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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 71 approvals and 55 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 July 1, 2025

▲ 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

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

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Approved but yet to launch

Class	Immunomodulators									Bone health	
Molecule	Infliximab	Etanercept	Adalimumab		Natalizumab	Tocilizumab	Ustekinumab	Eculizumab	Omalizumab	Denosumab	
Reference Products Manufacturer	REMICADE J&J	ENBREL Amgen	HUMIRA AbbVie		TYSABRI Biogen	ACTEMRA IV/SC Genentech	STELARA IV/SC J&J	SOLIRIS Alexion	XOLAIR Genentech	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 Methenol Jul 2023	TYRUKO Sandoz Aug 2023	TYENNE Fresenius Apr 2024	WEZLANA Optum Jan 2025	BKEMV Amgen Apr 2025	OMLYCLO Celltrion Mar 2025	JUBBONTI Sandoz Jun 2025	WYOST Sandoz Jun 2025
RENFLEXIS Organon Jul 2018	▲ CYLTEZO BI Jul 2023		HADLIMA Organon Jul 2023		TOFIDENCE Organon May 2024	SELARSDI Teva Feb 2025	EPYSQLI Teva Apr 2025		STOBOCLO Celltrion Jul 2025	OSENVELT Celltrion Jul 2025	
AVSOLA Amgen July 2020	▲ HULIO Bioson Jul 2023		IDACIO Fresenius Jul 2023		AVTOZMA Celltrion Jan 2025	PYZCHIVA Sandoz Feb 2025			CONEXENCE Fresenius Jul 2025	BOMYNTRA Fresenius Jul 2025	
NOT LAUNCHING IN U.S.	ERELZI Sandoz Aug 2016		▲ HYRIMOZ Sandoz Jul 2023	YUFLYMA Celltrion Jul 2023			YESINTEK Bioson Feb 2025			OSPOMYV Samsung Feb 2025	XBRYK Samsung Feb 2025
IXIFI Pfizer Dec 2017	ETICOVO Samsung Apr 2019		ABRILADA Pfizer Oct 2023	SIMLANDI Teva May 2024			OTULFI Fresenius Mar 2025				
		View detailed landscape of Adalimumab products					STEQEYMA Celltrion Mar 2025				
							IMULDOSA Accord Jul 2025				
							STARJEMZA Hikma May 2025				

[View detailed landscape of Adalimumab products](#)

Note: Prolia and Xgeva (Denosumab) were approved under the same BLA. While each was approved on a single BLA, brands and biosimilars are listed separately for tracking purposes.

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U.S. biosimilar pipeline landscape

As of July 1, 2025

Class	Supportive care			Oncology						Ophthalmology	
Molecule	Epoetin	Filgrastim	Pegfilgrastim	Rituximab*	Bevacizumab	Trastuzumab	Pertuzumab	Nivolumab	Pembrolizumab	Ranibizumab	Aflibercept
Reference Products 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
Pipeline Manufacturer Development stage	APO-EPO Apotex Ph 3	GRASTOFIL Accord-Apotex Pending	LAPELGA Accord-Apotex Pending	DRL RI Dr. Reddy's CRL	Aybintio Organon-Samsung Ph 3	TX05 Tanvex CRL	TBD Biocon Ph 3	ABP 206 Amgen Ph 3	GME751 Sandoz Ph 3	LUCAMZI Stada-Valorum Pending	CT-P42 Celltrion Pending
		LUPIFIL Lupin Ph 1	LUPIFIL-P Lupin CRL		Equidacent AstraZeneca Pending	Herwenda Sandoz CRL	HLX11 Organon Ph 3	JPB898 Sandoz Ph 3	BAT3306 Bio-Thera Ph 3	LUBT010 Lupin Ph 3	Amicogen Rophibio Ph 3
			TX04 Tanvex Ph 1		HD204 Prestige Ph 3	HD201 Prestige Bio Ph 3			SB27 Samsung Ph 3		SCD411 Fresenius Ph 3
					TX16 Tanvex Ph 1				ABP 234 Amgen Ph 3		AVT06 Alvotect Pending
									CT-P51 Celltrion Ph 3		
									HLX-17 Henlius Ph 3		
									MB12 Fresenius 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 July 1, 2025



Class



Molecule



Reference
Products
Manufacturer



Pipeline
Manufacturer
Development stage

Immunomodulators

Infliximab	Etanercept	Tocilizumab	Certolizumab	Golimumab	Omalizumab	Vedolizumab	Secukinumab	Abatacept
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REMICADE J&J	ENBREL Amgen	ACTEMRA IV/SC Genentech	CIMZIA UCB	SIMPONI J&J	XOLAIR Genentech	ENTYVIO Takeda	COSENTYX Novartis	ORENCIA BMS
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NI-071 Sagent Ph 3	YLB113 Lupin Ph 3	DRL_TC Dr. Reddy's Ph 3	XB003 Xbrane Pre-clin	BAT2506 Bio-Thera Ph 3	BP11 Aurobindo Ph 3	PB016 Polpharma Ph 3	BAT2306 Bio-Thera Ph 3	DRL_AB Dr. Reddy's Ph 3
				AVT05 Alvotect Pending	ADL-018 Amneal Ph 3	AVT16 Alvotect-Teva Ph 3	CT-P55 Celltrion 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 July 1, 2025

Class	Bone health		Insulin (rapid-acting)		Insulin (long-acting)	
Molecule	Denosumab		Insulin Lispro	Insulin Aspart	Insulin Glargine	
Reference Products Manufacturer	PROLIA Amgen	XGEVA Amgen	HUMALOG Eli Lilly	NOVOLOG Novo Nordisk	LANTUS Sanofi	TOUJEO Sanofi
Pipeline Manufacturer Development stage	TVB-009 Teva Pending AVT03 Alvotech/Dr Reddy's Pending EB1001 Eden Ph 3 LY06006 Boan Ph 3 HLX14 Organon Pending MB09 Amneal Pending	RGB-14P Hikma Pending INTP23 Accord Pending Bmab 1000 Biocon Pending Enz215 Enzene Ph 3 MAB-22 Meitheal Ph 3	Prandiin Sandoz Pending Insulin Lispro Biocon Pre-clin Insulin Lispro Meitheal Pre-clin GEN1504 Civica Pre-clin	MYL-1601D Biocon Pending RAPILIN Sandoz Pending AMP-004 Amphastar Pending Insulin aspart HEC Lannett Pre-clin GEN1503 Civica Pre-clin Insulin Aspart Meitheal Pre-clin	BASALIN Sandoz Pending Insulin Glargine Lannett Ph 1 Insulin Glargine Biocon Pre-clin Insulin Glargine Amphastar Pre-clin GEN1501 Civica Pre-clin Insulin Glargine Meitheal Pre-clin	Insulin Glargine 300 Biocon Pre-clin

▲ Unbranded version is also available

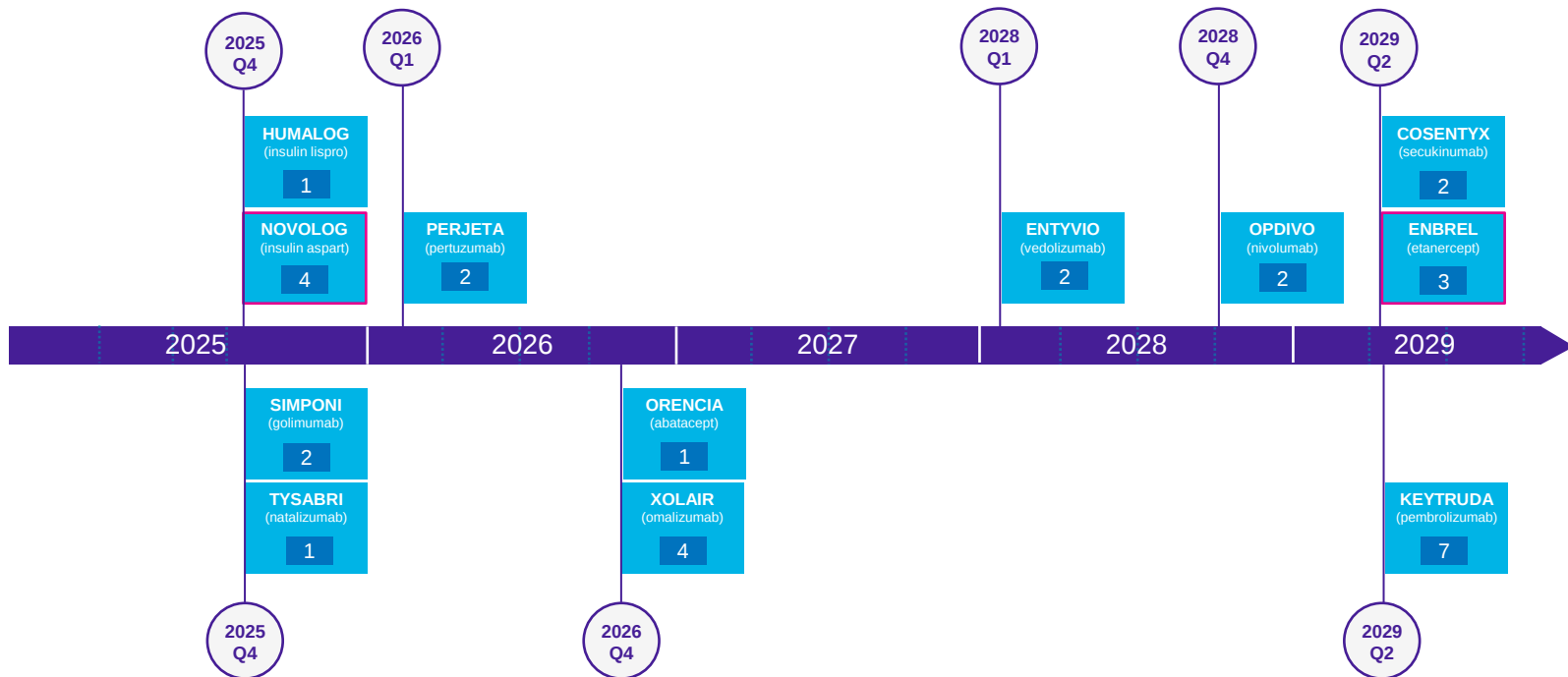
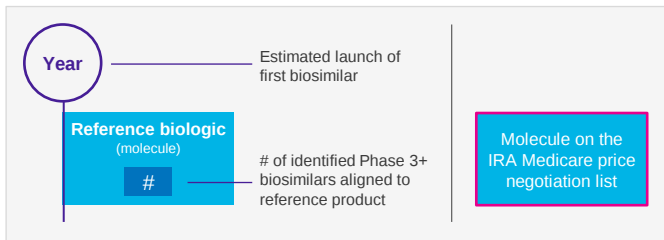
● Interchangeability approval by the FDA. For more details on interchangeability, please visit <https://www.fda.gov/media/151094/download>

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.

New biosimilar launches

Reference products included have no marketed biosimilars



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Definitions

Product	Definition
Reference products¹	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.
Biosimilars¹	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.
Interchangeable biosimilars¹	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.
Unbranded reference products¹	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.
Follow-on biologics	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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