

AmerisourceBergen

# U.S. Biosimilar Report

Presented by

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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 25 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 December 19, 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) NIVESTYM (Pfizer Oct 2018)   UDENYCA (Coherus Jan 2019) RELEUKO (Amneal Nov 2022)   ZIEXTENZO (Sandoz Nov 2019) NYVEPRIA (Pfizer Dec 2020)	TRUXIMA (Teva Nov 2019)   MVASI (Amgen Jul 2019)   KANJINTI (Amgen Jul 2019) RUXIENCE (Pfizer Jan 2020)   ZIRABEV (Pfizer Jan 2020)   OGIVRI (Mylan Nov 2019) RIABNI (Amgen Jan 2021)   ALYMSYS (Amneal Oct 2022)   TRAZIMERA (Pfizer Feb 2020) HERZUMA (Teva March 2020) ONTRUZANT (Organon Apr 2020)	<sup>INT</sup> SEMGLEE (Viatris/Mylan Nov 2021)	BYOOVIZ (Biogen Jul 2022) <sup>INT</sup> CIMERLI (Coherus Oct 2022)
Approved Manufacturer FDA approval date	FYLNETRA (Amneal May 2022) STIMUFEND (Fresenius Sep 2022)	VEGZELMA (Celltrion Sep 2022)	<sup>INT</sup> REZVOGLAR (Eli Lilly Dec 2021)	

More details on the Insulin market on page 7

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

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# U.S. biosimilar market landscape

As of December 19, 2022

Class	Immunomodulators			
Molecule	Infliximab	Etanercept	Adalimumab	
Innovator	<b>REMICADE</b> (JnJ)	<b>ENBREL</b> (Amgen)	<b>HUMIRA</b> (AbbVie)	
Launched Manufacturer launch date	<b>INFLECTRA</b> Pfizer Nov 2016  <b>RENFLEXIS</b> Organon Jul 2018  <b>AVSOLA</b> Amgen July 2020	Ongoing litigation forecasted launch 2028/2029	Biosimilars referencing Humira will launch in 2023 <a href="#">View landscape</a>	
Approved Manufacturer FDA approval date	<b>IXIFI</b> Pfizer Dec 2014  *Not launching in the U.S.	<b>ETICOVO</b> Samsung Apr 2019	<b>ERELZI</b> Amgen Aug 2016  <b>AMJEVITA</b> Amgen Sep 2016  <b>INT</b> <b>CYLTEZO</b> BI Aug 2017  <b>HYRIMOZ</b> Sandoz Oct 2018  <b>HADLIMA</b> Organon Jul 2019  <b>ABRILADA</b> Pfizer Nov 2019	<b>HULIO</b> Mylan Jul 2020  <b>YUSIMRY</b> Coherus Dec 2021  <b>IDACIO</b> Fresenius Dec 2022

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

# U.S. biosimilar pipeline landscape

As of December 19, 2022

Class	Supportive care	Oncology	Ophthalmology																																										
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Pipeline Manufacturer clinical phase	<table border="1"> <tr> <td>GRASTOFIL Accord-Apotex Pending</td> <td>APO-EPO Apotex Ph III</td> <td>LAPELGA Accord-Apotex Pending</td> </tr> <tr> <td>TX01 Tanvex Pending</td> <td></td> <td>LUPIFIL-P Lupin Pending</td> </tr> <tr> <td>LUPIFIL Lupin Ph I</td> <td></td> <td>TX04 Tanvex Ph I</td> </tr> </table>	GRASTOFIL Accord-Apotex Pending	APO-EPO Apotex Ph III	LAPELGA Accord-Apotex Pending	TX01 Tanvex Pending		LUPIFIL-P Lupin Pending	LUPIFIL Lupin Ph I		TX04 Tanvex Ph I	<table border="1"> <tr> <td>DRL RI Dr. Reddy's Ph III</td> <td>SB8 Organon-Samsung Pending</td> <td>TRASTUZUMAB Apotex Pre-Clin</td> </tr> <tr> <td>SAIT101 AZ-Archigen Ph III</td> <td>BEVACIZUMAB Apotex Ph I</td> <td>TX05 Tanvex Pending</td> </tr> <tr> <td>RITUXIMAB Apotex Ph I</td> <td>FKB238 AZ-Centus Pending</td> <td>EG12014 Sandoz Pending</td> </tr> <tr> <td>MABIONCD20 Mabion Ph III</td> <td>TX16 Tanvex Ph I</td> <td>HD201 Prestige Bio Ph III</td> </tr> <tr> <td></td> <td>ABEVMY Mylan-Biocon Pending</td> <td>AP063 Nichi-Iko/Sagent Ph I</td> </tr> <tr> <td></td> <td>BAT1706 Bio-Thera Pending</td> <td></td> </tr> </table>	DRL RI Dr. Reddy's Ph III	SB8 Organon-Samsung Pending	TRASTUZUMAB Apotex Pre-Clin	SAIT101 AZ-Archigen Ph III	BEVACIZUMAB Apotex Ph I	TX05 Tanvex Pending	RITUXIMAB Apotex Ph I	FKB238 AZ-Centus Pending	EG12014 Sandoz Pending	MABIONCD20 Mabion Ph III	TX16 Tanvex Ph I	HD201 Prestige Bio Ph III		ABEVMY Mylan-Biocon Pending	AP063 Nichi-Iko/Sagent Ph I		BAT1706 Bio-Thera Pending		<table border="1"> <tr> <td>XLUCANE Xbrane-Bausch Ph III</td> <td>M710/MYL-1701P Mylan-Momenta Pending</td> <td>SCD411 Sam Chun Dang Ph III</td> </tr> <tr> <td>LUBT010 Lupin Ph III</td> <td>ABP 938 Amgen Ph III</td> <td>AVT06 Alvotect Ph III</td> </tr> <tr> <td></td> <td>FYB203 Formycon Ph III</td> <td>CT-P42 Celltrion Ph III</td> </tr> <tr> <td></td> <td>SB15 Biogen-Samsung Ph III</td> <td>SOK583A1 Sandoz-Hexal Ph III</td> </tr> <tr> <td></td> <td>ALT-L9 Alteogen Pre-Clin</td> <td></td> </tr> </table>	XLUCANE Xbrane-Bausch Ph III	M710/MYL-1701P Mylan-Momenta Pending	SCD411 Sam Chun Dang Ph III	LUBT010 Lupin Ph III	ABP 938 Amgen Ph III	AVT06 Alvotect Ph III		FYB203 Formycon Ph III	CT-P42 Celltrion Ph III		SB15 Biogen-Samsung Ph III	SOK583A1 Sandoz-Hexal Ph III		ALT-L9 Alteogen Pre-Clin	
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# U.S. biosimilar pipeline landscape

As of December 19, 2022



Class

Immunomodulators



Molecule

Infliximab	Etanercept	Adalimumab	Ustekinumab	Tocilizumab	Certolizumab	Golimumab	Eculizumab	Omalizumab	Natalizumab
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Innovator

REMICADE (JnJ)	ENBREL (Amgen)	HUMIRA (AbbVie)	STELARA IV/SC (JnJ)	ACTEMRA IV/SC (Genentech)	CIMZIA (UCB)	SIMPONI (JnJ)	SOLIRIS (Alexion)	XOLAIR (Alexion)	TYSABRI (Biogen)
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Pipeline  
Manufacturer  
clinical phase

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	SB12 Samsung Bioepis Ph I	CT-P39 Celltrion Ph I	PB006 Sandoz-Polpharma Pending
GP2018 Sandoz Ph I	Pro-S02 Protheragen Pre-Clin	AVT02 (CF) Alvotech-Teva Pending	CT-P43 Celltrion Ph III	AVT04 Alvotech-Alvogen Ph III	MSB11456 Fresenius Pending		AVT05 Alvotech Pre-Clin	ABP 959 Amgen Ph III	GBR 310 Glenmark Ph I	
		MYL-1401A Mylan-Biocon Ph III	FYB202 Formycon-Bioeq Ph III	SB17 Samsung Bioepis Ph III	LUSINEX Mycenax-Gedeon Ph II				BP11 Aurobindo Ph I	
		ONS-3010 Outlook Ph III	DMB-3115 Dong-A / Meiji Ph III	BFI-751 BioFactura Ph I	CT-P47 Celltrion Ph III				TEV-45779 Teva Ph III	
		YUFLYMA (CF) Celltrion Pending	BAT2206 Hikma/Bio-Thera Ph III							

# U.S. insulin biosimilar market landscape and pipeline

As of December 19, 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/Generic	HUMALOG AG (Eli Lilly)	NOVOLOG AG (Novo Nordisk)	Insulin Glargine (Sanofi)		
Follow-on Biologic	ADMELOG (Sanofi)		BASAGLAR (Eli Lilly)	SEMGLLEE (Viatris/Mylan)	
Launched Manufacturer launch date			<b>INT</b> SEMGLLEE (Viatris/Mylan) Nov 2021	<b>Note: 2 Biosimilar Versions</b>	
Approved Manufacturer FDA approval date			<b>INT</b> 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*

**SEMGLLEE (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

**SEMGLLEE-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)

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

# U.S. biosimilar pipeline landscape

As of December 19, 2022

Class	Bone health	Growth hormone	Infertility
Molecule	Denosumab	Somatropin, Somapacitan	Corifollitropin Alfa, Follitropin Alfa, Follitropin Delta
Innovator	PROLIA / XGEVA (Amgen)	GENOTROPIN (Pfizer), NORDITROPIN (NovoNordisk)	N/A (New formulation), GONAL-F (EMD Serono), N/A (Similar to Gonal-F)
Pipeline Manufacturer clinical phase	<p>GP2411 Prolia Sandoz-Hexal Ph III</p> <p>LY06006 Prolia Luye Ph I</p> <p>TVB-009 Prolia Teva Ph III</p> <p>SB-16 Prolia Samsung Ph III</p> <p>FKS518 Prolia Fresenius Ph III</p> <p>JHL1266 Prolia Eden Ph I</p> <p>CT-P41 Prolia Celltrion Ph III</p> <p>Denosumab Intas Intas Ph I</p> <p>LY01011 Xgeva Luye Ph I</p> <p>RGB-14-P Gedeon Richter Ph III</p>	<p>MOD-4023 Somatrogen Inj OPKO-Pfizer Ph III</p> <p>TransCon hGH – SubQ Ascendis Pending</p> <p>NN8640 – SubQ Novo Ph III</p>	<p>Elonva – SubQ Merck CRL</p> <p>Afolia – SubQ Fertility-Gedeon Ph III</p> <p>Rekovelle – SubQ Ferring Ph III</p>



## Connect with us

Find out how AmerisourceBergen is creating sustainability and longevity for biosimilars

For more information, please contact us [here](#)



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