

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 69 approvals and 49 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 April 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 Gargine Insulin Lispro Insulin Aspart	Ranibizumab Aflibercept
Reference Products Manufacturer	NEUPOGEN Amgen EPOGEN/PROCRIT 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 NIVESTYM Pfizer Oct 2018 RELEUKO Amneal Nov 2022 NYPOZI Tanvex Jun 2024	TRUXIMA Teva Nov 2019 RUXIENCE Pfizer Jan 2020 RIABNI Amgen Jan 2021	SEMGLEE Biocron Nov 2021 REZVOGLAR Eli Lilly Apr 2023	BYOOVIZ Biogen Jul 2022 CIMERLI Sandoz Oct 2022
Biosimilar Products Manufacturer Launch date or approval date	RETACRIT Pfizer-Vifor Nov 2018 UDENYCA Coherus Jan 2019 ZIEXTENZO Sandoz Nov 2019 NYVEPRIA Pfizer Dec 2020 STIMUFEND Fresenius Feb 2023 FYLNETRA Amneal May 2023	MVASI Amgen Jul 2019 ZIRABEV Pfizer Jan 2020 ALYMSYS Amneal Oct 2022 VEGZELMA Cellion Apr 2023 AVZIVI Sandoz Dec 2023	KANJINTI Amgen Jul 2019 OGVIRI Biocron Nov 2019 TRAZIMERA Pfizer Feb 2020 HERZUMA Teva March 2020 ONTRUZANT Originol Apr 2020 HERCESSI Accord Jan 2025	PAVBLU Amgen Oct 2024 YESAFILI Biocron May 2024 OPUVIZ Biogen May 2024 AHZANTIVE Formycon Jun 2024 ENZEEVU Sandoz Aug 2024
Follow-on biologics Manufacturer Launch date or approval date			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 RENFLEXIS Organon Jul 2018 AVSOLA Amgen July 2020 NOT LAUNCHING IN U.S. IXIFI Pfizer Dec 2017	Ongoing litigation forecasted launch 2028/2029 ERELZI Sandoz Aug 2016 ETICOVO Samsung Apr 2019	● AMJEVITA Amgen Jan 2023 ▲ CYLTEZO BI Jul 2023 ▲ HULIO Biocron Jul 2023 ● HYRIMOZ Sandoz Jul 2023 ● ABRILADA Pfizer Oct 2023	● YUSIMRY Methel Jul 2023 ● HADLIMA Organon Jul 2023 ▲ IDACIO Fresenius Jul 2023 ● YUFLYMA Celltrion Jul 2023 ● SIMLANDI Teva May 2024	● TYRUKO Sandoz Aug 2023 ● AVOZMA Sandoz Jan 2025	● TYENNE Fresenius Apr 2024 ● TOFIDENCE Biogen May 2024 ● AVOZMA Sandoz Jan 2025	● WEZLANA Optum Jan 2025 ● SELARSDI Teva Feb 2025 ● PYZCHIVA Sandoz Feb 2025 ● YESINTEK Biocron Feb 2025 ● OTULFI Fresenius Mar 2025 ● STEQEYMA Celltrion Mar 2025 ● IMULDOSA Accord Oct 2024	● BKEMV Amgen May 2024 ● EPYSQLI	● OMLYCLO Celltrion Mar 2025	● JUBBONTI Sandoz Mar 2024 ● OSPOMYV Samsung Feb 2025 ● STOBOCLO Celltrion Feb 2025 ● CONEXENCE Fresenius Mar 2025	● WYOST Sandoz Mar 2024 ● XBRYK Samsung Feb 2025 ● OSENVELT Celltrion Feb 2025 ● BOMYNTRA Fresenius Mar 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 April 1, 2025

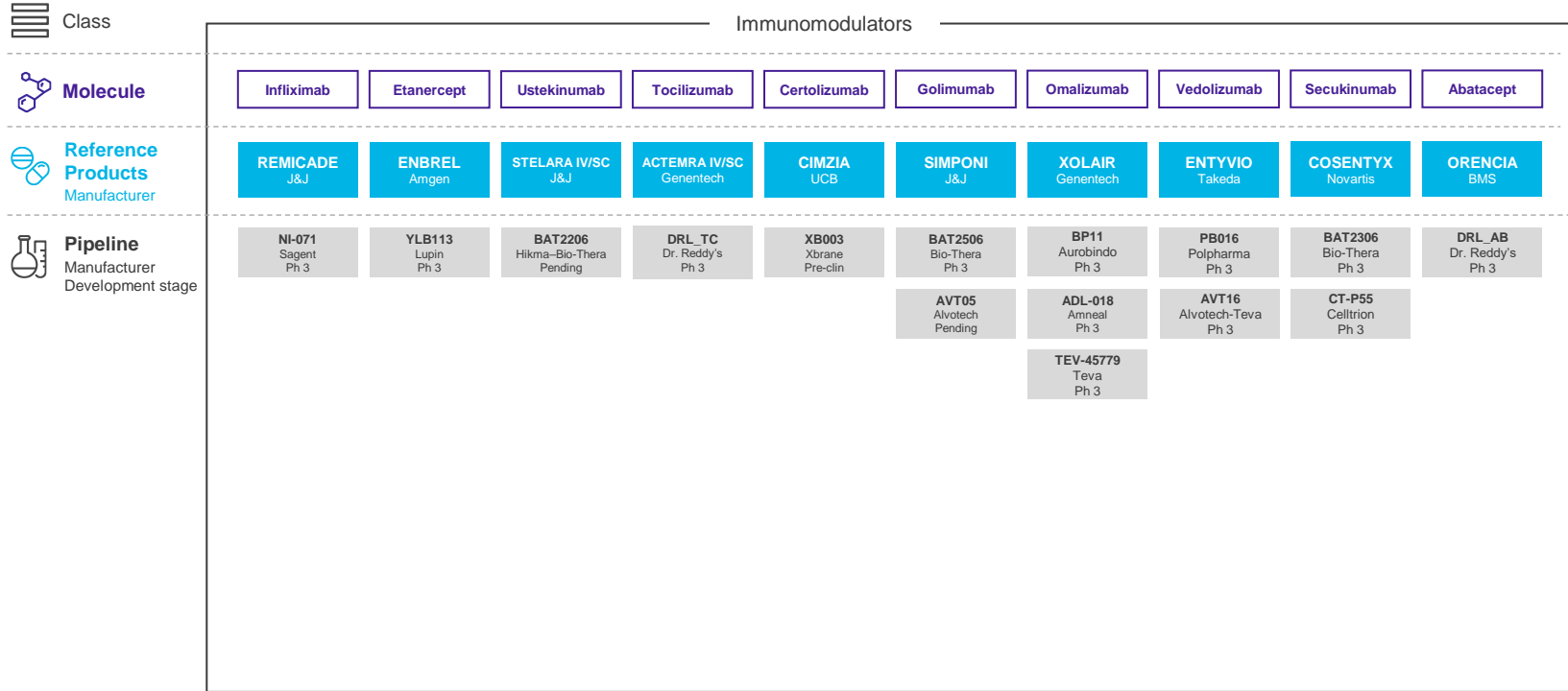
Class	Supportive care	Oncology	Ophthalmology
Molecule	Epoetin, Filgrastim, Pegfilgrastim	Rituximab*, Bevacizumab, Trastuzumab, Pertuzumab, Nivolumab, Pembrolizumab	Ranibizumab, Aflibercept
Reference Products Manufacturer	EPOGEN/PROCRIT (Amgen/J&J), NEUPOGEN (Amgen), NEULASTA (Amgen)	RITUXAN (Genentech), AVASTIN (Genentech), HERCEPTIN (Genentech), PERJETA (Genentech), OPDIVO (BMS), KEYTRUDA (Merck)	LUCENTIS (Genentech), EYLEA (Regeneron)
Pipeline Manufacturer Development stage	<p>APO-EPO (Apotex Ph 3), GRASTOFIL (Accord-Apotex Pending), LAPELGA (Accord-Apotex Pending)</p> <p>LUPIFIL (Lupin Ph 1), LUPIFIL-P (Lupin CRL), TX04 (Tanvex Ph 1)</p>	<p>DRL R1 (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)</p> <p>MABIONCD20 (Biocon Ph 3), Kraveva (Biocon Pending), Herwenda (Sandoz CRL), HLX11 (Organon Ph 3), JPB898 (Sandoz Ph 3), BAT3306 (Bio-Thera Ph 3)</p> <p>Equidacent (AstraZeneca Pending), HD201 (Prestige Bio Ph 3), SB27 (Samsung Ph 3)</p> <p>HD204 (Prestige Ph 3), ABP 234 (Amgen Ph 3)</p> <p>TX16 (Tanvex Ph 1), CT-P51 (Celltrion Ph 3), HLX-17 (Henlius Ph 3), MB12 (Fresenius Ph 3)</p>	<p>LUCAMZI (Stada-Valorum Pending), CT-P42 (Celltrion Pending)</p> <p>LUBT010 (Lupin Ph 3), Amicogen (Rophibio Ph 3), SCD411 (Fresenius Ph 3), AVT06 (Alvotech Ph 3)</p>

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 April 1, 2025



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 April 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 RGB-14P Hikma Pending AVT03 Alvotech/Dr Reddy's Pending INTP23 Accord Pending EB1001 Eden Ph 3 Bmab 1000 Biocon Pending LY06006 Boan Ph 3 Enz215 Enzene Ph 3 HLX14 Organon Pending MAB-22 Meitheal Ph 3 MB09 Amneal Pending	Prandiin Sandoz Pending MYL-1601D Biocon Pending Insulin Lispro Biocon Pre-clin RAPILIN Sandoz Pending Insulin Lispro Meitheal Pre-clin AMP-004 Amphastar Pending GEN1504 Civica Pre-clin Insulin aspart HEC Lannett Pre-clin GEN1503 Civica Pre-clin Insulin Aspart Meitheal Pre-clin	BASALIN Sandoz Pending Insulin Glargine 300 Biocon Pre-clin Insulin Glargine Lannett Ph 1 Insulin Glargine Biocon Pre-clin Insulin Glargine Amphastar Pre-clin GEN1501 Civica Pre-clin Insulin Glargine Meitheal Pre-clin

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

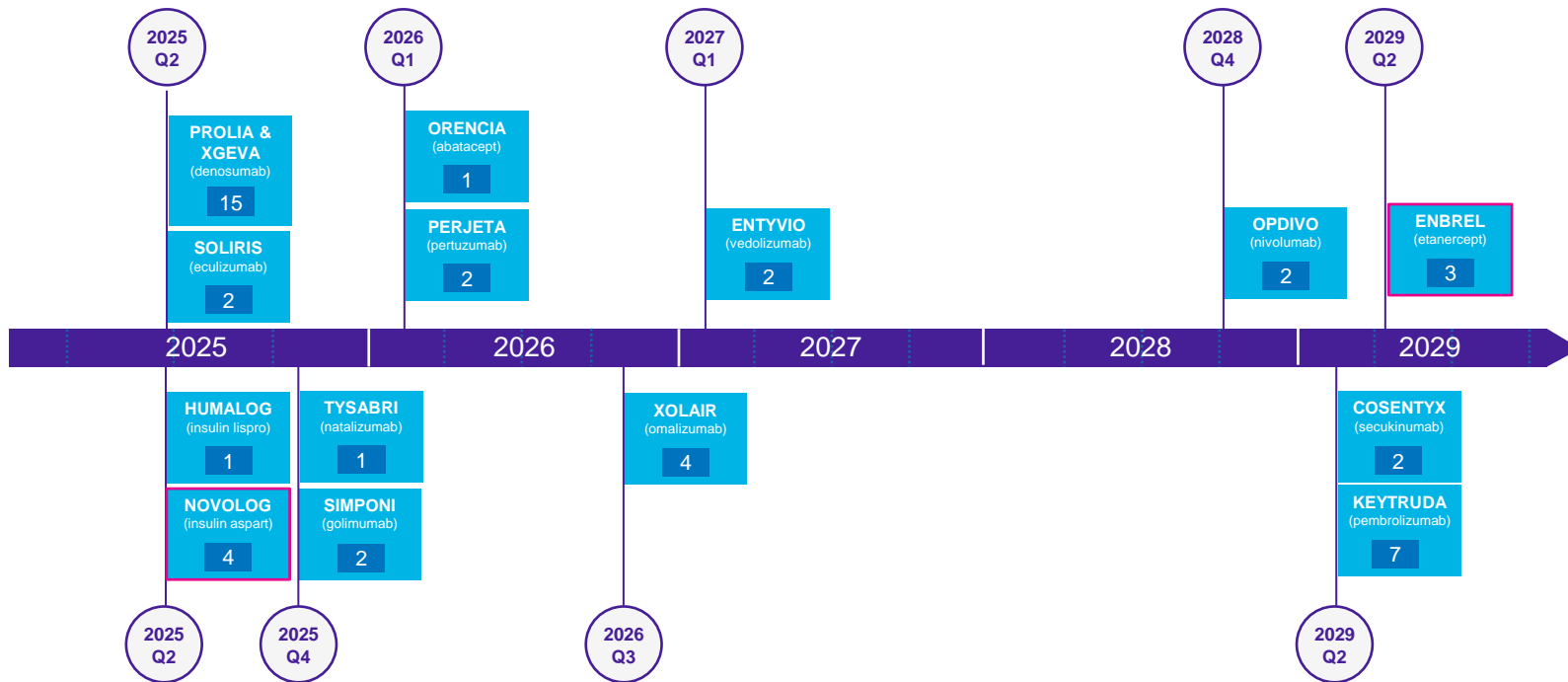
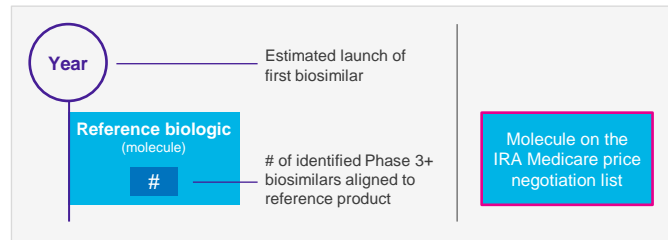
* Indicates that a biosimilar product has a different route of administration than its innovator product.

▲ 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
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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