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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 59 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 September 1, 2024

Class	Supportive care			Oncology			Insulin		Ophthalmology	
Molecule	Filgrastim	Epoetin	Pegfilgrastim	Rituximab	Bevacizumab	Trastuzumab	Insulin Gargine	Insulin Lispro	Ranibizumab	Aflibercept
Reference Products	<b>NEUPOGEN</b> Amgen	<b>EPOGEN/ PROCRIT</b> Amgen/J&J	<b>NEULASTA</b> Amgen	<b>RITUXAN</b> Genentech	<b>AVASTIN</b> Genentech	<b>HERCEPTIN</b> Genentech	<b>LANTUS</b> Sanofi		<b>LUCENTIS</b> Genentech	<b>Eylea</b> Regeneron
Biosimilar Products	<b>ZARXIO</b> Sandoz Sep 2015	<b>RETACRIT</b> Pfizer-Vifor Nov 2018	<b>FULPHILA</b> Bionco Jul 2018	<b>TRUXIMA</b> Teva Nov 2019	<b>MVASI</b> Amgen Jul 2019	<b>KANJINTI</b> Amgen Jul 2019	▲ <b>SEMGLEE</b> Bionco Nov 2021		<b>BYOOVIZ</b> Bionco Jul 2022	<b>YESAFILI</b> Bionco May 2024
Manufacturer	Pfizer	Pfizer	Amgen	Pfizer	Pfizer	Pfizer	Eli Lilly		Coherus	Bionco
Launch date or Approval date	Oct 2018		Jan 2019	Jan 2020	Jan 2020	Nov 2019	Apr 2023		Oct 2022	May 2024
Manufacturer	Amneal		Sandoz	Amgen	Amneal	Pfizer			Farmcyon	Bionco
Launch date or Approval date	Nov 2022		Nov 2019	Jan 2021	Oct 2022	Feb 2020			Jun 2024	May 2024
Manufacturer	Amneal		Pfizer		Celion	Teva			Sandoz	Amgen
Launch date or Approval date	Jun 2024		Dec 2020		Apr 2023	March 2020			Aug 2024	Aug 2024
Manufacturer			Fresenius		Origin	Amgen				Amgen
Launch date or Approval date			Feb 2023		Apr 2020					Aug 2024
Manufacturer			Amneal		Accord					
Launch date or Approval date			May 2023		May 2024					
Follow-on biologics							<b>BASAGLAR</b> Eli Lilly Dec 2016	<b>ADMELOG</b> 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 September 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	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						
IXIFI Pfizer Dec 2017	ETICOVO Samsung Apr 2019	ABRILADA Pfizer Oct 2023	SIMLANDI Teva May 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 September 1, 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), 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), 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), ALT-L9 (Alteogen Pre-clin), AVT06 (Alvotect Ph 3), CT-P42 (Celltrion Pending)

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 September 1, 2024

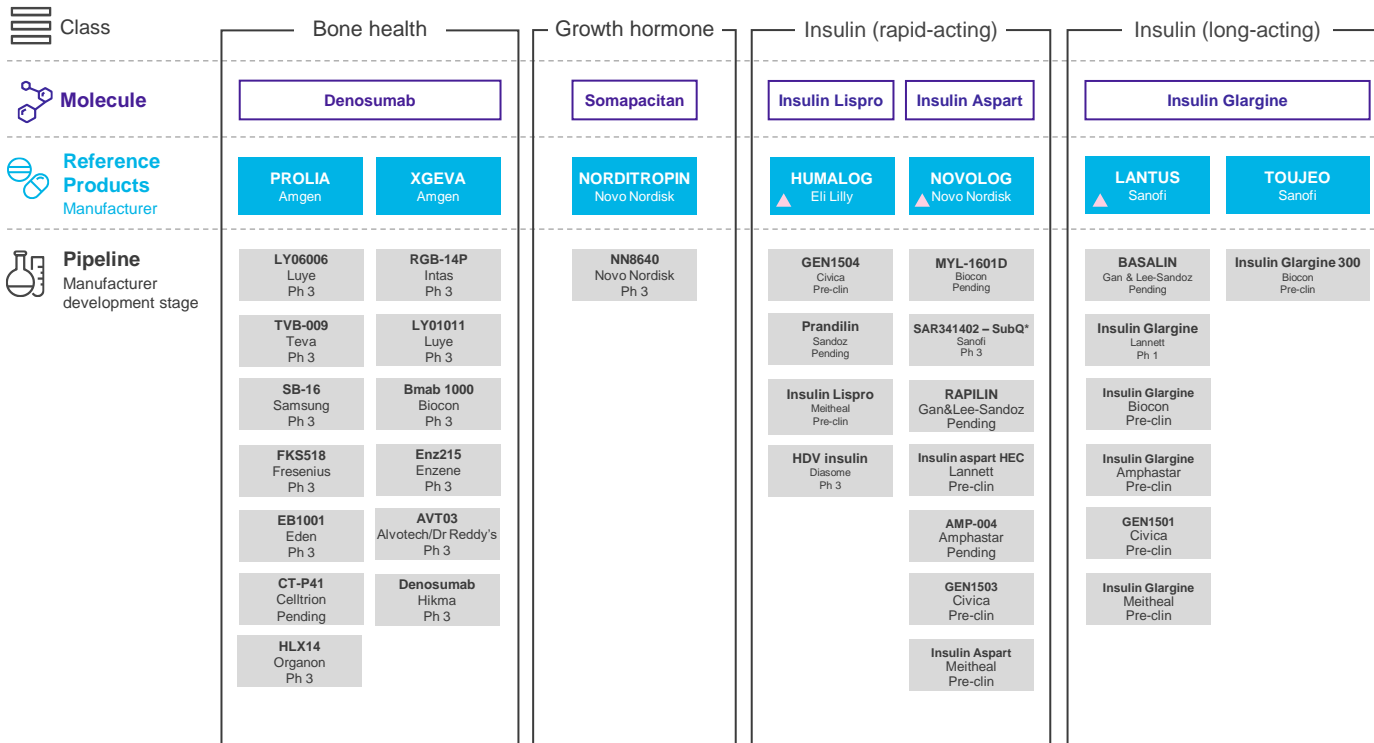
Class	Immunomodulators									
Molecule	Infliximab	Etanercept	Ustekinumab	Tocilizumab	Certolizumab	Golimumab	Eculizumab	Omalizumab	Vedolizumab	Secukinumab
Reference Products Manufacturer	REMICADE J&J	ENBREL Amgen	STELARA IV/SC J&J	ACTEMRA IV/SC Genentech	CIMZIA UCB	SIMPONI J&J	SOLIRIS Alexion	XOLAIR 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
			FYB202 Fresenius Pending	BAT2206 Hikma-Bio-Thera Ph 3	DRL_TC Dr. Reddy's Ph 3	AVT05 Alvotech Ph 3		BP11 Aurobindo Ph 3	AVT16 Alvotech-Teva Ph 1	
			DMB-3115 Accord Pending					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 September 1, 2024

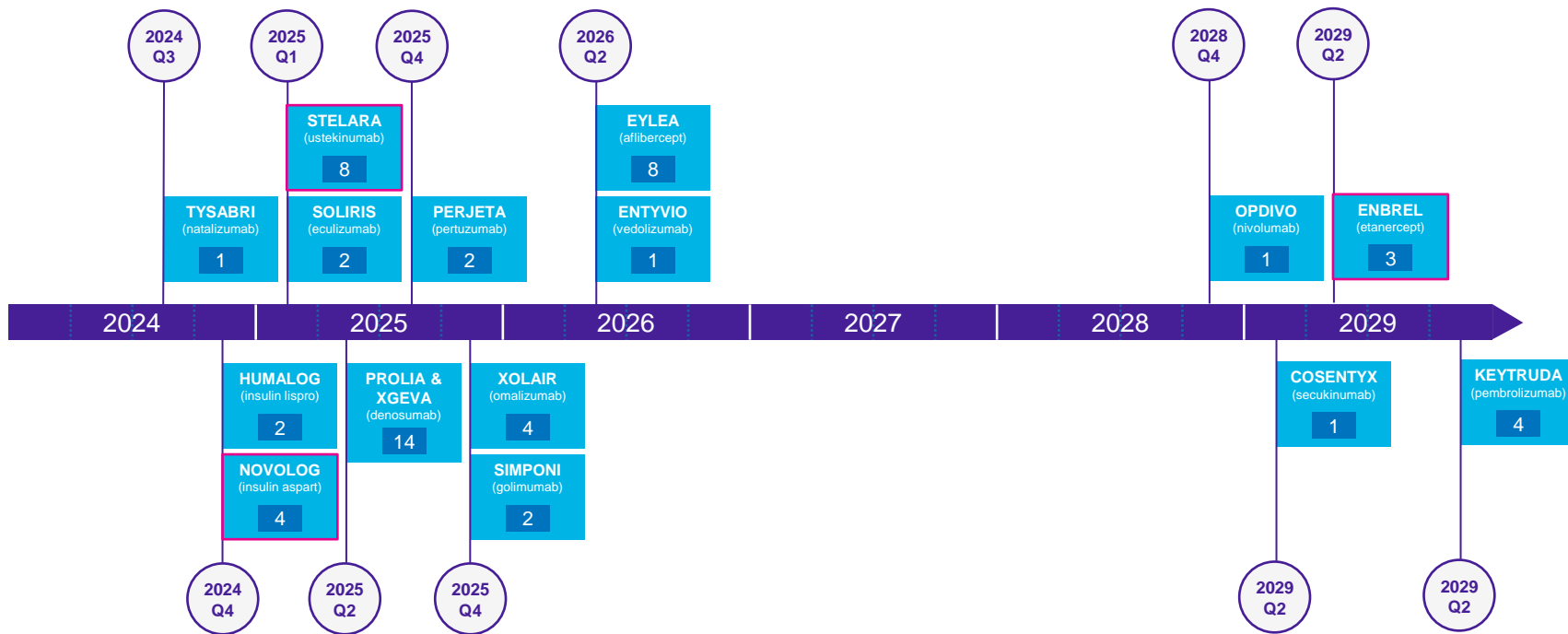
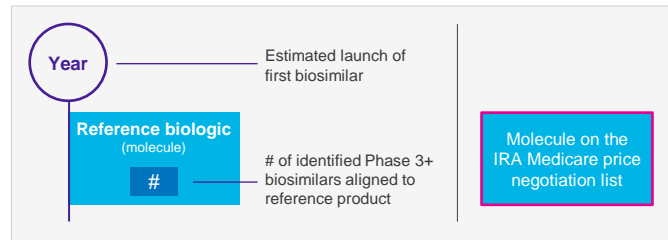


Note: Pending is defined as any stage of development between BLA/aBLA submission and full FDA approval.  
 \*Indicates that a biosimilar product has a different route of administration than its innovator product.

- ▲ 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



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# 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](#).



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