

AmerisourceBergen

U.S. Biosimilars Report

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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 40 approvals and 29 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 FDA-approved biosimilars (highlighted in white) and biosimilars launched to date (highlighted in green) organized in columns under the relevant molecule and innovator product.

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 April 10, 2023

Class	Supportive care			Oncology			Insulin	Ophthalmology
Molecule	Filgrastim	Epoetin	Pegfilgrastim	Rituximab	Bevacizumab	Trastuzumab	Insulin Glargine	Ranibizumab
Innovator Manufacturer	NEUPOGEN Amgen	EPOGEN/ PROCRIT Amgen/J&J	NEULASTA Amgen	RITUXAN Genentech	AVASTIN Genentech	HERCEPTIN Genentech	LANTUS Sanofi	LUCENTIS Genentech
Launched Manufacturer Launch 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	INT SEMGLEE Viatris-Mylan Nov 2021	BYOOVIZ Biogen Jul 2022
	NIVESTYM Pfizer Oct 2018		UDENYCA Coherus Jan 2019	RUXIENCE Pfizer Jan 2020	ZIRABEV Pfizer Jan 2020	OGIVRI Mylan Nov 2019	INT REZVOGLAR Eli Lilly Apr 2023	INT CIMERLI Coherus Oct 2022
	RELEUKO Amneal Nov 2022		ZIEXTENZO Sandoz Nov 2019	RIABNI Amgen Jan 2021	ALYMSYS Amneal Oct 2022	TRAZIMERA Pfizer Feb 2020	More details on the insulin market are on page 7	
			NYVEPRIA Pfizer Dec 2020		VEGZELMA Celltrion Apr 2023	HERZUMA Teva March 2020		
			STIMUFEND Fresenius Feb 2023			ONTRUZANT Organon Apr 2020		
Approved Manufacturer FDA approval date			FYLNETRA Amneal May 2022					

INT = Interchangeability approval by the FDA. For more details on interchangeability, please visit <https://www.fda.gov/media/151094/download>

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U.S. biosimilar market landscape

As of April 10, 2023

Class	Immunomodulators			
Molecule	Infliximab	Etanercept	Adalimumab	
Innovator Manufacturer	REMICADE J&J	ENBREL Amgen	HUMIRA AbbVie	
Launched Manufacturer Launch date	<p>INFLECTRA Pfizer Nov 2016</p> <p>RENFLEXIS Organon Jul 2018</p> <p>AVSOLA Amgen July 2020</p>	<p>Ongoing litigation forecasted launch 2028/2029</p>	<p>AMJEVITA Amgen Jan 2023</p> <p>View detailed landscape of Adalimumab biosimilars</p>	
Approved Manufacturer FDA approval date	<p>IXIFI Pfizer Dec 2014</p> <p>*Not launching in the U.S.</p>	<p>ERELZI Sandoz Aug 2016</p> <p>ETICOVO Samsung Apr 2019</p>	<p>INT CYLTEZO BI Aug 2017</p> <p>HYRIMOZ Sandoz Oct 2018</p> <p>HADLIMA Organon Jul 2019</p> <p>ABRILADA Pfizer Nov 2019</p>	<p>HULIO Mylan Jul 2020</p> <p>YUSIMRY Coherus Dec 2021</p> <p>IDACIO Fresenius Dec 2022</p>

INT = Interchangeability approval by the FDA. For more details on interchangeability, please visit <https://www.fda.gov/media/151094/download>

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U.S. biosimilar pipeline landscape

As of April 10, 2023

Class	Supportive care	Oncology	Ophthalmology
Molecule	Filgrastim Epoetin Pegfilgrastim	Rituximab Bevacizumab Trastuzumab	Ranibizumab Aflibercept
Innovator Manufacturer	NEUPOGEN Amgen EPOGEN/PROCRIT Amgen/J&J NEULASTA Amgen	RITUXAN Genentech AVASTIN Genentech HERCEPTIN Genentech	LUCENTIS Genentech EYLEA Regeneron
Pipeline Manufacturer Development stage	GRASTOFIL Accord-Apotex Pending TX01 Tanvex Pending LUPIFIL Lupin Ph 1 APO-EPO Apotex Ph 3 LAPELGA Accord-Apotex Pending LUPIFIL-P Lupin Pending TX04 Tanvex Ph 1	DRL RI Dr. Reddy's Ph 3 SAIT101 AZ-Archigen Ph 3 RITUXIMAB Apotex Ph 1 MABIONCD20 Mabion Ph 3 SB8 Organon-Samsung Pending BEVACIZUMAB Apotex Ph 1 TX16 Tanvex Ph 1 ABEVMY Mylan-Biocon Pending BAT1706 Bio-Thera Pending TRASTUZUMAB Apotex Pre-clin TX05 Tanvex Pending EG12014 Sandoz Pending HD201 Prestige Bio Ph 3 AP063 Nichi-Iko-Aprogen Ph 1	XLUCANE Xbrane-Bausch Ph 3 LUBT010 Lupin Ph 3 M710/MYL-1701P Mylan-Momenta Pending ABP 938 Amgen Ph 3 FYB203 Coherus Ph 3 SB15 Biogen-Samsung Ph 3 ALT-L9 Alteogen Pre-clin SCD411 Sam Chun Dang Ph 3 AVT06 Alvotech Ph 3 CT-P42 Celltrion Ph 3 SOK583A1 Sandoz-Hexal 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 April 10, 2023



Class

Immunomodulators



Molecule

Infliximab	Etanercept	Adalimumab	Ustekinumab	Tocilizumab	Certolizumab	Golimumab	Eculizumab	Omalizumab	Natalizumab
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Innovator
Manufacturer

REMICADE J&J	ENBREL Amgen	HUMIRA AbbVie	STELARA IV/SC J&J	ACTEMRA IV/SC Genentech	CIMZIA UCB	SIMPONI J&J	SOLIRIS Alexion	XOLAIR Alexion	TYSABRI Biogen
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Pipeline
Development stage

NI-071 Nichi-Iko Ph 3	YLB113 Lupin Ph 3	M923 Momenta Withdrawn	NEULARA NeuClone Ph 1	ABP654 Amgen Ph 3	BAT1806 Biogen-Bio-Thera Ph 3	Xcimzane Xbrane-Biogen Pre-clin	BAT2506 Bio-Thera Ph 3	SB12 Samsung Bioepis Ph 1	CT-P39 Celltrion Ph 1	PB006 Sandoz-Polpharma Pending
GP2018 Sandoz Ph 1	Pro-S02 Protheragen Pre-clin	AVT02 Alvotech-Teva Pending	CT-P43 Celltrion Ph 3	AVT04 Alvotech-Alvogen Pending	MSB11456 Fresenius Pending		AVT05 Alvotech Pre-clin	ABP 959 Amgen Ph 3	GBR 310 Glenmark Ph 1	
		MYL-1401A Mylan-Biocon Ph 3	FYB202 Formycon-Bioeq Ph 3	SB17 Samsung Bioepis Ph 3	LUSINEX Richter Ph 3				BP11 Aurobindo Ph 1	
		ONS-3010 Outlook Ph 3	DMB-3115 Dong-A-Meiji Ph 3	BFI-751 BioFactura Ph 1	CT-P47 Celltrion Ph 3				TEV-45779 Teva Ph 3	
		YUFLYMA Celltrion Pending	BAT2206 Hikma-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. insulin biosimilar market landscape and pipeline

As of April 10, 2023

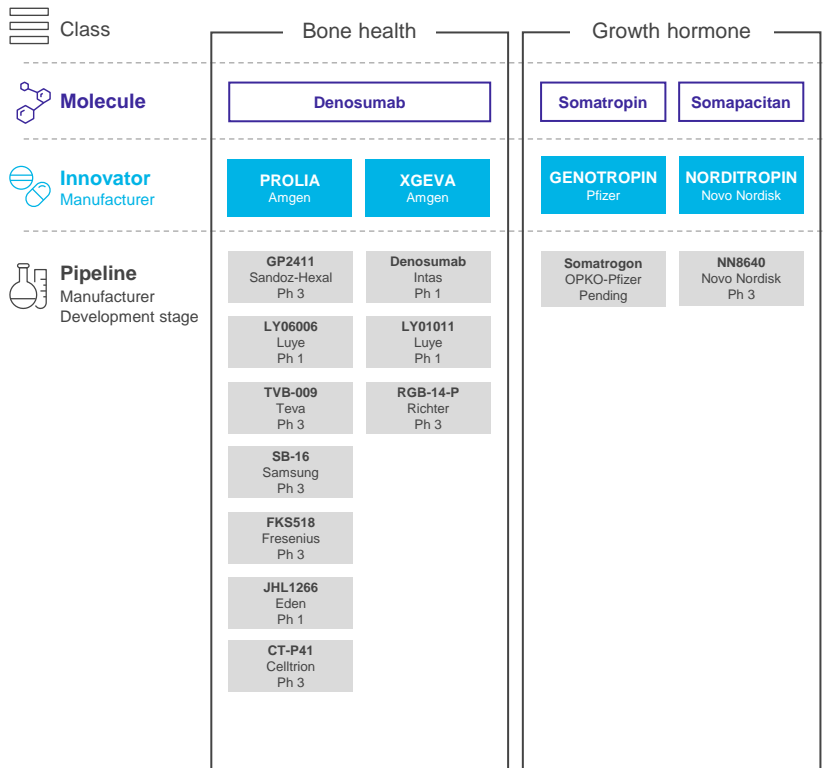
	Insulin (rapid-acting)			Insulin (long-acting)			
Molecule	Insulin lispro		Insulin aspart	Insulin glargine		Insulin detemir	
Innovator Manufacturer	HUMALOG Eli Lilly		NOVOLOG Novo Nordisk	FIASP Novo Nordisk	LANTUS Sanofi	TOUJEO Sanofi	LEVEMIR Novo Nordisk
Unbranded biologic Manufacturer	Insulin lispro Eli Lilly		Insulin aspart Novo Nordisk	Insulin glargine Sanofi			
Follow-on biologic Manufacturer	ADMELOG Sanofi			BASAGLAR Eli Lilly			
Launched Manufacturer Launch date				DISCONTINUED-SEMGLEE Viatris-Mylan	SEMGLEE (follow-on biologic) was DISCONTINUED on November 15, 2021 by the manufacturer.		
Pipeline biosimilars Manufacturer Development stage	HDV insulin Diasome Ph 2 Insulin lispro Biocon-Mylan Pre-clin		MYL-1601D Mylan-Biocon Pending SAR341402 – SubQ* Sanofi Ph 3 RAPILIN Gan&Lee-Sandoz Ph 1 Insulin aspart HEC Lannett Pre-clin	-DISCONTINUED-SEMGLEE Viatris-Mylan INT SEMGLEE Viatris-Mylan Nov 2021 INT REZVOGLAR Eli Lilly Apr 2023	Note: 2 versions of biosimilar Biosimilar version 1: Branded SEMGLEE (insulin glargine-yfgn) Brand NDC list: • 49502-250-80 (vial) • 49502-251-75 (pen)		Biosimilar version 2: Unbranded / authorized (Insulin glargine-yfgn) Unbranded NDC list: • 49502-393-80 (vial) • 49502-394-75 (pen)
				BASALIN Gan&Lee-Sandoz Ph 3 Insulin glargine 300 Biocon-Viatris-Mylan Pre-clin Insulin glargine Lannett Ph 1			
				INT = Interchangeability approval by the FDA. For more details on interchangeability, please visit https://www.fda.gov/media/151094/download			

* Indicates that a biosimilar product has a different route of administration than its innovator product.
 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 10, 2023



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

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