

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
2	INFLECTRA (infliximab-dyyb)	Celltrion	REMICADE [#1]	Apr. 5, 2016	Nov. 21, 2016	Janssen v. Celltrion
3	ERELZI (etanercept-szszs)	Sandoz	ENBREL [#1]	Aug. 30, 2016	N/A	Immunex v. Sandoz
4	AMJEVITA (adalimumab-atto)	Amgen	HUMIRA [#1]	Sept. 23, 2016	Jan. 31, 2023	AbbVie v. Amgen
5	RENFLEXIS (infliximab-abda)	Samsung Bioepis	REMICADE [#2]	Apr. 21, 2017	July 24, 2017	Janssen v. Samsung Bioepis
6	CYLTEZO (adalimumab-adbm)	Boehringer Ingelheim	HUMIRA [#2]	Aug. 25, 2017; May 22, 2023 (autoinjector)	July 1, 2023	AbbVie v. BI
7	MVASI (bevacizumab-awwb)	Amgen	AVASTIN [#1]	Sept. 14, 2017	July 19, 2019	Genentech v. Amgen
8	OGIVRI (trastuzumab-dkst)	Mylan	HERCEPTIN [#1]	Dec. 1, 2017	Dec. 2, 2019	None
9	IXIFI (infliximab-qbtx)	Pfizer	REMICADE [#3]	Dec. 13, 2017	N/A	None
10	RETACRIT (epoetin alfa-epbx)	Hospira	EPOGEN/ PROCRIPT [#1]	May 15, 2018	Nov. 12, 2018	Amgen v. Hospira
11	FULPHILA (pegfilgrastim-jmdb)	Mylan	NEULASTA [#1]	June 4, 2018	July 26, 2018	Amgen v. Mylan

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12	NIVESTYM (filgrastim-aafi)	Pfizer	NEUPOGEN [#2]	July 20, 2018	Oct. 1, 2018	Amgen v. Hospira
13	HYRIMOZ (adalimumab-adaz)	Sandoz	HUMIRA [#3]	Oct. 30, 2018 (approval of 50 mg/ml product) March 21, 2023 (approval of 100 mg/ml product)	July 1, 2023	AbbVie v. Sandoz
14	UDENYCA (pegfilgrastim-cbqv)	Coherus	NEULASTA [#2]	Nov. 2, 2018 Dec. 26, 2023 (on-body injector)	Jan. 3, 2019	Amgen v. Coherus
15	TRUXIMA (rituximab-abbs)	Celltrion	RITUXAN [#1]	Nov. 28, 2018	Nov. 11, 2019	Genentech v. Celltrion
16	HERZUMA (trastuzumab-pkrb)	Celltrion	HERCEPTIN [#2]	Dec. 14, 2018	Mar. 16, 2020	Genentech v. Celltrion
17	ONTRUZANT (trastuzumab-dttb)	Samsung Bioepis	HERCEPTIN [#3]	Jan. 18, 2019	Apr. 15, 2020	Genentech v. Samsung Bioepis
18	TRAZIMERA (trastuzumab-qyyp)	Pfizer	HERCEPTIN [#4]	Mar. 11, 2019	Feb. 15, 2020	Genentech v. Pfizer
19	ETICOVO (etanercept-ykro)	Samsung Bioepis	ENBREL [#2]	Apr. 25, 2019	N/A	Immunex v. Samsung Bioepis
20	KANJINTI (trastuzumab-anns)	Amgen	HERCEPTIN [#5]	June 13, 2019	July 19, 2019	Genentech v. Amgen
21	ZIRABEV (bevacizumab-bvzr)	Pfizer	AVASTIN [#2]	June 28, 2019	Dec. 31, 2019	Genentech v. Pfizer

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22	RUXIENCE (rituximab-pvvr)	Pfizer	RITUXAN [#2]	July 23, 2019	Jan. 23, 2020	None
23	HADLIMA (adalimumab-bwwd)	Samsung Bioepis	HUMIRA [#4]	July 23, 2019 (50 mg/ml) August 15, 2022 (100 mg/ml)	July 1, 2023	None
24	ZIEXTENZO (pegfilgrastim-bmez)	Sandoz	NEULASTA [#3]	Nov. 4, 2019	Nov. 15, 2019	Amgen v. Sandoz
25	ABRILADA (adalimumab-afzb)	Pfizer	HUMIRA [#5]	Nov. 15, 2019 Oct. 5, 2023 (interchangeable status)	October 2023	None
26	AVSOLA (infliximab-axxq)	Amgen	REMICADE [#4]	Dec. 6, 2019	July 2020	None
27	NYVEPRIA (pegfilgrastim-apgf)	Pfizer	NEULASTA [#4]	June 10, 2020	Late 2020 or early 2021	Amgen v. Hospira
28	HULIO (adalimumab-fkjp)	Mylan	HUMIRA [#6]	July 6, 2020	July 3, 2023	None
29	RIABNI (rituximab-arrx)	Amgen	RITUXAN [#3]	Dec. 17, 2020	Jan. 12, 2021	None
30	SEMGLEE (insulin glargine-yfgn)	Viartis	LANTUS [#1]	July 28, 2021	Nov. 16, 2021	None
31	BYOOVIZ (ranibizumab-nuna)	Biogen/ Samsung Bioepis	LUCENTIS [#1]	Sep. 20, 2021	June 2, 2022	None

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32	YUSIMRY (adalimumab-aqvh)	Coherus	HUMIRA [#7]	Dec. 20, 2021	July 3, 2023	None
33	REZVOGLAR (insulin glargine-aglr)	Eli Lilly	LANTUS [#2]	Dec. 20, 2021 (original approval) Nov. 16, 2022 (approved as an interchangeable)	April 1, 2023	None
34	RELEUKO (filgrastim-ayow)	Amneal/Kashiv	NEUPOGEN [#3]	Mar. 1, 2022	Nov. 22, 2022	None
35	ALYMSYS (bevacizumab-maly)	Amneal/ mAbxience	AVASTIN [#3]	Apr. 13, 2022	Oct. 3, 2022	None
36	FYLNETRA (pegfilgrastim-pbbk)	Amneal/Kashiv	NEULASTA [#5]	May 27, 2022	May 16, 2023	None
37	CIMERLI (ranibizumab-eqrn)	Coherus	LUCENTIS [#2]	Aug. 2, 2022	Oct. 3, 2022	None
38	STIMUFEND (pegfilgrastim-fpgk)	Fresenius Kabi	NEULASTA [#6]	Sept. 1, 2022	Feb. 16, 2023	None
39	VEGZELMA (bevacizumab-adcd)	Celltrion	AVASTIN (#4)	Sept. 27, 2022	Apr. 17, 2023	None
40	IDACIO (adalimumab-aacf)	Fresenius Kabi	HUMIRA [#8]	Dec. 14, 2022	July 3, 2023	None

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41	YUFLYMA (adalimumab-aaty)	Celltrion	HUMIRA [#9]	May 24, 2023 (40 mg/0.4 mL); Oct. 2, 2023 (80 mg/0.8 mL, 20 mg/0.2 mL)	July 2, 2023	None
42	TYRUKO (natalizumab-sztn)	Sandoz	TYSABRI [#1]	Aug. 24, 2023	N/A	Biogen v. Sandoz
43	TOFIDENCE (tocilizumab-bavi)	Biogen	ACTEMRA (#1)	Sept. 29, 2023	N/A	Genentech v. Biogen
44	ZYMFENTRA (infliximab-dyyb) (subcutaneous)	Celltrion	REMICADE (#5)	Oct. 23, 2023	March 18, 2024	None
45	WEZLANA (ustekinumab-auub) (interchangeable)	Amgen	STELARA (#1)	Oct. 31, 2023	N/A	Janssen Biotech v. Amgen
46	AVZIVI (bevacizumab-tjnj)	Bio-Thera Solutions, Ltd.	AVASTIN (#5)	Dec. 7, 2023	N/A	None
47	SIMLANDI (adalimumab-ryvk) (interchangeable)	Alvotech	HUMIRA (#10)	Feb. 23, 2024	N/A	Abbvie v. Alvotech
48	TYENNE (tocilizumab-aazg)	Fresenius	ACTEMRA (#2)	March 5, 2024	April 15, 2024	None
49	WYOST (denosumab-bddz) JUBBONTI (denosumab-bddz)	Sandoz	XGEVA (#1) PROLIA (#1)	March 5, 2024	N/A	Amgen v. Sandoz

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50	SELARSDI (ustekinumab-aekn)	Alvotech	STELARA (#1)	April 16, 2024	N/A	None

Last Updated: April 17, 2024