

New Drug, Generic, and Biosimilar Pipeline Report

Q1 2025

What follows is a summary of significant predicted forthcoming drug launches of newly approved brand drugs, generic drug, and biosimilars.

New Drug Pipeline

GENERIC NAME	BRAND NAME (Manufacturer if drug name unavailable)	ROUTE OF ADMINISTRATION	STATUS	ESTIMATED COST	THERAPEUTIC AREA	SPECIALTY OR TRADITIONAL
Lazertinib	Lazcluze	Oral	Approved Aug 2024	\$200,000- \$300,000 annually	Cancer: Non- Small Cell Lung Cancer	Specialty
Arimoclomol	Miplyffa	Oral	Approved Sept 2024	\$500,000- \$1,000,000	Endocrine: Niemann-Pick disease Type C	Specialty
Lebrikizumab	Ebglyss	Subcutaneous	2H2024 Approved Sept 2024	\$50,000	Dermatology: Atopic Dermatitis	Specialty
Tradipitant	(Vanda Pharmaceuticals)	Oral	Sept 2024 CRL Sept 2024	\$10,000 per course	Gastroenterology: Nausea	Specialty
Xanomeline; Trospium Chloride	Cobenfy	Oral	Approved Sept 2024	\$20,000-\$30,000 annually	Central Nervous System: Schizophrenia	Traditional
Garadacimab	(CSL Behring)	Subcutaneous	2H2024 CRL Oct 2024	\$750,000 annually	Immunology	Specialty
Marstacimab	Hympavzi	Subcutaneous	Approved Oct 2024	\$500,000- \$750,000 annually	Hematology	Specialty
Vicagrel	(Jiangsu Vcare Pharmatech)	Oral	4Q2024	\$5,000-\$10,000 annually	Cardiovascular: Acute Coronary Syndrome	Specialty
Acoramidis	Attruby	Oral	4Q2024 Approved Nov 2024	\$200,000 - \$300,000 annually	Endocrine: Metabolic	Specialty
Inavolisib	Itovebi	Oral	Nov 2024	\$300,000 annually	Cancer	Specialty
Revumenib	Revuforj	Oral	Sept 2024 Approved Nov 2024	\$300,000- \$500,000 annually	Cancer: Leukemia	Specialty
Govorestat	(Applied Therapeutics)	Oral	2H2024 CRL	\$300,000- \$500,000 annually	Endocrine: Metabolic	Specialty
Crinecerfont	(Neurocrine Biosciences)	Oral	Dec 2024	\$300,000 annually	Endocrinology	Specialty
Glepaglutide	(Zeland Pharma)	Subcutaneous	Dec 2024	\$540,000 annually	Gastrointestinal: Short Bowel Syndrome	Specialty
Olezarsen	(Ionis Pharma)	Subcutaneous	Dec 2024	\$300,000-\$500,00 annually	Cardiovascular	Specialty
Sotagliflozin	(Lexicon Pharmaceuticals)	Oral	Dec 2024	\$5,000-\$10,000 annually	Endocrinology: Diabetes	Traditional

Key

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CRL

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Complete Response Letter - Incomplete FDA Application

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Deutivacaftor; Tezacaftor; Vanzacaftor	(Vertex Pharmaceuticals)	Oral	Jan 2025	\$350,000 annually	Central Nervous System	Specialty
Elamipretaide	(Stealth BioTherapeutics)	Ophthalmic	Jan 2025	\$750,000-\$1,000,000 annually	Central Nervous System	Specialty
Sotorasib	Lumakras	Oral	Jan 2025	\$250,000 annually	Cancer: Colon	Specialty
Suzetrigine	(Vertex)	Oral	Jan 2025	\$1,000 per course	Pain Management	Traditional
Mirdametinib	(Pfizer)	Oral	Feb 2025	\$100,000-\$200,000 annually	Cancer	Specialty
Vimseltinib	(Ono Pharmaceuticals)	Oral	Feb 2025	\$200,000-\$300,000 annually	Cancer	Specialty
Diazoxide Choline	Soleno Therapeutics	Oral	Mar 2025	\$200,000-\$400,000 annually	Endocrine	Specialty
Defactinib	Pfizer	Oral	2Q2025	\$200,000-\$300,000 annually	Cancer: Ovarian	Specialty
Etripamil	Cardamyst	Nasal	Mar 2025	\$5,000 per course	Cardiovascular	Specialty
Fitusiran	Sanofi	Subcutaneous	Mar 2025	\$500,000-\$750,000 annually	Hematology	Specialty
Avutometinib	Roche	Oral	2Q2025	\$200,000-\$300,000 annually	Cancer: Ovarian	Specialty
Sebetralstat	KalVista Pharmaceuticals	Oral	Jun 2025	\$200,000-\$300,000 annually	Immunology	Specialty
Chenodal	Mirum Pharmaceuticals	Oral	2H2025	\$500,000-\$750,000 annually	Endocrine	Specialty
Delgocitinib	LEO Pharma	Topical	2H2025	\$5,000-\$10,000 annually	Dermatology	Specialty
Plozasiran	Arrowhead	Subcutaneous	3Q2025	\$300,000-\$500,000 annually	Cardiovascular	Specialty

Generic and Biosimilar Pipeline

DRUG NAME	BRAND NAME	ROUTE OF ADMINISTRATION	STATUS	ESTIMATED 2023 US SALES (MILLIONS)	THERAPEUTIC AREA	BIOSIMILAR OR TRADITIONAL
Raltegravir	ISENTRESS	Oral	2025	\$355	Anti-Infectives: HIV	Traditional
Phentermine/ Topiramate	Qsymia	Oral	Dec 2024	\$51	Endocrine: Obesity	Traditional
Teduglutide	Gattex	Subcutaneous	2025	\$500	Gastrointestinal	Biosimilar
Denosumab	Prolia	Subcutaneous	Nov 2024 2025	\$3,753	Cancer	Biosimilar
Insulin Aspart (AMP-004)	Novolog	Intravenous/Subcutaneous	4Q2024 1H2025	\$3,390	Endocrine: Diabetes	Traditional

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Denosumab	Prolia	Subcutaneous	Nov 2024 2025	\$3,753	Cancer	Biosimilar
Tocilizumab (Tyenne)	Actemra	Intravenous* Subcutaneous*	2024-2025 Jan 2025	\$1,048	Anti-Inflammatory	Biosimilar
Ustekinumab (Wezlana)	Stelara	Subcutaneous	Jan 2025	\$20,616	Anti-Inflammatory	Biosimilar
Simlandi	Humira	Subcutaneous	Feb 2025	\$89,994	Anti-Inflammatory	Biosimilar
Ustekinumab (Selarsdi)	Stelara	Subcutaneous	Feb 2025	\$20,616	Anti-Inflammatory	Biosimilar
Ustekinumab (Pyzchiva)	Stelara	Subcutaneous	Feb 2025	\$20,616	Anti-Inflammatory	Biosimilar
Denosumab (Jubbonti)	Prolia	Subcutaneous	Mar 2025	\$3,760	Musculoskeletal: Osteoporosis	Biosimilar
Denoxumab (Wyost)	Xgeva	Subcutaneous	Mar 2025	\$2,061	Cancer	Biosimilar
Ustekinumab (CT-P43)	Stelara	Subcutaneous	Mar 2025	\$20,616	Anti-Inflammatory	Biosimilar
Ustekinumab (BAT2206)	Stelara	Subcutaneous	2Q2025	\$20,616	Anti-Inflammatory	Biosimilar
Cyltezo HC	Humira	Subcutaneous	Apr 2025	\$89,994	Anti-Inflammatory	Biosimilar
Hercessi	Herceptin	Intravenous	Apr 2025	\$559	Cancer	Biosimilar
Selarsdi	Stelara	Subcutaneous	Apr 2025	\$20,616	Anti-Inflammatory	Biosimilar
Concizumab	Novo Nordisk	Subcutaneous	2H2025	\$500,000- \$750,000 annually	Hematology	Biosimilar
Lecanemab	Leqembi	Subcutaneous	2H2025	\$20,000- \$50,000 annually	Central Nervous System	Specialty
Nilotinib	Tasigna	Oral	1H2024 2H2025	\$1,242	Cancer: Leukemia	Biosimilar
Ahzantive	Neupogen	Intravenous Subcutaneous	Jun 2025	\$139	Hematologic	Biosimilar
Pyzchiva	Stelara	Intravenous Subcutaneous	Jun 2025	\$20,616	Anti-Inflammatory	Biosimilar
Otulfi	Stelara	Subcutaneous	Sep 2025	\$20,616	Anti-Inflammatory	Biosimilar
Imuldosa	Stelara	Subcutaneous	Oct 2025	\$20,616	Anti-Inflammatory	Biosimilar
Selarsdi	Stelara	Intravenous	Oct 2025	\$20,616	Anti-Inflammatory	Biosimilar
Yesintek	Stelara	Subcutaneous Intravenous	Nov 2025	\$20,616	Anti-Inflammatory	Biosimilar

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*New Formulation of an Existing Product

Source: IPD Analytics, 2024

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