

cencora

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 53 approvals and 41 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.

The pipeline charts also capture the expansion of biosimilars into new therapeutic areas, including growth hormone, bone health, and immunomodulators.

U.S. biosimilar market landscape

As of June 1, 2024

Class	Supportive care			Oncology			Insulin		Ophthalmology	
Molecule	Filgrastim	Epoetin	Pegfilgrastim	Rituximab	Bevacizumab	Trastuzumab	Insulin Glargine	Insulin Lispro	Ranibizumab	Afibercept
Reference Products	NEUPOGEN Amgen	EPOGEN/ PROCRIT Amgen/J&J	NEULASTA Amgen	RITUXAN Genentech	AVASTIN Genentech	HERCEPTIN Genentech	LANTUS Sanofi		LUCENTIS Genentech	Eylea Regeneron
Biosimilar Products	ZARXIO Sandoz Sep 2015	RETACRIT Pfizer-Vifor Nov 2018	FULPHILA Mylan Jul 2018	TRUXIMA Teva Nov 2019	MVASI Amgen Jul 2019	KANJINTI Amgen Jul 2019	▲ SEMGLÉE Viatris-Mylan Nov 2021		BYOOVIZ Biogen Jul 2022	YESAFILI Bionn May 2024
Manufacturer										
Launch date or Approval date	NIVESTYM Pfizer Oct 2018		UDENYCA Coherus Jan 2019	RUXIENCE Pfizer Jan 2020	ZIRABEV Pfizer Jan 2020	OGIVRI Mylan Nov 2019	REZVOGLAR Eli Lilly Apr 2023		CIMERLI Coherus Oct 2022	OPUVIZ Biogen May 2024
Manufacturer										
Launch date or Approval date	RELEUKO Amneal Nov 2022		ZIEXTENZO Sandoz Nov 2019	RIABNI Amgen Jan 2021	ALYMSYS Amneal Oct 2022	TRAZIMERA Pfizer Feb 2020				
Manufacturer										
Launch date or Approval date			NYVEPRIA Pfizer Dec 2020		VEGZELMA Celltrion Apr 2023	HERZUMA Teva March 2020				
Manufacturer										
Launch date or Approval date			STIMUFEND Fresenius Feb 2023		AVZIVI Sandoz Dec 2023	ONTRUZANT Originion Apr 2020				
Manufacturer										
Launch date or Approval date			FYLNETRA Amneal May 2023			HERCESSI Accord May 2024				
Manufacturer										
Launch date or Approval date										
Follow-on biologics							BASAGLAR Eli Lilly Dec 2016	ADMELOG Sanofi Dec 2017		
Manufacturer										
Launch date or Approval date										

▲ 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 June 1, 2024

Class	Immunomodulators							Bone health			
Molecule	Infliximab	Etanercept	Adalimumab		Natalizumab	Tocilizumab	Ustekinumab	Eculizumab	Denosumab		
Reference Products	REMICADE J&J	ENBREL Amgen	HUMIRA AbbVie		TYTABRI 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					
AVSOLA Amgen July 2020	▲ HULIO Viatris Jul 2023		▲ IDACIO Fresenius Jul 2023								
NOT LAUNCHING IN U.S.	ERELZI Sandoz Aug 2016		▲ HYRIMOZ Sandoz Jul 2023	YUFLYMA Celltrion Jul 2023							
IXIFI Pfizer Dec 2017	ETICOVO Samsung Apr 2019	● ABRILADA Pfizer Oct 2023	● SIMLANDI Teva May 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 June 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), TX01 (Tanvex Pending), LUPIFIL-P (Lupin Pending), LUPIFIL (Lupin Ph 1), 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), BAT3306 (Bio-Thera Ph 3), TX16 (Tanvex Ph 1), HD201 (Prestige Bio Ph 3), Krabeva (Biocon Pending), Equidacent (AstraZeneca Pending)	LUCAMZI (Stada - Valorum Pending), ABP 938 (Amgen Pending), SCD411 (Sam Chun Dang Ph 3), LUBT010 (Lupin Ph 3), FYB203 (Formycon Pending), AVT06 (Alvotech Ph 3), ALT-L9 (Alteogen Pre-clin), CT-P42 (Celltrion Pending), SOK583A1 (Sandoz-Hexal 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 June 1, 2024

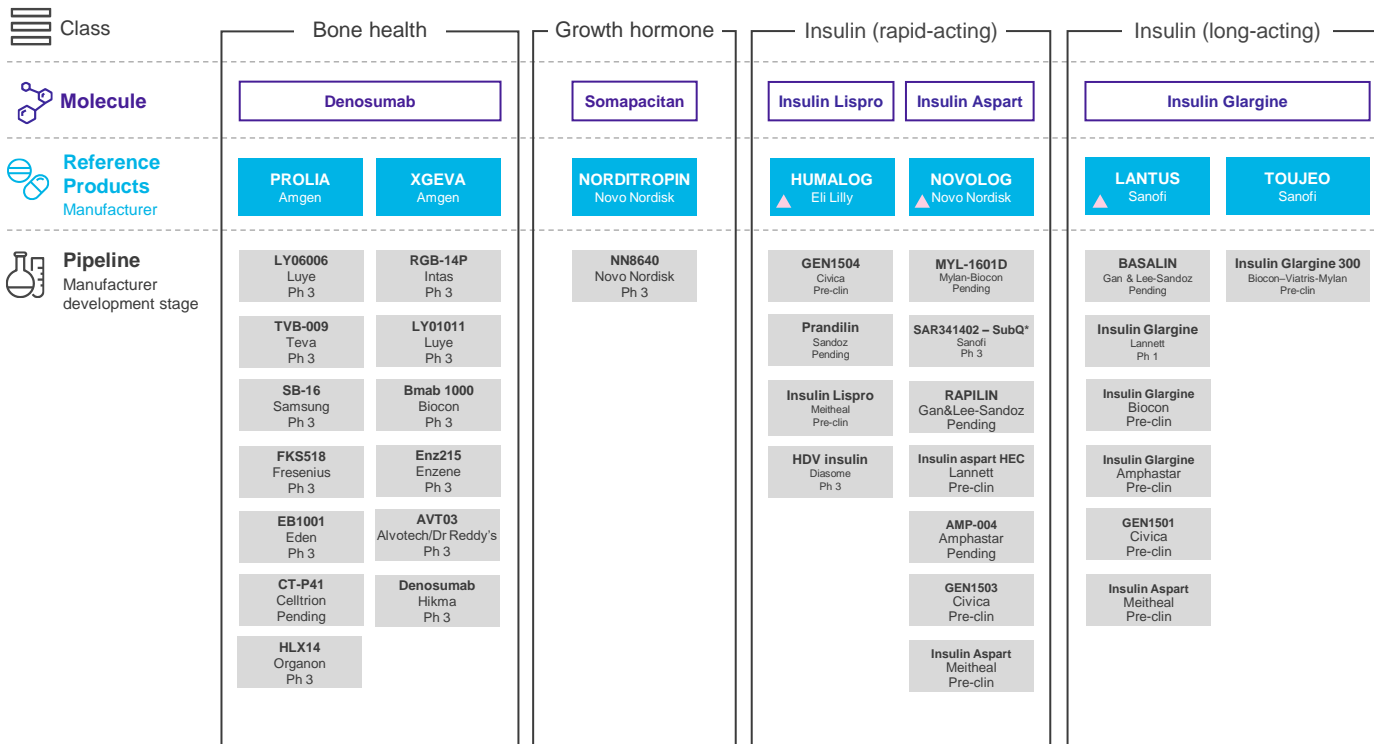
Class	Immunomodulators										
Molecule	Infliximab	Etanercept	Ustekinumab	Tocilizumab	Certolizumab	Golimumab	Eculizumab	Omalizumab	Vedolizumab	Secukinumab	
Reference Products Manufacturer	REMICADE J&J	ENBREL Amgen	STELARA IV/SC J&J	ACTEMRA IV/SC Genentech	CIMZIA UCB	SIMPONI J&J	SOLIRIS Alexion	XOLAIR Alexion	ENTYVIO Takeda	COSENTYX Novartis	
Pipeline Manufacturer development stage	NI-071 Sagent Ph 3	YLB113 Lupin Ph 3	NEULARA NeuClone Ph 1 CT-P43 Celltrion Pending FYB202 Fresenius Pending DMB-3115 Accord Pending	SB17 Samsung Bioepis Pending Bmab1200 Biocon Pending BAT2206 Hikma-Bio-Thera Ph 3	CT-P47 Celltrion Pending DRL_TC Dr. Reddy's Ph 3	Xcimzane Xbrane-Biogen Pre-clin	BAT2506 Bio-Thera Ph 3 AVT05 Alvotech Ph 3	SB12 Samsung Bioepis Pending	CT-P39 Celltrion Pending BP11 Aurobindo Ph 3 ADL-018 Amneal Ph 3 TEV-45779 Teva Ph 3	PB016 Polpharma Ph 3 AVT16 Alvotech-Teva Ph 1	BAT2306 Bio-Thera 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 June 1, 2024



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

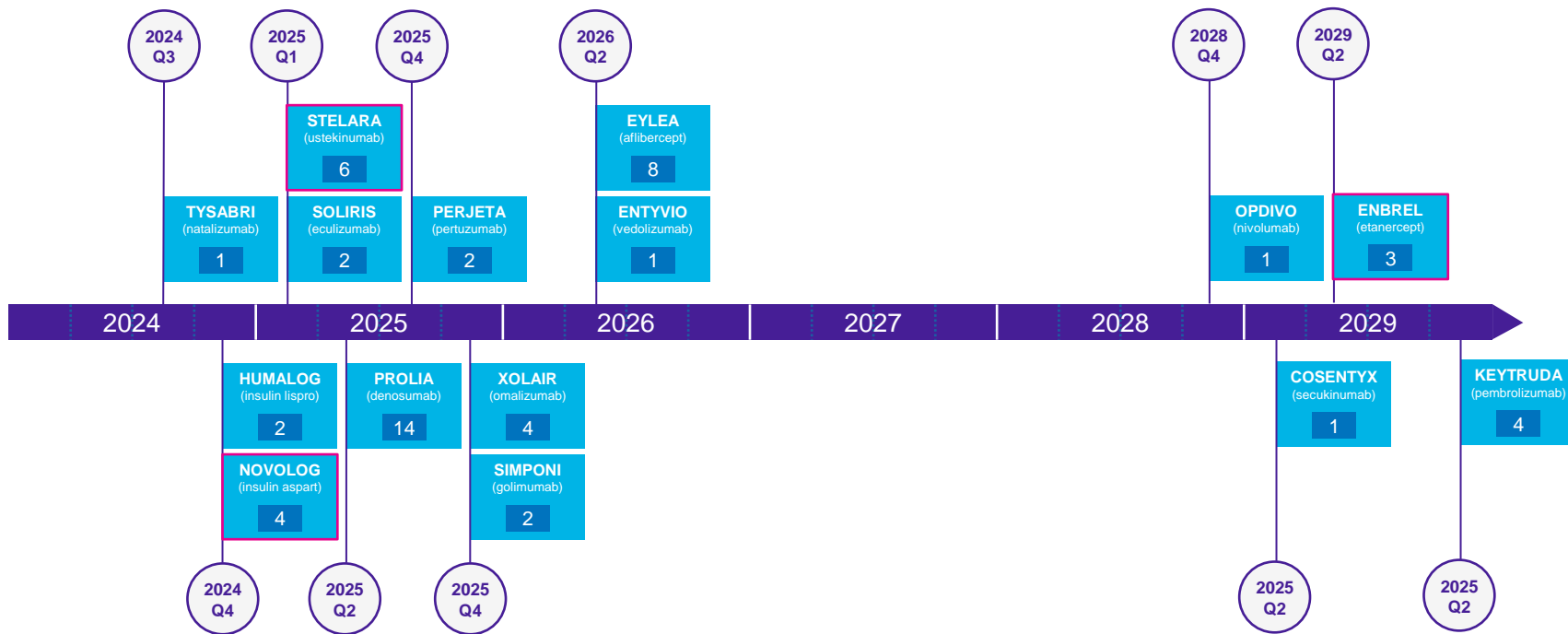
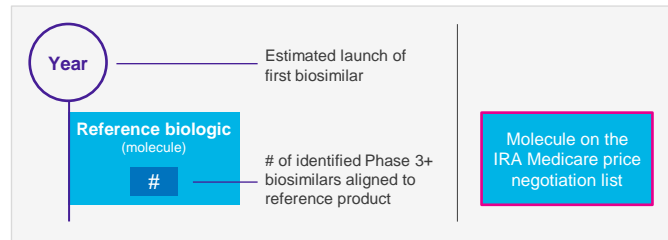
*Indicates that a biosimilar product has a different route of administration than its innovator product.

▲ 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 marketed biosimilars and 1+ pipeline asset in trials



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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 formerly approved under an NDA and subsequently deemed a BLA by the FDA.

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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