

# Morgan Lewis



**BLOCKBUSTER BIOLOGICS REVIEW** ISSUE 20

## **FDA: Biosimilar Approvals**

## > **New biosimilar approved in the US in Q2 2023.**

- Celltrion USA launched Yuflyma® (adalimumab-aaty), a high-concentration (100mg/mL) and citrate-free formulation of Humira® (adalimumab).
- Yuflyma is indicated for the treatment of eight conditions, including rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, plaque psoriasis, and hidradenitis suppurativa.

# US Biosimilar Approvals – 41 Total

Drug Name	Approval Date	Drug Name	Approval Date
Yuflyma (adalimumab-aaty)	May 2023	Byooviz (ranibizumab-nuna)	September 2021
Idacio (adalimumab-aacf)	December 2022	Semglee (insulin glargine-yfgn)	July 2021
Vegzelma (bevacizumab-adcd)	September 2022	Riabni (rituximab-arrx)	December 2020
Stimufend (pegfilgrastim-fpgk)	September 2022	Hulio (adalimumab-fkjp)	July 2020
Cimerli (ranibizumab-eqrn)	August 2022	Nyvepria (pegfilgrastim-appg)	June 2020
Fylnetra (pegfilgrastim-pbbk)	May 2022	Avsola (infliximab-axxq)	December 2019
Almysys (bevacizumab-maly)	April 2022	Abrilada (adalimumab-afzb)	November 2019
Releuko (filgrastim-ayow)	February 2022	Ziextenzo (pegfilgrastim-bmez)	November 2019
Yusimry (adalimumab-aqvh)	December 2021	Hadlima (adalimumab-bwwd)	July 2019
Rezvoglar (insulin glargine-aglr)	December 2021*	Ruxience (rituximab-pvvr)	July 2019

# US Biosimilar Approvals – 41 Total (cont.)

Drug Name	Approval Date	Drug Name	Approval Date
Zirabev (bevacizumab-bvzr)	June 2019	Fulphila (pegfilgrastim-jmdb)	June 2018
Kanjinti (trastuzumab-anns)	June 2019	Retacrit (epoetin alfa-epbx)	May 2018
Eticovo (etanercept-ykro)	April 2019	Ixifi (infliximab-qbtx)	December 2017
Trazimera (trastuzumab-qyyp)	March 2019	Ogivri (trastuzumab-dkst)	December 2017
Ontruzant (trastuzumab-dttb)	January 2019	Mvasi (bevacizumab-awwb)	September 2017
Herzuma (trastuzumab-pkrb)	December 2018	Cyltezo (adalimumab-adbm)	August 2017
Truxima (rituximab-abbs)	November 2018	Renflexis (infliximab-abda)	April 2017
Udenyca (pegfilgrastim-cbqv)	November 2018	Amjevita (adalimumab-atto)	September 2016
Hyrimoz (adalimumab-adaz)	October 2018	Erelzi (etanercept-szsz)	August 2016
Nivestym (filgrastim-aafi)	July 2018	Inflectra (infliximab-dyyb)	April 2016
		Zarxio (filgrastim-sndz)	March 2015

# Biosimilars by Reference Product

- **Avastin (bevacizumab) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
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

- **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

- **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

- **Herceptin (trastuzumab) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
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

- **Humira (adalimumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Yuflyma (adalimumab-aaty)	Biosimilar	Celltrion USA	May 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

- **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

- **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

- **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

- **Neupogen (filgrastim) biosimilars**

<b>Name</b>	<b>Regulatory Designation</b>	<b>Company Name</b>	<b>FDA Approved</b>
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

- **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

- **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

# 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
<b>aBLA 761024</b>	Amjevita™	Adalimumab-atto	Amgen	Nov. 25, 2015	Sep. 23, 2016	NA	303 days	NA	NA
<b>aBLA 761058</b>	Cyltezo®	Adalimumab-abdm	Boehringer Ingelheim	Oct. 27, 2016	Aug. 25, 2017	NA	302 days	NA	NA
<b>aBLA 761071</b>	Hyrimoz™	Adalimumab-adaz	Sandoz	Oct. 30, 2017	Oct. 30, 2018	NA	365 days	NA	NA
<b>aBLA 761059</b>	Hadlima™	Adalimumab-bwwd	Samsung Bioepis	Jul. 23, 2018	Jul. 23, 2019	NA	365 days	NA	NA
<b>aBLA 761118</b>	Abrilada™	Adalimumab-afzb	Pfizer	Nov. 16, 2018	Nov. 18, 2019	NA	410 days	NA	NA
<b>aBLA 761154</b>	Hulio®	Adalimumab-fkjp	Mylan / Biocon	Jul. 12, 2019	Jul. 6, 2020	NA	360 days	NA	NA
<b>aBLA 761216</b>	Yusimry™	Adalimumab-aqvh	Coherus	Dec. 18, 2020	Dec. 17, 2021	NA	364 days	NA	NA
<b>aBLA 761028</b>	Mvasi™	Bevacizumab-awwb	Amgen	Nov. 14, 2016	Sep. 14, 2017	Jul. 19, 2019	304 days	977 days	673 days
<b>aBLA 761099</b>	Zirabev™	Bevacizumab-bvzr	Pfizer	Jun. 29, 2018	Jun. 27, 2019	Dec. 31, 2019	363 days	550 days	187 days
<b>aBLA 761231</b>	Alymsys®	Bevacizumab-maly	Amneal / mAbxience	Apr. 13, 2021	Apr. 13, 2022	NA	365 days	NA	NA



# 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 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	NA	397 days	NA	NA
<b>aBLA 761066</b>	Eticovo™	Etanercept-ykro	Samsung Bioepis	May 25, 2017	Apr. 25, 2019	NA	700 days	NA	NA
<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	NA	1,693 days	NA	NA
<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

# 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 761072</b>	Ixifi™	Infliximab-qbtx	Pfizer	Feb. 13, 2017	Dec. 13, 2017	NA	303 days	NA	NA
<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	NA	365 days	NA	NA
<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

# 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 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>	Fylnetra®	Pegfilgrastim-pbbk	Kashiv / Amneal	Aug. 11, 2020	May 26, 2022	NA	653 days	NA	NA
<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 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 761074</b>	Ogivri™	Trastuzumab-dkst	Mylan / Biocon	Nov. 3, 2016	Dec. 1, 2017	Dec. 2, 2019	393 days	1,124 days	731 days

\*Estimated

# 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 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>Average:</b>							<b>515.6 days</b>	<b>774.4 days</b>	<b>246.4 days</b>

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