

AmerisourceBergen

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 34 approvals and 21 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 ophthalmology, insulin, growth hormone, infertility and immunosuppressants.

U.S. biosimilar market landscape

As of February 25, 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 SEMGLÉE (Viatris/Mylan) Nov 2021 Interchangeability designation | |
| Approved Manufacturer FDA approval date | RELEUKO Amneal Feb 2022 | | UDENYCA Coherus Jan 2019 | RUXIENCE Pfizer Jan 2020 | ZIRABEV Pfizer Jan 2020 | OGIVRI Mylan Nov 2019 | More details on the Insulin market on page 7 | |
| | | | ZIEXTENZO Sandoz Nov 2019 | RIABNI Amgen Jan 2021 | | TRAZIMERA Pfizer Feb 2020 | | |
| | | | NYVEPRIA Pfizer Dec 2020 | | | HERZUMA Teva March 2020 | | |
| | | | | | | ONTRUZANT Organon Apr 2020 | | |
| | | | | | | | REZVOGLAR Eli Lilly Dec 2021 | BYOOVIZ Biogen Sept 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 February 25, 2022

| Class | TNF blockers | | | |
|---|--|--|---|---|
| Molecule | Infliximab | Etanercept | Adalimumab | |
| Innovator | REMICADE (JnJ) | 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> | Ongoing litigation forecasted launch 2028/2029 | Biosimilars referencing Humira will launch in 2023 | |
| 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>AMJEVITA Amgen Sep 2016</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> |

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 February 25, 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 | APO-EPO Apotex Ph III | TPI-120 Amneal-Adello Pending | DRL RI Dr. Reddy's Ph III | SB8 Organon-Samsung Pending | TRASTUZUMAB Apotex Pre-Clin | XLUCANE Xbrane-Bausch Ph III | M710/MYL-1701P Mylan-Momenta Pending | SCD411 Sam Chun Dang Ph III |
| | TX01 Tanvex Pending | | LAPELGA Accord-Apotex Pending | SAIT101 AZ-Archigen Ph III | CT-P16 Celltrion Pending | TX05 Tanvex Pending | LUBT010 Lupin Ph III | ABP 938 Amgen Ph III | CHS-2020 Coherus Withdrawn |
| | LUPIFIL Lupin Ph I | | PEG-GRAFEEL Dr Reddy's Ph I | RITUXIMAB Apotex Ph I | BEVACIZUMAB Apotex Ph I | EG12014 Sandoz Pending | FYB201-CHS201 Coherus-Formycon Pending | FYB203 Formycon Ph III | CT-P42 Celltrion Ph III |
| | | | LUPIFIL-P Lupin Pending | MABIONCD20 Mabion Ph III | FKB238 AZ-Centus Pending | HD201 Prestige Bio Ph III | | SB15 Biogen-Samsung Ph III | SOK583A1 Sandoz-Hexal Ph III |
| | | | MSB11455 Fresenius/DRL Pending | | TX16 Tanvex Ph I | AP063 Nichi-Iko/Sagent Ph I | | ALT-L9 Alteogen Pre-Clin | |
| | | | TX04 Tanvex Ph I | | ALYMSYS Amneal Pending | | | | |
| | | | | | ABEVMY Mylan-Biocon Pending | | | | |
| | | | | | BAT1706 Bio-Thera Pending | | | | |

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U.S. biosimilar pipeline landscape

As of February 25, 2022

| Class | TNF blockers | | | | | | | |
|--|----------------------------|------------------------------------|--|--------------------------------------|-------------------------------------|--------------------------------------|--------------------------------|--|
| Molecule | Infliximab | Etanercept | Adalimumab | Ustekinumab | Tocilizumab | Certolizumab | Golimumab | |
| Innovator | REMICADE (JnJ) | ENBREL (Amgen) | HUMIRA (AbbVie) | STELARA IV/SC (JnJ) | ACTEMRA IV/SC (Genentech) | CIMZIA (UCB) | SIMPONI (JnJ) | |
| 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 |
| | 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 Ph III | | 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 February 25, 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 Generic | HUMALOG AG (Eli Lilly) | NOVOLOG AG (Novo Nordisk) | | | |
| Follow-on Biologic | ADMELOG (Sanofi) | | BASAGLAR (Eli Lilly) | SEMGLLEE (Viatris/Mylan) | |
| Launched Manufacturer launch date | | | INT SEMGLLEE (Viatris/Mylan) Nov 2021 | Note: 2 Biosimilar Versions 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) | |
| Approved Manufacturer FDA approval date | | | REZVOGLAR (Eli Lilly) Dec 2021 | 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) | |
| Pipeline Biosimilars Manufacturer clinical phase | HDV Insulin Lispro - SubQ Diasome Ph II Insulin Lispro Biocon - SubQ Biocon-Mylan Pre-Clin | MYL-1601D – Inj Mylan-Biocon Pending SAR341402 – SubQ Sanofi Ph III RAPILIN Gan&Lee-Sandoz Ph I | BASALIN SubQ (Lantus) Gan&Lee-Sandoz Ph III Insulin Glargine 300 (Toujeo) Biocon-Viatris/Mylan 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

INT = Interchangeability approval by the FDA. For more details on interchangeability, please visit <https://www.fda.gov/media/151084/download>

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U.S. biosimilar pipeline landscape

As of February 25, 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 | CT-P39 Celltrion Ph I | PB006 Sandoz-Polpharma Ph III | GP2411 Prolia Sandoz-Hexal Ph III | Denosumab Intas Intas Ph I | MOD-4023 Somatrogen Inj OPKO-Pfizer Ph III | NN8640 – SubQ Novo Ph III | Elonva – SubQ Merck CRL | Afolia – SubQ Fertility-Gedeon Ph III | Rekovele – SubQ Ferring Ph III |
| | ABP 959 Amgen Ph III | GBR 310 Glenmark Ph I | | LY06006 Prolia Luye Ph I | LY01011 Xgeva Luye Ph I | TransCon hGH - SubQ Ascendis Pending | | | | |
| | | BP11 Aurobindo Ph I | | TVB-009 Prolia Teva Ph III | RGB-14-P Gedeon Richter Ph III | | | | | |
| | | TEV-45779 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 | | | | | | |

Connect with us

Find out how AmerisourceBergen is creating sustainability and longevity for biosimilars

Contact Brian and Connor by sending an email to biosimilars@amerisourcebergen.com



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