

2017 Personalized Drug Approvals

Approval Date	Drug	Company	Approval Type	Indication	Companion Dx ¹	Complementary Dx ²	Other Dx ³
3/13/17	Kisqali (ribociclib), aromatase inhibitor	Novartis	New	HR+, HER2-advanced BC			Yes
3/27/17	ZeJula (niraparib)	Tesaro	New	maintenance recurrent epithelial ovarian/ fallopian tube/ primary peritoneal cancer after platinum chemo response		Myriad Genetics' BRACAnalysis CDx	Yes
3/30/17	Tagrisso (osimertinib)	AstraZeneca	Full Approval (from accelerated)	EGFR T790M+ mNSCLC	Roche Cobas EGFR Mutation Test v2; FoundationOne CDx		Yes
4/28/17	Alunbrig (brigatinib)	Ariad (Takeda Pharmaceutical)	New	ALK+ mNSCLC progressed on crizotinib			Yes
4/28/17	Rydapt (midostaurin), chemotherapy	Novartis	New	newly diagnosed adults w/ AML; FLT3 mutations	Invivoscribe Technologies' LeukoStrat CDx FLT3 Mutation Assay		Yes
5/17/17	Kalydeco (ivacaftor)	Vertex Pharmaceuticals	Expanded	cystic fibrosis; 33 mutations in CFTR			Yes
5/23/17	Keytruda (pembrolizumab)	Merck	Expanded	adult, pediatric patients w/ microsatellite instability-high or mismatch repair deficient advanced solid tumor progressed on other treatments			Yes
5/26/17	Zykadia (ceritinib)	Novartis	Expanded	first-line ALK+ mNSCLC (w/ brain metastasis)	Roche Ventana ALK (D5F3) test; FoundationOne CDx		Yes
7/17/17	Nerlynx (neratinib)	Puma Biotechnology	New	extended adjuvant treatment early-stage, HER2+ BC; previous treatment w/ Herceptin			Yes
7/18/17	Vosevi (sofosbuvir/ velpatasvir/ voxilaprevir)	Gilead Sciences	New	chronic HCV genotypes 1-6 previously treated with NS5A inhibitor			Yes
8/1/17	Opdivo (nivolumab)	Bristol-Myers Squibb	Expanded	mismatch repair deficient and microsatellite instability-high mCRC w/ progression			Yes
8/1/17	Idhifa (enasidenib)	Celgene	New	IDH2 mutated relapsed/ refractory AML	Abbott Laboratories' RealTime IDH2 Assay		Yes
8/3/17	Mavyret (glecaprevir/ pibrentasvir)	AbbVie	New	chronic HCV genotypes 1-6			Yes
11/6/17	Solvadi (sofosbuvir)	Gilead Sciences	Expanded	pediatric HCV genotypes 2/3 without or compensated cirrhosis			Yes
9/22/17	Keytruda (pembrolizumab)	Merck	Expanded	PD-L1 expressing advanced gastric/ gastroesophageal junction	Dako PD-L1 IHC 22C3 pharmDx		Yes
9/28/17	Verzenio (abemaciclib)	Eli Lilly	New	HR+ HER2- mBC			Yes
11/6/17	Zelboraf (vemurafenib)	Genentech	Expanded	BRAF V600 mutated Erdheim-Chester Disease	Roche cobas BRAF V600 Mutation Test; FoundationOne CDx		Yes
11/6/17	Alecensa (alectinib)	Genentech	Full Approval (from accelerated)	ALK+ mNSCLC	Ventana ALK (D5F3) CDx Assay; FoundationOne CDx		Yes
12/20/17	Perjeta (pertuzumab)/ Herceptin (trastuzumab)/ docetaxel	Genentech	Expanded	previously untreated HER2-positive mBC	Ventana HER2 (4B5) test; FoundationOne CDx		Yes

¹ Required for the safe and effective use of a drug

² Tests for guiding treatment strategy

³ Testing options available through CLIA labs and/ or FDA approved tests

This list highlights personalized drugs that FDA approved in 2017 with a companion/complementary diagnostic, or drugs that rely on lab tests to identify who should receive them. The FDA did not review this list and may evaluate its personalized medicine approval record by other criteria.