

Supplementary information

The US biosimilars market after one decade

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Biosimilars approved by the FDA

There are 75 biosimilars approved by the FDA across 20 unique drug molecules. Of these, 50 biosimilars are launched in the US market. The following table depicts all approved biosimilars. The commercially launched biosimilars are marked with an asterisk.

Biosimilar	Molecule	Originator	Product characteristics	Indication
Starjemza	ustekinumab	Stelara	IL-12/23 inhibitor	Plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis
Jobevne	bevacizumab	Avastin	VEGF inhibitor	Metastatic colorectal/kidney cancer, non-small cell lung cancer, glioblastoma
Bomyntra	denosumab	Xgeva	RANKL inhibitor	Bone metastasis from solid tumours; giant cell tumour of bone
Conexence	denosumab	Prolia	RANKL inhibitor	Bone metastasis from solid tumours; giant cell tumour of bone
Omlyclo	omalizumab	Xolair	anti-IgE	Allergic asthma, chronic idiopathic urticaria, nasal polyps, and IgE-mediated food allergies
Osenvelt	denosumab	Xgeva	RANKL inhibitor	Bone metastasis from solid tumours; giant cell tumour of bone
Stoboclo	denosumab	Prolia	RANKL inhibitor	Bone metastasis from solid tumours; giant cell tumour of bone
Merilog	insulin aspart	Novolog	Human insulin analog	Rapid-acting insulin for type 1/2 diabetes
Xbryk	denosumab	Xgeva	RANKL inhibitor	Bone metastasis from solid tumours; giant cell tumour of bone
Ospomyv	denosumab	Prolia	RANKL inhibitor	Bone metastasis from solid tumours; giant cell tumour of bone
Avtozma	tocilizumab	Actemra	IL-6 inhibitor	Rheumatoid arthritis, giant cell arteritis, cytokine release syndrome
Steqeyma*	ustekinumab	Stelara	IL-12/23 inhibitor	Plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis
Yesintek*	ustekinumab	Stelara	IL-12/23 inhibitor	Plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis
Imuldosa	ustekinumab	Stelara	IL-12/23 inhibitor	Plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis.
Otulfi*	ustekinumab	Stelara	IL-12/23 inhibitor	Plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis
Pavblu*	aflibercept	Eylea	VEGF inhibitor	Wet AMD, macular oedema, diabetic retinopathy
Enzeevu	aflibercept	Eylea	VEGF inhibitor	Wet AMD, macular oedema, diabetic retinopathy
Epysqli	eculizumab	Soliris	Complement inhibitor	Paroxysmal nocturnal haemoglobinuria, atypical haemolytic uremic syndrome

Ahzantive	aflibercept	Eylea	VEGF inhibitor	Wet AMD, macular oedema, diabetic retinopathy
Pyzchiva*	ustekinumab	Stelara	IL-12/23 inhibitor	Plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis
Nypozi	filgrastim	Neupogen	G-CSF	Cancer patients receiving myelosuppressive chemotherapy
Bkemv	eculizumab	Soliris	Complement inhibitor	Paroxysmal nocturnal haemoglobinuria, atypical haemolytic uremic syndrome
Yesafili	aflibercept	Eylea	VEGF inhibitor	Wet AMD, macular oedema, diabetic retinopathy
Opuviz	aflibercept	Eylea	VEGF inhibitor	Wet AMD, macular oedema, diabetic retinopathy
Hercessi*	trastuzumab	Herceptin	HER2 inhibitor	HER2-positive breast cancer, metastatic gastric
Selarsdi*	ustekinumab	Stelara	IL-12/23 inhibitor	Plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis
Tyenne*	tocilizumab	Actemra	IL-6 inhibitor	Rheumatoid arthritis, giant cell arteritis, and cytokine release syndrome
Jubbonti*	denosumab	Prolia	RANKL inhibitor	Bone metastasis from solid tumours; giant cell tumour of bone
Wyost*	denosumab	Xgeva	RANKL inhibitor	Bone metastasis from solid tumours; giant cell tumour of bone
Simlandi*	adalimumab	Humira	TNF inhibitor	Autoimmune conditions, including rheumatoid arthritis, Crohn's, psoriatic arthritis
Avzivi	bevacizumab	Avastin	VEGF inhibitor	Metastatic colorectal/kidney cancer, non-small cell lung cancer, glioblastoma
Wezlana*	ustekinumab	Stelara	IL-12/23 inhibitor	Plaque psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis
Tofidence*	tocilizumab	Actemra	IL-6 inhibitor	Rheumatoid arthritis, giant cell arteritis, cytokine release syndrome
Tyruko	natalizumab	Tysabri	α 4 integrin inhibitor	Multiple sclerosis, Crohn's disease
Yuflyma*	adalimumab	Humira	TNF inhibitor	Autoimmune conditions, including rheumatoid arthritis, Crohn's, psoriatic arthritis
Idacio*	adalimumab	Humira	TNF inhibitor	Autoimmune conditions, including rheumatoid arthritis, Crohn's, psoriatic arthritis
Vegzelma	bevacizumab	Avastin	VEGF inhibitor	Metastatic colorectal/kidney cancer, non-small cell lung cancer, glioblastoma
Stimufend*	pegfilgrastim	Neulasta	G-CSF	Infection risk in patients receiving myelosuppressive chemotherapy

Cimerli*	ranibizumab	Lucentis	VEGF inhibitor	Age-related macular degeneration (AMD); macular oedema
Fylnetra*	pegfilgrastim	Neulasta	G-CSF	Infection risk in patients receiving myelosuppressive chemotherapy
Almysys*	bevacizumab	Avastin	VEGF inhibitor	Metastatic colorectal/kidney cancer, non-small cell lung cancer, glioblastoma
Releuko*	filgrastim	Neupogen	G-CSF	Cancer patients receiving myelosuppressive chemotherapy
Yusimry*	adalimumab	Humira	TNF inhibitor	Autoimmune conditions, including rheumatoid arthritis, Crohn's, psoriatic arthritis
Rezvoglar*	insulin glargine	Lantus	Human insulin analog	Long-acting insulin for type 1 and type 2 diabetes
Byooviz*	ranibizumab	Lucentis	VEGF inhibitor	Age-related macular degeneration (AMD); macular oedema
Semglee*	insulin glargine	Lantus	Human insulin analog	Long-acting insulin for type 1 and type 2 diabetes
Riabni*	rituximab	Rituxan	CD20 inhibitor	Non-Hodgkin's lymphoma; chronic lymphocytic leukaemia; rheumatoid arthritis
Hulio*	adalimumab	Humira	TNF inhibitor	Autoimmune conditions, including rheumatoid arthritis, Crohn's, psoriatic arthritis
Nyvepria*	pegfilgrastim	Neulasta	G-CSF	Infection risk in patients receiving myelosuppressive chemotherapy
Avsola*	infliximab	Remicade	TNF inhibitor	Crohn's disease, rheumatoid and psoriatic arthritis; ulcerative colitis
Abrilada*	adalimumab	Humira	TNF inhibitor	Autoimmune conditions, including rheumatoid arthritis, Crohn's, psoriatic arthritis
Ziextenzo*	pegfilgrastim	Neulasta	G-CSF	Infection risk in patients receiving myelosuppressive chemotherapy
Hadlima*	adalimumab	Humira	TNF inhibitor	Autoimmune conditions, including rheumatoid arthritis, Crohn's, psoriatic arthritis
Ruxience*	rituximab	Rituxan	CD20 inhibitor	Non-Hodgkin's lymphoma; chronic lymphocytic leukaemia; rheumatoid arthritis
Zirabev*	bevacizumab	Avastin	VEGF inhibitor	Metastatic colorectal/kidney cancer, non-small cell lung cancer, glioblastoma
Kanjinti*	trastuzumab	Herceptin	HER2 inhibitor	HER2-positive breast and gastric cancers
Eticovo	etanercept	Enbrel	TNF inhibitor	Rheumatoid and psoriatic arthritis, plaque psoriasis
Trazimera*	trastuzumab	Herceptin	HER2 inhibitor	HER2-positive breast and gastric cancers
Ontruzant*	trastuzumab	Herceptin	HER2 inhibitor	HER2-positive breast and gastric cancers

Herzuma*	trastuzumab	Herceptin	HER2 inhibitor	HER2-positive breast and gastric cancers
Truxima*	rituximab	Rituxan	CD20 inhibitor	Non-Hodgkin's lymphoma; chronic lymphocytic leukaemia; rheumatoid arthritis
Udenyca*	pegfilgrastim	Neulasta	G-CSF	Infection risk in patients receiving myelosuppressive chemotherapy
Hyrimoz*	adalimumab	Humira	TNF inhibitor	Autoimmune conditions, including rheumatoid arthritis, Crohn's, psoriatic arthritis
Nivestym*	filgrastim	Neupogen	G-CSF	Cancer patients receiving myelosuppressive chemotherapy
Fulphila*	pegfilgrastim	Neulasta	G-CSF	Infection risk in patients receiving myelosuppressive chemotherapy
Retacrit*	epoetin alfa	Epogen	Human erythropoietin	Anaemia of chronic renal failure patients
Ixifi	infliximab	Remicade	TNF inhibitor	Crohn's disease, rheumatoid and psoriatic arthritis; ulcerative colitis
Ogivri*	trastuzumab	Herceptin	HER2 inhibitor	HER2-positive breast and gastric cancers
Mvasi*	bevacizumab	Avastin	VEGF inhibitor	Metastatic colorectal/kidney cancer, non-small cell lung cancer, glioblastoma
Cyltezo*	adalimumab	Humira	TNF inhibitor	Autoimmune conditions, including rheumatoid arthritis, Crohn's, psoriatic arthritis
Renflexis*	infliximab	Remicade	TNF inhibitor	Crohn's disease, rheumatoid and psoriatic arthritis; ulcerative colitis
Amjevita*	adalimumab	Humira	TNF inhibitor	Autoimmune conditions, including rheumatoid arthritis, Crohn's, psoriatic arthritis
Erelzi	etanercept	Enbrel	TNF inhibitor	Rheumatoid and psoriatic arthritis, plaque psoriasis
Inflectra*	infliximab	Remicade	TNF inhibitor	Crohn's disease, rheumatoid and psoriatic arthritis; ulcerative colitis
Zarxio*	filgrastim	Neupogen	G-CSF	Cancer patients receiving myelosuppressive chemotherapy

*Commercially launched in the United States market. CD20, B-lymphocyte antigen CD20; G-CSF, granulocyte colony stimulating factor; HER2, human epidermal growth factor receptor 2; IgE, immunoglobulin E; IL, interleukin; RANKL, receptor activator of nuclear factor kappa-B ligand; TNF, tumour necrosis factor; VEGF, vascular endothelial growth factor. Sources: <https://biosimilarsrr.com/us-biosimilar-filings/>; www.fda.gov

Calculations for saving by biosimilars

The estimated value of each drug was calculated by applying the brand-name price prior to patent expiry to the volume of biosimilars sold annually. This figure reflects the potential expenditure on branded drugs, had biosimilars not entered the market. The savings was determined by subtracting historic generic spending from the estimated brand spending in the absence of biosimilar competition. Incremental days of patient therapy were calculated by determining the number of treatment days that would not have occurred without biosimilar competition. The calculations are based on the data captured by IQVIA and reported in the U.S. Generic and Biosimilar Medicines Savings Report (September 2024): <http://accessiblemeds.org/wp-content/uploads/2025/01/AAM-2024-Generic-Biosimilar-Medicines-Savings-Report.pdf>

Figure 1

The 10 reference drugs selected for this figure are those with leading share of the biosimilars market in 2024 and have biosimilar competitors that were commercially launched in the market by December 2023. Altogether, these 10 reference drugs have biosimilars that comprise >83% of all commercially launched biosimilars (40/48) in the US market. The following table depicts the data used to create Figure 1 in the article.

Reference drug	First biosimilar approved	Leading biosimilar (Q4;2024)	Biosimilars market share (2024)	Leading biosimilar's percentage within the biosimilars	No. of biosimilars launched	US sales (\$ millions) of the reference drug
Herceptin	Kanjinti; Jul 2019	Kanjinti	86%	37%	5	369
Avastin	Mvasi; Jul 2019	Mvasi	90%	54%	4	447
Rituxan	Truxima; Nov 2019	Ruxience	75%	47%	3	970
Neupogen	Zarxio; Sep 2015	Zarxio	87%	51%	3	NA*
Neulasta	Fulphila; Jul 2019	Fulphila	84%	46%	6	318
Epogen	Retacrit; Nov 2018	Retacrit	40%	100%	1	125
Remicade	Inflectra; Nov 2016	Inflectra	48%	58%	3	1,009
Humira	Amgevita; Jan 2023	Hyrimoz	23%	48%	10	7,142
Lantus	Semglee; Nov 2021	Toujeo	36%	44%	2	720
Lucentis	Byooviz; Jul 2022	Cimerli	49%	86%	2	1,044

*Total sales of \$1,115 million, which comprises of Aimovig®, Kanjinti®, Riabni®, Avsola®, Neupogen®, Corlanor®, Imlygic®, Bekemv™, Pavblu™, Wezlana™/Wezenla™, Sensipar®/Mimpara™ and horizon-acquired products including Rayos®, Pennsaid® and Duexis®. Sources: this table was created using information from the Samsung Bioepis Biosimilar Market report. The calculations in this report were made using data from IQVIA MIDAS. Sales data was obtained from company annual reports and SEC filings.