

Morgan Lewis



BLOCKBUSTER BIOLOGICS REVIEW ISSUE 14

FDA: Biosimilar Approvals

Biosimilar Approvals and Launches Updates

> **Two new biosimilars were approved:**

- > **July 2021:** Semglee (insulin glargine-yfgn) approved as an interchangeable biosimilar to LANTUS
 - > Launched in November 2021 as first-ever interchangeable biosimilar in the US
- > **September 2021:** Byooviz (ranibizumab-nuna) approved as first biosimilar to Lucentis

US Biosimilar Approvals – 31 Total

Drug Name	Approval Date	Drug Name	Approval Date
Byooviz (ranibizumab-nuna)	September 2021	Hadlima (adalimumab-bwwd)	July 2019
Semglee (insulin glargine-yfgn)	July 2021	Ruxience (rituximab-pvvr)	July 2019
Riabni (rituximab-arrx)	December 2020	Zirabev (bevacizumab-bvzr)	June 2019
Hulio (adalimumab-fkjp)	July 2020	Kanjinti (trastuzumab-anns)	June 2019
Nyvepria (pegfilgrastim-apgf)	June 2020	Eticovo (etanercept-ykro)	April 2019
Avsola (infliximab-axxq)	December 2019	Trazimera (trastuzumab-qyyp)	March 2019
Abrilada (adalimumab-afzb)	November 2019	Ontruzant (trastuzumab-dttb)	January 2019
Ziextenzo (pegfilgrastim-bmez)	November 2019	Herzuma (trastuzumab-pkrb)	December 2018

US Biosimilar Approvals – 31 Total (cont.)

Drug Name	Approval Date
Truxima (rituximab-abbs)	November 2018
Udenyca (pegfilgrastim-cbqv)	November 2018
Hyrimoz (adalimumab-adaz)	October 2018
Nivestym (filgrastim-aafi)	July 2018
Fulphila (pegfilgrastim-jmdb)	June 2018
Retacrit (epoetin alfa-epbx)	May 2018
Ixifi (infliximab-qbtx)	December 2017
Ogivri (trastuzumab-dkst)	December 2017

Drug Name	Approval Date
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

US Biosimilar Approval Statistics (cont.)



aBLA No.	Biosimilar Brand Name	Biosimilar Scientific Name	aBLA Holder	aBLA Acceptance Date	Date of Biosimilar License	US Biosimilar Launch Date	Pendency from Acceptance to Licensure	Pendency from Acceptance to Launch	Pendency from Licensure to Launch
aBLA 761024	Amjevita™	Adalimumab-atto	Amgen	Nov. 25, 2015	Sep. 23, 2016	NA	303 days	NA	NA
aBLA 761058	Cyltezo®	Adalimumab-abdm	Boehringer Ingelheim	Oct. 27, 2016	Aug. 25, 2017	NA	302 days	NA	NA
aBLA 761071	Hyrimoz™	Adalimumab-adaz	Sandoz	Oct. 30, 2017	Oct. 30, 2018	NA	365 days	NA	NA
aBLA 761059	Hadlima™	Adalimumab-bwwd	Samsung Bioepis	Jul. 23, 2018	Jul. 23, 2019	NA	365 days	NA	NA
aBLA 761118	Abrilada™	Adalimumab-afzb	Pfizer	Nov. 16, 2018	Dec. 31, 2019	NA	410 days	NA	NA
aBLA 761154	Hulio®	Adalimumab-afzb	Mylan / Biocon	Jul. 12, 2019	Jul. 6, 2020	NA	360 days	NA	NA
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

US Biosimilar Approval Statistics (cont.)



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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-szszs	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 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.)



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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 205692	Basaglar®	Insulin Glargine	Eli Lilly	Oct. 17, 2013	Dec. 16, 2015	---	790 days	NA	NA
aBLA 210605 aBLA 761201	Semglee® (interchangeable)	Insulin Glargine	Mylan / Biocon	Apr. 27, 2017	Jul. 28., 2021	---	1,553 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.)



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aBLA 761111	Nyvepria™	Pegfilgrastim-apgf	Pfizer / Hospira	Jun. 10, 2019	Jun. 11, 2020	NA	367 days	NA	NA
aBLA 761202	Byooviz™	Ranibizumab-nuna	Samsung Bioepis	Sep. 17, 2020	Sep. 20, 2021	NA	368 days	NA	NA
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 211939	Bonsity®	Teriparatide	Pfenex	Dec. 7, 2018	Oct. 7, 2019	---	304 days	NA	NA
aBLA 761074	Ogivri™	Trastuzumab-dkst	Mylan / Biocon	Nov. 3, 2016	Dec. 1, 2017	Dec. 2, 2019	393 days	1,124 days	731 days

US Biosimilar Approval Statistics (cont.)



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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
Average:							527.4 days	807.2 days	253.7 days

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