

cencora

# U.S. Biosimilar Landscape

Developed by:

**Brian Biehn**

Senior Director, Biosimilars

**Connor Nell**

Director, Biosimilars



## 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 48 approvals and 38 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 March 11, 2024



Class

Supportive care

Oncology

Insulin

Ophthalmology



Molecule

Filgrastim

Epoetin

Pegfilgrastim

Rituximab

Bevacizumab

Trastuzumab

Insulin Glargine

Insulin Lispro

Ranibizumab



Reference Products  
Manufacturer

**NEUPOGEN**  
Amgen

**EPOGEN/ PROCRIT**  
Amgen/J&J

**NEULASTA**  
Amgen

**RITUXAN**  
Genentech

**AVASTIN**  
Genentech

**HERCEPTIN**  
Genentech

**LANTUS**  
Sanofi

**LUCENTIS**  
Genentech



Biosimilar Products  
Manufacturer  
Launch date or  
Approval date

**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

**SEMGLEE**  
Viatris-Mylan  
Nov 2021

**BYOOVIZ**  
Biogen  
Jul 2022

**INVESTYM**  
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

**RELEUKO**  
Amneal  
Nov 2022

**ZIEXTENZO**  
Sandoz  
Nov 2019

**RIABNI**  
Amgen  
Jan 2021

**ALYMSYS**  
Amneal  
Oct 2022

**TRAZIMERA**  
Pfizer  
Feb 2020

**VEGZELMA**  
Callitron  
Apr 2023

**HERZUMA**  
Teva  
March 2020

**NYVEPRIA**  
Pfizer  
Dec 2020

**AVZIVI**  
Sandoz  
Dec 2023

**ONTRUZANT**  
Organon  
Apr 2020

**STIMUFEND**  
Fresenius  
Feb 2023

**FYLNETRA**  
Amneal  
May 2023

**BASAGLAR**  
Eli Lilly  
Dec 2016

**ADMELOG**  
Sanofi  
Dec 2017



Follow-on biologics  
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

# U.S. biosimilar market landscape

As of March 11, 2024

Class	Immunomodulators						Bone health		
Molecule	Infliximab	Etanercept	Adalimumab		Natalizumab	Tocilizumab	Ustekinumab		
Reference Products	REMICADE J&J	ENBREL Amgen	HUMIRA AbbVie		TYSABRI Biogen	ACTEMRA IV/SC Genentech	STELARA IV/SC J&J		
Biosimilar Products	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 Viatris Jul 2023  HYRIMOZ Sandoz Jul 2023  ABRILADA Pfizer Oct 2023	YUSIMRY Coherus Jul 2023  HADLIMA Organon Jul 2023  IDACIO Fresenius Jul 2023  YUFLYMA Celltrion Jul 2023  SIMLANDI Teva Feb 2024	TYRUKO Sandoz Aug 2023  TYENNE Fresenius Mar 2024	TOFIDENCE Biogen Sep 2023	WEZLANA Amgen Oct 2023	JUBBONTI Sandoz Mar 2024	WYOST Sandoz Mar 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

Continued on next page

# U.S. biosimilar pipeline landscape

As of March 11, 2024

Class	Supportive care	Oncology	Ophthalmology
<b>Molecule</b>	Filgrastim, Epoetin, Pegfilgrastim	Rituximab*, Bevacizumab, Trastuzumab, Pertuzumab, Nivolumab, Pembrolizumab	Ranibizumab, Aflibercept
<b>Reference Products</b> 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)
<b>Pipeline</b> 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 Ph 3), 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), SB27 (Samsung Ph 1), Krabeva (Biocon Pending), Zercepac (Accord Pending), Equidacent (AstraZeneca Pending)	XLUCANE (Stada Pending), Yesafyll (Biocon Pending), SCD411 (Sam Chun Dang Ph 3), LUBT010 (Lupin Ph 3), ABP 938 (Amgen Pending), AVT06 (Alvotech Ph 3), FYB203 (Formycon Pending), CT-P42 (Celltrion Pending), SB15 (Biogen-Samsung Pending), SOK583A1 (Sandoz-Hexal Ph 3), ALT-L9 (Alteogen Pre-clin)

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.

Continued on next page

# U.S. biosimilar pipeline landscape

As of March 11, 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

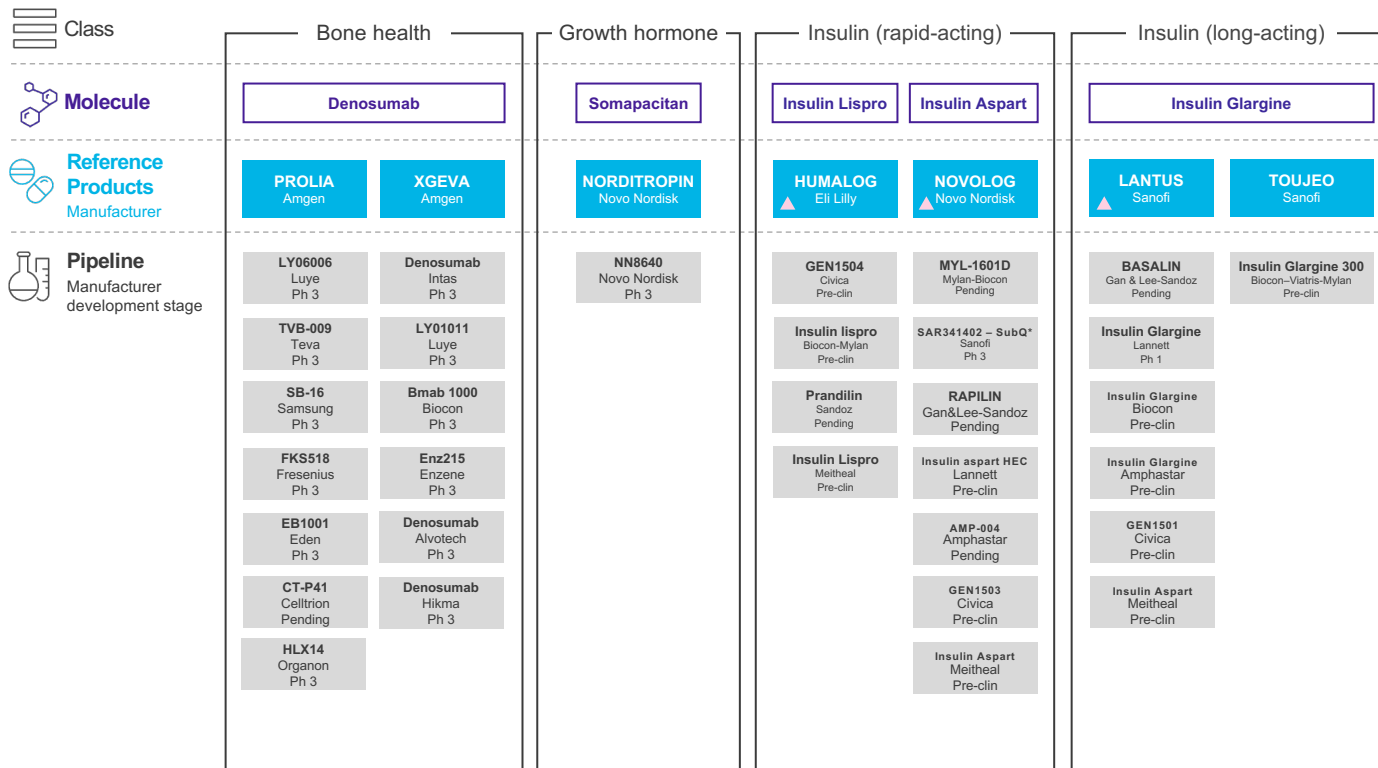
NI-071 Sagent Ph 3	YLB113 Lupin Ph 3	NEULARA NeuClone Ph 1	AVT04 Alvotech-Alvogen Pending	CT-P47 Celltrion Ph 3	Xcizmzane Xbrane-Biogen Pre-clin	BAT2506 Bio-Thera Ph 3	SB12 Samsung Bioepis Ph 3	CT-P39 Celltrion Pending	PB016 Polpharma Ph 3	BAT2306 Bio-Thera Ph 3
		CT-P43 Celltrion Pending	SB17 Samsung Bioepis Pending	DRL_TC Dr. Reddy's Ph 3		AVT05 Alvotech Ph 3	ABP 959 Amgen Pending	BP11 Aurobindo Ph 3	AVT16 Alvotech-Teva Pre-clin	
		FYB202 Fresenius Pending	Bmab1200 Biocon Ph 3	LusiNex Gedeon Richter Ph 1				ADL-018 Amneal Ph 3		
		DMB-3115 Accord Ph 3						TEV-45779 Teva Ph 3		
		BAT2206 Hikma-Bio-Thera Ph 3								

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

Continued on next page

# U.S. biosimilar pipeline landscape

As of March 11, 2024



▲ 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.

# 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 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](#).



Brian Biehn  
Senior Director, Biosimilars  
Cencora



Connor Nell  
Director, Biosimilars  
Cencora