



## Appendix A: Biosimilars Approved as of 2025

Biosimilar	Reference Product	Non-Proprietary Name	Initial FDA Approval Date	Time from Initial BLA Submission to Approval	Initial Commercial Launch Date	Reported Discount at Launch
Boncresta™ and Oziltus™ (Amneal)	Prolia® and Xgeva® (Amgen)	denosumab-mobz	Dec. 2025 (Interchangeable)	15 months		
Nufymco™ (Formycon / Bioeq)	Lucentis® (Roche / Genentech)	ranibizumab-leyk	Dec. 2025 (Interchangeable)	12 months		
Armlupeg (Lupin / Valorum)	Neulasta® (Amgen)	pegfilgrastim-unne	Nov. 2025	56 months		
Poherdy® (Henlius)	Perjeta (Genentech)	pertuzumab-dpzb	Nov. 2025 (Interchangeable)	12 months		
Osvyrti® and Jubereq® (Accord)	Prolia® and Xgeva® (Amgen)	denosumab-desu	Oct. 2025 (Interchangeable)	19.5 months	Not earlier than Oct. 1, 2026 per settlement and consent injunction	
Eydenzelt® (Celltrion)	Eylea® (Regeneron)	aflibercept-boav	Oct. 2025	27 months	Licensed entry date on Dec. 31, 2026 per settlement	
Enoby™ and Xtrenbo™ (Hikma)	Prolia® and Xgeva® (Amgen)	denosumab-qbde	Sep. 2025 (Interchangeable: Oct. 2025)	12 months	Jan. 2026	

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Bosaya™ and Aukelso™ (Biocon)	Prolia® and Xgeva® (Amgen)	denosumab-kyqq	Sep. 2025 (Interchangeable: Oct. 2025)	12 months	Not earlier than Oct. 1, 2025 per settlement and consent injunction	
Bildyos® and Bilprevda® (Henlius)	Prolia® and Xgeva® (Amgen)	denosumab-nxxp	Aug. 2025 (Interchangeable: Oct. 2025)	12 months	Sep. 2025	~55% off WAC for Prolia® and ~51% off WAC of Xgeva®
Kirsty (Biocon)	Novolog® (Novo Nordisk)	insulin aspart-xjhz	July 2025	60 months		
Starjemza (Bio-Thera / Hikma)	Stelara® (Johnson & Johnson / Janssen)	ustekinumab-hmny	May 2025 (Interchangeable)	12 months	Nov. 6, 2025	
Jobevne™ (Biocon)	Avastin® (Roche / Genentech)	bevacizumab-nwgd	Apr. 2025	63 months		
Bomynta® and Conexence® (Fresenius Kabi)	Prolia® and Xgeva® (Amgen)	denosumab-bnht	Mar. 2025 (Interchangeable: Oct. 2025)	12 months	July 2025	
Omlyclo® (Celltrion)	Xolair® (Genentech)	omalizumab-igec	Mar. 2025 (Interchangeable)	12 months		

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Osenvelt® and Stoboclo® (Celltrion)	Prolia® and Xgeva® (Amgen)	denosumab-bmwo	Feb. 2025 (Interchangeable: Oct. 2025)	15 months	July 2025	
Merilog® (Sanofi)	Novolog® (Novo Nordisk)	insulin aspart-szjj	Feb. 2025	29 months		
Ospomyv™ and Xbryk™ (Samsung Bioepis)	Prolia® and Xgeva® (Amgen)	denosumab-dssb	Feb. 2025 (Interchangeable: Oct. 2025)	12 months		
Avtozma® (Celltrion)	Actemra® (Genentech)	tocilizumab-anoh	Jan. 2025 (Interchangeable)	12 months	Oct. 2025	
Steqeyma® (Celltrion)	Stelara® (Johnson & Johnson / Janssen)	ustekinumab-stba	Dec. 2024 (Interchangeable: Apr. 2025)	17.5 months	Mar. 2025	85% off WAC of Stelara®
Yesintek™ (Biocon)	Stelara® (Johnson & Johnson / Janssen)	ustekinumab-kfce	Nov. 2024 (Interchangeable: Apr. 2025)	12 months	Feb. 2025	90% off WAC of Stelara®
Imuldosa™ (Accord)	Stelara® (Johnson & Johnson)	ustekinumab-slrf	Oct. 2024	12 months	Aug. 2025	92% off WAC of Stelara®

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	Johnson / Janssen)					
Otulfi™ (Fresenius Kabi / Formycon)	Stelara® (Johnson & Johnson / Janssen)	ustekinumab-aauz	Sept. 2024 (Interchangeable: Apr. 2025)	12 months	Mar. 2025	Not reported
Pavblu™ (Amgen)	Eylea® (Regeneron)	aflibercept-ayyh	Aug. 2024	12 months	Oct. 30, 2024	10% off WAC of Eylea®
Enzeevu™ (Sandoz)	Eylea® (Regeneron)	aflibercept-abzv	Aug. 2024	12 months	Licensed entry by Q4 2026 per settlement	
Epysqli® (Samsung Bioepis / Teva)	Soliris® (AstraZeneca / Alexion)	eculizumab-aagh	July 2024 (Interchangeable: Nov. 2025)	15 months	Apr. 2025	30% off WAC of Soliris®
Ahzantive® (Formycon / Klinge)	Eylea® (Regeneron)	aflibercept-mrbb	June 2024	12 months	Licensed entry by Q4 2026 per settlement	
Nypozi™ (Tanvex)	Neupogen® (Amgen)	filgrastim-txid	June 2024	5 years, 9 months		
Pyzchiva® (Samsung Bioepis / Sandoz)	Stelara® (Johnson & Johnson / Janssen)	ustekinumab-ttwe	July 2024 (Interchangeable: Apr. 2025)	15 months	Feb. 2025	80% off WAC of Stelara®

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Bkempv™ (Amgen)	Soliris® (AstraZeneca / Alexion)	eculizumab-aeeb	May 2024 (Interchangeable)	15 months	Mar. 2025	10% off WAC of Soliris®
Yesafili™ (Biocon)	Eylea® (Regeneron)	aflibercept-jbvf	May 2024 (Interchangeable)	31 months	Licensed entry in 2nd half of 2026 per settlement	
Opuviz™ (Samsung Bioepis)	Eylea® (Regeneron)	aflibercept-yszy	May 2024 (Interchangeable)	15 months	Licensed entry in Jan. 2027 per settlement	
Hercessi™ (Henlius / Accord)	Herceptin® (Roche / Genentech)	trastuzumab-strf	Apr. 2024	16 months	Nov. 29, 2024	Not reported
Selarsdi™ (Alvotek / Teva)	Stelara® (Johnson & Johnson / Janssen)	ustekinumab-aekn	Apr. 2024 (Interchangeable: Apr. 2025)	18 months	Feb. 2025	85% off WAC of Stelara®
Tyenne® (Fresenius Kabi)	Actemra® (Genentech)	tocilizumab-aazg	Mar. 2024	21 months	July 2024	26% off WAC of Actemra®
Jubbonti® and Wyost® (Sandoz)	Prolia® and Xgeva® (Amgen)	denosumab-bbdz	Mar. 2024 (Interchangeable)	21 months	June 2025	Not reported

Biosimilar	Reference Product	Non-Proprietary Name	Initial FDA Approval Date	Time from Initial BLA Submission to Approval	Initial Commercial Launch Date	Reported Discount at Launch
Simlandi® (Alvotect / Teva)	Humira® (AbbVie)	adalimumab-ryvk	Feb. 2024 (High Concentration; Interchangeable)	26 months	May 2024	Launched at 85% off WAC of Humira®; private label adalimumab-ryvk launched at 46% off WAC of Humira®
Avzivi® (Bio-Thera / Sandoz)	Avastin® (Roche / Genentech)	bevacizumab-trjn	Dec. 2023	36 months		
Wezlana™ (Amgen)	Stelara® (Johnson & Johnson / Janssen)	ustekinumab-auub	Oct. 2023 (Interchangeable)	12 months	Jan. 2025	Launched high WAC version at 5.5% off WAC of Stelara® and low WAC version at 81% off WAC of Stelara®
Tofidence™ (Biogen / Bio-Thera)	Actemra® (Roche / Genentech)	tocilizumab-bavi	Sept. 2023	12 months	May 2024	16% off WAC of Actemra®
Tyruko® (Sandoz)	Tysabri® (Biogen)	natalizumab-sztn	Aug. 2023	15 months	Nov. 2025	Not reported
Yuflyma® (Celltrion)	Humira® (AbbVie)	adalimumab-aaty	May 2023	30 months	July 2023	Launched branded Yuflyma® at 5% off

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			(Interchangeable: Apr. 2025)			WAC of Humira® and unbranded adalimumab-aaty at 85% off WAC of Humira®
Idacio® (Fresenius Kabi)	Humira® (AbbVie)	adalimumab-aacf	Dec. 2022	12 months	July 2023	Launched branded Idacio® at 5% off WAC of Humira® and unbranded adalimumab-aacf at 87% off WAC of Humira®
Vegzelma® (Celltrion)	Avastin® (Roche / Genentech)	bevacizumab-adcd	Sept. 2022	12 months	Apr. 2023	Not reported
Stimufend® (Fresenius Kabi)	Neulasta® (Amgen)	pegfilgrastim-fpgk	Sept. 2022	17 months	Feb. 2023	Not reported
Cimerli® (Coherus / Bioeq)	Lucentis® (Roche / Genentech)	ranibizumab-eqrn	Aug. 2022 (Interchangeable)	12 months	Oct. 2022	30% off WAC of Lucentis®
Fylnetra® (Amneal / Kashiv)	Neulasta® (Amgen)	pegfilgrastim-pbbk	June 2022	22 months	May 2023	Not reported

Biosimilar	Reference Product	Non-Proprietary Name	Initial FDA Approval Date	Time from Initial BLA Submission to Approval	Initial Commercial Launch Date	Reported Discount at Launch
Alymsys® (Amneal / mAbxience)	Avastin® (Roche / Genentech)	bevacizumab-maly	Apr. 2022	12 months	Oct. 2022	Not reported
Releuko® (Amneal / Kashiv)	Neupogen® (Amgen)	filgrastim-ayow	Feb. 2022	43.5 months	Nov. 2022	52% off WAC of Neupogen®
Yusimry® (Coherus)	Humira® (AbbVie)	adalimumab-aqvh	Dec. 2021	12 months	July 2023	86% off WAC of Humira®
Rezvoglar™ (Eli Lilly)	Lantus® (Sanofi)	insulin glargine-aglr	Dec. 2021 (Interchangeable: Nov. 2022)	12 months	Apr. 2023	78% off WAC of Lantus®
Byooviz™ (Samsung Bioepis / Biogen)	Lucentis® (Roche / Genentech)	ranibizumab-nuna	Sept. 2021 (Interchangeable: Oct. 2023)	12 months	June 2022	40% off WAC of Lucentis®
Semglee® (Mylan (Viatris) / Biocon)	Lantus® (Sanofi)	insulin glargine-yfgn	July 2021 (Interchangeable)	31 months <sup>1</sup>	Aug. 2020	Launched unbranded insulin glargine-yfgn at 65% off WAC of Lantus® and branded

<sup>1</sup> Mylan filed its New Drug Application (NDA) for Semglee® on April 27, 2017, and on March 23, 2020, Mylan's NDA was deemed to be a BLA.

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						Semlgee® at 5% off WAC of Lantus®
Riabni® (Amgen)	Rituxan® (Roche / Genentech)	rituximab-arrx	Dec. 2020	12 months	Jan. 2021	16.7% off ASP and 23.7% off WAC of Rituxan®; and 15.2% off WAC of Truxima®
Hulio® (Mylan (Viatris) / Biocon)	Humira® (AbbVie)	adalimumab-fkjp	July 2020	12 months	July 2023	Launched branded Hulio® at 5% off WAC of Humira® and unbranded adalimumab-fkjp at 85% off WAC of Humira®.
Nyvepria™ (Pfizer)	Neulasta® (Amgen)	pegfilgrastim-apgf	June 2020	12 months	Dec. 2020	37% off WAC of Neulasta®
Avsola® (Amgen)	Remicade® (Johnson & Johnson / Janssen)	infliximab-axxq	Dec. 2019	12 months	July 2020	57% off WAC of Remicade®
Abrilada™ (Pfizer)	Humira® (AbbVie)	adalimumab-afzb	Nov. 2019	12 months	Oct. 2023	Launched high WAC version at 5% off WAC of

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						Humira® and low WAC version at 60% off WAC of Humira®
Ziextenzo® (Sandoz)	Neulasta® (Amgen)	pegfilgrastim-bmez	Nov. 2019	50 months	Nov. 2019	37% off WAC of Neulasta®
Hadlima™ (Samsung Bioepis / Organon)	Humira® (AbbVie)	adalimumab-bwwd	July 2019 (Interchangeable: June 2024; High Concentration Interchangeable: May 2025)	12 months	July 2023	85% off WAC of Humira®
Ruxience® (Pfizer)	Rituxan® (Roche / Genentech)	rituximab-pvvr	July 2019	12 months	Jan. 2020	24% off WAC of Rituxan®
Kanjinti® (Amgen/ Allergan)	Herceptin® (Roche / Genentech)	trastuzumab-anns	June 2019	22.5 months	July 2019	13% off ASP and 15% off WAC of Herceptin®
Zirabev® (Pfizer)	Avastin® (Roche / Genentech)	bevacizumab-bvzr	June 2019	12 months	Dec. 2019	23% off WAC of Avastin®
Eticovo™	Enbrel® (Amgen)	etanercept-ykro	Apr. 2019	23 months		

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(Samsung Bioepis)						
Trazimera® (Pfizer)	Herceptin® (Roche / Genentech)	trastuzumab-qyyp	Mar. 2019	20.5 months	Feb. 2020	22% off WAC of Herceptin®
Ontruzant® (Samsung Bioepis / Merck)	Herceptin® (Roche / Genentech)	trastuzumab-dttb	Jan. 2019	15 months	Apr. 2020	15% off WAC of Herceptin®
Herzuma® (Celltrion / Teva)	Herceptin® (Roche / Genentech)	trastuzumab-pkrb	Dec. 2018	18.5 months	Mar. 2020	10% off WAC of Herceptin®
Truxima® (Celltrion / Teva)	Rituxan® (Roche / Genentech)	rituximab-abbs	Nov. 2018	19 months	Nov. 2019	10% off WAC of Rituxan®
Udenyca® (Coherus)	Neulasta® (Amgen)	pegfilgrastim-cbqv	Nov. 2018	27 months	Jan. 2019	33% off WAC of Neulasta®
Hyrimoz® (Sandoz)	Humira® (AbbVie)	adalimumab-adaz	Oct. 2018 (Interchangeable: Apr. 2024)	12 months	July 2023	Launched branded Hyrimoz® at 5% off WAC of Humira® and unbranded adalimumab-adaz at 81% off WAC of

Biosimilar	Reference Product	Non-Proprietary Name	Initial FDA Approval Date	Time from Initial BLA Submission to Approval	Initial Commercial Launch Date	Reported Discount at Launch
						Humira®; private label Hyrimoz® launched at 81% off WAC of Humira®
Nivestym® (Pfizer / Hospira)	Neupogen® (Amgen)	filgrastim-aafi	July 2018	10 months	Oct. 2018	30.3% off WAC of Neupogen®; 20.3% off WAC of Zarxio®; and 14.1% off WAC of Granix®
Fulphila® (Mylan / Biocon)	Neulasta® (Amgen)	pegfilgrastim-jmdb	June 2018	18 months	July 2018	33% off WAC of Neulasta®
Retacrit® (Pfizer/ Hospira)	Epogen®/ Procrit® (Amgen / Johnson & Johnson)	epoetin alfa-epbx	May 2018	41 months	Nov. 2018	33.5% off WAC of Epogen®; 57.1% off WAC of Procrit®
Ixifi™ (Pfizer)	Remicade® (Johnson & Johnson / Janssen)	infliximab-qbtx	Dec. 2017	10 months	No U.S. launch intended	

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Ogivri® (Mylan)	Herceptin® (Roche / Genentech)	trastuzumab-dkst	Dec. 2017	13 months	Dec. 2019	15% off WAC of Herceptin®
Mvasi® (Amgen / Allergan)	Avastin® (Roche / Genentech)	bevacizumab-awwb	Sept. 2017	10 months	July 2019	12% off ASP and 15% off WAC of Avastin®
Cyltezo® (Boehringer Ingelheim)	Humira® (AbbVie)	adalimumab-adbm	Aug. 2017 (Interchangeable: Oct. 2021)	10 months	July 2023	Launched branded Cyltezo® at 5% off WAC of Humira® and unbranded adalimumab-adbm at 81% off WAC of Humira®; private label adalimumab-adbm launched at 46% off WAC of Humira®
Renflexis® (Samsung Bioepis / Merck)	Remicade® (Johnson & Johnson / Janssen)	infliximab-abda	Apr. 2017	13 months	July 2017	35% off WAC of Remicade®
Amjevita® (Amgen)	Humira® (AbbVie)	adalimumab-atto	Sept. 2016	10 months	Jan. 2023	Launched low WAC version at 55% off WAC of

Biosimilar	Reference Product	Non-Proprietary Name	Initial FDA Approval Date	Time from Initial BLA Submission to Approval	Initial Commercial Launch Date	Reported Discount at Launch
						Humira® and high WAC version at 5% off WAC of Humira®
Erelzi® (Sandoz)	Enbrel® (Amgen)	etanercept-szszs	Aug. 2016	13 months		
Inflectra® (Pfizer / Celltrion)	Remicade® (Johnson & Johnson / Janssen)	infliximab-dyyb	Apr. 2016	20 months	Nov. 2016	15% off WAC of Remicade®
Zarxio® (Sandoz)	Neupogen® (Amgen)	filgrastim-sndz	Mar. 2015	10 months	Sept. 2015	15% off WAC of Neupogen®

### Appendix B. Ongoing and settled BPCIA cases from 2025

Case Name	Court	Filing Date	Biosimilar at Issue	Reference Product at Issue	# Asserted Patents <sup>2</sup>	Status
<i>Regeneron v. Mylan, Biocon</i> (1:22-cv-00061)	N.D.W. Va.	8/2/2022	Yesafili™	Eylea®	24	Settled.
<i>Regeneron v. Celltrion</i>	N.D.W. Va.	11/8/2023	Eydenzelt®	Eylea®	38	Settled.

<sup>2</sup> Patents asserted in the original complaints.

Case Name	Court	Filing Date	Biosimilar at Issue	Reference Product at Issue	# Asserted Patents <sup>2</sup>	Status
(1:23-cv-00089)						
<i>Regeneron v. Samsung Bioepis</i> (1:23-cv-00094)	N.D.W. Va.	11/21/2023	Opuviz™	Eylea®	37	Settled.
<i>Regeneron v. Formycon</i> (1:23-cv-00097)	N.D.W. Va.	11/29/2023	Ahzantive®	Eylea®	39	Settled.
<i>Regeneron v. Samsung Bioepis</i> (1:23-cv-00106)	N.D.W. Va.	12/27/2023	Opuviz™	Eylea®	51	Settled.
<i>Regeneron v. Amgen</i> (1:24-cv-00039)	C.D. Cal./ N.D.W. Va. <sup>3</sup>	1/10/2024	Pavblu™	Eylea®	32	Pending.
<i>Regeneron v. Celltrion</i> (1:24-cv-00053)	N.D.W. Va.	5/17/2024	Eydenzelt®	Eylea®	25	Settled.
<i>Regeneron v. Sandoz</i> (1:24-cv-00085)	D.N.J./ N.D.W. Va. <sup>4</sup>	8/26/2024	Enzeevu™	Eylea®	46	Settled.
<i>Regeneron v. Amgen</i> (1:25-cv-00074)	C.D. Cal./ N.D.W. Va. <sup>5</sup>	6/17/2025	Pavblu™	Eylea®	1	Pending.
<i>Biogen v. Sandoz</i> (1:22-cv-01190)	D. Del.	9/9/2022	Tyruko®	Tysabri®	28	Pending.

<sup>3</sup> This case was originally filed in the Central District of California with case number 2:24-cv-00264. In April 2024, the case was transferred to the Northern District of West Virginia and assigned case number 1:24-cv-00039.

<sup>4</sup> This case was originally filed in the District of New Jersey with case number 2:24-cv-08760. In September 2024, the case was transferred to the Northern District of West Virginia and assigned case number 1:24-cv-00085.

<sup>5</sup> This case was originally filed in the Central District of California with case number 2:25-cv-05499. In July 2025, the case was transferred to the Northern District of West Virginia and assigned case number 1:25-cv-00074.

Case Name	Court	Filing Date	Biosimilar at Issue	Reference Product at Issue	# Asserted Patents <sup>2</sup>	Status
<i>Amgen v. Samsung Bioepis</i> (1:24-cv-08417)	D.N.J.	8/12/2024	Ospomyv™ and Xbryk™	Prolia® and Xgeva®	34	Settled.
<i>Amgen v. Fresenius Kabi</i> (1:24-cv-09555)	N.D. Ill.	10/4/2024	Bomynta® and Conexence®	Prolia® and Xgeva®	33	Settled.
<i>Amgen v. Accord</i> (5:24-cv-00642)	E.D.N.C.	11/13/2024	Osvyrti® and Jubereq®	Prolia® and Xgeva®	34	Settled.
<i>Amgen v. Sandoz</i> (1:23-cv-02406)	D.N.J.	5/1/2023	Jubbonti® and Wyost®	Prolia® and Xgeva®	21	Settled.
<i>Amgen v. Celltrion</i> (1:24-cv-06497)	D.N.J.	5/28/2024	Osenvelt® and Stoboclo®	Prolia® and Xgeva®	29	Settled.
<i>Amgen v. Biocon,</i> (1:25-cv-13358)	D. Mass./ D.N.J. <sup>6</sup>	6/30/2025	Bosaya™ and Aukelso™	Prolia® and Xgeva®	34	Settled.
<i>Amgen v. Hikma</i> (1:25-cv-12152)	D.N.J.	6/25/2025	Enoby™ and Xtrenbo™	Prolia® and Xgeva®	32	Settled.
<i>Amgen v. Shanghai Henlius</i> (1:25-cv-12160)	D.N.J.	6/25/2025	Bildyos® and Bilprevda®	Prolia® and Xgeva®	26	Pending.
<i>Amgen v. Dr. Reddy's Labs.,</i> (1:25-cv-17277)	D.N.J.	11/6/2025	AVT03	Prolia® and Xgeva®	31	Pending.
<i>Amgen v. Amneal</i> (1:25-cv-17278)	D.N.J.	11/6/2025	Boncresa™ and Oziltus™	Prolia® and Xgeva®	31	Pending.
<i>Amgen v. Alkem</i> (1:25-cv-17596)	D.N.J.	11/14/2025	ENZ215	Prolia® and Xgeva®	33	Pending.

<sup>6</sup> This case was originally filed in the District of Massachusetts with case number 1:25-cv-11867. In July 2025, the case was transferred to the District of New Jersey and assigned case number 1:25-cv-13358.

Case Name	Court	Filing Date	Biosimilar at Issue	Reference Product at Issue	# Asserted Patents <sup>2</sup>	Status
<i>Genentech v. Shanghai Henlius</i> (2:25-cv-14684)	D.N.J.	8/14/2025	Poherdy®	Perjeta®	24	Settled.