

Precision Oncology Drug Approvals in 2022 - New Drugs and Expanded Indications

Approval Date	Drug	Company	New/ Expanded Indication	Indication	Companion Dx1	Other Dx2
1/26/2022	Kimmtrak (tebentafusp)	Immunocore	N	unresectable or metastatic uveal melanoma; HLA-A*02:01 positive	Thermo Fisher Scientific's SeCore CDx HLA Sequencing System; approved 12/7/2022	
2/28/2022	Carvykti (ciltacabtagene autoleucel)	Janssen/ Legend Biotech	N	fifth-line relapsed or refractory multiple myeloma, after a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody		
3/11/2022	Lynparza (olaparib)	AstraZeneca/ Merck	E	adjuvant treatment of early-stage high-risk HER2-negative breast cancer; after neoadjuvant or adjuvant chemotherapy; germline BRCA1/2 mutations	Myriad Genetics' BRACAnalysis CDx	
3/23/2022	Pluvicto (177Lu-PSMA-617) w/ Locametz (gallium Ga 68 gozetotide)	Novartis	N	progressive, metastatic castration-resistant prostate cancer previously on androgen receptor pathway inhibition and taxane-based chemotherapy; prostate-specific membrane antigen expression determined by Locametz imaging agent		
4/1/2022	Yescarta (axicabtagene ciloleucel)	Gilead Sciences (Kite Pharma)	E	large B-cell lymphoma; refractory to or relapsed within a year of first-line chemo-immunotherapy		
5/4/2022	Enhertu	AstraZeneca/ Daiichi Sankyo	E	second-line therapy for patients with unresectable or metastatic breast cancer or as neoadjuvant or adjuvant treatment after relapse in six months; HER2-positive		Y
5/25/2022	Tibsovo (ivosidenib) w/azacitidine	Servier	E	newly diagnosed acute myeloid leukemia patients; at least 75 years old; cannot have induction chemotherapy due to comorbidities; IDH1 mutation	Abbott Laboratories' RealTime IDH1 Assay	
5/27/2022	Kymriah (tisagenlecleucel)	Novartis	E	relapsed or refractory follicular lymphoma; after at least two lines of systemic therapy		
6/22/2022	Tafinlar (dabrafenib) plus Mekinist (trametinib)	Novartis	E	ages six and older with unresectable, metastatic solid tumors; progressed on other treatment and no other options; BRAF V600E mutation		Y

6/24/2022	Breyanzi (lisocabtagene maraleucel)	Bristol Myers Squibb (Juno Therapeutics)	E	large B-cell lymphoma; refractory to first-line chemo- immunotherapy or relapsed within a year of first-line chemo- immunotherapy		
6/24/2022	Breyanzi (lisocabtagene maraleucel)	Bristol Myers Squibb (Juno Therapeutics)	E	large B-cell lymphoma; refractory to first-line chemo- immunotherapy or relapsed after first-line chemo-immunotherapy and can't have hematopoietic stem cell transplantation due to comorbidities or age		
7/14/2022	Xalkori (crizotinib)	Pfizer	E	ages one year and older with unresectable, recurrent, or refractory inflammatory myofibroblastic tumor; ALK- positive		Y
8/5/2022	Enhertu (trastuzumab- deruxtecan)	AstraZeneca/ Daiichi Sankyo	E	unresectable or metastatic breast cancer; received prior chemotherapy for metastatic cancer or developed recurrence within six months of adjuvant chemotherapy; low HER2 expression (IHC 1+ or IHC 2+/ISH-)	Roche Pathway Anti-HER2/neu (4B5) Rabbit Monoclonal Primary Antibody test (approved 10/4/2022)	
8/11/2022	Enhertu (trastuzumab- deruxtecan)	AstraZeneca/ Daiichi Sankyo	E	unresectable or metastatic non- small cell lung cancer; prior systemic therapy; activating HER2 mutation	Guardant Health's Guardant360 CDx; Thermo Fisher Scientific's Oncomine Dx Target Test	
8/26/2022	Pemazyre (pemigatinib)	Incyte	E	relapsed or refractory myeloid/lymphoid neoplasms; FGFR1 rearrangements		Y
9/22/2022	Retevmo (selpercatinib)	Eli Lilly (Loxo Oncology)	E	locally advanced or metastatic solid tumors; progressed on prior systemic therapy or have no remaining treatment options; RET gene fusions		Y
9/30/2022	Lytgobi (futibatinib)	Taiho Oncology	N	previously treated, unresectable, locally advanced, or metastatic intrahepatic bile duct cancer; FGFR2 fusions or other rearrangements		Y
10/17/2022	Yescarta (axicabtagene ciloleucel)	Gilead Sciences	E	a second-line treatment for patients with relapsed or refractory diffuse large B-cell lymphoma and high-grade B-cell lymphoma		

11/14/2022	Elahere (mirvetuximab soravtansine)	ImmunoGen	N	platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer; up to three prior systemic treatments; folate receptor alpha-positive	Roche's Ventana FOLR1 Rx Dx Assay	
12/1/2022	Rezlidhia (olutasidenib)	Rigel Pharmaceuticals	N	relapsed or refractory acute myeloid leukemia; IDH1 mutations	Abbott Laboratories' RealTime IDH1 Assay	
12/12/2022	Krazati (adagrasib)	Mirati Therapeutics	N	locally advanced or metastatic non-small cell lung cancer, one prior systemic therapy; KRAS G12C mutation	Agilent's Resolution ctDx FIRST; Qiagen's theascreen KRAS RGQ PCR kit	

N - New drug; E - Expanded indication

1 FDA cleared/approved test alongside drug approval

2 Other FDA and non-FDA approved tests available for identifying the treatment-eligible patient population

This list highlights precision oncology drugs the FDA approved in 2022 that rely on biomarker assessment 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 or others may consider personalized based on other criteria.