

Big Molecule Watch Biosimilar FDA Approvals Tracker

#	Biosimilar	Applicant	Reference Product	BLA Approval	U.S. Launch	Related BPCIA Litigation
1	ZARXIO (filgrastim-sndz)	Sandoz	NEUPOGEN [#1]	Mar. 6, 2015	Sept. 3, 2015	Amgen v. Sandoz , No. 14-4741 (N.D. Cal.)
2	INFLECTRA (infliximab-dyyb)	Celltrion	REMICADE [#1]	Apr. 5, 2016	Nov. 21, 2016	Janssen v. Celltrion , No. 17-11008 (D. Mass.)
3	ERELZI (etanercept-szszs)	Sandoz	ENBREL [#1]	Aug. 30, 2016	N/A	Immunex v. Sandoz , No. 16-01118 (D.N.J.)
4	AMJEVITA (adalimumab-atto)	Amgen	HUMIRA [#1]	Sept. 23, 2016	Jan. 31, 2023	AbbVie v. Amgen , No. 16-666 (D. Del.)
5	RENFLEXIS (infliximab-abda)	Samsung Bioepis	REMICADE [#2]	Apr. 21, 2017	July 24, 2017	Janssen v. Samsung Bioepis , No. 17-3524 (D. N.J.)
6	CYLTEZO (adalimumab- adbm)	Boehringer Ingelheim	HUMIRA [#2]	Aug. 25, 2017	July 1, 2023	AbbVie v. BI , No. 17-1065 (D. Del.)
7	MVASI (bevacizumab- awwb)	Amgen	AVASTIN [#1]	Sept. 14, 2017	July 19, 2019	Genentech v. Amgen , Nos. 17-1407, 17-1471, 19-602 (D. Del.)
8	OGIVRI (trastuzumab-dkst)	Mylan	HERCEPTIN [#1]	Dec. 1, 2017	Dec. 2, 2019	N/A

Big Molecule Watch Biosimilar FDA Approvals Tracker

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9	IXIFI (infliximab-qbtx)	Pfizer	REMICADE [#3]	Dec. 13, 2017	N/A	N/A
10	RETACRIT (epoetin alfa-epbx)	Hospira	EPOGEN/ PROCRIPT [#1]	May 15, 2018	Nov. 12, 2018	Amgen v. Hospira , No. 15-839 (D. Del.)
11	FULPHILA (pegfilgrastim- jmdb)	Mylan	NEULASTA [#1]	June 4, 2018	July 26, 2018	Amgen v. Mylan , No. 17-1235 (W.D. Pa.)
12	NIVESTYM (filgrastim-aafi)	Pfizer	NEUPOGEN [#2]	July 20, 2018	Oct. 1, 2018	Amgen v. Hospira , Nos. 18-1064, 20-561 (D. Del.)
13	HYRIMOZ (adalimumab- adaz)	Sandoz	HUMIRA [#3]	Oct. 30, 2018	July 2023	AbbVie v. Sandoz , No. 18-12668 (D. N.J.)
14	UDENYCA (pegfilgrastim- cbqv)	Coherus	NEULASTA [#2]	Nov. 2, 2018	Jan. 3, 2019	Amgen v. Coherus , No. 17-546 (D. Del.)
15	TRUXIMA (rituximab-abbs)	Celltrion	RITUXAN [#1]	Nov. 28, 2018	Nov. 11, 2019	Genentech v. Celltrion , Nos. 18-574, 18-11553 (D. N.J.)
16	HERZUMA (trastuzumab- pkrb)	Celltrion	HERCEPTIN [#2]	Dec. 14, 2018	Mar. 16, 2020	Genentech v. Celltrion , Nos. 18-00095, 18-01025 (D. Del.)

Big Molecule Watch Biosimilar FDA Approvals Tracker

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17	ONTRUZANT (trastuzumab-dttb)	Samsung Bioepis	HERCEPTIN [#3]	Jan. 18, 2019	Apr. 15, 2020	Genentech v. Samsung Bioepis , No. 18-1363 (D. Del.)
18	TRAZIMERA (trastuzumab-qyyp)	Pfizer	HERCEPTIN [#4]	Mar. 11, 2019	Feb. 15, 2020	Genentech v. Pfizer , No. 17-1672 (D. Del.)
19	ETICOVO (etanercept-ykro)	Samsung Bioepis	ENBREL [#2]	Apr. 25, 2019	N/A	Immunex v. Samsung Bioepis , No. 19-11755 (D. N.J.)
20	KANJINTI (trastuzumab-anns)	Amgen	HERCEPTIN [#5]	June 13, 2019	July 19, 2019	Genentech v. Amgen , No. 18-924 (D. Del.)
21	ZIRABEV (bevacizumab-bvzr)	Pfizer	AVASTIN [#2]	June 28, 2019	Dec. 31, 2019	Genentech v. Pfizer , No. 19-638 (D. Del.)
22	RUXIENCE (rituximab-pvvr)	Pfizer	RITUXAN [#2]	July 23, 2019	Jan. 23, 2020	N/A
23	HADLIMA (adalimumab-bwwd)	Samsung Bioepis	HUMIRA [#4]	July 23, 2019	July 1, 2023	N/A

Big Molecule Watch Biosimilar FDA Approvals Tracker

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24	ZIEXTENZO (pegfilgrastim-bmez)	Sandoz	NEULASTA [#3]	Nov. 4, 2019	Nov. 15, 2019	Amgen v. Sandoz , No. 16-2581 (N.D. Cal.)
25	ABRILADA (adalimumab-afzb)	Pfizer	HUMIRA [#5]	Nov. 15, 2019	October 2023	N/A
26	AVSOLA (infliximab-axxq)	Amgen	REMICADE [#4]	Dec. 6, 2019	July 2020	N/A
27	NYVEPRIA (pegfilgrastim-apgf)	Pfizer	NEULASTA [#4]	June 10, 2020	Late 2020 or early 2021	Amgen v. Hospira , No. 20-210 (D. Del.)
28	HULIO (adalimumab-fkjp)	Mylan	HUMIRA [#6]	July 6, 2020	July 3, 2023	N/A
29	RIABNI (rituximab-arrx)	Amgen	RITUXAN [#3]	Dec. 17, 2020	Jan. 12, 2021	N/A
30	SEMGLEE (insulin glargine-yfgn)	Viartis	LANTUS [#1]	July 28, 2021	Nov. 16, 2021	N/A

Big Molecule Watch Biosimilar FDA Approvals Tracker

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31	BYOOVIZ (ranibizumab-nuna)	Biogen/ Samsung Bioepis	LUCENTIS [#1]	Sept. 20, 2021	June 2, 2022	N/A
32	YUSIMRY (adalimumab-aqvh)	Coherus	HUMIRA [#7]	Dec. 17, 2021	July 3, 2023	N/A
33	REZVOGLAR (insulin glargine-aglr)	Eli Lilly	LANTUS [#2]	Dec. 20, 2021	April 1, 2023	N/A
34	RELEUKO (filgrastim-ayow)	Amneal/Kash iv	NEUPOGEN [#3]	Feb. 25, 2022	Nov. 22, 2022	N/A
35	ALYMSYS (bevacizumab-maly)	Amneal/ mAbxience	AVASTIN [#3]	Apr. 13, 2022	Oct. 3, 2022	N/A
36	FYLNETRA (pegfilgrastim-pbbk)	Amneal/Kash iv	NEULASTA [#5]	May 26, 2022	May 16, 2023	N/A
37	CIMERLI (ranibizumab-eqrn)	Coherus	LUCENTIS [#2]	Aug. 2, 2022	Oct. 3, 2022	N/A

Big Molecule Watch Biosimilar FDA Approvals Tracker

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38	STIMUFEND (pegfilgrastim-fpgk)	Fresenius Kabi	NEULASTA [#6]	Sept. 1, 2022	Feb. 16, 2023	N/A
39	VEGZELMA (bevacizumab-adcd)	Celltrion	AVASTIN [#4]	Sept. 27, 2022	Apr. 17, 2023	N/A
40	IDACIO (adalimumab-aacf)	Fresenius Kabi	HUMIRA [#8]	Dec. 13, 2022	July 3, 2023	N/A
41	YUFLYMA (adalimumab-aaty)	Celltrion	HUMIRA [#9]	May 23, 2023	July 2, 2023	N/A
42	TYRUKO (natalizumab-sztn)	Sandoz	TYSABRI [#1]	Aug. 24, 2023	Nov. 17, 2025	Biogen v. Sandoz , No. 1:22-cv-1190 (D. Del.)
43	TOFIDENCE (tocilizumab-bavi)	Biogen	ACTEMRA [#1]	Sept. 29, 2023	May 6, 2024	Genentech v. Biogen , No. 1:23-cv-11573 (D. Mass.)
44	ZYMFENTRA (infliximab-dyyb)	Celltrion	REMICADE [#5]	Oct. 23, 2023	Mar. 18, 2024	N/A

Big Molecule Watch Biosimilar FDA Approvals Tracker

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45	WEZLANA (ustekinumab-aub)	Amgen	STELARA [#1]	Oct. 31, 2023	Jan. 1, 2025	Janssen Biotech v. Amgen , No. 1-22-cv-1549 (D. Del.)
46	AVZIVI (bevacizumab-tjnj)	Bio-Thera Solutions, Ltd.	AVASTIN [#5]	Dec. 6, 2023	N/A	N/A
47	SIMLANDI (adalimumab-ryvk)	Alvotech	HUMIRA [#10]	Feb. 23, 2024	May 20, 2024	Abbvie v. Alvotech , Nos. 21-2258, 21-2899 (N.D. Ill.); No. 2-21-00265 (E.D. Va.)
48	TYENNE (tocilizumab-aazg)	Fresenius	ACTEMRA [#2]	Mar. 5, 2024	Apr. 15, 2024	N/A
49	WYOST (denosumab-bddz)	Sandoz	XGEVA [#1]	Mar. 5, 2024	June 2, 2025	Amgen v. Sandoz , No. 2-23-cv-02406 (D.N.J.)
50	JUBBONTI (denosumab-bddz)	Sandoz	PROLIA [#1]	Mar. 5, 2024	June 2, 2025	Amgen v. Sandoz , No. 2-23-cv-02406 (D.N.J.)
51	SELARSDI (ustekinumab-aekn)	Alvotech/ Teva	STELARA [#2]	Apr. 16, 2024	Feb. 21, 2025	N/A

Big Molecule Watch Biosimilar FDA Approvals Tracker

#	Biosimilar	Applicant	Reference Product	BLA Approval	U.S. Launch	Related BPCIA Litigation
52	HERCESSI (trastuzumab-strf)	Accord BioPharma	HERCEPTIN [#6]	Apr. 25, 2024	Dec. 2, 2024	N/A
53	YESAFILI (afibercept-jbyf)	Biocon Biologics	EYLEA [#1]	May 20, 2024	N/A	Regeneron v. Mylan , No. 1-22-cv-00061 (N.D. W. Va.)
54	OPUVIZ (alibercept-yszy)	Samsung Bioepis	EYLEA [#2]	May 20, 2024	N/A	Regeneron v. Samsung Bioepis , Nos. 1-23-cv-00094, 1-23-cv-00106 (N.D. W.Va.)
55	BKEMV (eculizumab-aeab)	Amgen	SOLIRIS [#1]	May 28, 2024	Mar. 5, 2025	None
56	AHZANTIVE (afibercept-mrbb)	Formycon	EYLEA [#3]	June 28, 2024	N/A	Regeneron v. Formycon , 1-23-cv-00097 (N.D. W. Va.)
57	NYPOZI (filgrastim-txid)	Tanvex BioPharma USA, Inc.	NEUPOGEN [#4]	June 28, 2024	N/A	Amgen v. Tanvex , No. 19-1374 (S.D. Cal.)
58	PYZCHIVA (ustekinumab-ttwe)	Samsung Bioepis	STELARA [#3]	June 28, 2024	Feb. 24, 2025	N/A
59	EPYSQLI (eculizumab-aagh)	Samsung Bioepis	SOLIRIS [#2]	July 19, 2024	Apr. 7, 2025	Alexion v. Samsung Bioepis , No. 1-24-cv-00005 (D. Del.)

Big Molecule Watch Biosimilar FDA Approvals Tracker

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60	ENZEEVU (afibercept-abzv)	Sandoz	EYLEA [#4]	Aug. 9, 2024	N/A	Regeneron v. Sandoz , No. 1-24-cv-00085 (N.D. W.Va.)
61	PAVBLU (afibercept-ayyh)	Amgen	EYLEA [#5]	Aug. 23, 2024	Oct. 30, 2024	Regeneron v. Amgen , Nos. 1-24-cv-00039, 1-25-cv-00074 (N.D. W. Va.)
62	OTULFI (ustekinumab-aauz)	Fresenius Kabi	STELARA [#4]	Sept. 27, 2024	Mar. 3, 2025	N/A
63	IMULDOSA (ustekinumab-srlf)	Accord Biopharma	STELARA (#5)	Oct. 10, 2024	Aug. 18, 2025	N/A
64	YESINTEK (ustekinumab-kfce)	Biocon Biologics Ltd.	STELARA [#6]	Nov. 29, 2024	Feb. 24, 2025	N/A
65	STEQEYMA (ustekinumab-stba)	Celltrion	STELARA [#7]	Dec. 17, 2024	Mar. 12, 2025	N/A
66	AVTOZMA (tocilizumab-anoh)	Celltrion	ACTEMRA [#3]	Jan. 24, 2025	Oct. 2, 2025	N/A
67	OSPOMYV (denosumab-dssb)	Samsung Bioepis	PROLIA [#2]	Feb. 13, 2025	N/A	Amgen v. Samsung Bioepis , No. 1-24-cv-08417 (D.N.J.)

Big Molecule Watch Biosimilar FDA Approvals Tracker

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68	XBRYK (denosumab-dssb)	Samsung Bioepis	XGEVA [#2]	Feb. 13, 2025	N/A	Amgen v. Samsung Bioepis , No. 1-24-cv-08417 (D.N.J.)
69	MERILOG (insulin aspart-sjzz)	Sanofi Aventis	NOVOLOG [#1]	Feb. 14, 2025	N/A	N/A
70	STOBOCLO (denosumab-bnwo)	Celltrion	PROLIA [#3]	Feb. 28, 2025	July 7, 2025	Amgen v. Celltrion , No. 1:24-cv-06497 (D. N.J.)
71	OSENVELT (denosumab-bnwo)	Celltrion	XGEVA [#3]	Feb. 28, 2025	July 7, 2025	Amgen v. Celltrion , No. 1:24-cv-06497 (D. N.J.)
72	OMLYCLO (omalizumab-igec)	Celltrion	XOLAIR [#1]	Mar. 7, 2025	N/A	N/A
71	BOMYNATA (denosumab-bnht)	Fresenius	XGEVA [#4]	Mar. 25, 2025	July 1, 2025	Amgen v. Fresenius Kabi USA, LLC , No. 1-25-01080 (D. N.J.)
72	CONEXXENCE (denosumab-bnht)	Fresenius	PROLIA [#4]	Mar. 25, 2025	July 1, 2025	Amgen v. Fresenius Kabi USA, LLC , No. 1-25-01080 (D. N.J.)
73	JOBEVNE (bevacizumab-nwgd)	Biocon	AVASTIN [#6]	Apr. 9, 2025	N/A	N/A

Big Molecule Watch Biosimilar FDA Approvals Tracker

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74	STARJEMZA (ustekinumab-hmny)	Bio-Thera Solutions	STELARA [#8]	May 22, 2025	Nov. 6, 2025	N/A
75	KIRSTY (insulin-aspart-xjhz)	Biocon	NOVOLOG [#2]	July 15, 2025	N/A	N/A
76	BILDYOS (denosumab-nxxp)	Shanghai Henlius Biotech	XGEVA [#5]	Aug. 29, 2025	N/A	Amgen v. Shanghai Henlius Biotech, Inc. , No. 1:25-12160 (D. N.J.)
77	BILPREVDA (denosumab-kyqq)	Shanghai Henlius Biotech	PROLIA [#5]	Aug. 29, 2025	N/A	Amgen v. Shanghai Henlius Biotech, Inc. , No. 1:25-12160 (D. N.J.)
78	AUKELSO (denosumab-kyqq)	Biocon	XGEVA [#6]	Sept. 16, 2025	N/A	Amgen v. Biocon Biologics, Inc. , No. 1:25-cv-143358 (D. N.J.)
79	BOSAYA (denosumab-kyqq)	Biocon	PROLIA [#6]	Sept. 16, 2025	N/A	Amgen v. Biocon Biologics, Inc. , No. 1:25-cv-143358 (D. N.J.)
78	XTRENBO (denosumab-qdbe)	Hikma	XGEVA [#7]	Sept. 26, 2025	N/A	Amgen v. Hikma , No. 1:25-cv-143358 (D. N.J.)

Big Molecule Watch Biosimilar FDA Approvals Tracker

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79	ENOBY (denosumab-qdbe)	Hikma	PROLIA [#7]	Sept. 26, 2025	N/A	Amgen v. Hikma , No. 1:25-cv-143358 (D. N.J.)
80	EYDENZELT (aflibercept-boav)	Celltrion	EYLEA [#6]	Oct. 2, 2025	N/A	Regeneron v. Celltrion , Nos. 1:23-cv-00089, 1:24-cv-00053 (N.D.W. Va.)
81	POHERDY (pertuzumab-dpzb)	Shanghai Henlius Biotech	PERJETA [#1]	Nov. 13, 2025	N/A	Genentech v. Shanghai Henlius Biotech , No. 2:25-cv-14648 (D. N.J.)
82	JUBEREQ (denosumab-desu)	Accord Biopharma, Inc.	XGEVA [#8]	Nov. 20, 2025	N/A	Amgen v. Accord Biopharma, Inc. , No. 1-25-cv-01305 (D.N.J.)
83	OSVYRTI (denosumab-desu)	Accord Biopharma, Inc.	PROLIA [#8]	Nov. 20, 2025	N/A	Amgen v. Accord Biopharma, Inc. , No. 1-25-cv-01305 (D.N.J.)
84	NUFYMCO (randibizumab-leyk)	Formycon AG	LUCENTIS [#3]	Dec. 18, 2025	N/A	N/A
85	OZILTUS (denosumab-mobz)	Amneal	XGEVA [#9]	Dec. 22, 2025	N/A	Amgen Inc. et al. v. Amneal Pharms LLC et al. , 1-25-17278 (D. N.J.)

Big Molecule Watch Biosimilar FDA Approvals Tracker

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86	BONCRESA (denosumab-mobz)	Amneal	PROLIA [#9]	Dec. 22, 2025	N/A	Amgen Inc. et al. v. Amneal Pharms LLC et al., 1-25-17278 (D. N.J.)
86	FILKRI (filgrastim-laha)	Accord Biopharma	NEUPOGEN [#5]	Jan. 15, 2026	N/A	N/A
87	PONLIMSI (denosumab-abed)	Teva	PROLIA [#10]	Mar. 30, 2026	N/A	N/A

Last Updated: March 31, 2026