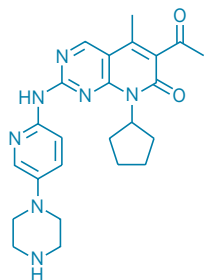
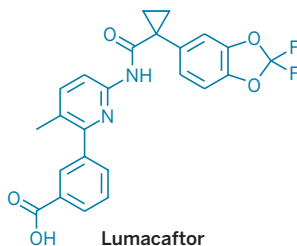


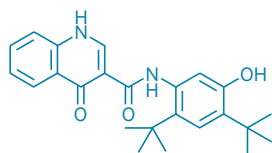
NEW PEAK New drug approvals in the U.S. reached a nearly 20-year high, but innovation was in short supply.



1 Ibrance (palbociclib)

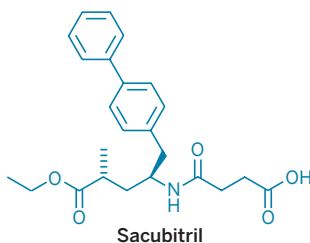


Lumacaftor

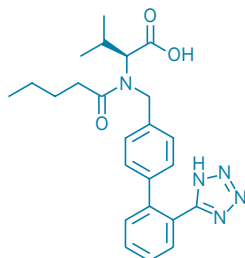


Ivacaftor

4 Orkambi



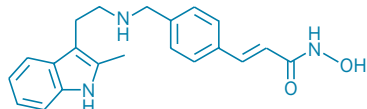
Sacubitril



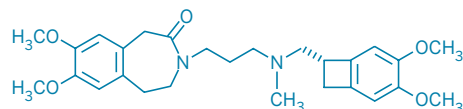
Valsartan

5 Entresto

DRUG NAME	ACTIVE INGREDIENT	APPLICANT	INDICATION	MODE OF ACTION
Savaysa	Edoxaban	Daiichi Sankyo	Anticoagulant	Factor Xa inhibitor
Cosentyx	Secukinumab	Novartis	Psoriasis	IL17A antagonist ◆
Natpara	Parathyroid hormone	NPS Pharmaceuticals ^a	Low calcium levels in hypoparathyroidism	Parathyroid hormone replacement ■
1 Ibrance	Palbociclib	Pfizer	Metastatic breast cancer	CDK inhibitor ▲●◆
Lenvima	Lenvatinib	Eisai	Thyroid cancer	VEGF, FGFR, PDGFR, KIT, RET inhibitor ■●
2 Farydak	Panobinostat	Novartis	Multiple myeloma	HDAC inhibitor ■●
Avycaz	Ceftazidime-avibactam	Forest Laboratories ^a	Antibiotic	Bacterial cell-wall synthesis inhibitor/non-β-lactam β-lactamase inhibitor ●
Cresemba	Isavuconazonium sulfate	Astellas	Antifungal	Prodrug of lanosterol 14 α-demethylase inhibitor ■●
Unituxin	Dinutuximab	United Therapeutics	Children with neuroblastoma	Ganglioside GD2 binding ■◆★
Cholbam	Cholic acid	Asklepiion Pharmaceuticals ^a	Bile acid synthesis disorders	Unknown ■●★
3 Corlanor	Ivabradine	Amgen	Heart failure	HCN channel inhibitor ●◆
Kybella	Deoxycholic acid	Kythera Biopharmaceuticals ^a	Reduce chin fat	Fat cell lysis
Viberzi	Eluxadoline	Forest Laboratories ^a	Irritable bowel syndrome	μ-Opioid receptor agonist and δ-opioid receptor antagonist ●
Kengreal	Cangrelor	The Medicines Co.	Anticoagulant	P2Y12 inhibitor
4 Orkambi	Lumacaftor/ivacaftor	Vertex Pharmaceuticals	Cystic fibrosis	CFTR corrector/CFTR modulator ■▲◆◆
5 Entresto	Sacubitril/valsartan	Novartis	Heart failure	Neprilysin inhibitor/angiotensin receptor blocker ●◆
Rexulti	Brexipiprazole	Lundbeck/Otsuka	Schizophrenia	D ₂ dopamine partial agonist
Praluent	Alirocumab	Sanofi/Regeneron	High cholesterol	PCSK9 inhibitor ◆
Odomzo	Sonidegib	Novartis	Basal cell carcinoma	SMO inhibitor
6 Daklinza	Daclatasvir	Bristol-Myers Squibb	Hepatitis C	NS5A inhibitor ●
7 Addyi	Flibanserin	Sprout Pharmaceuticals ^a	Low libido in women	5-HT1A receptor agonist ◆
Repatha	Evolocumab	Amgen	High cholesterol	PCSK9 inhibitor ■
Varubi	Rolapitant	Tesaro	Chemotherapy-induced nausea	Substance P/NK-1 receptor antagonist



2 Farydak (panobinostat)

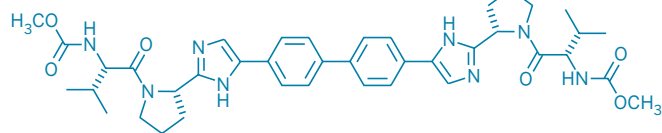


3 Corlanor (ivabradine)

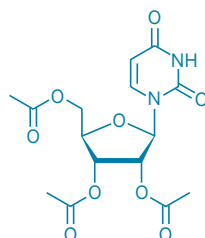
KEY: ■ Small molecule ■ Antibody fragment ■ Peptide ■ Antibody ■ Enzyme
■ Orphan drug ▲ FDA breakthrough status ● FDA priority review ◆ Novel mode of action ★ Priority review voucher earned

DRUG NAME	ACTIVE INGREDIENT	APPLICANT	INDICATION	MODE OF ACTION
8 Xuriden	Uridine triacetate	Wellstat Therapeutics	Hereditary orotic aciduria	Uridine replacement ■▲ ●◆★
Vraylar	Cariprazine	Allergan/Gedeon Richter	Schizophrenia	D ₂ and D ₃ receptor partial agonist
Lonsurf	Trifluridine/tipiracil	Taiho Oncology	Colon cancer	Cytotoxin/thymidine phosphorylase inhibitor
Tresiba	Insulin degludec	Novo Nordisk	Diabetes	Insulin
Aristada	Aripiprazole lauroxil	Alkermes	Schizophrenia	Unknown
Praxbind	Idarucizumab	Boehringer Ingelheim	Reversal of anticoagulant effects of BI's Pradaxa	Dabigatran reversal agent ■▲◆◆
Veltassa	Patiromer	Relypsa	Hyperkalemia	Potassium binding agent
9 Yondelis	Trabectedin	PharmaMar/Johnson & Johnson	Soft-tissue sarcoma	DNA binding agent ●
Strensiq	Asfotase alfa	Alexion Pharmaceuticals	Juvenile-onset hypophosphatase	TNSALP enzyme replacement ■▲◆◆★
Nucala	Mepolizumab	GlaxoSmithKline	Asthma	Interleukin-5 antagonist ◆
Genvoia	Elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide	Gilead Sciences	HIV	Antivirals
10 Cotellic	Cobimetinib	Genentech	Melanoma	MEK inhibitor ■●
11 Tagrisso	Osimertinib	AstraZeneca	EGFR T790M mutation-positive lung cancer	EGFR inhibitor ■▲●
Darzalex	Daratumumab	Johnson & Johnson	Multiple myeloma	Anti-CD38 antibody ■▲ ●◆
Ninlaro	Ixazomib	Takeda Pharmaceutical	Multiple myeloma	Proteasome inhibitor ■●
Portrazza	Necitumumab	Eli Lilly & Co.	Lung cancer	EGFR inhibitor ■
Empliciti	Elotuzumab	Bristol-Myers Squibb/AbbVie	Multiple myeloma	SLAMF7 targeted ■▲◆◆
Kanuma	Sebelipase alfa	Alexion Pharmaceuticals	Lysosomal acid lipase deficiency	Lysosomal acid lipase replacement ■▲◆◆★
Alecensa	Alectinib	Genentech/Roche	ALK-positive lung cancer	ALK fusion inhibitor ■▲●
12 Bridion	Sugammadex	Merck & Co.	Anesthesia reversal	Selective relaxant binding agent ●◆
Uptravi	Selexipag	Actelion Pharmaceuticals	Pulmonary arterial hypertension	Prostacyclin receptor agonist ■
Zurampic	Lesinurad	AstraZeneca	Hyperuricemia	Urate transporter inhibitor

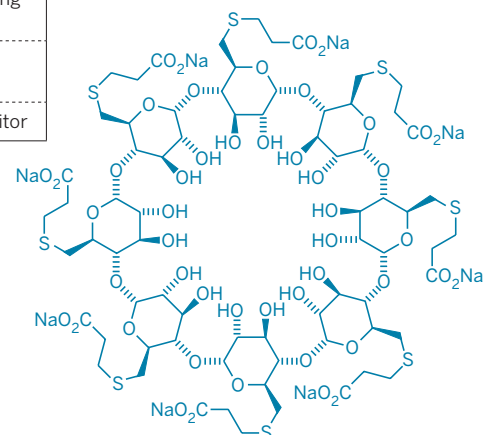
^a Applicant was acquired **SOURCE:** FDA



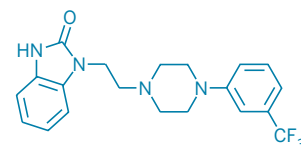
6 Daklinza (daclatasvir)



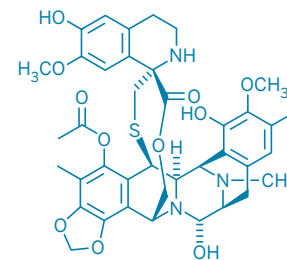
8 Xuriden (uridine triacetate)



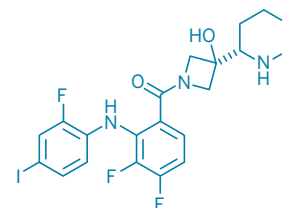
12 Bridion (sugammadex)



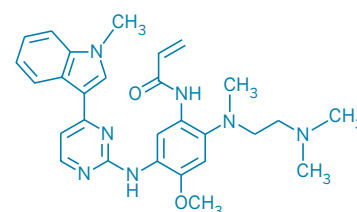
7 Addyi (flibanserin)



9 Yondelis (trabectedin)



10 Cotellic (cobimetinib)



11 Tagrisso (osimertinib)