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# U.S. Biosimilar Landscape

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## About this report

**Biosimilars are a promising product category, one that can provide patients and doctors with more affordable treatment options.**

To date, there have been 63 approvals and 44 launches in the U.S. biosimilar market. As this market matures, its pipeline continues to grow. This reference guide is a useful tool to visualize and understand the current product landscape and potential future of this emerging market.

The market landscape chart is grouped by therapeutic class with Biosimilars and Follow-on Biologics organized in columns under the relevant molecule and Reference Product. Additional information regarding interchangeability designation ● and unbranded versions ▲ is highlighted via symbols.

The market pipeline charts show products that have not received FDA approval and are expected to launch in 1 to 4 years. These charts suggest a bright future for biosimilars, as they document a large number of existing and new suppliers investing in biosimilars.

# U.S. biosimilar market landscape

As of January 1, 2025

Class	Supportive care			Oncology			Insulin		Ophthalmology	
Molecule	Filgrastim	Epoetin	Pegfilgrastim	Rituximab	Bevacizumab	Trastuzumab	Insulin Gargine	Insulin Lispro	Ranibizumab	Aflibercept
Reference Products Manufacturer	<b>NEUPOGEN</b> Amgen	<b>EPOGEN/ PROCRIT</b> Amgen/J&J	<b>NEULASTA</b> Amgen	<b>RITUXAN</b> Genentech	<b>AVASTIN</b> Genentech	<b>HERCEPTIN</b> Genentech	<b>LANTUS</b> Sanofi	<b>HUMALOG</b> Lilly	<b>LUCENTIS</b> Genentech	<b>EYLEA</b> Regeneron
Biosimilar Products Manufacturer Launch date or approval date	<b>ZARXIO</b> Sandoz Sep 2015	<b>RETACRIT</b> Pfizer-Vifor Nov 2018	<b>FULPHILA</b> Biocon Jul 2018	<b>TRUXIMA</b> Teva Nov 2019	<b>MVASI</b> Amgen Jul 2019	<b>KANJINTI</b> Amgen Jul 2019	▲ <b>SEMGLÉE</b> Biocon Nov 2021	<b>REZVOGLAR</b> Eli Lilly Apr 2023	<b>BYOOVIZ</b> Biocon Jul 2022	<b>PAVBLU</b> Amgen Oct 2024
	<b>NIVESTYM</b> Pfizer Oct 2018		<b>UDENYCA</b> Coherus Jan 2019	<b>RUXIENCE</b> Pfizer Jan 2020	<b>ZIRABEV</b> Pfizer Jan 2020	<b>OGIVRI</b> Biocon Nov 2019			<b>CIMERLI</b> Sandoz Oct 2022	<b>YESAFILI</b> Biocon May 2024
	<b>RELEUKO</b> Amneal Nov 2022		<b>ZIEXTENZO</b> Sandoz Nov 2019	<b>RIABNI</b> Amgen Jan 2021	<b>ALYMSYS</b> Amneal Oct 2022	<b>TRAZIMERA</b> Pfizer Feb 2020				<b>OPUVIZ</b> Biocon May 2024
	<b>NYPOZI</b> Tanvex Jun 2024		<b>NYVEPRIA</b> Pfizer Dec 2020		<b>VEGZELMA</b> Cellion Apr 2023	<b>HERZUMA</b> Teva March 2020				<b>AHZANTIVE</b> Formycon Jun 2024
			<b>STIMUFEND</b> Fresenius Feb 2023		<b>AVZIVI</b> Sandoz Dec 2023	<b>ONTRUZANT</b> Oligeron Apr 2020				<b>ENZEEVU</b> Sandoz Aug 2024
			<b>FYLNETRA</b> Amneal May 2023			<b>HERCESSI</b> Accord Jan 2025				
Follow-on biologics Manufacturer Launch date or approval date							<b>BASAGLAR</b> Eli Lilly Dec 2016	<b>ADMELOG</b> Sanofi Dec 2017		

▲ Unbranded version is also available

● Interchangeability approval by the FDA. For more details on interchangeability, please visit <https://www.fda.gov/media/151094/download>

Approved but yet to launch

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# U.S. biosimilar market landscape

As of January 1, 2025

Class	Immunomodulators							Bone health		
Molecule	Infliximab	Etanercept	Adalimumab		Natalizumab	Tocilizumab	Ustekinumab	Eculizumab	Denosumab	
Reference Products Manufacturer	REMICADE J&J	ENBREL Amgen	HUMIRA AbbVie		TY SABRI Biogen	ACTEMRA IV/SC Genentech	STELARA IV/SC J&J	SOLIRIS Alexion	PROLIA Amgen	XGEVA Amgen
Biosimilar Products Manufacturer Launch date or approval date	INFLECTRA Pfizer Nov 2016	Ongoing litigation forecasted launch 2028/2029	AMJEVITA Amgen Jan 2023	YUSIMRY Methel Jul 2023	TYRUKO Sandoz Aug 2023	TYENNE Fresenius Apr 2024	WEZLANA Optum Jan 2025	BKEMV Amgen May 2024	JUBBONTI Sandoz Mar 2024	WYOST Sandoz Mar 2024
RENFLEXIS Organon Jul 2018	▲ CYLTEZO BI Jul 2023		HADLIMA Organon Jul 2023	TOFIDENCE Biogen May 2024	SELARSDI Teva Apr 2024	EPYSQLI Samsung Jul 2024				
AVSOLA Amgen Jul 2020	▲ HULIO Bionco Jul 2023		▲ IDACIO Fresenius Jul 2023	PYZCHIVA Sandoz Jun 2024						
NOT LAUNCHING IN U.S.	ERELZI Sandoz Aug 2016		▲ HYRIMOZ Sandoz Jul 2023	YUFLYMA Celltrion Jul 2023	OTULFI Fresenius Sep 2024					
IXIFI Pfizer Dec 2017	ETICOVO Samsung Apr 2019	● ABRILADA Pfizer Oct 2023	● SIMLANDI Teva May 2024	IMULDOSA Accord Oct 2024	YESINTEK Bionco Nov 2024					
					STEEQYMA Celltrion Dec 2024					

[View detailed landscape of Adalimumab products](#)

▲ Unbranded version is also available

● Interchangeability approval by the FDA. For more details on interchangeability, please visit <https://www.fda.gov/media/151094/download>

Approved but yet to launch

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# U.S. biosimilar pipeline landscape

As of January 1, 2025

Class	Supportive care	Oncology	Ophthalmology
<b>Molecule</b>	Epoetin, Filgrastim, Pegfilgrastim	Rituximab*, Bevacizumab, Trastuzumab, Pertuzumab, Nivolumab, Pembrolizumab	Ranibizumab, Aflibercept
<b>Reference Products</b> Manufacturer	EPOGEN/PROCRIT (Amgen/J&J), NEUPOGEN (Amgen), NEULASTA (Amgen)	RITUXAN (Genentech), AVASTIN (Genentech), HERCEPTIN (Genentech), PERJETA (Genentech), OPDIVO (BMS), KEYTRUDA (Merck)	LUCENTIS (Genentech), EYLEA (Regeneron)
<b>Pipeline</b> Manufacturer Development stage	APO-EPO (Apotex Ph 3), GRASTOFIL (Accord-Apotex Pending), LAPELGA (Accord-Apotex Pending), LUPIFIL (Lupin Ph 1), LUPIFIL-P (Lupin Pending), TX04 (Tanvex Ph 1)	DRL R1 (Dr. Reddy's Pending), SB8 (Organon-Samsung Pending), TX05 (Tanvex Pending), TBD (Biocon Ph 3), ABP 206 (Amgen Ph 3), GME751 (Sandoz Ph 3), MABIONCD20 (Biocon Ph 3), Kraveva (Biocon Pending), Herwenda (Sandoz Pending), HLX11 (Organon Ph 3), JPB898 (Sandoz Ph 3), BAT3306 (Bio-Thera Ph 3), Equidacent (AstraZeneca Pending), HD201 (Prestige Bio Ph 3), HD204 (Prestige Ph 3), TX16 (Tanvex Ph 1), SB27 (Samsung Ph 3), ABP 234 (Amgen Ph 3)	LUCAMZI (Stada-Valorum Pending), CT-P42 (Celltrion Pending), LUBT010 (Lupin Ph 3), RBS-001 (Rophio Ph 3), SCD411 (Sam Chun Dang Ph 3), AVT06 (Alvotech Ph 3)

Note: Pending is defined as any stage of development between BLA/aBLA submission and full FDA approval.  
 \*Rituximab products are also approved for indications outside of oncology such as autoimmune indications.

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# U.S. biosimilar pipeline landscape

As of January 1, 2025

☰ Class

🧬 Molecule

🧪 Reference Products  
Manufacturer

🧪 Pipeline  
Manufacturer  
Development stage

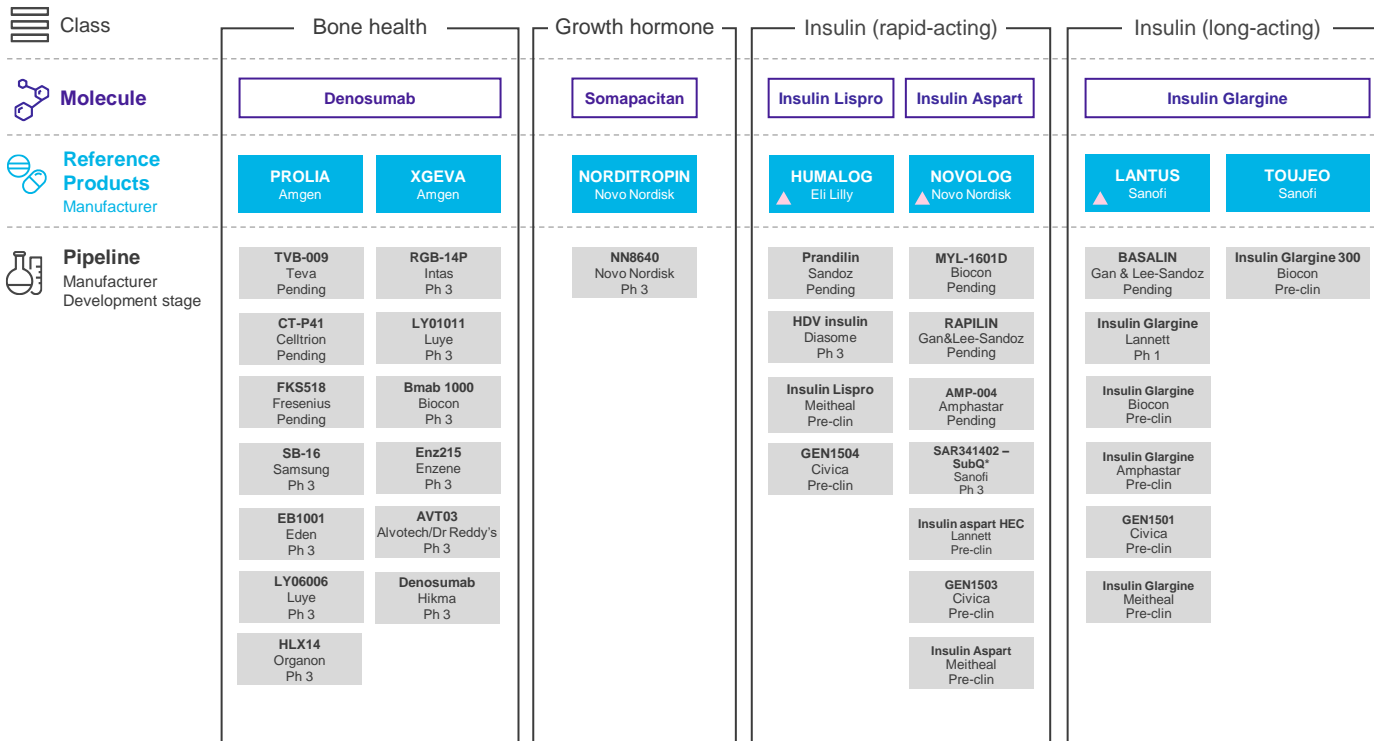
Immunomodulators								
Infliximab	Etanercept	Ustekinumab	Tocilizumab	Certolizumab	Golimumab	Omalizumab	Vedolizumab	Secukinumab
REMICADE J&J	ENBREL Amgen	STELARA IV/SC J&J	ACTEMRA IV/SC Genentech	CIMZIA UCB	SIMPONI J&J	XOLAIR Alexion	ENTYVIO Takeda	COSENTYX Novartis
NI-071 Sagent Ph 3	YLB113 Lupin Ph 3	BAT2206 Hikma-Bio-Thera Pending	CT-P47 Celltrion Pending	Xcimzane Xbrane Pre-clin	BAT2506 Bio-Thera Ph 3	CT-P39 Celltrion Pending	PB016 Polpharma Ph 3	BAT2306 Bio-Thera Ph 3
			DRL_TC Dr. Reddy's Ph 3		AVT05 Alvotech Ph 3	BP11 Aurobindo Ph 3	AVT16 Alvotech-Teva Ph 3	CT-P55 Celltrion Ph 3
						ADL-018 Amneal Ph 3		
						TEV-45779 Teva Ph 3		

Note: Pending is defined as any stage of development between BLA/aBLA submission and full FDA approval.

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# U.S. biosimilar pipeline landscape

As of January 1, 2025



Note: Pending is defined as any stage of development between BLA/aBLA submission and full FDA approval.

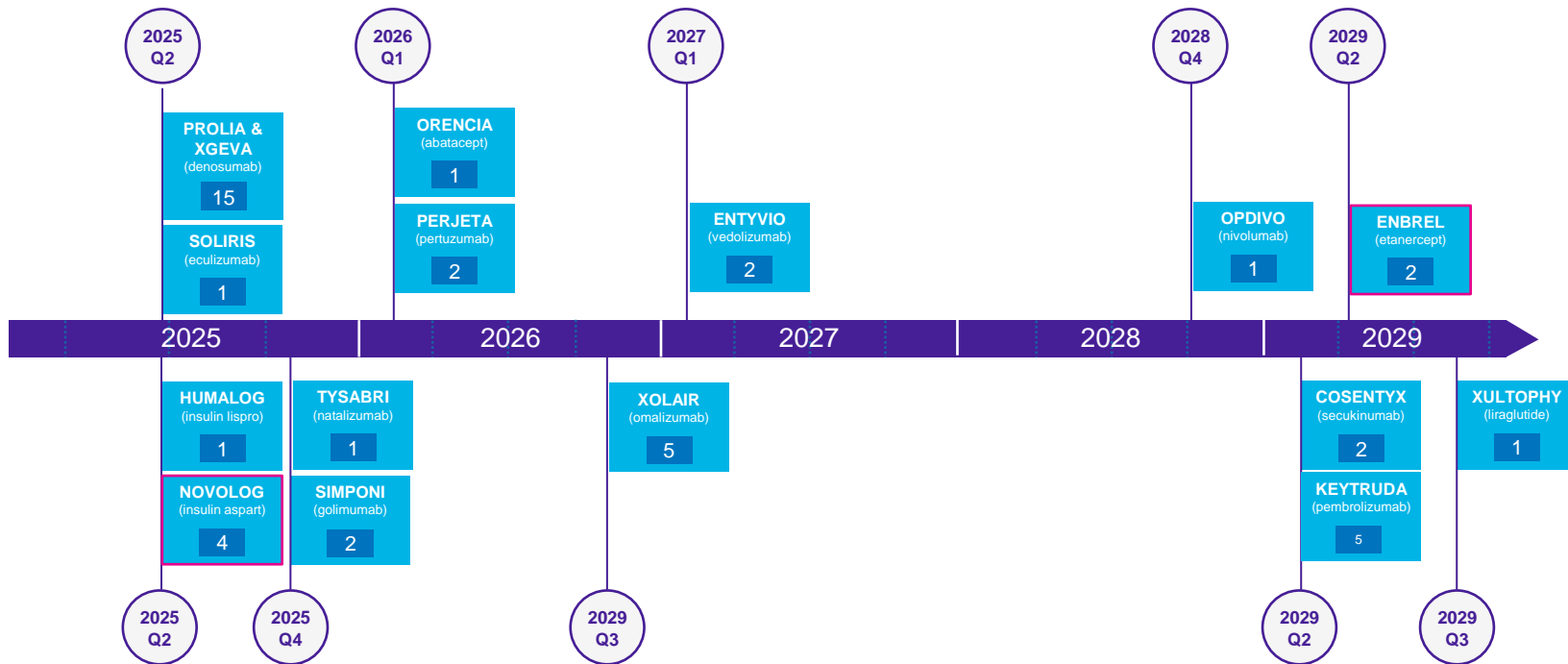
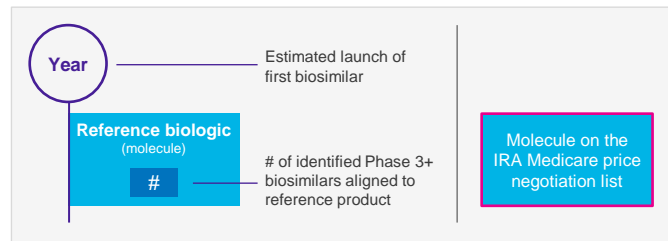
\*Indicates that a biosimilar product has a different route of administration than its innovator product.

▲ Unbranded version is also available

● Interchangeability approval by the FDA. For more details on interchangeability, please visit <https://www.fda.gov/media/151094/download>

# New biosimilar launches

Reference products included have no marketed biosimilars



# Definitions

Product	Definition
<b>Reference products<sup>1</sup></b>	A reference product is a single biological product, already licensed (approved) by the FDA under section 351(a) of the Public Health Service Act, against which a proposed biosimilar or interchangeable product is compared. A reference product is approved based on, among other things, a full complement of safety and effectiveness data.
<b>Biosimilars<sup>1</sup></b>	A biosimilar product is a biological product that is highly similar to and has no clinically meaningful differences in terms of safety or effectiveness from an existing FDA-licensed (approved) reference product.
<b>Interchangeable biosimilars<sup>1</sup></b>	An interchangeable product is a biological product that meets the requirements for a biosimilar product and is approved based on information that is sufficient to show that it can be expected to produce the same clinical result as the reference product in any given patient; and for a biological product that is administered more than once to an individual, there is not a greater safety risk or risk of reduced efficacy from alternating or switching between use of the interchangeable product and its reference product. An interchangeable product can be substituted for the reference product without the intervention of the prescribing healthcare provider.
<b>Unbranded reference products<sup>1</sup></b>	An unbranded reference product generally describes an approved brand name biological product that is marketed under its approved BLA without its brand name (proprietary name) on its label. An “unbranded reference product” is not an “interchangeable biosimilar.” However, an unbranded reference product is considered by the FDA to be equivalent to its brand name biological product because it is the same product as the brand name biological product under the same BLA.
<b>Follow-on biologics</b>	A follow-on biologic is a competing brand product to a reference product and was approved under an NDA pathway before the biosimilar approval pathway (351k) was available.

Key: BLA – Biologics License Application; FDA – Food and Drug Administration; NDA – New Drug Application.

1. FDA. Purple Book. Last updated October 24, 2023. Accessed November 3, 2023. <https://purplebooksearch.fda.gov/>

Find out how Cencora is creating sustainability and longevity for biosimilars.

For more information, please contact us [here](#).



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