

**Precision Oncology Drug Approvals in 2021 - New Drugs and Expanded Indications**

Approval Date	Drug	Company	New/ Expanded Indication	Indication	Companion Dx1	Other Dx2
1/14/2021	crizotinib (Xalkori)	Pfizer	E	Pediatric patients w/ relapsed/ refractory systemic anaplastic large-cell lymphoma; ALK positive		Y
1/15/2021	fam-trastuzumab deruxtecan (Enhertu)	Daiichi Sankyo/ AstraZeneca	E	Locally advanced/metastatic gastric or gastroesophageal junction cancer; previously on trastuzumab; HER2 positive		Y
2/3/2021	tepotinib (Tepmetko)	Merck KGaA/EMD Serono	N	Metastatic non-small cell lung cancer; MET exon 14 skipping mutation		Y
2/5/2021	lisocabtagene maraleucel (Breyanzi)	Bristol Myers Squibb/Juno Therapeutics	N	Third-line relapsed/refractory large B-cell lymphoma		
2/22/2021	cemiplimab-rwlc (Libtayo)	Regeneron Pharmaceuticals/ Sanofi	E	First-line locally advanced/metastatic non-small cell lung cancer, not eligible for surgery; PD-L1-positive; no EGFR/ALK/ROS1 alterations	Agilent Technologies' PD- L1 IHC 22C3 pharmDx	
3/3/2021	lorlatinib (Lorbrena)	Pfizer	E	First-line metastatic non-small cell lung cancer; ALK-positive	Roche's Ventana ALK (D5F3) CDx Assay	
3/5/2021	axicabtagene ciloleucel (Yescarta)	Gilead/Kite Pharma	E	Third-line relapsed/refractory follicular lymphoma		
3/26/2021	idecabtagene vicleucel (Abecma)	Bluebird Bio/ Bristol Myers Squibb	N	Fifth-line relapsed/ refractory multiple myeloma		
4/22/2021	dostarlimab (Jemperli)	GlaxoSmithKline	N	Recurrent/advanced endometrial cancer; progressed on platinum- based treatment; mismatch repair deficient	Roche's Ventana MMR RxDx IHC Panel	
5/5/2021	pembrolizumab (Keytruda) plus trastuzumab (Herceptin) and chemotherapy	Merck	E	First-line locally advanced/unresectable/ metastatic gastric or gastroesophageal junction cancer; HER2 positive		Y
5/21/2021	amivantamab (Rybrevant)	Janssen Biotech	N	Locally advanced/metastatic non- small cell lung cancer; progressed on platinum chemo; EGFR exon 20 insertion mutations	Guardant Health's Guardant360 CDx; Thermo Fisher Scientific's Oncomine Dx Target Test	

5/28/2021	infigratinib (Truseltiq)	Helsinn Group/ BridgeBio (QED Therapeutics)	N	Previously treated, unresectable/locally advanced/metastatic cholangiocarcinoma; FGFR2 fusion/other rearrangement	FoundationOne CDx	
5/28/2021	sotorasib (Lumakras)	Amgen	N	Previously treated, locally advanced/metastatic non-small cell lung cancer; KRAS G12C mutation	Guardant Health's Guardant360 CDx; Qiagen's Therascreen KRAS RGQ PCR kit	
6/16/2021	avapritinib (Ayvakit)	Blueprint Medicines	E	Advanced, aggressive systemic mastocytosis, systemic mastocytosis with an associated hematological neoplasm and mast cell leukemia; KIT D816V mutation		Y
8/13/2021	belzutifan (Welireg)	Merck	N	Von Hippel-Lindau-associated renal cell cancer, pancreatic neuroendocrine tumors, or CNS hemangioblastomas; not requiring immediate surgery; germline VHL mutation		Y
8/17/2021	dostarlimab (Jemperli)	GlaxoSmithKline	E	Recurrent/advanced solid tumors; progressed on other treatments and no other options; mismatch repair deficient	Roche's Ventana MMR RxDx IHC Panel	
8/25/2021	ivosidenib (Tibsovo)	Servier Pharmaceuticals	E	Previously treated, locally advanced/metastatic cholangiocarcinoma; IDH1 mutation	Thermo Fisher Scientific's Oncomine Dx Target Test	
9/15/2021	mobocertinib (Exkivity)	Takeda Pharmaceutical	N	Locally advanced/metastatic NSCLC, progressed on platinum-based chemo; EGFR exon 20 insertion mutations	Thermo Fisher Scientific's Oncomine Dx Target Test	
9/23/2021	nilotinib (Tasigna)	Novartis	E	Philadelphia chromosome-positive chronic/accelerated phase CML; pediatric patients one year or older; resistant to prior tyrosine kinase inhibitor and CML-AP resistant or intolerant to prior tyrosine-kinase inhibitor therapy.		Y
10/1/2021	brexucabtagene autoleucel (Tecartus)	Gilead/Kite Pharma	E	Relapsed/refractory B-cell precursor acute lymphoblastic leukemia		

10/13/2021	abemaciclib (Verzenio) w/endocrine therapy	Eli Lilly	E	Early-stage, node-positive breast cancer; HR-positive, HER2-negative, high Ki67 test score	Agilent Technologies' Ki-67 IHC MIB-1 pharmDx (Dako Omnis)	
10/13/2021	pembrolizumab (Keytruda) w/chemo; with or without bevacizumab (Roche's Avastin)	Merck	E	Persistent, recurrent, or metastatic cervical cancer; PD-L1 positive	Agilent Technologies' PD-L1 IHC 22C3 PharmDx	
10/15/2021	atezolizumab (Tecentriq)	Genentech	E	Stage II-IIIa non-small cell lung cancer after surgery and platinum-based chemotherapy; PD-L1 positive	Roche's Ventana PD-L1 (SP263) Assay	
10/29/2021	asciminib (Scemblix)	Novartis	N	Philadelphia chromosome-positive, chronic phase CML; previously treated w/at least two tyrosine kinase inhibitors		Y
10/29/2021	asciminib (Scemblix)	Novartis	N	Philadelphia chromosome-positive, chronic phase CML; T315I mutation		
12/3/2021	rituximab w/chemo (Rituxan)	Genentech	E	Pediatric, advanced non-Hodgkin's lymphomas: diffuse large B-cell lymphoma, Burkitt lymphoma, Burkitt-like lymphoma, mature B-cell acute leukemia; CD-20 positive		Y
<p>N - New drug; E - Expanded indication</p> <p>1 FDA cleared/approved test alongside drug approval</p> <p>2 Other FDA and non-FDA approved tests available for identifying the treatment-eligible patient population</p>						
<p><i>This list highlights precision oncology drugs the FDA approved in 2021 that rely on biomarker testing to determine who should receive them, or are n-of-one treatments (i.e. autologous CAR T-cell therapies). This list does not include drugs that the FDA may consider personalized based on other criteria.</i></p>						