

Approval Date	Drug	Company	New (N), Expanded (E), Amended (A) Indication	Indication	Biomarker	N-of-1 Treatment	Gene Therapy
1/6/2023	Leqembi (lecanemab)	Eisai	N	mild cognitive impairment or mild dementia in Alzheimer's disease	beta-amyloid pathology		
1/19/2023	Tukysa (tucatinib)	Seagen/ Genentech	E	with Herceptin (trastuzumab) for unresectable or metastatic colorectal cancer progressed on fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy	RAS wild-type, HER2-positive		
1/27/2023	Orserdu (elacestrant)	Menarini Group	N	postmenopausal women or adult men with advanced or metastatic breast cancer; disease progression on at least one prior endocrine therapy	estrogen receptor-positive, HER2-negative, ESR1-mutated		
2/3/2023	Trodely (sacituzumab govitecan)	Gilead Sciences	E	unresectable, locally advanced or metastatic breast cancer; after endocrine therapy and two systemic therapies	hormone receptor-positive, HER2-negative (IHC 0, IHC 1+ or IHC 2+/ISH-negative)		
3/3/2023	Verzenio (abemaciclib)	Eli Lilly	E	in combination with endocrine therapy for adjuvant treatment of early-stage breast cancer; high-risk of recurrence due to nodal status, tumor size, and tumor grade	hormone receptor-positive HER2-negative <i>*Requirement for Ki-67 testing in 2021 approval rescinded</i>		
3/16/2023	Tafinlar plus Mekinist (dabrafenib plus trametinib)	Novartis	E	low-grade glioma requiring systemic therapy; at least 1 years old	BRAF V600E mutation		
4/25/2023	Qalsody (tofersen)	Biogen	N	amyotrophic lateral sclerosis	SOD1 gene mutation		
4/26/2023	Trikafta (elexacaftor, tezacaftor, ivacaftor and ivacaftor)	Vertex Pharmaceuticals	E	cystic fibrosis; 2 to 5 years old	at least one copy of the CFTR F508del mutation or certain mutations that are responsive to Trikafta based on lab data		
5/3/2023	Kalydeco (ivacaftor)	Vertex Pharmaceuticals	E	cystic fibrosis; 1 month to less than 4 months of age	at least one mutation in the CFTR gene that is responsive to Kalydeco based on clinical and/or <i>in vitro</i> assay data		
5/19/2023	Vyjuvek (beremagene geperpavec-svdt)	Krystal Biotech	N	wounds in pediatric and adult patients with dystrophic epidermolysis bullosa	COL7A1 gene mutations		X
5/31/2023	Lynparza (olaparib)	AstraZeneca	E	with Zytiga (abiraterone) and a steroid for metastatic castration-resistant prostate cancer	deleterious or suspected deleterious BRCA1/2 mutation		
6/20/2023	Talzenna (talazoparib)	Pfizer	E	with Xtandi (enzalutamide) for metastatic castration-resistant prostate cancer	homologous recombination repair gene mutations		
6/22/2023	Elevidys (delandistrogene moxeparovec)	Sarepta Therapeutics	N	ambulatory Duchenne muscular dystrophy; between ages 4 and 5 years old	confirmed DMD gene mutation; contraindicated in those with DMD exon 8/9 deletion		X
6/26/2023	Rystiggo (rozanolixizumab)	UCB	N	generalized myasthenia gravis	AChR or MuSK antibody positive		
6/29/2023	Roctavian (valoctocogene roxaparovec)	BioMarin	N	severe hemophilia A	without antibodies to adeno-associated virus serotype 5		X
7/20/2023	Vanflyta (quizartinib)	Daiichi Sankyo	N	with standard cytarabine and anthracycline induction and cytarabine consolidation, followed by Vanflyta maintenance, for newly diagnosed acute myeloid leukemia	FLT3-internal tandem duplication positive		
7/31/2023	Jemperli (dostarlimab)	GlaxoSmithKline	E	with carboplatin and paclitaxel followed by single-agent Jemperli for primary advanced or recurrent endometrial cancer	mismatch repair deficient or microsatellite instability high		
8/11/2023	Akeega (niraparib and abiraterone acetate)	Janssen	N	with prednisone for metastatic castration-resistant prostate cancer	deleterious or suspected deleterious BRCA1/2 mutation		

9/26/2023	Bosulif (bosutinib)	Pfizer	E	chronic-phase chronic myelogenous leukemia that is newly diagnosed or resistant or intolerant to prior therapy; pediatric patients at least 1 years old	Philadelphia chromosome positive		
10/11/2023	Braftovi (encorafenib) and Mektovi (binimetinib)	Pfizer	E	metastatic non-small cell lung cancer	BRAF V600E mutation		
10/17/2023	Zilbrysq (zilucoplan)	UCB	N	generalized myasthenia gravis	AChR antibody positive		
10/20/2023	Rozlytrek (entrectinib)	Genentech	E	metastatic, unresectable, or refractory solid tumors; pediatric patients older than 1 month <i>*Expanded age requirement from 12 years and older indication with 2019 accelerated approval</i>	NTRK gene fusion		
10/24/2023	Tibsovo (ivosidenib)	Servier Pharmaceuticals	E	relapsed or refractory myelodysplastic syndromes	IDH1 mutations		
11/15/2023	Augtyro (repotrectinib)	Bristol Myers Squibb	N	locally advanced or metastatic non-small cell lung cancer	ROS1 positive		
11/16/2023	Keytruda (pembrolizumab)	Merck	A	with Herceptin (trastuzumab), fluoropyrimidine, and platinum-containing chemotherapy for first-line locally advanced, unresectable or metastatic gastric or gastroesophageal junction adenocarcinoma	HER2 positive; PD-L1 tumor expression (CPS \geq 1) <i>*Prior accelerated approval in 5/5/2021 amended to require PD-L1 testing</i>		
11/16/2023	Truqap (capiivasertib)	AstraZeneca	N	with fulvestrant for locally advanced or metastatic breast cancer; progression on at least one endocrine-based regimen for metastatic disease or recurrence within 12 months of adjuvant therapy	HR-positive, HER2-negative; PIK3CA, AKT1, or PTEN alterations		
12/8/2023	Casgevy (exagamglogene autotemcel)	Vertex Pharmaceuticals	N	sickle cell disease with recurrent vaso occlusive crises; 12 years and older			X
12/8/2023	Lyfgenia (lovetibeglogene autotemcel)	Bluebird Bio	N	sickle cell disease with history of vaso occlusive events; 12 years and older			X

Source: FDA databases, company announcements

Does not include conversions from accelerated to full approval of the same indication.