Morgan Lewis

BLOCKBUSTER BIOLOGICS REVIEW ISSUE 28

FDA: Biosimilar Approvals

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Biosimilar Approvals and Launches – Updates

- **New biosimilars approved in the United States in Q2 2025.**
  - The FDA approved Starjemza® in May 2025.
    - Starjemza® is a biosimilar to Stelara®.
      - It is a human interleukin-12 and -23 antagonist indicated for the treatment of:
        - adult patients with moderate to severe plaque psoriasis (PsO) who are candidates for phototherapy or systemic therapy, active psoriatic arthritis (PsA), moderately to severely active Crohn's disease (CD), or moderately to severely active ulcerative colitis; and
        - pediatric patients six years and older with PsO, who are candidates for phototherapy or systemic therapy or PsA.

Biosimilar Approvals and Launches – Updates

- **New biosimilars approved in the United States in Q3 2025.**
  - The FDA approved Kirsty™ in July 2025.
    - Kirsty™ is a biosimilar to NovoLog®.
      - It is a rapid-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus.

US Biosimilar Approvals – 76 Total

Drug Name	Approval Date
Kirsty (insulin aspart-xjhz)	July 2025
Starjemza (ustekinumab-hmny)	May 2025
Jobevne (bevacizumab-nwgd)	April 2025
Bomyntra and Conexxence (denosumab-bnht)	March 2025
Omlyclo (omalizumab-igec)	March 2025
Osenvelt and Stoboclo (denosumab-bmwo)	February 2025
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

Drug Name	Approval Date
Pavblu (aflibercept-ayyh)	August 2024
Enzeevu (aflibercept-abzv)	August 2024
Epysqli (eculizumab-aagh)	July 2024
Ahzantive (aflibercept-mrbb)	June 2024
Nypozi (filgrastim-txid)	June 2024
Pyzchiva (ustekinumab-ttwe)	June 2024
Bkemv (eculizumab-aeeb)	May 2024
Yesafili (aflibercept-jbvf)	May 2024
Opuviz (aflibercept-yszy)	May 2024
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-tnjn)	December 2023

US Biosimilar Approvals – 76 Total (cont.)

Drug Name	Approval Date
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
Cimerli (ranibizumab-eqrn)	August 2022
Fylnetra (pegfilgrastim-pbbk)	May 2022
Alymsys (bevacizumab-maly)	April 2022
Releuko (filgrastim-ayow)	February 2022
Yusimry (adalimumab-aqvh)	December 2021
Rezvoglar (insulin glargine-aglr)	December 2021*

Drug Name	Approval Date
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 (infliximab-axxq)	December 2019
Abrilada (adalimumab-afzb)	November 2019
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

*Subsequently approved as an interchangeable on November 16, 2022.

US Biosimilar Approvals – 76 Total (cont.)

Drug Name	Approval Date
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
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

Drug Name	Approval Date
Renflexis (infliximab-abda)	May 2017
Amjevita (adalimumab-atto)	September 2016
Erelzi (etanercept-szzs)	August 2016
Inflectra (infliximab-dyyb)	April 2016
Zarxio (filgrastim-sndz)	March 2015

Biosimilars by Reference Product

- **Actemra (tocilizumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
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**

Name	Regulatory Designation	Company Name	FDA Approved
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**

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

Biosimilars by Reference Product (cont.)

- **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 (cont.)

- **Herceptin (trastuzumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
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**

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 (cont.)

- **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 (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**

Name	Regulatory Designation	Company Name	FDA Approved
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**

Name	Regulatory Designation	Company Name	FDA Approved
Bomyntra and Conexxence (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**

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 (cont.)

- **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 (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	Alvotech and Teva Pharmaceuticals	April 16, 2024
Wezlana (ustekinumab-auub)	Biosimilar	Amgen Inc.	October 31, 2023

Biosimilars by Reference Product (cont.)

- **Tysabri (natalizumab) biosimilars**

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

Biosimilars by Reference Product (cont.)

- **Eylea (aflibercept) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
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**

Name	Regulatory Designation	Company Name	FDA Approved
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**

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

Biosimilars by Reference Product (cont.)

- **Xolair (omalizumab) biosimilars**

Name	Regulatory Designation	Company Name	FDA Approved
Omlyclo (omalizumab-igec)	Biosimilar	Celltrion, Inc.	March 7, 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	Alvotech / 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
aBLA 761268	Vegzelma®	Bevacizumab-adcd	Celltrion	Sep. 30, 2021	Sep. 27, 2022	Apr. 17, 2023	362 days	564 days	202 days
aBLA 761198	Avzivi®	Bevacizumab-tnjn	Bio-Thera / Sandoz	Nov. 27, 2020	Dec. 6, 2023	N/A	1,104 days	N/A	N/A
aBLA 761362	Jubbonti®	Denosumab-bbdz	Sandoz	Dec. 5, 2022	Mar. 5, 2024	May 31, 2025*	455 days	908 days	452 days
aBLA 761362	Wyost®	Denosumab-bbdz	Sandoz	Dec. 5, 2022	Mar. 5, 2024	May 31, 2025*	455 days	908 days	452 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-szzs	Sandoz	Jul. 30, 2015	Aug. 30, 2016	N/A	397 days	N/A	N/A
aBLA 761066	Eticovo™	Etanercept-ykro	Samsung Bioepis	May 25, 2017	Apr. 25, 2019	N/A	700 days	N/A	N/A
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
aBLA 761072	Ixifi™	Infliximab-qbtx	Pfizer	Feb. 13, 2017	Dec. 13, 2017	N/A	303 days	N/A	N/A

*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 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	N/A	457 days	N/A	N/A
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
aBLA 761111	Nyvepría™	Pegfilgrastim-apgf	Pfizer / Hospira	Jun. 10, 2019	Jun. 11, 2020	Jan. 1, 2021*	367 days	571 days	204 days
aBLA 761084	Fylnetra®	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	1,056 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-eqrn	Coherus / Bioeq / Formycon	Aug. 2, 2021	Aug. 2, 2022	Oct. 3, 2022	365 days	427 days	62 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 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 761354	Tofidence™	Tocilizumab-bavi	Biogen / Bio-Thera	Sep. 29, 2022	Sep. 29, 2023	May 6, 2024	365 days	585 days	220 days
aBLA 761275	Tyenne®	Tocilizumab-aazg	Fresenius Kabi	May 30, 2022	Mar. 5, 2024	Apr. 15, 2024	645 days	686 days	41 days
aBLA 761074	Ogivri™	Trastuzumab-dkst	Mylan / Biocon	Nov. 3, 2016	Dec. 1, 2017	Dec. 2, 2019	393 days	1,124 days	731 days
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 761346	Hercessi™	Trastuzumab-strf	Accord BioPharma / Henlius	Dec. 13, 2022	Apr. 25, 2024	Nov. 29, 2024	499 days	717 days	218 days
aBLA 761285 / 76133	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
aBLA 761343	Selarsdi™	Ustekinumab-aekn	Alvotech / Teva	Oct. 11, 2022	Apr. 16, 2024	Feb. 21, 2025	553 days	864 days	311 days
aBLA 761350	Opuviz®	Aflibercept-yszy	Samsung Bioepis Co., Ltd.	Feb. 17, 2023	May 20, 2024	N/A	458 days	N/A	N/A
aBLA 761274	Yesafili®	Aflibercept-jbvf	Biocon Biologics Inc.	Oct. 29, 2021	May 20, 2024	N/A	934 days	N/A	N/A
aBLA 761333	Bkemv®	Eculizumab-aeeb	Amgen Inc.	Feb. 28, 2023	May 28, 2024	Mar. 5, 2025	455 days	736 days	281 days
aBLA 761373	Pyzchiva®	Ustekinumab-ttwe	Samsung Bioepis Co., Ltd.	Mar. 30, 2023	Jun. 28, 2024	Feb. 24, 2025	456 days	698 days	242 days
aBLA 761126	Nypozi®	Filgrastim-txid	Tanvex BioPharma USA, Inc.	Sep. 28, 2018	Jun. 28, 2024	N/A	2,100 days	N/A	N/A
aBLA 761378	Ahzantive®	Aflibercept-mrbb	Formycon AG	Jun. 28, 2023	Jun. 28, 2024	N/A	364 days	N/A	N/A
aBLA 761340	Epysqli®	Eculizumab-aagh	Samsung Bioepis Co., Ltd.	Apr. 21, 2023	Jul. 19, 2024	Apr. 7, 2025	455 days	718 days	263 days
aBLA 761382	Enzeevu®	Aflibercept-abzv	Sandoz Inc.	Aug. 10, 2023	Aug. 9, 2024	N/A	365 days	N/A	N/A
BLA 761298	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
BLA 761379	Otulfi®	Ustekinumab-aauz	Fresenius Kabi USA, LLC	Sep. 28, 2023	Sep. 27, 2024	Mar. 3, 2025	365 days	523 days	158 days
BLA 761364	Imuldosa®	Ustekinumab-srlf	Accord BioPharma, Inc.	Oct. 9, 2023	Oct. 10, 2024	N/A	366 days	N/A	N/A
BLA 761406	Yesintek®	Ustekinumab-kfce	Biocon Biologics Inc.	Nov. 29, 2023	Nov. 29, 2024	Feb. 24, 2025	366 days	453 days	87 days
BLA 761338	Steqeyma®	Ustekinumab-stba	Celltrion, Inc.	Jun. 30, 2023	Dec. 17, 2024	Mar. 12, 2025	536 days	621 days	85 days
BLA 761420	Avtozma®	Tocilizumab-anoh	Celltrion, Inc.	Jan. 26, 2024	Jan. 24, 2025	N/A	364 days	N/A	N/A
BLA 761392	Ospomyvtm®	Denosumab-dssb	Samsung Bioepis Co., LTD.	Feb. 11, 2024	Feb. 13, 2025	Jun. 2, 2025	368 days	477 days	109 days
BLA 761392	Xbryktm®	Denosumab-dssb	Samsung Bioepis Co., LTD.	Feb. 12, 2024	Feb. 13, 2025	N/A	367 days	N/A	N/A
BLA 761325	Merilog®	Insulin aspart-szjj	Sanofi-Aventis U.S. LLC	Sep. 8, 2022	Feb. 14, 2025	N/A	890 days	N/A	N/A
BLA 761404	Stoboclo®	Denosumab-bmwo	Celltrion, Inc.	Nov. 30, 2023	Feb. 28, 2025	Jul. 7, 2025	456 days	585 days	129 days
BLA 761404	Osenvelt®	Denosumab-bmwo	Celltrion, Inc.	Nov. 30, 2023	Feb. 28, 2025	Jul. 7, 2025	456 days	585 days	129 days
BLA 761399	Omlyclo®	Omalizumab-igec	Celltrion, Inc.	Mar. 8, 2024	Mar. 7, 2025	N/A	364 days	N/A	N/A
BLA 761398	Bomyntra®	Denosumab-bnht	Fresenius Kabi USA, LLC	Mar. 25, 2024	Mar. 25, 2025	N/A	365 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
BLA 761398	Conexxence®	Denosumab-bnht	Fresenius Kabi USA, LLC	Mar. 25, 2024	Mar. 25, 2025	Jul. 1, 2025	365 days	463 days	98 days
BLA 761175	Jobevne®	Bevacizumab-nwgd	Biocon Biologics Inc.	Dec. 27, 2019	Apr. 9, 2025	N/A	1930 days	N/A	N/A
BLA 761419	Starjemza®	Ustekinumab-hmny	Bio-Thera Solutions, Ltd.	May 22, 2024	May 22, 2025	N/A	365 days	N/A	N/A
BLA 761188	Kirsty™	Insulin aspart-xjhz	Biocon Biologics Inc.	Jul. 16, 2020	Jul. 15, 2025	N/A	1825 days	N/A	N/A
						Average:	**504.9 days**	**889.7 days**	**384.6 days**

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