

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 31 approvals and 20 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 September 17, 2021

| 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) 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 (Pfizer, Jan 2021) TRAZIMERA (Pfizer, Feb 2020) HERZUMA (Teva, March 2020) ONTRUZANT (Organon, Apr 2020) | | |
| Approved Manufacturer FDA approval date | | | | |
| | | | SEMGLEE* (Vialta/Mylan, July 2021) <small>*Interchangeability approval by FDA</small> | BYOOVIZ (Biogen, Sept 2021) |

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U.S. biosimilar market landscape

As of September 17, 2021

| 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 |
| Approved Manufacturer FDA approval date | IXIFI Pfizer Dec 2014 | ETICOVO Samsung Apr 2019 | AMJEVITA Amgen Sep 2016 HYRIMOZ Sandoz Oct 2018 HADLIMA Organon Jul 2019 ABRILADA Pfizer Nov 2019 HULIO Mylan Jul 2020 |

*Not launching in the U.S.

U.S. biosimilar pipeline landscape

As of September 17, 2021

| 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 | <p>GRASTOFIL Accord-Apotex Pending</p> <p>FILGRASTIM KASHIV Amneal-Adello Pending</p> <p>LUPIFIL Lupin Ph I</p> <p>TX01 Tanvex CRL</p> <p>APO-EPO Apotex Ph III</p> <p>TPI-120 Amneal-Adello Pending</p> <p>LAPELGA Accord-Apotex Pending</p> <p>PEG-GRAFEEL Dr Reddy's Ph I</p> <p>LUPIFIL-P Lupin Pending</p> <p>MSB11455 Fresenius Pending</p> <p>TX04 Tanvex Ph I</p> | <p>DRL RI Dr. Reddy's Ph III</p> <p>SAIT101 AZ-Archigen Ph III</p> <p>RITUXIMAB Apotex Ph I</p> <p>MABIONCD20 Mabion Ph III</p> <p>SB8 Organon-Samsung Pending</p> <p>CT-P16 Celltrion Ph I</p> <p>BEVACIZUMAB Apotex Ph I</p> <p>FKB238 AZ-Centus Pending</p> <p>TX16 Tanvex Ph I</p> <p>ALYMSYS Amneal Pending</p> <p>Abevmy Mylan-Biocon Pending</p> <p>BAT1706 Bio-Thera Pending</p> <p>TRASTUZUMAB Apotex Pre-Clin</p> <p>TX05 Tanvex Ph III</p> <p>EG12014 Sandoz Ph III</p> <p>HD201 Prestige Bio Ph III</p> <p>AP063 Nichi-iko/Sagent Ph I</p> | <p>XLUCANE Xbrane-Bausch Ph III</p> <p>LUBT010 Lupin Ph III</p> <p>FYB201 Coherus-Formycon Pending</p> <p>CHS-3351 Coherus Withdrawn</p> <p>M710/MYL-1701P Mylan-Momenta Ph III</p> <p>ABP 938 Amgen Ph III</p> <p>FYB203 Formycon Ph III</p> <p>SB15 Biogen-Samsung Ph III</p> <p>ALT-L9 Alteogen Pre-Clin</p> <p>SCD411 Sam Chun Dang Ph III</p> <p>CHS-2020 Coherus Withdrawn</p> <p>CT-P42 Celltrion Ph III</p> <p>SOK583A1 Sandoz-Hexal Ph III</p> |

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U.S. biosimilar pipeline landscape

As of September 17, 2021

| Class | TNF blockers | | | | | |
|--|----------------------------|----------------------------------|--------------------------------------|--------------------------------------|-------------------------------------|--------------------------------------|
| Molecule | Infliximab | Etanercept | Adalimumab | Ustekinumab | Tocilizumab | |
| Innovator | REMICADE (JnJ) | ENBREL (Amgen) | HUMIRA (AbbVie) | STELARA IV / SC (JnJ) | ACTEMRA IV/SC (Genentech) | |
| Pipeline Manufacturer clinical phase | NI-071 Sagent Ph III | CHS-0214 Coherus Withdrawn | CHS-1420 Coherus Pending | NEULARA NeuClone Ph I | ABP654 Amgen Ph III | BAT1806 Biogen-BioThera Ph III |
| | GP2018 Sandoz Ph I | YLB113 Lupin Ph III | M923 Momenta Withdrawn | CT-P43 Celltrion Ph III | AVT04 Alvotech-Alvogen Ph III | MSB11456 Fresenius Ph III |
| | | | MSB11022 Fresenius Ph III | FYB202 Formycon-Bioeq Ph III | SB17 Samsung Bioepis Ph I | LUSINEX Mycenax-Gedeon Ph II |
| | | | AVT02 Alvotech-Teva Pending | DMB-3115 Dong-A / Meiji Ph III | BFI-751 BioFactura Ph I | |
| | | | MYL-1401A Mylan-Biocon Ph III | BAT2206 Hikma/Bio-Thera Ph III | | |
| | | | ONS-3010 Outlook Ph III | | | |
| | | | YUFLYMA (CF) Celltrion Pending | | | |

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U.S. insulin biosimilar market landscape & pipeline

As of September 17, 2021

| | Insulin (Long Acting) | | | Insulin (Rapid Acting) | | |
|---|---|-----------------|---|--|---------------------------|----------------------|
| Molecule | Insulin Glargine | | Insulin Detemir | Insulin Lispro | Insulin Aspart | |
| Innovator | LANTUS (Sanofi) | TOUJEO (Sanofi) | LEVEMIR (Novo Nordisk) | HUMALOG (Eli Lilly) | NOVOLOG (Novo Nordisk) | FIASP (Novo Nordisk) |
| Authorized Generic | | | | HUMALOG AG (Eli Lilly) | NOVOLOG AG (Novo Nordisk) | |
| Follow-on Biologic | BASAGLAR (Eli Lilly) | | <p>SEMGLEE (Follow-on biologic)</p> <ul style="list-style-type: none"> Aug'20 – FDA approved as brand (follow-on biologic) via the 351(a) pathway Currently available <p>NDC list 49502-195-80, 49502-196-71, 49502-196-73, 49502-196-75</p> | ADMELOG (Sanofi) | | |
| Approved but not yet Launched Biosimilars Manufacturer FDA approval date | SEMGLEE (Viatris/Mylan) July 2021 | | | <p>SEMGLEE (Biosimilar)</p> <ul style="list-style-type: none"> Jul'21 – FDA approved as an interchangeable biosimilar via the 351(k) pathway NOT currently available Only interchangeable with Lantus First and currently only biosimilar with interchangeability status <p>NDC list 49502-250-80, 49502-251-71, 49502-251-73, 49502-251-35, 49502-251-98, 49502-251-99</p> | | |
| Pipeline Biosimilars Manufacturer clinical phase | BASALIN SubQ (Lantus) Gan&Lee-Sandoz Ph III | | <p>HDV Insulin Lispro - SubQ Diasome Ph II</p> <p>Insulin Lispro Biocon - SubQ Biocon-Mylan Pre-Clin</p> <p>MYL-1601D – Inj Mylan-Biocon Pending</p> <p>SAR341402 – SubQ Sanofi Ph III</p> <p>RAPILIN Gan&Lee-Sandoz Ph I</p> | | | |

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U.S. biosimilar pipeline landscape

As of September 17, 2021

| 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 III | PB006 Sandoz-Polpharma Ph III | GP2411 Prolia Sandoz-Hexal Ph III | Denosumab Xgeva 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 | Rekovelte – 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 | | | | |
| | | Omalizumab Momenta-Mylan Withdrawn | | TVB-009 Prolia Teva Ph III | | | | | | |
| | | TEV-45779 Teva Ph III | | SB-16 Prolia Samsung Ph III | | | | | | |
| | | | | FKS518 Prolia Fresenius Ph III | | | | | | |
| | | | | JHL1266 Prolia JHL Biotech Ph I | | | | | | |
| | | | | CT-P41 Prolia Celltrion Ph III | | | | | | |

Connect with us

Find out how AmerisourceBergen is creating sustainability and longevity for biosimilars

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