

Morgan Lewis



BLOCKBUSTER BIOLOGICS REVIEW ISSUE 21

FDA: Biosimilar Approvals

Biosimilar Approvals and Launches Updates

> **New biosimilars approved in the US in Q3 2023.**

- > The FDA approved Sandoz's Tyruko® (natalizumab-sztn) in August.
 - Tyruko, a biosimilar of Tysabri, is the first biosimilar for relapsing multiple sclerosis (MS) approved in the US.
 - Tyruko is indicated for multiple forms of relapsing MS, including clinically isolated syndrome (CIS), relapsing-remitting MS (RRMS) and active secondary progressive disease, as well as Crohn's disease in adults.

> **New biosimilars approved in the US in Q3 2023.**

- > The FDA approved Biogen's Tofidence® (tocilizumab-bavi) in September.
 - Tofidence is the first Actemra biosimilar approved in the US.
 - Tofidence is indicated for the treatment of moderately to severely active rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and systemic juvenile idiopathic arthritis.

US Biosimilar Approvals – 43 Total

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

US Biosimilar Approvals – 43 Total (cont.)

Drug Name	Approval Date
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)	April 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

- **Avastin (bevacizumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
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**

Name	Regulatory Designation	Company Name	FDA Approved
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**

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

Biosimilars by Reference Product

- **Herceptin (trastuzumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
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**

Name	Regulatory Designation	Company Name	FDA Approved
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**

Name	Regulatory Designation	Company Name	FDA Approved
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**

Name	Regulatory Designation	Company Name	FDA Approved
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**

Name	Regulatory Designation	Company Name	FDA Approved
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**

Name	Regulatory Designation	Company Name	FDA Approved
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

- **Tysabri (natalizumab) biosimilars**

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

Biosimilars by Reference Product

- **Actemra (tocilizumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Tofidence (tocilizumab-bavi)	Biosimilar	Biogen Inc.	September 29, 2023

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	2624 days	2321 days
aBLA 761058	Cyltezo®	Adalimumab-abdm	Boehringer Ingelheim	Oct. 27, 2016	Aug. 25, 2017	Jul. 1, 2023	302 days	2438 days	2136 days
aBLA 761071	Hyrimoz™	Adalimumab-adaz	Sandoz	Oct. 30, 2017	Oct. 30, 2018	Jul. 1, 2023	365 days	2070 days	1705 days
aBLA 761059	Hadlima™	Adalimumab-bwwd	Samsung Bioepis	Jul. 23, 2018	Jul. 23, 2019	Jul. 1, 2023	365 days	1804 days	1439 days
aBLA 761118	Abrilada™	Adalimumab-afzb	Pfizer	Nov. 16, 2018	Nov. 18, 2019	NA	410 days	NA	NA
aBLA 761154	Hulio®	Adalimumab-fkjp	Mylan / Biocon	Jul. 12, 2019	Jul. 6, 2020	Jul. 3, 2023	360 days	1452 days	1092 days
aBLA 761216	Yusimry™	Adalimumab-aqvh	Coherus	Dec. 18, 2020	Dec. 17, 2021	Jul. 3, 2023	364 days	927 days	563 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
aBLA 761268	Vegzelma®	Bevacizumab-adcd	Celltrion	Sep. 30, 2021	Sep. 27, 2022	Apr. 17, 2023	362 days	564 days	202 days
aBLA 125545	Retacrit®	Epoetin Alfa-epbx	Hospira / Pfizer	Dec. 16, 2014	May 15, 2018	Nov. 12, 2018	1,246 days	1,427 days	181 days
aBLA 761042	Erelzi®	Etanercept-szsz	Sandoz	Jul. 30, 2015	Aug. 30, 2016	NA	397 days	NA	NA
aBLA 761066	Eticovo™	Etanercept-ykro	Samsung Bioepis	May 25, 2017	Apr. 25, 2019	NA	700 days	NA	NA
aBLA 125553	Zarxio®	Filgrastim-sndz	Sandoz	May 8, 2014	Mar. 6, 2015	Sep. 3, 2015	302 days	483 days	181 days
aBLA 761080	Nivestym™	Filgrastim-aafi	Pfizer	Sep. 21, 2017	Jul. 20, 2018	Oct. 1, 2018	272 days	375 days	103 days
aBLA 761082	Releuko™	Filgrastim-ayow	Kashiv	Jul. 8, 2017	Feb. 25, 2022	Nov. 29, 2022	1,693 days	1,970 days	277 days
aBLA 125544	Inflectra®	Infliximab-dyyb	Celltrion / Pfizer	Aug. 8, 2014	Apr. 5, 2016	Nov. 28, 2016	606 days	843 days	237 days
aBLA 761054	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
aBLA 761072	Ixifi™	Infliximab-qbtx	Pfizer	Feb. 13, 2017	Dec. 13, 2017	NA	303 days	NA	NA
aBLA 761086	Avsola®	Infliximab-axxq	Amgen	Dec. 14, 2018	Dec. 6, 2019	Jul. 6, 2020	357 days	570 days	213 days
aBLA 761201	Semglee® (interchangeable)	Insulin Glargine-yfgn	Mylan / Biocon	Jul. 29, 2020	Jul. 28, 2021	Nov. 16, 2021	365 days	476 days	112 days
aBLA 761215	Rezvoglar®	Insulin Glargine-aglr	Eli Lilly	Dec. 17, 2020	Dec. 17, 2021	Apr. 1, 2023	365 days	835 days	470 days
aBLA 761322	Tyruko®	Natalizumab-sztn	Sandoz / Polpharma	May 24, 2022	Aug. 24, 2023	NA	457 days	NA	NA
aBLA 761075	Fulphila®	Pegfilgrastim-jmdb	Mylan / Biocon	Dec. 9, 2016	Jun. 4, 2018	Jul. 30, 2018	542 days	598 days	56 days
aBLA 761039	Udenyca™	Pegfilgrastim-cbqv	Coherus	Aug. 9, 2016	Nov. 2, 2018	Jan. 3, 2019	569 days	877 days	308 days
aBLA 761045	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
aBLA 761111	Nyvepria™	Pegfilgrastim-apgf	Pfizer / Hospira	Jun. 10, 2019	Jun. 11, 2020	Jan. 1, 2021*	367 days	571 days	204 days
aBLA 761084	Fynetra®	Pegfilgrastim-pbbk	Kashiv / Amneal	Aug. 11, 2020	May 26, 2022	May 16, 2023	653 days	1,008 days	355 days
aBLA 761173	Stimufend®	Pegfilgrastim-fpgk	Fresenius Kabi	Mar. 27, 2020	Sep. 1, 2022	Feb. 16, 2023	888 days	1056 days	168 days
aBLA 761202	Byooviz™	Ranibizumab-nuna	Samsung Bioepis	Sep. 17, 2020	Sep. 20, 2021	Jul. 1, 2022	368 days	652 days	284 days
aBLA 761165	Cimerli™	Ranibizumab-eqrm	Coherus / Bioeq / Formycon	Aug. 2, 2021	Aug. 2, 2022	Oct. 3, 2022	365 days	427 days	62 days
aBLA 761088	Truxima®	Rituximab-abbs	Celltrion / Teva	Apr. 28, 2017	Nov. 28, 2018	Nov. 11, 2019	579 days	927 days	348 days
aBLA 761103	Ruxience®	Rituximab-pvvr	Pfizer	Jul. 25, 2018	Jul. 23, 2019	Jan. 23, 2020	363 days	547 days	184 days
aBLA 761140	Riabni™	Rituximab-arrx	Amgen / Allergan	Dec. 19, 2019	Dec. 17, 2020	Jan. 12, 2021	364 days	390 days	26 days
aBLA 761074	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
aBLA 761091	Herzuma®	Trastuzumab-pkrb	Celltrion / Teva	May 30, 2017	Dec. 14, 2018	Mar. 16, 2020	563 days	1,021 days	458 days
aBLA 761100	Ontruzant®	Trastuzumab-dttb	Samsung Bioepis / Merck	Oct. 20, 2017	Jan. 18, 2019	Apr. 15, 2020	455 days	908 days	453 days
aBLA 761081	Trazimera™	Trastuzumab-qyyp	Pfizer	Jun. 22, 2017	Mar. 11, 2019	Feb. 15, 2020	627 days	968 days	341 days
aBLA 761073	Kanjinti™	Trastuzumab-anns	Amgen / Allergan	Jul. 28, 2017	Jun. 13, 2019	Jul. 19, 2019	685 days	721 days	36 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 761354	Tofidence™	Tocilizumab-bavi	Biogen / Bio-Thera	Sep. 29, 2022	Sep. 29, 2023	NA	365 days	NA	NA
Average:							518 days	980.2 days	449.3 days

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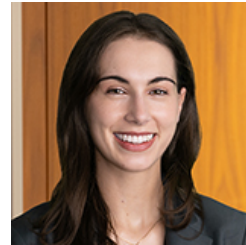
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