

2019 Personalized Drug Approvals - New Drugs					
Approval Date	Drug	Company	Indication	Companion Dx <sup>1</sup>	Other Dx <sup>2</sup>
4/12/2019	erdafitinib (Balversa)	Janssen Pharmaceuticals	locally advanced/metastatic bladder cancer progressed on platinum chemo; FGFR3 or FGFR2 alterations	Qiagen theascreen FGFR RGQ RT-PCR Kit	
5/24/2019	alpelisib (Piqray) and fulvestrant	Novartis	advanced or metastatic breast cancer; hormone receptor-positive; HER2-negative; PIK3CA mutated	Qiagen theascreen PIK3CA RGQ PCR Kit; Foundation Medicine FoundationOne CDx	
8/15/2019	entrectinib (Rozlytrek)	Genentech	adults and adolescents with solid tumors and without alternatives; NTRK fusions		Yes
8/15/2019	entrectinib (Rozlytrek)	Genentech	metastatic non-small cell lung cancer; ROS1 positive		Yes
10/21/2019	elexacaftor/tezacaftor/ivacaftor and ivacaftor (Trikafta)	Vertex Pharmaceuticals	12 years or older with cystic fibrosis with at least one F508del mutation in CFTR gene		Yes
12/12/2019	golodirsen (Vyondys 53)	Sarepta Therapeutics	Duchenne muscular dystrophy with confirmed mutation in dystrophin gene amenable to exon 53 skipping		Yes
12/20/2019	fam-trastuzumab deruxtecan-nxki (Enhertu)	Daiichi Sankyo/AstraZeneca	unresectable or metastatic breast cancer after at least two prior anti-HER2-based regimens; HER2 positive		Yes
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					
<i>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.</i>					