

U.S. Biosimilar 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 37 approvals and 22 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 one to four 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, infertility, bone health, and immunosuppressants.

U.S. biosimilar market landscape

As of August 4, 2022

Class	Supportive care			Oncology			Insulin	Ophthalmology
Molecule	Filgrastim	Epoetin	Pegfilgrastim	Rituximab	Bevacizumab	Trastuzumab	Insulin Glargine	Ranibizumab
Innovator	NEUPOGEN (Amgen)	EPOGEN / PROCRIT (Amgen / JnJ)	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 Interchangeability designation	BYOOVIZ Biogen Jul 2022
Approved Manufacturer FDA approval date	NIVESTYM Pfizer Oct 2018	UDENYCA Coherus Jan 2019	ZIEXTENZO Amgen Nov 2019	RUXIENCE Pfizer Jan 2020	ZIRABEV Pfizer Jan 2020	OGIVRI Mylan Nov 2019	More details on the Insulin market on page 7	
	RELEUKO Amneal Feb 2022	NYVEPRIA Pfizer Dec 2020	FYLNETRA Amneal May 2022	RIABNI Pfizer Jan 2021	HERZUMA Teva March 2020	ONTRUZANT Organon Apr 2020		INT CIMERLI Coherus Aug 2022 Interchangeability designation
				ALYMSYS Amneal Apr 2022			REZVOGLAR Eli Lilly Dec 2021	

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 August 4, 2022

Class	TNF blockers			
Molecule	Infliximab	Etanercept	Adalimumab	
Innovator	REMICADE (JnJ)	ENBREL (Amgen)	HUMIRA (AbbVie)	
Launched Manufacturer launch date	INFLECTRA Pfizer Nov 2016 RENFLEXIS Organon Jul 2018 AVSOLA Amgen July 2020	Ongoing litigation forecasted launch 2028/2029	Biosimilars referencing Humira will launch in 2023 View landscape	
Approved Manufacturer FDA approval date	IXIFI Pfizer Dec 2014 *Not launching in the U.S.	ERELZI Amgen Aug 2016 ETICOVO Samsung Apr 2019	AMJEVITA Amgen Sep 2016 CYLTEZO BI Aug 2017 HYRIMOZ Sandoz Oct 2018 HADLIMA Organon Jul 2019 ABRILADA Pfizer Nov 2019	HULIO Mylan Jul 2020 YUSIMRY Coharus Dec 2021

INT = Interchangeability approval by the FDA.
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U.S. biosimilar pipeline landscape

As of August 4, 2022

Class	Supportive care			Oncology			Ophthalmology		
Molecule	Filgrastim	Epoetin	Pegfilgrastim	Rituximab	Bevacizumab	Trastuzumab	Ranibizumab	Aflibercept	
Innovator	NEUPOGEN (Amgen)	EPOGEN / PROCRIT (Amgen / JnJ)	NEULASTA (Amgen)	RITUXAN (Genentech)	AVASTIN (Genentech)	HERCEPTIN (Genentech)	LUCENTIS (Genentech)	EYLEA (Regeneron)	
Pipeline Manufacturer clinical phase	GRASTOFIL Accord-Apotex Pending TX01 Tanvex Pending LUPIFIL Lupin Ph I	APO-EPO Apotex Ph III	LAPELGA Accord-Apotex Pending PEG-GRAFEEL Dr Reddy's Ph I LUPIFIL-P Lupin Pending MSB11455 Fresenius/DRL Pending TX04 Tanvex Ph I	DRL RI Dr. Reddy's Ph III SAIT101 AZ-Archigen Ph III RITUXIMAB Apotex Ph I MABIONCD20 Mabion Ph III	SB8 Organon-Samsung Pending CT-P16 Celltrion Pending BEVACIZUMAB Apotex Ph I FKB238 AZ-Centus Pending TX16 Tanvex Ph I ABEVMY Mylan-Biocon Pending BAT1706 Bio-Thera Pending	TRASTUZUMAB Apotex Pre-Clin TX05 Tanvex Pending EG12014 Sandoz Pending HD201 Prestige Bio Ph III AP063 Nichi-Iko/Sagent Ph I	XLUCANE Xbrane-Bausch Ph III LUBT010 Lupin Ph III	M710/MYL-1701P Mylan-Momenta Pending ABP 938 Amgen Ph III FYB203 Formycon Ph III SB15 Biogen-Samsung Ph III ALT-L9 Alteogen Pre-Clin	SCD411 Sam Chun Dang Ph III CHS-2020 Coherus Withdrawn CT-P42 Celltrion Ph III SOK583A1 Sandoz-Hexal Ph III

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U.S. biosimilar pipeline landscape

As of August 4, 2022



Class



Molecule



Innovator



Pipeline
Manufacturer
clinical phase

TNF blockers

TNF blockers								
Infliximab	Etanercept	Adalimumab	Ustekinumab		Tocilizumab	Certolizumab	Golimumab	
REMICADE (JnJ)	ENBREL (Amgen)	HUMIRA (AbbVie)	STELARA IV/SC (JnJ)		ACTEMRA IV/SC (Genentech)	CIMZIA (UCB)	SIMPONI (JnJ)	
NI-071 Sagent Ph III	YLB113 Lupin Ph III	M923 Momenta Withdrawn	NEULARA NeuClone Ph I	ABP654 Amgen Ph III	BAT1806 Biogen-BioThera Ph III	Xcimzane Xbrane Pre-Clin	BAT2506 Bio-Thera Solutions Ph III	
GP2018 Sandoz Ph I	Pro-S02 Protheragen Pre-Clin	MSB11022 Fresenius Ph III	CT-P43 Celltrion Ph III	AVT04 Alvotech-Alvogen Ph III	MSB11456 Fresenius Pending	AVT05 Alvotech Pre-Clin		
		AVT02 (CF) Alvotech-Teva Pending	FYB202 Formycon-Bioeq Ph III	SB17 Samsung Bioepis Ph III	LUSINEX Mycenax-Gedeon Ph II			
		MYL-1401A Mylan-Biocon Ph III	DMB-3115 Dong-A / Meiji Ph III	BFI-751 BioFactura Ph I	CT-P47 Celltrion Ph I			
		ONS-3010 Outlook Ph III	BAT2206 Hikma/Bio-Thera Ph III					
		YUFLYMA (CF) Celltrion Pending						

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U.S. insulin biosimilar market landscape and pipeline

As of August 4, 2022

	Insulin (Rapid Acting)			Insulin (Long Acting)		
 Molecule	Insulin Lispro	Insulin Aspart		Insulin Glargine	Insulin Detemir	
 Innovator	HUMALOG (Eli Lilly)	NOVOLOG (Novo Nordisk)	FIASP (Novo Nordisk)	LANTUS (Sanofi)	TOUJEO (Sanofi)	LEVEMIR (Novo Nordisk)
 Authorized Brand/Generics	HUMALOG AG (Eli Lilly)	NOVOLOG AG (Novo Nordisk)		Insulin Glargine (Sanofi)		
 Follow-on Biologic	ADMELOG (Sanofi)			BASAGLAR (Eli Lilly)		
				SEMGLEE (Viatris/Mylan)		
 Launched Manufacturer launch date				INT SEMGLEE (Viatris/Mylan) Nov 2021	Note: 2 Biosimilar Versions	
 Approved Manufacturer FDA approval date				REZVOGLAR (Eli Lilly) Dec 2021		
 Pipeline Biosimilars Manufacturer clinical phase	HDV Insulin Lispro - SubQ Diasome Ph II	MYL-1601D - Inj Mylan-Biocon Pending		BASALIN SubQ (Lantus) Gan&Lee-Sandoz Ph III	Insulin Glargine 300 (Toujeo) Biocon-Viatris/Mylan Pre-Clin	
	Insulin Lispro Biocon - SubQ Biocon-Mylan Pre-Clin	SAR341402 - SubQ Sanofi Ph III		Insulin Glargine Lannett Ph I		
		RAPILIN Gan&Lee-Sandoz Ph I				
		Insulin Aspart HEC Lannett Pre-Clin				

BASAGLAR (Follow-on biologic)

Basaglar is a follow-on biologic that launched in Dec'16 to compete with Lantus, as at the time the FDA did not allow biosimilar competition for insulin biologic products (which changed in Mar'20).

Currently available

SEMGLEE (Follow-on biologic)

Aug'20 – FDA approved as brand (follow-on biologic) via the 351(a) pathway

Manufactured Discontinued eff 11/15/2021

NDC list
49502-195-80, 49502-196-71,
49502-196-73, 49502-196-75

SEMGLEE-yfgn (Biosimilar) Branded Version

Jul'21 – FDA approved as an interchangeable biosimilar via the 351(k)(4) pathway

Launched in US 11/15/2021

Only interchangeable with Lantus

First and currently only biosimilar with interchangeability status

NDC list:
Semglee-yfgn:
49502-250-80 (vial)
49502-251-75 (pen)

INSULIN GLARGINE-yfgn (Biosimilar) Unbranded / Authorized Version

Jul'21 – FDA approved as an interchangeable biosimilar via the 351(k)(4) pathway

Launched in US 11/15/2021

Only interchangeable with Lantus

First and currently only biosimilar with interchangeability status

NDC list:
Insulin Glargine-yfgn:
49502-393-80 (vial)
49502-394-75 (pen)

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For more details on interchangeability, please visit <https://www.fda.gov/media/151094/download>

U.S. biosimilar pipeline landscape

As of August 4, 2022

Class	Immunosuppressant			Bone health	Growth hormone		Infertility		
Molecule	Eculizumab	Omalizumab	Natalizumab	Denosumab	Somatropin	Somapacitan	Corifollitropin Alfa	Follitropin Alfa	Follitropin Delta
Innovator	SOLIRIS (Alexion)	XOLAIR (Alexion)	TYSABRI (Biogen)	PROLIA / XGEVA (Amgen)	GENOTROPIN (Pfizer)	NORDITROPIN (NovoNordisk)	N/A <i>New formulation</i>	GONAL-F (EMD Serono)	N/A <i>Similar to Gonal-F</i>
Pipeline Manufacturer clinical phase	SB12 Samsung Bioepis Ph I ABP 959 Amgen Ph III	CT-P39 Celltrion Ph I GBR 310 Glenmark Ph I BP11 Aurobindo Ph I TEV-45779 Teva Ph III	PB006 Sandoz-Polpharma Pending	GP2411 Prolia Sandoz-Hexal Ph III LY06006 Prolia Luye Ph I TVB-009 Prolia Teva Ph III SB-16 Prolia Samsung Ph III FKS518 Prolia Fresenius Ph III JHL1266 Prolia Eden Ph I CT-P41 Prolia Celltrion Ph III	Denosumab Intas Intas Ph I LY01011 Xgeva Luye Ph I RGB-14-P Gedeon Richter Ph III	MOD-4023 Somatrogen Inj OPKO-Pfizer Ph III TransCon hGH – SubQ Ascendis Pending	NN8640 – SubQ Novo Ph III	Elonva – SubQ Merck CRL	Afolia – SubQ Fertility-Gedeon Ph III Rekovelle – SubQ Ferring Ph III

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