myeloid leukemia (AML) with a susceptible IDH1 mutation, as detected by an FDA-approved test, in patients who are at least 75 years of age or who have comorbidities that preclude the use of intensive induction chemotherapy.
December 2018	
Tagraxofusp-erzs (Elzonris)	A CD123-directed cytotoxin, for blastic plasmacytoid dendritic cell neoplasm (BPDCN) in adults and in pediatric patients 2 years and older.
Calaspargase pegol-mknl (Asparlas)	An asparagine-specific enzyme, as a component of a multiagent chemotherapeutic regimen for acute lymphoblastic leukemia (ALL) in pediatric and young adult patients age 1 month to 21 years.
Olaparib (Lynparza)	For the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy.
November 2018	
Gilteritinib (Xospata)	For treatment of adult patients who have relapsed or refractory acute myeloid leukemia (AML) with an FLT3 mutation as detected by an FDA-approved test.
Truxima (rituximab-abbs)	The first biosimilar to Rituxan (rituximab) for patients with CD20-positive, B-cell non-Hodgkin lymphoma (NHL) to be used as a single agent or in combination with chemotherapy.
Larotrectinib (Vitrakvi)	For adult and pediatric patients with solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation, that are either metastatic or where surgical resection is likely to result in severe morbidity, and who have no satisfactory alternative treatments or in whom the cancer has progressed following treatment.

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TABLE A1. FDA Approvals of Anticancer Therapies (November 2018 to October 2019) (continued)

New Approvals	Comments
New indications	
September 2019	
Daratumumab (DARZALEX)	For adult patients with multiple myeloma in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for autologous stem cell transplant.
Apalutamide (ERLEADA)	For patients with metastatic castration-sensitive prostate cancer.
Pembrolizumab (KEYTRUDA) and lenvatinib (LENVIMA)	For the treatment of patients with advanced endometrial carcinoma that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR) and who have disease progression following prior systemic therapy but are not candidates for curative surgery or radiation.
July 2019	
Selinexor (XPOVIOs)	In combination with dexamethasone for adult patients with relapsed or refractory multiple myeloma who have received at least four prior therapies and in whom the disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody.
June 2019	
Pembrolizumab (KEYTRUDA)	For patients with metastatic small-cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy and at least one other prior line of therapy.
Daratumumab (DARZALEX)	In combination with lenalidomide and dexamethasone for patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant.
Polatuzumab vedotin-piic (POLIVY)	A CD79b-directed antibody-drug conjugate indicated in combination with bendamustine and a rituximab product for adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, after at least two prior therapies.
May 2019	
Lenalidomide (REVLIMID)	In combination with a rituximab product for previously treated follicular lymphoma and previously treated marginal zone lymphoma.
Alpelisib (PIQRAY)	In combination with fulvestrant for postmenopausal women, and men, with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced or metastatic breast cancer as detected by an FDA-approved test following progression on or after an endocrine-based regimen.
Avelumab (BAVENCIO)	In combination with axitinib for first-line treatment of patients with advanced renal cell carcinoma (RCC).
Ramucirumab (CYRAMZA)	A single agent for hepatocellular carcinoma (HCC) in patients who have an α -fetoprotein (AFP) of ≥ 400 ng/mL and have been previously treated with sorafenib.
April 2019	
Pembrolizumab (KEYTRUDA)	In combination with axitinib for the first-line treatment of patients with advanced renal cell carcinoma (RCC).
Pembrolizumab (KEYTRUDA)	For the first-line treatment of patients with stage III non-small-cell lung cancer (NSCLC) who are not candidates for surgical resection or definitive chemoradiation or metastatic NSCLC. Patients' tumors must have no EGFR or ALK genomic aberrations and express PD-L1 (Tumor Proportion Score [TPS] $\geq 1\%$) determined by an FDA-approved test.
March 2019	
Atezolizumab (TECENTRIQ)	In combination with carboplatin and etoposide, for the first-line treatment of adult patients with extensive-stage small-cell lung cancer.
Atezolizumab	For PD-L1-positive unresectable locally advanced or metastatic triple-negative breast cancer.
February 2019	
Trastuzumab and hyaluronidase-oyks injection (Herceptin HYLECTA)	For subcutaneous use for the treatment of HER2-overexpressing breast cancer, injection is a combination of trastuzumab, a HER2/neu receptor antagonist, and hyaluronidase, an endoglycosidase.
Trifluridine/tipiracil tablets (LONSURF)	A fixed combination of trifluridine, a nucleoside metabolic inhibitor, and tipiracil, a thymidine phosphorylase inhibitor—for adult patients with metastatic gastric or gastroesophageal junction (GEJ) adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and, if appropriate, HER2/neu-targeted therapy.

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TABLE A1. FDA Approvals of Anticancer Therapies (November 2018 to October 2019) (continued)

New Approvals	Comments
Pembrolizumab (KEYTRUDA)	For the adjuvant treatment of patients with melanoma with involvement of lymph node(s) following complete resection.
January 2019	
Cabozantinib (CABOMETYX)	For patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.
December 2018	
Pembrolizumab (KEYTRUDA)	For adult and pediatric patients with recurrent locally advanced or metastatic Merkel cell carcinoma.
Herzuma (trastuzumab-pkrb)	Approved as a biosimilar to trastuzumab for patients with HER2-overexpressing breast cancer.
Atezolizumab (TECENTRIQ)	In combination with bevacizumab, paclitaxel, and carboplatin for the first-line treatment of patients with metastatic nonsquamous, non–small-cell lung cancer (NSCLC) with no EGFR or ALK genomic tumor aberrations.
November 2018	
Venetoclax (VENCLEXTA)	In combination with azacitidine or decitabine or low-dose cytarabine for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.
Glasdegib (DAURISMO)	In combination with low-dose cytarabine (LDAC), for newly diagnosed acute myeloid leukemia (AML) in patients who are 75 years old or older or who have comorbidities that preclude intensive induction chemotherapy.
Brentuximab vedotin (ADCETRIS)	In combination with chemotherapy for previously untreated systemic anaplastic large cell lymphoma or other CD30-expressing peripheral T-cell lymphomas.
Pembrolizumab (KEYTRUDA)	For patients with hepatocellular carcinoma (HCC) who have been previously treated with sorafenib.
Lorlatinib (LORBRENA)	For patients with anaplastic lymphoma kinase (ALK)-positive metastatic non–small-cell lung cancer (NSCLC) with disease that has progressed on crizotinib and at least one other ALK inhibitor for metastatic disease or with disease that has progressed on alectinib or ceritinib as the first ALK inhibitor therapy for metastatic disease.

NOTE. Data from US Food and Drug Administration. Hematology/Oncology (Cancer) Approvals & Safety Notifications. <https://www.fda.gov/drugs/resources-information-approved-drugs/hematologyoncology-cancer-approvals-safety-notifications>.