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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 61 approvals and 42 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 November 1, 2024

Class	Supportive care			Oncology			Insulin		Ophthalmology	
Molecule	Filgrastim	Epoetin	Pegfilgrastim	Rituximab	Bevacizumab	Trastuzumab	Insulin Gargine	Insulin Lispro	Ranibizumab	Aflibercept
Reference Products Manufacturer	NEUPOGEN Amgen	EPOGEN/PROCRIT Amgen/J&J	NEULASTA Amgen	RITUXAN Genentech	AVASTIN Genentech	HERCEPTIN Genentech	LANTUS Sanofi		LUCENTIS Genentech	Eylea Regeneron
Biosimilar Products Manufacturer Launch date or Approval date	ZARXIO Sandoz Sep 2015	RETACRIT Pfizer-Vifor Nov 2018	FULPHILA Bioncon Jul 2018	TRUXIMA Teva Nov 2019	MVASI Amgen Jul 2019	KANJINTI Amgen Jul 2019	▲ SEMGLEE Bioncon Nov 2021		BYOOVIZ Bioncon Jul 2022	PAVBLU Amgen Oct 2024
	NIVESTYM Pfizer Oct 2018		UDENYCA Coherus Jan 2019	RUXIENCE Pfizer Jan 2020	ZIRABEV Pfizer Jan 2020	OGIVRI Bioncon Nov 2019	REZVOGLAR Eli Lilly Apr 2023		CIMERLI Coherus Oct 2022	YESAFILI Bioncon May 2024
	RELEUKO Amneal Nov 2022		ZIEXTENZO Sandoz Nov 2019	RIABNI Amgen Jan 2021	ALYMSYS Amneal Oct 2022	TRAZIMERA Pfizer Feb 2020			OPUVIZ Bioncon May 2024	
	NYPOZI Tanvex Jun 2024		NYVEPRIA Pfizer Dec 2020		VEGZELMA Cellion Apr 2023	HERZUMA Teva March 2020			AHZANTIVE Formycon Jun 2024	
			STIMUFEND Fresenius Feb 2023		AVZIVI Sandoz Dec 2023	ONTRUZANT Origin Apr 2020			ENZEEVU Sandoz Aug 2024	
			FYLNETRA Amneal May 2023			HERCESSI Accord May 2024				
Follow-on biologics Manufacturer Launch date or Approval date							BASAGLAR Eli Lilly Dec 2016	ADMELOG 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 November 1, 2024

Class	Immunomodulators							Bone health		
Molecule	Infliximab	Etanercept	Adalimumab		Natalizumab	Tocilizumab	Ustekinumab	Eculizumab	Denosumab	
Reference Products	REMICADE J&J	ENBREL Amgen	HUMIRA AbbVie		TYSABRI Biogen	ACTEMRA IV/SC Genentech	STELARA IV/SC J&J	SOLIRIS Alexion	PROLIA Amgen	XGEVA Amgen
Biosimilar Products	INFLECTRA Pfizer Nov 2016	Ongoing litigation forecasted launch 2028/2029	AMJEVITA Amgen Jan 2023	YUSIMRY Coherus Jul 2023	TYRUKO Sandoz Aug 2023	TYENNE Fresenius Apr 2024	WEZLANA Amgen Oct 2023	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 July 2020	▲ HULIO Bionon 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						

[View detailed landscape of Adalimumab products](#)

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● 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 November 1, 2024

Class	Supportive care	Oncology	Ophthalmology
Molecule	Filgrastim, Epoetin, Pegfilgrastim	Rituximab*, Bevacizumab, Trastuzumab, Pertuzumab, Nivolumab, Pembrolizumab	Ranibizumab, Aflibercept
Reference Products Manufacturer	NEUPOGEN (Amgen), EPOGEN/PROCRIT (Amgen/J&J), NEULASTA (Amgen)	RITUXAN (Genentech), AVASTIN (Genentech), HERCEPTIN (Genentech), PERJETA (Genentech), OPDIVO (BMS), KEYTRUDA (Merck)	LUCENTIS (Genentech), EYLEA (Regeneron)
Pipeline Manufacturer development stage	GRASTOFIL (Accord-Apotex Pending), APO-EPO (Apotex Ph 3), LAPELGA (Accord-Apotex Pending), LUPIFIL (Lupin Ph 1), LUPIFIL-P (Lupin Pending), TX04 (Tanvex Ph 1)	DRL RI (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), HD204 (Prestige Ph 3), Herwenda (Sandoz Pending), HLX11 (Organon Ph 3), JPB898 (Sandoz Ph 3), BAT3306 (Bio-Thera Ph 3), TX16 (Tanvex Ph 1), HD201 (Prestige Bio Ph 3), SB27 (Samsung Ph 3), Kraveva (Biocon Pending), ABP 234 (Amgen Ph 3), Equidacent (AstraZeneca Pending)	LUCAMZI (Stada-Valorum Pending), RBS-001 (Rophibio Ph 3), SCD411 (Sam Chun Dang Ph 3), LUBT010 (Lupin Ph 3), CT-P42 (Celltrion Pending), AVT06 (Alvotect 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 November 1, 2024

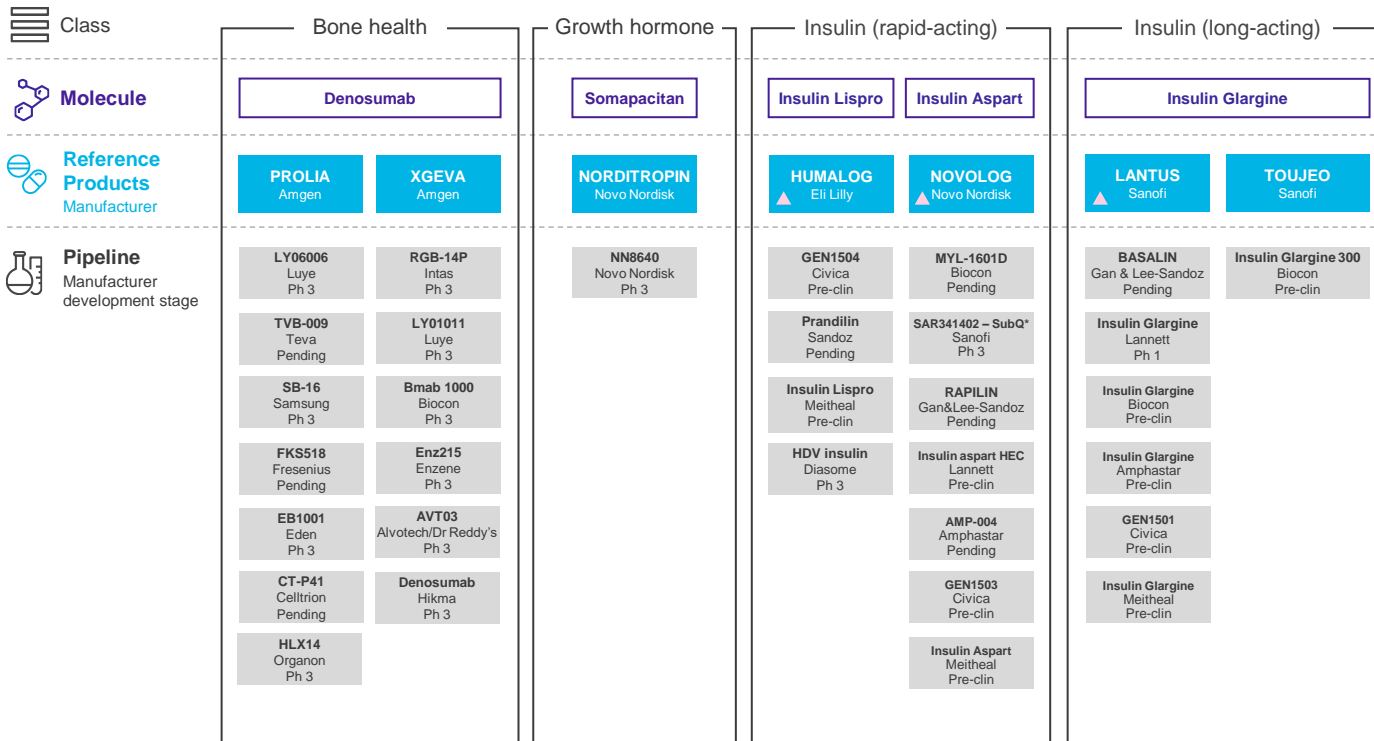
Class	Immunomodulators										
Molecule	Infliximab	Etanercept	Ustekinumab	Tocilizumab	Certolizumab	Golimumab	Eculizumab	Omalizumab	Vedolizumab	Secukinumab	
Reference Products Manufacturer	REMICADE J&J	ENBREL Amgen	STELARA IV/SC J&J	ACTEMRA IV/SC Genentech	CIMZIA UCB	SIMPONI J&J	SOLIRIS Alexion	XOLAIR Alexion	ENTYVIO Takeda	COSENTYX Novartis	
Pipeline Manufacturer development stage	NI-071 Sagent Ph 3	YLB113 Lupin Ph 3	CT-P43 Celltrion Pending	Bmab1200 Biocon 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	
			BAT2206 Hikma-Bio-Thera Pending		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 November 1, 2024



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

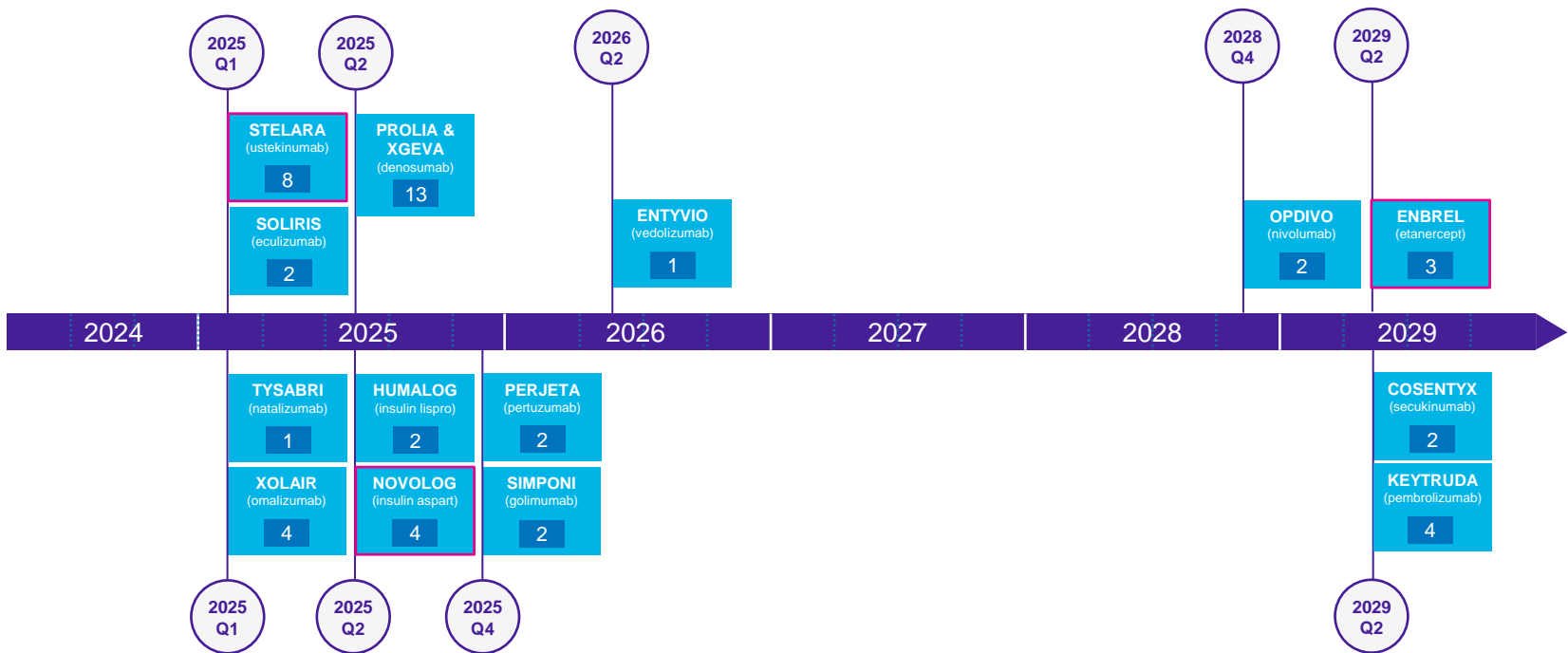
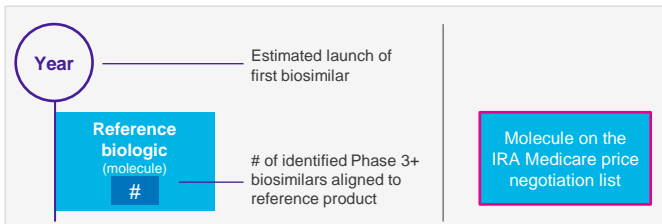
*Indicates that a biosimilar product has a different route of administration than its innovator product.

▲ 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 launched 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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