

## New Drug, Generic, and Biosimilar Pipeline Report

Q2 2025

Below is a summary of significant predicted forthcoming drug launches of newly approved brand drugs, generic drugs, 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
Vicagrel	(Jiangsu Vcare Pharmatech)	Oral	Pending FDA Approval	\$5,000-\$10,000 annually	Cardiovascular	Specialty
Inavolisib	Itovebi	Oral	Approved Oct 2024	\$300,000 annually	Cancer	Specialty
Crinecerfont	Crenessity	Oral	Approved Dec 2024	\$300,000 annually	Endocrinology	Specialty
Olezarsen	Tryngolza	Subcutaneous	Approved Dec 2024	\$300,000-\$500,00 annually	Cardiovascular	Specialty
Glepaglutide	(Zeland Pharma)	Subcutaneous	CRL Dec 2024	\$540,000 annually	Gastrointestinal: Short Bowel Syndrome	Specialty
Sotagliflozin	Zynquista	Oral	CRL Dec 2024	\$5,000-\$10,000 annually	Endocrinology	Traditional
Sotorasib	Lumakras	Oral	Approved Jan 2025	\$250,000 annually	Cancer: Colon	Specialty
Suzetrigine	Journavx	Oral	Approved Jan 2025	\$1,000 per course	Pain Management	Traditional
Chenodiol	CTEXLI	Oral	Approved Feb 2025	\$500,000-\$750,000 annually	Endocrine	Specialty
Mirdametinib	Gomekli	Oral	Approved Feb 2025	\$100,000-\$200,000 annually	Cancer	Specialty
Vimseltinib	Romvimza	Oral	Approved Feb 2025	\$200,000-\$300,000 annually	Cancer	Specialty
Etripamil	Cardamyst	Nasal	CRL Mar 2025	\$5,000 per course	Cardiovascular	Specialty
Deutivacaftor; Tezacaftor; Vanzacaftor	Alyftrek	Oral	Approved Dec 2025	\$350,000 annually	Central Nervous System	Specialty
Diazoxide Choline	Vykat XR	Oral	Mar 2025	\$200,000-\$400,000 annually	Endocrinology	Specialty
Elamipretaide	(Stealth BioTherapeutics)	Ophthalmic	Jan 2025 Apr 2025	\$750,000-\$1,000,000 annually	Central Nervous System	Specialty
Delgocitinib	Corectim	Topical	2H2025	\$5,000-\$10,000 annually	Dermatology	Specialty
Sebetralstat	(KalVista Pharmaceuticals)	Oral	Jun 2025	\$200,000-\$300,000 annually	Immunology	Specialty

#### Key

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#### Withdrawn

CRL  
 EST LOE  
 PROB

Drug has been withdrawn from FDA approval

Complete Response Letter - Incomplete FDA Application

Estimated Loss of Exclusivity Probability based on IPD Analytics' proprietary estimate of the probability of a generic launch, based on patent analysis and knowledge of generic launches

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Fitusiran	(Sanofi)	Subcutaneous	Pending	\$500,000-\$750,000 annually	Hematology	Specialty
Defactinib	Verastem	Oral	<del>2Q2025</del> Jul 2025	\$200,000-\$300,000 annually	Cancer: Ovarian	Specialty
Avutometinib	(Roche)	Oral	<del>2Q2025</del> Jul 2025	\$200,000-\$300,000 annually	Cancer: Ovarian	Specialty
Plozasiran	(Arrowhead)	Subcutaneous	<del>3Q2025</del> Nov 2025	\$300,000-\$500,000 annually	Cardiovascular	Specialty

## Generic and Biosimilar Pipeline

DRUG NAME	BRAND NAME	ROUTE OF ADMINISTRATION	STATUS / EST LOE PROB	ESTIMATED 2024 US SALES (MILLIONS)	THERAPEUTIC AREA	BIOSIMILAR OR TRADITIONAL
Raltegravir	Isentress	Oral	2025 (80%)	\$355	Anti-Infectives: HIV	Traditional
Teduglutide	Gattex	Subcutaneous	2025 (50%)	\$500	Gastrointestinal	Biosimilar
Insulin Aspart (AMP- 004)	Novolog	Intravenous/Subcutaneous	<del>4H2025</del> Approved Feb 2025	\$3,390	Endocrine: Diabetes	Traditional
Denosumab	Prolia	Subcutaneous	<del>Nov 2024</del> Jun 2025	\$4,317	Cancer	Biosimilar
Phentermine/ Topirimate	Qsymia	Oral	<del>Dec 2024</del> Jun 2025 (60%)	\$51	Endocrine: Obesity	Traditional
Ustekinumab (Steqeyma)	Stelara	Subcutaneous	Approved Dec 2024	\$22,196	Anti-Inflammatory	Biosimilar
Ipratropium	Atrovent HFA	Inhaler	2025 (50%)	\$224	Respiratory	Traditional
Rivaroxaban	Xarelto 2.5 mg	Oral	1H2025	<\$10	Cardiovascular	Traditional
Tocilizumab (Tyenne)	Actemra	Intravenous* Subcutaneous*	<del>2024-2025</del> Approved Jan 2025	\$1,048	Anti-Inflammatory	Biosimilar
Ustekinumab (Wezlana)	Stelara	Subcutaneous	Approved Jan 2025	\$22,196	Anti-Inflammatory	Biosimilar
Simlandi	Humira	Subcutaneous	Approved Feb 2025	\$89,994	Anti-Inflammatory	Biosimilar
Ustekinumab (Pyzchiva)	Stelara	Subcutaneous	Approved Feb 2025	\$22,196	Anti-Inflammatory	Biosimilar
Otufi	Stelara	Subcutaneous	Launched Feb 2025	\$22,196	Anti-Inflammatory	Biosimilar
Yesintek	Stelara	Subcutaneous Intravenous	Launched Feb 2025	\$22,196	Anti-Inflammatory	Biosimilar
Ustekinumab (Selarsdi)	Stelara	Subcutaneous	Approved Feb 2025	\$22,196	Anti-Inflammatory	Biosimilar
Concizumab	Alhemo	Subcutaneous	<del>2H2025</del> May 2025	\$500,000-\$750,000 annually	Hematology	Biosimilar

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Eslicarbazepine	Aptiom	Oral	May 2025 (70%)	\$408M	Central Nervous System	Traditional
Perampanel	Fycompa	Oral	May 2025 (60%)	\$225	Central Nervous System	Traditional
Ticagrelor	Brilinta	Oral	May 2025 (80%)	\$1,400	Cardiovascular	Traditional
Ustekinumab (BAT2206)	Stelara	Subcutaneous	2Q2025 May 2025	\$22,196	Anti-Inflammatory	Biosimilar
Eltrombopag	Promacta	Oral	2H2025 (70%)	\$2,228	Hematology	Biosimilar
Nilotinib	Tasigna	Oral	4H2024 2H2025 (60%)	\$1,209	Cancer	Biosimilar
Denosumab (Wyost)	Xgeva	Subcutaneous	Jun 2025	\$2,136	Cancer	Biosimilar
Glycerol Phenybutyrate	Ravicti	Oral	Jul 2025 (90%)	\$528	Endocrinology	Biosimilar
Sacubitril; Valsartan	Entresto	Oral	Jul 2025 (60%)	\$6,558	Cardiovascular	Traditional
Linagliptin	Tradjenta	Subcutaneous	Nov 2025 (70%)	\$1,444	Endocrinology	Traditional
Macitentan	Opsumit	Oral	4Q2025 (60%)	TBD	Cardiovascular	Biosimilar
Tolvaptan	Jynarque	Oral	2025 (60%)	\$1,851	Endocrinology	Biosimilar
Bosutinib	Bosulif	Oral	2025 (70%)	\$654	Cancer	Biosimilar

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\*New Formulation of an Existing Product

Source: IPD Analytics, 2025

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