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Supplementary information

Approvals in 2021: dangling Accelerated Approvals, drug dosing, new approvals and beyond

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Supplementary Table 1 | Summary of FDA oncology drug approvals in 2021 (in decreasing chronological order)

Drug	Indication	Type	Comments
Pembrolizumab	Adjuvant treatment of adult or paediatric patients (≥12 years of age) with stage IIB–IIC melanoma following complete resection	Suppl	AAid, ODD, PR, RTOR
Rituximab	For paediatric patients (≥6 months to <18 years of age) with previously untreated, advanced-stage, $CD20^+$ DLBLC, Burkitt lymphoma, Burkitt-like lymphoma or mature B cell acute leukaemia	Suppl	AAid, PR
Daratumumab + hyaluronidase-fihj	In combination with carfilzomib and dexamethasone in patients with R/R MM who have received 1–3 prior lines of therapy	Suppl	AAid
Pafolacianine	For adult women with ovarian cancer as an adjunct for interoperative identification of malignant lesions	New	ODD, PR
Sirolimus protein-bound particles for injectable suspension	For adults with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumours	New	AAid, BTD, ODD, PR
Pembrolizumab	Adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions	Suppl	AAid, PR, Orbis[a]
Asciminib	AA for patients with Ph^+ CML in chronic phase, previously treated with ≥2 TKIs; regular approval for adults with Ph^+ CML in chronic phase harbouring T315I mutation in *BCR–ABL1*	New	AA, AAid, BTD, ODD, PR, RTOR
Atezolizumab	Adjuvant treatment following resection and platinum-based chemotherapy in patients with stage II–IIIA NSCLC and PD-L1 expression on ≥1% of tumour cells, as determined by an FDA-approved test	Suppl	AAid, Orbis[a], PR, RTOR,
Pembrolizumab	For patients with persistent, recurrent or metastatic cervical cancer that is positive for PD-L1 expression (CPS ≥1), as determined by an FDA-approved test, in combination with chemotherapy, with or without bevacizumab	Suppl	AAid, Orbis[a], PR
Abemaciclib	In combination with endocrine therapy (tamoxifen or an aromatase inhibitor) for adjuvant treatment in patients with HR^+HER2^-, node-positive, early-stage breast cancer at high risk of recurrence and with a Ki-67 score ≥20%, as determined by an FDA-approved test	Suppl	AAid, RTOR

Brexucabtagene autoleucel	For adult patients with R/R B cell precursor ALL	Suppl	AAid, BTD, ODD, PR
Ruxolitinib	Chronic GVHD after failure of 1–2 lines of systemic therapy in adult and paediatric patients (≥12 years of age)	Suppl	ODD, Orbis[a], PR
Tisotumab vedotin-tftv	Patients with recurrent or metastatic cervical cancer with disease progression on or after chemotherapy	New	AA, AAid, PR
Cabozantinib	For adult and paediatric patients (≥12 years of age) with locally advanced or metastatic differentiated thyroid cancer that has progressed following VEGFR-targeted therapy and who are ineligible for or refractory to radioactive iodine	Suppl	AAid, BTD, ODD, PR
Mobocertinib	For adults with locally advanced or metastatic NSCLC with *EGFR* exon 20 insertion mutations, as detected by an FDA-approved test, that has progressed on or after platinum-based chemotherapy	New	AA, AAid, BTD, ODD, Orbis[a], PR
Zanubrutinib	For adults with R/R MZL after at least one anti-CD20-based regimen	Suppl	AA, AAid, ODD, PR
Zanubrutinib	For adults with Waldenström macroglobulinaemia	Suppl	AAid, ODD
Ivosidenib	For adults with previously treated, locally advanced or metastatic cholangiocarcinoma with an *IDH1* mutation, as detected by an FDA-approved test.	Suppl	AAid, ODD, PR
Nivolumab	Adjuvant treatment of patients with urothelial carcinoma who are at high risk of recurrence after undergoing radical resection	Suppl	AAid, PR, RTOR
Dostarlimab-gxly	For adults with dMMR recurrent or advanced solid tumours, as determined by an FDA-approved test, that have progressed on or following prior treatment and who have no satisfactory alternative treatment options	New	AA, AAid, PR
Belzutifan	For adults with von Hippel–Lindau disease who require therapy for associated RCC, CNS haemangioblastomas or pancreatic neuroendocrine tumours, not requiring immediate surgery	New	AAid, Orbis[a], PR, RTOR
Lenvatinib	In combination with pembrolizumab for first-line treatment of advanced RCC	Suppl	AAid, BTD, PR, RTOR
Pembrolizumab	In combination with lenvatinib for first-line treatment of advanced RCC	Suppl	AAid, BTD, PR, RTOR

Pembrolizumab	As monotherapy for patients with high-risk, early stage TNBC in combination with chemotherapy as neoadjuvant treatment, and then continued as a single agent as adjuvant treatment after surgery; in combination with chemotherapy for patients with locally recurrent unresectable or metastatic TNBC expressing PD-L1 (CPS ≥10), as determined by an FDA-approved test	Suppl	AAid, BTD, PR, RTOR
Pembrolizumab	In combination with lenvatinib for women with advanced endometrial carcinoma that is not MSI-H or dMMR, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation	Suppl	AAid, BTD, PR
Lenvatinib	In combination with pembrolizumab for women with advanced endometrial carcinoma that is not MSI-H or dMMR, who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation	Suppl	AAid, BTD, PR
Belumosudil	For adult and paediatric patients (≥12 years of age) with chronic GVHD after ≥2 prior lines of systemic therapy	New	AAid, BTD, Orbis[a], PR, RTOR
Daratumumab and hyaluronidase-fihj	In combination with pomalidomide and dexamethasone for the treatment of patients with MM after at least one prior line of therapy including lenalidomide and a proteasome inhibitor	Suppl	AAid
Enfortumab vedotin-ejfv	Locally advanced or metastatic urothelial cancer	Suppl	AAid, BTD, Orbis[a], PR, RTOR
Asparaginase erwinia chrysanthemi (recombinant)-rywn	As a component of a multi-agent chemotherapeutic regimen for the treatment of ALL and lymphoblastic lymphoma in adults and paediatric patients (≥1 month of age) who have hypersensitivity to *E. coli*-derived asparaginase	New	AAid, ODD, Orbis[a], RTOR
Avapritinib	For adult patients with advanced systemic mastocytosis	Suppl	BTD, ODD, PR
Infigratinib	For adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma harbouring an *FGFR2* fusion or other rearrangement, as detected by an FDA-approved test	New	AA, AAid, ODD, Orbis[a], PR, RTOR

Sotorasib	For adults with *KRAS*^{G12C}-mutated locally advanced or metastatic NSCLC, as determined by an FDA-approved test, who have received at least one prior systemic therapy	New	AA, AAid, BTD, ODD, Orbis[a], PR, RTOR
Piflufolastat F-18 injection	For PET detection of PSMA^{+} lesions in men with prostate cancer with suspected metastasis who are candidates for initial definitive therapy or with suspected disease recurrence based on elevated serum PSA levels	New	PR
Amivantamab-vmjw	For adults with locally advanced or metastatic NSCLC with *EGFR* exon 20 insertion mutations, as detected by an FDA-approved test, that has progressed on or after platinum-based chemotherapy	New	AA, AAid, BTD, Orbis[a], PR
Nivolumab	For patients with completely resected oesophageal or GEJ cancer with residual pathological disease following neoadjuvant chemoradiotherapy	Suppl	AAid, ODD, Orbis[a], PR, RTOR
Pembrolizumab	First-line treatment of patients with locally advanced unresectable or metastatic HER2^{+} G/GEJ adenocarcinoma in combination with trastuzumab, fluoropyrimidine-containing and platinum-containing chemotherapy	Suppl	AA, AAid, PR, RTOR
Loncastuximab tesirine-lpyl	For adults with R/R LBCL after ≥2 lines of systemic therapy, including DLBCL not otherwise specified, DLBCL arising from low-grade lymphoma, and high-grade B cell lymphoma	New	AA, AAid, ODD, PR
Dostarlimab-gxly	For women with recurrent or advanced-endometrial cancer that is dMMR, as determined by an FDA-approved test, and has progressed on or following a prior platinum-containing regimen	New	AA, AAid, BTD, PR, RTOR
Nivolumab	For patients with advanced or metastatic G/GEJ or oesophageal adenocarcinoma in combination with fluoropyrimidine-containing and platinum-containing chemotherapy	Suppl	AAid, ODD, Orbis[a], PR, RTOR
Sacituzumab govitecan	For patients with locally advanced or metastatic urothelial cancer who previously received a platinum-containing chemotherapy and either an anti-PD-1 or anti-PD-L1 antibody	Suppl	AA, AAid, PR, RTOR
Sacituzumab govitecan	For patients with unresectable locally advanced or metastatic TNBC who have received ≥2 prior systemic therapies, at least one of them for metastatic disease	Suppl	AAid, BTD Orbis[a], PR, RTOR
Cetuximab	*KRAS*-wild-type, *EGFR*$^{+}$ CRC or HNSCC	Suppl	

Isatuximab-irfc	In combination with carfilzomib and dexamethasone for the treatment of adults with R/R MM who have received 1–3 prior lines of therapy	Suppl	AAid, ODD
Idecabtagene vicleucel	For adults with R/R MM after ≥4 prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor and an anti-CD38 monoclonal antibody	New	BTD, ODD, PR
Pembrolizumab	In combination with platinum and fluoropyrimidine-based chemotherapy, for patients with metastatic or locally advanced oesophageal or GEJ (tumours with epicentre 1 –5 cm above the gastrointestinal junction) carcinoma who are not candidates for surgical resection or definitive chemoradiotherapy	Suppl	AAid, Orbis[a], PR, RTOR
Tivozanib	For adults with R/R advanced RCC following ≥2 prior systemic therapies	New	
Axicabtagene ciloleucel	For adults with R/R FL after ≥2 lines of systemic therapy	Suppl	BTD, PR
Lorlatinib	For patients with metastatic NSCLC that is *ALK*-rearranged, as detected by an FDA-approved test	Suppl	AAid, ODD, Orbis[a], PR, RTOR
Melphalan flufenamide	For adults with R/R MM who have received ≥4 prior lines of therapy and with disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent and one anti-CD38 monoclonal antibody	New	AA, ODD, PR
Cemiplimab-rwlc	First-line treatment of patients with advanced NSCLC (patients with locally advanced disease who are not candidates for surgical resection or definitive chemoradiation, or with metastatic disease) and who have high tumoural PD-L1 expression (TPS ≥50%), as determined by an FDA-approved test, with no *EGFR*, *ALK* or *ROS1* aberrations.	Suppl	AAid, PR
Cemiplimab-rwlc	Regular approval for patients with locally advanced BCC previously treated with a Hedgehog inhibitor or for whom such an inhibitor is not appropriate; AA for patients with metastatic BCC previously treated with a Hedgehog inhibitor or for whom such an inhibitor is not appropriate	Suppl	AA, AAid, PR

Lisocabtagene maraleucel	For adults with R/R LBCL after ≥2 lines of systemic therapy, including DLBCL not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B cell lymphoma, primary mediastinal LBCL and FL grade 3B	New	BTD, ODD, PR, RMATD
Umbralisib	For adults with R/R MZL who have received at least one prior anti-CD20-based regimen and for adults with R/R FL who have received ≥3 prior lines of systemic therapy	New	AA, AAid, ODD, PR
Tepotinib	For adults with metastatic NSCLC harbouring *MET* exon 14 skipping alterations	New	AA, AAid, Orbis[a], PR, RTOR
Cabozantinib	First-line treatment of patients with advanced RCC in combination with nivolumab	Suppl	AAid, PR, RTOR
Nivolumab	First-line treatment of patients with advanced RCC in combination with cabozantinib	Suppl	AAid, PR, RTOR
Daratumumab + hyaluronidase	For adults with newly diagnosed light-chain amyloidosis, in combination with bortezomib, cyclophosphamide and dexamethasone	Suppl	AA, AAid, Orbis[a], RTOR
Fam-trastuzumab deruxtecan-nxki	For adults with locally advanced or metastatic $HER2^+$ G/GEJ adenocarcinoma who have received a prior trastuzumab-based regimen	Suppl	AAid, BTD, ODD, PR
Crizotinib	For paediatric patients (≥1 year of age) and young adults with R/R systemic *ALK*-rearranged ALCL	Suppl	AAid, BTD, ODD, PR

AA, accelerated approval; ALCL, anaplastic large cell lymphoma; AAid, assessment aid; ALL, acute lymphoblastic leukaemia; BCC, basal cell carcinoma; BTD, breakthrough therapy designation; CNS, central nervous system; CPS, combined positive score; CRC, colorectal cancer; dMMR, mismatch-repair deficient; DLBLC, diffuse large B cell lymphoma; FL, follicular lymphoma; GEJ, gastroesophageal junction; G/GEJ, gastric or GEJ; GVHD, graft-versus-host disease; HNSCC, squamous cell carcinoma of the head and neck; LBCL, large B cell lymphoma; MM, multiple myeloma; MSI-H, microsatellite instability high; MZL, marginal zone lymphoma; NSCLC, non-small-cell lung cancer; ODD, orphan drug designation; Ph^+ CML, Philadelphia chromosome-positive chronic myeloid leukaemia; PR, priority review; RCC, renal cell carcinoma; RMATD, regenerative medicine advanced therapy designation; R/R, relapsed and/or refractory; RTOR, Real-Time Oncology Review; Suppl, supplement; TKI, tyrosine-kinase inhibitor; TNBC, triple-negative breast cancer; TPS, tumour proportion score.

[a]Concurrent submission and review of oncology products among international partners through Project Orbis.