

2019 Personalized Drug Approvals - Expanded Indications

Approval Date	Drug	Company	Indication	Companion Dx ₁	Other Dx ₂
1/30/2019	pembrolizumab (Keytruda) and pemetrexed injection	Merck	first-line metastatic, non-squamous, non-small cell lung cancer; without EGFR or ALK alterations		Yes
2/28/2019	trastuzumab and hyaluronidase-oysk (Herceptin Hylecta)	Genentech	early breast cancer; HER2 positive	various	
3/8/2019	atezolizumab (Tecentiq) and nab-paclitaxel	Genentech	adults with unresectable locally advanced or metastatic triple-negative breast cancer; PD-L1 positive	Roche Ventana PD-L1 (SP142) Assay	
3/11/2019	ribociclib (Kisqali) and fulvestrant	Novartis	advanced/metastatic, postmenopausal breast cancer as initial endocrine therapy or after progression; HR-positive; HER2 negative		Yes
4/4/2019	palbociclib (Ibrance) and an aromatase inhibitor or fulvestrant	Pfizer	advanced or metastatic breast cancer; men and women; HR positive; HER2 negative		Yes
4/11/2019	pembrolizumab (Keytruda)	Merck	stage III unresectable non-small cell lung cancer; can't receive chemoradiation or metastatic NSCLC; without EGFR or ALK alterations; PD-L1 positive	Agilent Technologies Dako PD-L1 IHC 22C3 pharmDx assay	
4/29/2019	ivacaftor (Kalydeco)	Vertex Pharmaceuticals	cystic fibrosis patients 6 months and older; one mutation in the CFTR gene responsive to ivacaftor based on clinical and/or <i>in vitro</i> assay data		Yes
5/2/2019	ivosidenib (Tibsovo)	Agios Pharmaceuticals	75 years or older, newly-diagnosed acute myeloid leukemia; cannot receive induction chemotherapy; IDH1 mutation	Abbott RealTime IDH1	
5/3/2019	ado-trastuzumab emtansine (Kadcyla)	Genentech	adjuvant treatment of early breast cancer with residual invasive disease after neoadjuvant taxane/trastuzumab based treatment; HER2 positive	various	
5/10/2019	ramucirumab (Cyramza)	Eli Lilly	hepatocellular carcinoma treated with sorafenib and alpha fetoprotein of ≥ 400 ng/mL		Yes
5/16/2019	pitavastatin (Livalo)	Kowa Pharmaceuticals America	8 years or older with heterozygous familial hypercholesterolemia to reduce elevated total cholesterol, LDL-C, and Apo B		Yes
6/10/2019	pembrolizumab (Keytruda)	Merck	first-line metastatic or unresectable, recurrent head and neck squamous cell cancer; PD-L1 positive	Agilent Technologies Dako PD-L1 IHC 22C3 pharmDx assay	
6/21/2019	tezacaftor/ivacaftor and ivacaftor (Symdeko)	Vertex Pharmaceuticals	cystic fibrosis ages 6 to 11 years; two copies of the F508del CFTR mutation or one mutation in CFTR		Yes

			responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence		
7/30/2019	pembrolizumab (Keytruda)	Merck	recurrent locally advanced or metastatic esophageal squamous cell cancer; PD-L1 positive	Agilent Technologies Dako PD-L1 IHC 22C3 pharmDx assay	
8/28/2019	ledipasvir and sofosbuvir (Harvoni)	Gilead Sciences	patients 3 years and older, weighing at least 17 kg, with chronic hepatitis C virus; genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis; genotype 1 infection with decompensated cirrhosis, in combination with ribavirin; genotype 1 or 4 liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin		Yes
8/28/2019	sofosbuvir (Solvadi)	Gilead Sciences	patients 3 years or older, weighing at least 17 kg, with chronic hepatitis C virus: genotype 2 or 3 infection without cirrhosis or with compensated cirrhosis, in combination with ribavirin		Yes
9/17/2019	pembrolizumab (Keytruda) and lenvatinib (Lenvima)	Merck/Eisai	advanced endometrial carcinoma progressing after systemic therapy and cannot receive surgery or radiation; not microsatellite instability high and mismatch repair deficient		Yes
10/23/2019	niraparib (Zejula)	GlaxoSmithKline	advanced ovarian, fallopian tube, or primary peritoneal cancer; received at least three prior chemotherapy regimens; BRCA1/2 mutation or homologous recombination deficiency positive	Myriad Genetics myChoice CDx	
12/3/2019	atezolizumab (Tecentriq) with paclitaxel protein-bound and carboplatin	Genentech	first-line metastatic non-squamous non-small cell lung cancer; without EGFR or ALK alterations		Yes
12/30/2019	olaparib (Lynparza)	AstraZeneca/Merck	maintenance treatment of platinum-responsive, metastatic pancreatic cancer; germline BRCA1/2 mutations	Myriad Genetics BRACAnalysis CDx	

1 FDA cleared/approved tests required for the safe and effective use of a drug

2 Other tests for identifying patient population that can receive treatment

This list highlights personalized drugs that the FDA approved in 2019 with a companion diagnostic, or drugs that rely on other molecular diagnostics to identify who should receive them. This list does not include drugs that may be considered personalized based on other criteria.