2019 Precision Oncology Drug Approvals - New Drugs and Expanded Indications						
Approval Date	**Drug**	**Company**	**New/ Expanded Indication**	**Indication**	**Companion Dx[1]**	**Other Dx[2]**
1/30/2019	pembrolizumab (Keytruda) and pemetrexed injection	Merck	E	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	E	early breast cancer; HER2 positive	various	
3/8/2019	atezolizumab (Tecentriq) and nab-paclitaxel	Genentech	E	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	E	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	E	advanced or metastatic breast cancer; men and women; HR positive; HER2 negative		Yes
4/11/2019	pembrolizumab (Keytruda)	Merck	E	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	
4/12/2019	erdafitinib (Balversa)	Janssen Pharmaceuticals	N	locally advanced/ metastatic bladder cancer progressed on platinum chemo; FGFR3 or FGFR2 alterations	Qiagen therascreen FGFR RGQ RT-PCR Kit	
5/2/2019	ivosidenib (Tibsovo)	Agios Pharmaceuticals	E	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	E	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	E	hepatocellular carcinoma treated with sorafenib and alpha fetoprotein of ≥400 ng/mL		Yes
5/24/2019	alpelisib (Piqray) and fulvestrant	Novartis	N	advanced or metastatic breast cancer; hormone receptor-positive; HER2 negative; PIK3CA mutated	Qiagen therascreen PIK3CA RGQ PCR Kit; Foundation	

					Medicine FoundationOne CDx	
6/10/2019	pembrolizumab (Keytruda)	Merck	E	first-line metastatic or unresectable, recurrent head and neck squamous cell cancer; PD-L1 positive	Agilent Technologies Dako PD-L1 IHC 22C3 pharmDx assay	
7/30/2019	pembrolizumab (Keytruda)	Merck	E	recurrent locally advanced or metastatic esophageal squamous cell cancer; PD-L1 positive	Agilent Technologies Dako PD-L1 IHC 22C3 pharmDx assay	
8/15/2019	entrectinib (Rozlytrek)	Genentech	N	adults and adolescents with solid tumors and without alternatives; NTRK fusions		Yes
8/15/2019	entrectinib (Rozlytrek)	Genentech	N	metastatic non-small cell lung cancer; ROS1 positive		Yes
9/17/2019	pembrolizumab (Keytruda) and lenvatinib (Lenvima)	Merck/Eisai	E	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	E	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	E	first-line metastatic non-squamous non-small cell lung cancer; without EGFR or ALK alterations		Yes
12/20/2019	fam-trastuzumab deruxtecan-nxki (Enhertu)	Daiichi Sankyo/ AstraZeneca	N	unresectable or metastatic breast cancer after at least two prior anti-HER2-based regimens; HER2 positive		Yes
12/30/2019	olaparib (Lynparza)	AstraZeneca/ Merck	E	maintenance treatment of platinum-responsive, metastatic pancreatic cancer; germline BRCA1/2 mutations	Myriad Genetics BRACAnalysis CDx	

N - New drug; E - Expanded indication

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 precision oncology 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 the FDA considers personalized based on other criteria.