

# Morgan Lewis



**BLOCKBUSTER BIOLOGICS REVIEW** ISSUE 29

## **FDA: Biosimilar Approvals**

# Biosimilar Approvals and Launches – Updates

## > **New biosimilars approved in the United States in Q3 2025.**

- > The FDA approved several Prolia<sup>®</sup> and Xgeva<sup>®</sup> biosimilars including:
  - > Bildyos<sup>®</sup> and Bilprevda<sup>®</sup> (approved August 2025),
  - > Aukelso<sup>®</sup> and Bosaya<sup>®</sup> (approved September 2025),
  - > Enoby<sup>®</sup> and Xtrenbo<sup>®</sup> (approved September 2025), and
  - > Osvyrti<sup>®</sup> and Jubereq<sup>®</sup> (approved October 2025).
- > These approvals follow a wave of approvals and launches of Prolia<sup>®</sup> and Xgeva<sup>®</sup> biosimilars.
  - > Eight companies have biosimilars with seven biosimilars having entered the US market.

## Biosimilar Approvals and Launches – Updates (cont.)

### > **New biosimilars approved in the United States in Q3 2025.**

- > The FDA approved the Eylea<sup>®</sup> biosimilar Eydenzelt<sup>®</sup> in October 2025.
  - > Eydenzelt<sup>®</sup> is a vascular endothelial growth factor (VEGF) inhibitor approved for the treatment of:
    - > Neovascular (Wet) Age-Related Macular Degeneration;
    - > Macular Edema Following Retinal Vein Occlusion;
    - > Diabetic Macular Edema; and
    - > Diabetic Retinopathy.
- > The FDA also approved the first Perjeta<sup>®</sup> biosimilar Poherdy<sup>®</sup> in November 2025.
  - > Poherdy<sup>®</sup> is a HER2/neu receptor antagonist approved for the treatment of HER2-positive breast cancer in combination with trastuzumab and additional chemotherapies.

# US Biosimilar Approvals – 78 Total

Drug Name	Approval Date
Poherdy (pertuzumab-dpzb)	November 2025
Osvyrti and Jubereq (denosumab-desu)	October 2025
Eydenzelt (afibercept-boav)	October 2025
Enoby and Xtrenbo (denosumab-qbde)	September 2025
Aukelso and Bosaya (denosumab-kyqq)	September 2025
Bildyos and Bilprevda (denosumab-nxxp)	August 2025
Kirsty (insulin aspart-xjhz)	July 2025
Starjemza (ustekinumab-hmny)	May 2025
Jobevne (bevacizumab-nwgd)	April 2025
Bomynta and Conexence (denosumab-bnht)	March 2025
Omlyclo (omalizumab-igec)	March 2025
Stoboclo and Osenvelt (denosumab-bmwo)	February 2025

Drug Name	Approval Date
Merilog (insulin aspart-szjj)	February 2025
Ospomyvtm and Xbryktm (denosumab-dssb)	February 2025
Avtozma (tocilizumab-anoh)	January 2025
Steqeyma (Ustekinumab-stba)	December 2024
Yesintek (ustekinumab-kfce)	November 2024
Imuldosa (ustekinumab-srlf)	October 2024
Otulfi (ustekinumab-aauz)	September 2024
Pavblu (afibercept-ayyh)	August 2024
Enzeevu (afibercept-abzv)	August 2024
Epysqli (eculizumab-aagh)	July 2024
Ahzantive (afibercept-mrbb)	June 2024
Nypozi (filgrastim-txid)	June 2024
Pyzchiva (ustekinumab-ttwe)	June 2024
Bkemv (eculizumab-aeeb)	May 2024
Yesafili (afibercept-jbvf)	May 2024
Opuviz (afibercept-yszy)	May 2024

# US Biosimilar Approvals – 78 Total (cont.)

Drug Name	Approval Date
Hercessi (trastuzumab-strf)	April 2024
Selarsdi (ustekinumab-aekn)	April 2024
Tyenne (tocilizumab-aazg)	March 2024
Jubbonti and Wyost (denosumab-bbdz)	March 2024
Simlandi (adalimumab-ryvk)	February 2024
Avzivi (bevacizumab-tjnj)	December 2023
Wezlana (ustekinumab-auub)	October 2023
Tofidence (tocilizumab-bavi)	September 2023
Tyruko (natalizumab-sztn)	August 2023
Yuflyma (adalimumab-aaty)	May 2023
Idacio (adalimumab-aacf)	December 2022
Vegzelma (bevacizumab-adcd)	September 2022
Stimufend (pegfilgrastim-fpgk)	September 2022

Drug Name	Approval Date
Cimerli (ranibizumab-eqrn)	August 2022
Fynetra (pegfilgrastim-pbbk)	May 2022
Alymsys (bevacizumab-maly)	April 2022
Releuko (filgrastim-ayow)	February 2022
Yusimry (adalimumab-aqvh)	December 2021
Rezvoglar (insulin glargine-agr)	December 2021*
Byooviz (ranibizumab-nuna)	September 2021
Semglee (insulin glargine-yfgn)	July 2021
Riabni (rituximab-arrx)	December 2020
Hulio (adalimumab-fkjp)	July 2020
Nyvepria (pegfilgrastim-apgf)	June 2020
Avsola (influximab-axxq)	December 2019
Abrilada (adalimumab-afzb)	November 2019

# US Biosimilar Approvals – 78 Total (cont.)

Drug Name	Approval Date
Ziextenzo (pegfilgrastim-bmez)	November 2019
Hadlima (adalimumab-bwwd)	July 2019
Ruxience (rituximab-pvvr)	July 2019
Zirabev (bevacizumab-bvzr)	June 2019
Kanjinti (trastuzumab-anns)	June 2019
Eticovo (etanercept-ykro)	April 2019
Trazimera (trastuzumab-qyyp)	March 2019
Ontruzant (trastuzumab-dttb)	January 2019
Herzuma (trastuzumab-pkrb)	December 2018
Truxima (rituximab-abbs)	November 2018
Udenyca (pegfilgrastim-cbqv)	November 2018
Hyrimoz (adalimumab-adaz)	October 2018
Nivestym (filgrastim-aafi)	July 2018

Drug Name	Approval Date
Fulphila (pegfilgrastim-jmdb)	June 2018
Retacrit (epoetin alfa-epbx)	May 2018
Ixifi (infliximab-qbtx)	December 2017
Ogivri (trastuzumab-dkst)	December 2017
Mvasi (bevacizumab-awwb)	September 2017
Cyltezo (adalimumab-adbm)	August 2017
Renflexis (infliximab-abda)	May 2017
Amjevita (adalimumab-atto)	September 2016
Erelzi (etanercept-szsz)	August 2016
Inflectra (infliximab-dyyb)	April 2016
Zarxio (filgrastim-sndz)	March 2015

# Biosimilars by Reference Product

- **Actemra (tocilizumab) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Avtozma (tocilizumab-anoh)	Biosimilar	Celltrion, Inc.	January 24, 2025
Tyenne (tocilizumab-aazg)	Biosimilar	Fresenius Kabi USA LLC	March 7, 2024
Tofidence (tocilizumab-bavi)	Biosimilar	Biogen Inc.	September 29, 2023

# Biosimilars by Reference Product (cont.)

- **Avastin (bevacizumab) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Jobevne (bevacizumab-nwgd)	Biosimilar	Biocon Biologics Inc.	April 9, 2025
Avzivi (bevacizumab-tnjn)	Biosimilar	Bio-Thera Solutions, Ltd.	December 6, 2023
Vegzelma (bevacizumab-adcd)	Biosimilar	Celltrion, Inc.	September 27, 2022
Alymsys (bevacizumab-maly)	Biosimilar	Amneal Pharmaceuticals, Inc.	April 13, 2022
Zirabev (bevacizumab-bvzr)	Biosimilar	Pfizer Inc.	June 27, 2019
Mvasi (bevacizumab-awwb)	Biosimilar	Amgen Inc.	September 14, 2017



# Biosimilars by Reference Product (cont.)

- **Enbrel (etanercept) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Eticovo (etanercept-ykro)	Biosimilar	Samsung Bioepis Co., Ltd.	April 25, 2019
Erelzi (etanercept-szsz)	Biosimilar	Sandoz Inc.	August 30, 2016

## Biosimilars by Reference Product (cont.)

- **Epogen/Procrit (epoetin alfa) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Retacrit (epoetin alfa-epbx)	Biosimilar	Hospira Inc.	May 15, 2018

# Biosimilars by Reference Product (cont.)

- Herceptin (trastuzumab) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Hercessi (trastuzumab-strf)	Biosimilar	Accord BioPharma Inc.	April 29, 2024
Kanjinti (trastuzumab-anns)	Biosimilar	Amgen Inc.	June 13, 2019
Trazimera (trastuzumab-qyyp)	Biosimilar	Pfizer Inc.	March 11, 2019
Ontruzant (trastuzumab-dttb)	Biosimilar	Samsung Bioepis Co., Ltd.	January 18, 2019
Herzuma (trastuzumab-pkrb)	Biosimilar	Celltrion, Inc.	December 14, 2018
Ogivri (trastuzumab-dkst)	Biosimilar	Mylan GmbH	December 1, 2017

# Biosimilars by Reference Product (cont.)

- **Humira (adalimumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Simlandi (adalimumab-ryvk)	Biosimilar	Alvotech and Teva Pharmaceuticals	February 24, 2024
Yuflyma (adalimumab-aaty)	Biosimilar	Celltrion USA	May 24, 2023
Idacio (adalimumab-aacf)	Biosimilar	Fresenius Kabi	December 13, 2022
Yusimry (adalimumab-aqvh)	Biosimilar	Coherus BioSciences, Inc.	December 17, 2021
Hulio (adalimumab-fkjp)	Biosimilar	Mylan Pharmaceuticals Inc.	July 6, 2020
Abrilada (adalimumab-afzb)	Biosimilar	Pfizer Inc.	November 15, 2019
Hadlima (adalimumab-bwwd)	Biosimilar	Samsung Bioepis Co., Ltd.	July 23, 2019
Hyrimoz (adalimumab-adaz)	Biosimilar	Sandoz Inc.	October 30, 2018
Cyltezo (adalimumab-adbm)	Interchangeable	Boehringer Ingelheim Pharmaceuticals, Inc.	August 25, 2017
Amjevita (adalimumab-atto)	Biosimilar	Amgen Inc.	September 23, 2016

# Biosimilars by Reference Product (cont.)

- **Lantus (insulin glargine) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Rezvoglar (insulin glargine-aglr)	Interchangeable	Eli Lilly and Company	November 16, 2022
Cimerli (ranibizumab-eqrn)	Interchangeable	Coherus BioSciences, Inc.	August 2, 2022
Semglee (insulin glargine-yfgn)	Interchangeable	Mylan Pharmaceuticals Inc.	July 28, 2021

## Biosimilars by Reference Product (cont.)

- **Lucentis (ranibizumab) biosimilar**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Byooviz (ranibizumab-nuna)	Biosimilar	Samsung Bioepis Co., Ltd.	September 20, 2021

# Biosimilars by Reference Product (cont.)

- **Neulasta (pegfilgrastim) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Stimufend (pegfilgrastim-fpgk)	Biosimilar	Fresenius Kabi USA, LLC	September 1, 2022
Fylnetra (pegfilgrastim-pbbk)	Biosimilar	Amneal Pharmaceuticals, Inc.	May 26, 2022
Nyvepria (pegfilgrastim-apgf)	Biosimilar	Pfizer Inc.	June 10, 2020
Ziextenzo (pegfilgrastim-bmez)	Biosimilar	Sandoz Inc.	November 4, 2019
Udenyca (pegfilgrastim-cbqv)	Biosimilar	Coherus BioSciences, Inc.	November 2, 2018
Fulphila (pegfilgrastim-jmdb)	Biosimilar	Mylan N.V.	June 4, 2018

# Biosimilars by Reference Product (cont.)

- **Neupogen (filgrastim) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Nypozi (filgrastim-txid)	Biosimilar	Tanvex BioPharma USA, Inc.	June 28, 2024
Releuko (filgrastim-ayow)	Biosimilar	Kashiv BioSciences, LLC	February 25, 2022
Nivestym (filgrastim-aafi)	Biosimilar	Pfizer Inc.	July 20, 2018
Zarxio (filgrastim-sndz)	Biosimilar	Sandoz Inc.	March 6, 2015



# Biosimilars by Reference Product (cont.)

- Prolia and Xgeva (denosumab) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Osvyrti and Jubereq (denosumab-desu)	Biosimilar	Accord BioPharma, Inc.	October 2025
Enoby and Xtrenbo (denosumab-qbde)	Biosimilar	Hikma Pharmaceuticals USA Inc.	September 26, 2025
Aukelso and Bosaya (denosumab-kyqq)	Biosimilar	Biocon Biologics, Inc.	September 16, 2025
Bildyos and Bilprevda (denosumab-nxxp)	Biosimilar	Shanghai Henlius Biotech, Inc.	August 29, 2025

# Biosimilars by Reference Product (cont.)

- Prolia and Xgeva (denosumab) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Bomyntra and Conexence (denosumab-bnht)	Biosimilar	Fresenius Kabi USA, LLC	March 25, 2025
Osenvelt and Stoboclo (denosumab-bmwo)	Biosimilar	Celltrion, Inc.	February 28, 2025
Ospomyv (denosumab-dssb)	Biosimilar	Samsung Bioepis Co. LTD.	February 13, 2025
Xbryk (denosumab-dssb)	Biosimilar	Samsung Bioepis Co. LTD.	February 13, 2025
Jubbonti (denosumab-bbdz)	Biosimilar	Sandoz Inc.	March 5, 2024
Wyost (denosumab-bbdz)	Biosimilar	Sandoz Inc.	March 5, 2024

# Biosimilars by Reference Product (cont.)

- Remicade (infliximab) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Avsola (infliximab-axxq)	Biosimilar	Amgen Inc.	December 6, 2019
Ixifi (infliximab-qbtx)	Biosimilar	Pfizer Inc.	December 13, 2017
Renflexis (infliximab-abda)	Biosimilar	Samsung Bioepis Co., Ltd.	April 21, 2017
Inflectra (infliximab-dyyb)	Biosimilar	Celltrion, Inc.	April 5, 2016

# Biosimilars by Reference Product (cont.)

- Rituxan (rituximab) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Riabni (rituximab-arrx)	Biosimilar	Amgen Inc.	December 17, 2020
Ruxience (rituximab-pvvr)	Biosimilar	Pfizer Inc.	July 23, 2019
Truxima (rituximab-abbs)	Biosimilar	Celltrion, Inc.	November 28, 2018

# Biosimilars by Reference Product (cont.)

- Stelara (ustekinumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Starjemza (ustekinumab-hmny)	Biosimilar	Bio-thera Solutions, Ltd.	May 22, 2025
Steqeyma (ustekinumab-stba)	Biosimilar	Celltrion, Inc.	December 17, 2025
Yesintek (ustekinumab-kfce)	Biosimilar	Biocon Biologics Ltd.	November 29, 2024
Imuldosa (ustekinumab-srlf)	Biosimilar	Accord BioPharma, Inc.	October 10, 2024
Otulfi (ustekinumab-aauz)	Biosimilar	Fresenius Kabi USA, LLC	September 27, 2024
Pyzchiva (ustekinumab-ttwe)	Biosimilar	Samsung Bioepis Co., Ltd.	June 28, 2024
Selarsdi (ustekinumab-aekn)	Biosimilar	Alvotect and Teva Pharmaceuticals	April 16, 2024
Wezlana (ustekinumab-auub)	Biosimilar	Amgen Inc.	October 31, 2023

## Biosimilars by Reference Product (cont.)

- **Tysabri (natalizumab) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Tyruko (natalizumab-sztn)	Biosimilar	Sandoz Group AG	August 25, 2023

# Biosimilars by Reference Product (cont.)

- **Eylea (aflibercept) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Eydenzelt (aflibercept-boav)	Biosimilar	Celltrion, Inc.	October 2, 2025
Pavblu (aflibercept-ayyh)	Biosimilar	Amgen, Inc.	August 23, 2024
Enzeevu (aflibercept-abzv)	Biosimilar	Sandoz Inc.	August 9, 2024
Ahzantive (aflibercept-mrbb)	Biosimilar	Formycon AG	June 28, 2024
Yesafili (aflibercept-jbvf)	Biosimilar	Biocon Biologics Inc.	May 20, 2024
Opuviz (aflibercept-yszy)	Biosimilar	Samsung Bioepis Co., Ltd.	May 20, 2024

# Biosimilars by Reference Product (cont.)

- **Soliris (eculizumab) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Epysqli (eculizumab-aagh)	Biosimilar	Samsung Bioepis Co., Ltd.	July 19, 2024
Bkemv (eculizumab-aeeb)	Biosimilar	Amgen Inc.	May 28, 2024



## Biosimilars by Reference Product (cont.)

- **Novolog (insulin aspart) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Merilog (insulin aspart-szjj)	Biosimilar	Sanofi-Aventis U.S. LLC	February 14, 2025

## Biosimilars by Reference Product (cont.)

- **Xolair (omalizumab) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Omlyclo (omalizumab-igec)	Biosimilar	Celltrion, Inc.	March 7, 2025

## Biosimilars by Reference Product (cont.)

- **Perjeta (pertuzumab) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
Poherdy (pertuzumab-dpzb)	Biosimilar	Shanghai Henlius Biotech, Inc.	November 13, 2025

## Biosimilars by Reference Product (cont.)

- **Novolog (insulin aspart) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Kirsty (insulin aspart-xjhz)	Biosimilar	Biocon Biologics Inc.	July 15, 2025

# US Biosimilar Approval Statistics



aBLA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA Holder	aBLA Submission Date	Date of Biosimilar License	US Biosimilar Launch Date	Pendency from Submission to Licensure	Pendency from Submission to Launch	Pendency from Licensure to Launch
aBLA 761024	Amjevita™	Adalimumab-atto	Amgen	Nov. 25, 2015	Sep. 23, 2016	Jan. 31, 2023	303 days	2,624 days	2,321 days
aBLA 761058	Cyltezo®	Adalimumab-abdm	Boehringer Ingelheim	Oct. 27, 2016	Aug. 25, 2017	Jul. 1, 2023	302 days	2,438 days	2,136 days
aBLA 761071	Hyrimoz™	Adalimumab-adaz	Sandoz	Oct. 30, 2017	Oct. 30, 2018	Jul. 1, 2023	365 days	2,070 days	1,705 days
aBLA 761059	Hadlima™	Adalimumab-bwwd	Samsung Bioepis	Jul. 23, 2018	Jul. 23, 2019	Jul. 1, 2023	365 days	1,804 days	1,439 days
aBLA 761118	Abrilada™	Adalimumab-afzb	Pfizer	Nov. 16, 2018	Nov. 18, 2019	Nov. 1, 2023	367 days	1,811 days	1,444 days
aBLA 761154	Hulio®	Adalimumab-fkjp	Mylan / Biocon	Jul. 12, 2019	Jul. 6, 2020	Jul. 3, 2023	360 days	1,452 days	1,092 days
aBLA 761216	Yusimry™	Adalimumab-aqvh	Coherus	Dec. 18, 2020	Dec. 17, 2021	Jul. 3, 2023	364 days	927 days	563 days
aBLA 761255	Idacio®	Adalimumab-aacf	Fresenius Kabi	Dec. 13, 2021	Dec. 13, 2022	Jul. 3, 2023	365 days	567 days	202 days
aBLA 761219	Yuflyma®	Adalimumab-aaty	Celltrion	Nov. 24, 2020	May 23, 2023	Jul. 2, 2023	910 days	950 days	40 days
aBLA 761299	Simlandi®	Adalimumab-ryvk	Alvotect / Teva	Dec. 20, 2021	Feb. 23, 2024	May 20, 2024	795 days	882 days	87 days
aBLA 761028	Mvasi™	Bevacizumab-awwb	Amgen	Nov. 14, 2016	Sep. 14, 2017	Jul. 19, 2019	304 days	977 days	673 days
aBLA 761099	Zirabev™	Bevacizumab-bvzr	Pfizer	Jun. 29, 2018	Jun. 27, 2019	Dec. 31, 2019	363 days	550 days	187 days
aBLA 761231	Alymsys®	Bevacizumab-maly	Amneal / mAbxience	Apr. 13, 2021	Apr. 13, 2022	Oct. 3, 2022	365 days	538 days	173 days

# US Biosimilar Approval Statistics (cont.)



aBLA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA Holder	aBLA Submission Date	Date of Biosimilar License	US Biosimilar Launch Date	Pendency from Submission to Licensure	Pendency from Submission to Launch	Pendency from Licensure to Launch
<b>aBLA 761268</b>	Vegzelma®	Bevacizumab-adcd	Celltrion	Sep. 30, 2021	Sep. 27, 2022	Apr. 17, 2023	362 days	564 days	202 days
<b>aBLA 761198</b>	Avzivi®	Bevacizumab-tjnj	Bio-Thera / Sandoz	Nov. 27, 2020	Dec. 6, 2023	N/A	1,104 days	N/A	N/A
<b>aBLA 761362</b>	Jubbonti®	Denosumab-bbdz	Sandoz	Dec. 5, 2022	Mar. 5, 2024	May 31, 2025*	455 days	908 days	452 days
<b>aBLA 761362</b>	Wyost®	Denosumab-bbdz	Sandoz	Dec. 5, 2022	Mar. 5, 2024	May 31, 2025*	455 days	908 days	452 days
<b>aBLA 125545</b>	Retacrit®	Epoetin Alfa-epbx	Hospira / Pfizer	Dec. 16, 2014	May 15, 2018	Nov. 12, 2018	1,246 days	1,427 days	181 days
<b>aBLA 761042</b>	Erelzi®	Etanercept-szsz	Sandoz	Jul. 30, 2015	Aug. 30, 2016	N/A	397 days	N/A	N/A
<b>aBLA 761066</b>	Eticovo™	Etanercept-ykro	Samsung Bioepis	May 25, 2017	Apr. 25, 2019	N/A	700 days	N/A	N/A
<b>aBLA 125553</b>	Zarxio®	Filgrastim-sndz	Sandoz	May 8, 2014	Mar. 6, 2015	Sep. 3, 2015	302 days	483 days	181 days
<b>aBLA 761080</b>	Nivestym™	Filgrastim-aafi	Pfizer	Sep. 21, 2017	Jul. 20, 2018	Oct. 1, 2018	272 days	375 days	103 days
<b>aBLA 761082</b>	Releuko™	Filgrastim-ayow	Kashiv	Jul. 8, 2017	Feb. 25, 2022	Nov. 29, 2022	1,693 days	1,970 days	277 days
<b>aBLA 125544</b>	Inflectra®	Infliximab-dyyb	Celltrion / Pfizer	Aug. 8, 2014	Apr. 5, 2016	Nov. 28, 2016	606 days	843 days	237 days
<b>aBLA 761054</b>	Renflexis®	Infliximab-abda	Samsung Bioepis / Merck	Mar. 21, 2016	Apr. 21, 2017	Jul. 24, 2017	396 days	490 days	94 days
<b>aBLA 761072</b>	Ixifi™	Infliximab-qbtx	Pfizer	Feb. 13, 2017	Dec. 13, 2017	N/A	303 days	N/A	N/A

# US Biosimilar Approval Statistics (cont.)



aBLA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA Holder	aBLA Submission Date	Date of Biosimilar License	US Biosimilar Launch Date	Pendency from Submission to Licensure	Pendency from Submission to Launch	Pendency from Licensure to Launch
<b>aBLA 761086</b>	Avsola®	Infliximab-axxq	Amgen	Dec. 14, 2018	Dec. 6, 2019	Jul. 6, 2020	357 days	570 days	213 days
<b>aBLA 761201</b>	Semglee® (interchangeable)	Insulin Glargine-yfgn	Mylan / Biocon	Jul. 29, 2020	Jul. 28, 2021	Nov. 16, 2021	365 days	476 days	112 days
<b>aBLA 761215</b>	Rezvoglar®	Insulin Glargine-aglr	Eli Lilly	Dec. 17, 2020	Dec. 17, 2021	Apr. 1, 2023	365 days	835 days	470 days
<b>aBLA 761322</b>	Tyruko®	Natalizumab-sztn	Sandoz / Polpharma	May 24, 2022	Aug. 24, 2023	Nov. 17, 2025	457 days	1273 days	816 days
<b>aBLA 761075</b>	Fulphila®	Pegfilgrastim-jmdb	Mylan / Biocon	Dec. 9, 2016	Jun. 4, 2018	Jul. 30, 2018	542 days	598 days	56 days
<b>aBLA 761039</b>	Udenyca™	Pegfilgrastim-cbqv	Coherus	Aug. 9, 2016	Nov. 2, 2018	Jan. 3, 2019	569 days	877 days	308 days
<b>aBLA 761045</b>	Ziextenzo®	Pegfilgrastim-bmez	Sandoz	Aug. 27, 2015	Nov. 5, 2019	Nov. 15, 2019	1,531 days	1,541 days	10 days
<b>aBLA 761111</b>	Nyvepria™	Pegfilgrastim-apgf	Pfizer / Hospira	Jun. 10, 2019	Jun. 11, 2020	Jan. 1, 2021*	367 days	571 days	204 days
<b>aBLA 761084</b>	Fylneta®	Pegfilgrastim-pbbk	Kashiv / Amneal	Aug. 11, 2020	May 26, 2022	May 16, 2023	653 days	1,008 days	355 days
<b>aBLA 761173</b>	Stimufend®	Pegfilgrastim-fpgk	Fresenius Kabi	Mar. 27, 2020	Sep. 1, 2022	Feb. 16, 2023	888 days	1,056 days	168 days
<b>aBLA 761202</b>	Byooviz™	Ranibizumab-nuna	Samsung Bioepis	Sep. 17, 2020	Sep. 20, 2021	Jul. 1, 2022	368 days	652 days	284 days
<b>aBLA 761165</b>	Cimerli™	Ranibizumab-eqrn	Coherus / Bioeq / Formycon	Aug. 2, 2021	Aug. 2, 2022	Oct. 3, 2022	365 days	427 days	62 days

# US Biosimilar Approval Statistics (cont.)



aBLA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA Holder	aBLA Submission Date	Date of Biosimilar License	US Biosimilar Launch Date	Pendency from Submission to Licensure	Pendency from Submission to Launch	Pendency from Licensure to Launch
<b>aBLA 761088</b>	Truxima®	Rituximab-abbs	Celltrion / Teva	Apr. 28, 2017	Nov. 28, 2018	Nov. 11, 2019	579 days	927 days	348 days
<b>aBLA 761103</b>	Ruxience®	Rituximab-pvvr	Pfizer	Jul. 25, 2018	Jul. 23, 2019	Jan. 23, 2020	363 days	547 days	184 days
<b>aBLA 761140</b>	Riabni™	Rituximab-arrx	Amgen / Allergan	Dec. 19, 2019	Dec. 17, 2020	Jan. 12, 2021	364 days	390 days	26 days
<b>aBLA 761354</b>	Tofidence™	Tocilizumab-bavi	Biogen / Bio-Thera	Sep. 29, 2022	Sep. 29, 2023	May 6, 2024	365 days	585 days	220 days
<b>aBLA 761275</b>	Tyenne®	Tocilizumab-aazg	Fresenius Kabi	May 30, 2022	Mar. 5, 2024	Apr. 15, 2024	645 days	686 days	41 days
<b>aBLA 761074</b>	Ogivri™	Trastuzumab-dkst	Mylan / Biocon	Nov. 3, 2016	Dec. 1, 2017	Dec. 2, 2019	393 days	1,124 days	731 days
<b>aBLA 761091</b>	Herzuma®	Trastuzumab-pkrb	Celltrion / Teva	May 30, 2017	Dec. 14, 2018	Mar. 16, 2020	563 days	1,021 days	458 days
<b>aBLA 761100</b>	Ontruzant®	Trastuzumab-dttb	Samsung Bioepis / Merck	Oct. 20, 2017	Jan. 18, 2019	Apr. 15, 2020	455 days	908 days	453 days
<b>aBLA 761081</b>	Trazimera™	Trastuzumab-qyyp	Pfizer	Jun. 22, 2017	Mar. 11, 2019	Feb. 15, 2020	627 days	968 days	341 days
<b>aBLA 761073</b>	Kanjinti™	Trastuzumab-anns	Amgen / Allergan	Jul. 28, 2017	Jun. 13, 2019	Jul. 19, 2019	685 days	721 days	36 days
<b>aBLA 761346</b>	Hercessi™	Trastuzumab-strf	Accord BioPharma / Henlius	Dec. 13, 2022	Apr. 25, 2024	Nov. 29, 2024	499 days	717 days	218 days
<b>aBLA 761285 / 76133</b>	Wezlana®	Ustekinumab-auub	Amgen	Oct. 31, 2022	Oct. 31, 2023	Jan. 1, 2025	365 days	793 days	428 days



# US Biosimilar Approval Statistics (cont.)



aBLA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA Holder	aBLA Submission Date	Date of Biosimilar License	US Biosimilar Launch Date	Pendency from Submission to Licensure	Pendency from Submission to Launch	Pendency from Licensure to Launch
<b>aBLA 761343</b>	Selarsdi™	Ustekinumab-aekn	Alvotech / Teva	Oct. 11, 2022	Apr. 16, 2024	Feb. 21, 2025	553 days	864 days	311 days
<b>aBLA 761350</b>	Opuviz®	Aflibercept-yszy	Samsung Bioepis Co., Ltd.	Feb. 17, 2023	May 20, 2024	N/A	458 days	N/A	N/A
<b>aBLA 761274</b>	Yesafili®	Aflibercept-jbvf	Biocon Biologics Inc.	Oct. 29, 2021	May 20, 2024	N/A	934 days	N/A	N/A
<b>aBLA 761333</b>	Bkemv®	Eculizumab-aeeb	Amgen Inc.	Feb. 28, 2023	May 28, 2024	Mar. 5, 2025	455 days	736 days	281 days
<b>aBLA 761373</b>	Pyzchiva®	Ustekinumab-ttwe	Samsung Bioepis Co., Ltd.	Mar. 30, 2023	Jun. 28, 2024	Feb. 24, 2025	456 days	698 days	242 days
<b>aBLA 761126</b>	Nypozzi®	Filgrastim-txid	Tanvex BioPharma USA, Inc.	Sep. 28, 2018	Jun. 28, 2024	N/A	2,100 days	N/A	N/A
<b>aBLA 761378</b>	Ahzantive®	Aflibercept-mrbb	Formycon AG	Jun. 28, 2023	Jun. 28, 2024	N/A	364 days	N/A	N/A
<b>aBLA 761340</b>	Epysqli®	Eculizumab-aagh	Samsung Bioepis Co., Ltd.	Apr. 21, 2023	Jul. 19, 2024	Apr. 7, 2025	455 days	718 days	263 days
<b>aBLA 761382</b>	Enzeevu®	Aflibercept-abzv	Sandoz Inc.	Aug. 10, 2023	Aug. 9, 2024	Nov. 24, 2025	365 days	N/A	N/A
<b>BLA 761298</b>	Pavblu®	Aflibercept-ayyh	Amgen, Inc	Aug. 23, 2023	Aug. 23, 2024	Oct. 30, 2024	365 days	434 days	68 days

# US Biosimilar Approval Statistics (cont.)



aBLA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA Holder	aBLA Submission Date	Date of Biosimilar License	US Biosimilar Launch Date	Pendency from Submission to Licensure	Pendency from Submission to Launch	Pendency from Licensure to Launch
<b>BLA 761379</b>	Otulfi®	Ustekinumab-aauz	Fresenius Kabi USA, LLC	Sep. 28, 2023	Sep. 27, 2024	Mar. 3, 2025	365 days	523 days	158 days
<b>BLA 761364</b>	Imuldosa®	Ustekinumab-srlf	Accord BioPharma, Inc.	Oct. 9, 2023	Oct. 10, 2024	Aug. 18, 2025	366 days	679 days	312 days
<b>BLA 761406</b>	Yesintek®	Ustekinumab-kfce	Biocon Biologics Inc.	Nov. 29, 2023	Nov. 29, 2024	Feb. 24, 2025	366 days	453 days	87 days
<b>BLA 761338</b>	Steqeyma®	Ustekinumab-stba	Celltrion, Inc.	Jun. 30, 2023	Dec. 17, 2024	Mar. 12, 2025	536 days	621 days	85 days
<b>BLA 761420</b>	Avtozma®	Tocilizumab-anoh	Celltrion, Inc.	Jan. 26, 2024	Jan. 24, 2025	Oct. 13, 2025	364 days	626 days	262 days
<b>BLA 761392</b>	Ospomyvtm®	Denosumab-dssb	Samsung Bioepis Co., LTD.	Feb. 11, 2024	Feb. 13, 2025	Jun. 2, 2025	368 days	477 days	109 days
<b>BLA 761392</b>	Xbryktm®	Denosumab-dssb	Samsung Bioepis Co., LTD.	Feb. 12, 2024	Feb. 13, 2025	N/A	367 days	N/A	N/A
<b>BLA 761325</b>	Merilog®	Insulin aspart-szjj	Sanofi-Aventis U.S. LLC	Sep. 8, 2022	Feb. 14, 2025	N/A	890 days	N/A	N/A
<b>BLA 761404</b>	Stoboclo®	Denosumab-bmwo	Celltrion, Inc.	Nov. 30, 2023	Feb. 28, 2025	Jul. 7, 2025	456 days	585 days	129 days
<b>BLA 761404</b>	Osenvelt®	Denosumab-bmwo	Celltrion, Inc.	Nov. 30, 2023	Feb. 28, 2025	Jul. 7, 2025	456 days	585 days	129 days
<b>BLA 761399</b>	Omlyclo®	Omalizumab-igec	Celltrion, Inc.	Mar. 8, 2024	Mar. 7, 2025	Sep. 19, 2025	364 days	560 days	196 days
<b>BLA 761398</b>	Bomynta®	Denosumab-bnht	Fresenius Kabi USA, LLC	Mar. 25, 2024	Mar. 25, 2025	Jul. 1, 2025	365 days	463 days	98 days

# US Biosimilar Approval Statistics (cont.)



aBLA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA Holder	aBLA Submission Date	Date of Biosimilar License	US Biosimilar Launch Date	Pendency from Submission to Licensure	Pendency from Submission to Launch	Pendency from Licensure to Launch
<b>BLA 761398</b>	Conexence®	Denosumab-bnht	Fresenius Kabi USA, LLC	Mar. 25, 2024	Mar. 25, 2025	Jul. 1, 2025	365 days	463 days	98 days
<b>BLA 761175</b>	Jobevne®	Bevacizumab-nwgd	Biocon Biologics Inc.	Dec. 27, 2019	Apr. 9, 2025	N/A	1930 days	N/A	N/A
<b>BLA 761419</b>	Starjemza®	Ustekinumab-hmny	Bio-Thera Solutions, Ltd.	May 22, 2024	May 22, 2025	Nov. 6, 2025	365 days	533 days	168 days
<b>BLA 761188</b>	Kirsty™	Insulin aspart-xjhz	Biocon Biologics Inc.	Jul. 16, 2020	Jul. 15, 2025	N/A	1825 days	N/A	N/A
<b>BLA 761444</b>	Bildyos® and Bilprevda®	Denosumab-nxxp	Shanghai Henlius Biotech, Inc.	Aug. 30, 2024	Aug. 29, 2025	N/A	364 days	N/A	N/A
<b>BLA 761436</b>	Aukelso® and Bosaya®	Denosumab-kyqq	Biocon Biologics Inc.	Sep. 16, 2024	Sep. 16, 2025	Oct. 1, 2025	365 days	380 days	15 days
<b>BLA 761439</b>	Enoby® and Xtrenbo®	Denosumab-qbde	Hikma Pharmaceuticals USA Inc.	Sep. 27, 2024	Sep. 26, 2025	N/A	364 days	N/A	N/A
<b>BLA 761377</b>	Eydenzelt®	Aflibercept-boav	Celltrion, Inc.	Jun. 29, 2023	Oct. 2, 2025	N/A	826 days	N/A	N/A
<b>BLA 761450</b>	Poherdy®	Pertuzumab-dpzb	Shanghai Henlius Biotech, Inc.	Nov. 29, 2024	Nov. 13, 2025	N/A	349 days	N/A	N/A
<b>Average:</b>							<b>556.4 days</b>	<b>862.9 days</b>	<b>371.7 days</b>

# Contacts



**Christopher J. Betti, Ph.D.**  
Chicago  
T: +1.312.324.1449  
[christopher.betti@morganlewis.com](mailto:christopher.betti@morganlewis.com)



**Kelly A. Plummer, Ph.D.**  
Chicago  
T: +1.312.324.1490  
[kelly.plummer@morganlewis.com](mailto:kelly.plummer@morganlewis.com)



**Maarika L. Kimbrell**  
Washington, DC  
T: +1.202.739.5348  
[maarika.kimbrell@morganlewis.com](mailto:maarika.kimbrell@morganlewis.com)



**Maria E. Doukas**  
Chicago  
T: +1.312.324.1454  
[maria.doukas@morganlewis.com](mailto:maria.doukas@morganlewis.com)



**Margaret C. Harney**  
Chicago  
T: +1.312.324.1727  
[margaret.harney@morganlewis.com](mailto:margaret.harney@morganlewis.com)