SAMSUNG BIOEPIS

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Biosimilar Market Report

9th Edition, Q2 2025

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FOREWORD

The US biosimilar market has witnessed substantial growth in the first quarter of 2025, driven by key regulatory and competitive developments. Among the most significant milestones was the launch of multiple ustekinumab biosimilars following the loss of exclusivity for Stelara. This expansion has played a pivotal role in fostering market competition and encouraging more dynamic pricing strategies.

In addition to this rapid market growth, the FDA has intensified its efforts to streamline biosimilar approvals. Notably, the agency has proposed measures to waive Phase III clinical trials for select biosimilars, significantly reducing both time-to-market and development costs.

This quarter's report provides a comprehensive analysis of the regulatory shift, exploring its implications for market dynamics, competitive positioning, and broader industry trends. The FDA's evolving approach is poised to accelerate biosimilar adoption, creating new opportunities for manufacturers while intensifying competition across the sector.

Looking ahead, the US biosimilar market is expected to continue evolving as additional biosimilars enter the market and regulatory frameworks adapt. Our report continues to offer an in-depth perspective on current market trends, challenges, and strategic opportunities for stakeholders navigating this rapidly changing landscape.

Thomas Newcomer
Vice President
Head of US Commercial Operations, Samsung Bioepis US

SAMSUNG BIOEPIS

Our mission

Samsung Bioepis is a biopharmaceutical company dedicated to accelerating access to biologic medicines by bringing high-quality, clinically proven biosimilars to patients who need them

Our mission is reflected in our name, **bio-epis;** literally meaning life (**"bio"**) and science (**"episteme"**) in Greek

Unlocking the future of healthcare by breakthrough innovation and science

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I. US Biosimilars Approval & Launch Status

FDA Approval and Launch Status of US Biosimilars

* As of Mar 2025, the FDA has approved a total of 73 biosimilars across 19 unique biological molecules. Of the 73 approvals, 48 biosimilars (66%) have launched in the US market.

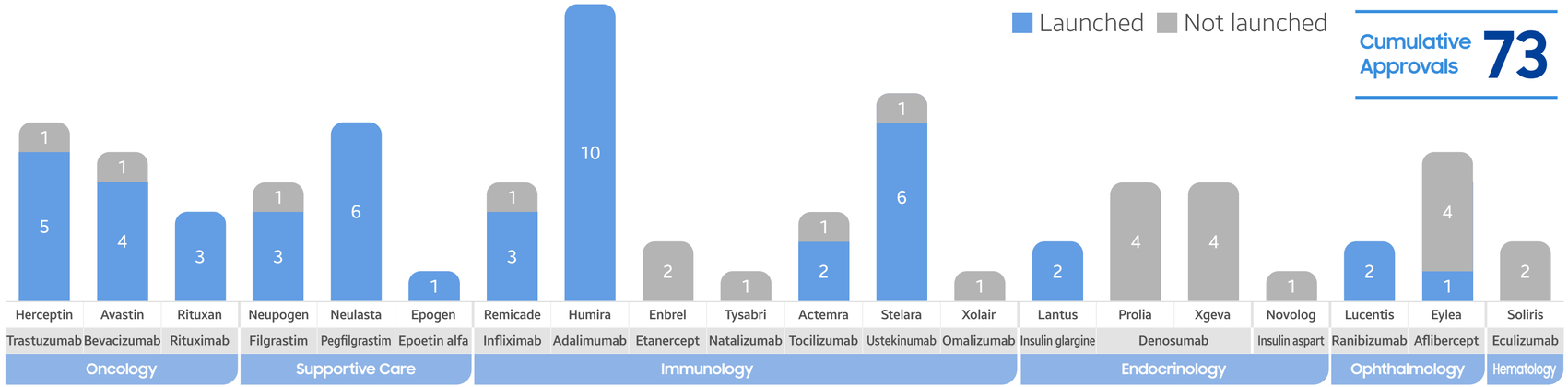
Figure 1-1. 10 FDA-approved Biosimilars in Q1`25

Reference Product	Biosimilar name	Biosimilar Manufacturer
Stelara	Steqeyma	Celltrion
Actemra	Avtozma	Celltrion
Xgeva	Xbryk	Samsung Bioepis
	Osenvelt	Celltrion
	Bomyntra	Fresenius Kabi
Prolia	Ospomyv	Samsung Bioepis
	Stoboclo	Celltrion
	Conexxence	Fresenius Kabi
Novolog	Merilog	Sanofi-Aventis
Xolair	Omlyclo	Celltrion

Figure 1-2. 7 Biosimilars Launched in the US Market in Q1`25

Reference Product	Biosimilar name	Biosimilar Manufacturer & Commercial Partner	Launch Date
Stelara	Wezlana	Amgen	Jan 2025
	Selarsdi	Alvotech & Teva	Feb 2025
	Pyzchiva	Samsung Bioepis & Sandoz	Feb 2025
	Yesintek	Biocon	Feb 2025
	Otulfi	Formycon & Fresenius Kabi	Mar 2025
	Steqeyma	Celltrion	Mar 2025

Figure 2. Biosimilars Approval and Launch Status in the US[1*] (As of Mar 2025)



FDA: Food and Drug Administration
*Trade marks are not described to all brands

Figure 3-1. Biosimilars Approval and Launch Status in the US[1*] (As of Mar 2025, with Suffix)

TA	Oncology			Immunology						
Molecule	Trastuzumab	Bevacizumab	Rituximab	Infliximab	Adalimumab	Etanercept	Natalizumab	Tocilizumab	Ustekinumab	Omalizumab
Reference Product	Herceptin (trastuzumab) Roche 1998	Avastin (bevacizumab) Roche 2004	Rituxan (rituximab) Genentech&Biogen 1997	Remicade (infliximab) Janssen 1998	Humira (adalimumab) AbbvVie 2002	Enbrel (etanercept) Amgen 2003	Tysabri (natalizumab) Biogen 2004	Actemra (tocilizumab) Genetech 2010	Stelara (ustekinumab) Janssen 2009	Xolair (omalizumab) Genentech&Novartis 2003
Biosimilar	Ogivri (trastuzumab-dkst) Biocon 2017	Mvasi (bevacizumab-awwb) Amgen 2017	Truxima (rituximab-abbs) Celltrion&Teva 2018	Inflectra (infliximab-dyyb) Celltrion&Pfizer 2016	Amjevita (adalimumab-atto) Amgen 2016	Erelzi (etanercept-szzs) Sandoz 2016	Tyruko (natalizumab-sztn) Sandoz 2023	Tofidence (tocilizumab-bavi) Biogen&Bio-Thera 2023	Wezlana (ustekinumab-auub) Amgen 2023	Omlyclo (omalizumab-igec) Celltrion 2025
	Herzuma (trastuzumab-pkrb) Celltrion&Teva 2018	Zirabev (bevacizumab-bvzr) Pfizer 2019	Ruxience (rituximab-pvvr) Pfizer 2019	Renflexis (infliximab-abda) Samsung Bioepis&Organon 2017	Cyltezo (adalimumab-adbm) Boehringer Ingelheim 2017	Eticovo (etanercept-ykro) Samsung Bioepis 2019		Tyenne (tocilizumab-aazg) Fresenius Kabi 2024	Selarsdi (ustekinumab-aekn) Alvotech&Teva 2024	
	Ontruzant (trastuzumab-dttb) Samsung Bioepis&Organon 2019	Alymsys (bevacizumab-maly) Amneal 2022	Riabni (rituximab-arrx) Amgen 2020	Avsola (infliximab-axxq) Amgen 2019	Hyrimoz (adalimumab-adaz) Sandoz 2018			Avtozma (tocilizumab-anoh) Celltrion 2025	Pyzchiva (ustekinumab-ttwe) Samsung Bioepis&Sandoz 2024	
	Trazimera (trastuzumab-qyyp) Pfizer 2019	Vegzelma (bevacizumab-adcd) Celltrion 2022		Ixifi (infliximab-qbtx) Pfizer 2017	Hadlima (adalimumab-bwwd) Samsung Bioepis&Organon 2019				Otulfi (ustekinumab-aauz) Formycon&Fresenius Kabi 2024	
	Kanjinti (trastuzumab-anns) Amgen 2019	Avzivi (bevacizumab-tnjn) Sandoz&Bio-Thera 2023			Abrilada (adalimumab-afzb) Pfizer 2019				Imuldosa (ustekinumab-srlf) Dong-A ST&Meji Seika &Accord Biopharma 2024	
	Hercessi (trastuzumab-strf) Accord BioPharma&Henlius 2024				Hulio (adalimumab-fkjp) Biocon 2020				Yeintek (ustekinumab-kfce) Biocon 2024	
					Yusimry (adalimumab-aqvh) Meitheal 2021				Steqeyma (Ustekinumab-stba) Celltrion 2024	
					Idacio (adalimumab-aacf) Fresenius Kabi 2022					
					Yuflyma (adalimumab-aaty) Celltrion 2023					
					Simlandi (adalimumab-ryvk) Alvotech&Teva 2024					

Launched Not launched

Continued on next page →

*Trade marks are not described to all brands

Figure 3-2. Biosimilars Approval and Launch Status in the US[1*] (As of Mar 2025, with Suffix)

TA	Endocrinology			Ophthalmology		Hematology	Supportive Care		
Molecule	Denosumab	Insulin glargine	Insulin aspart	Ranibizumab	Aflibercept	Eculizumab	Filgrastim	Pegfilgrastim	Epoetin alfa
Reference Product	Prolia/Xgeva (denosumab) Amgen 2010	Lantus (insulin glargine) Sanofi 2000	Novolog (insulin aspart) Novo Nordisk 2000	Lucentis (ranibizumab) Novartis 2006	Eylea (aflibercept) Regeneron 2011	Soliris (eculizumab) Alexion 2007	Neupogen (filgrastim) Amgen 1991	Neulasta (pegfilgrastim) Amgen 2002	Epogen (epoetin alfa) Amgen 1898
Biosimilar	Jubbonti/Wyost (denosumab-bbdz) Sandoz 2024	Semglee (insulin glargine-yfgn) Biocon 2021	Merilog (insulin aspart-szjj) Sanofi-Aventis 2025	Byooviz (ranibizumab-nuna) Samsung Bioepis 2021	Opuviz (aflibercept-yszy) Samsung Bioepis&Biogen 2024	Bkemv (eculizumab-aeeb) Amgen 2024	Zarxio (filgrastim-sndz) Sandoz 2015	Fulphila (pegfilgrastim-jmdb) Biocon 2018	Retacrit (epoetin alfa-epbx) Hospira&Pfizer 2018
	Ospomyv/Xbryk (denosumab-dssb) Samsung Bioepis 2025	Rezvoglar (insulin glargine-aglr) Eli Lilly 2021		Cimerli (ranibizumab-eqrn) Sandoz 2022	Yesafili (aflibercept-jbvf) Biocon 2024	Epysqli (eculizumab-aagh) Samsung Bioepis 2024	Nivestym (filgrastim-aafi) Hospira&Pfizer 2018	Udenyca (pegfilgrastim-cbqv) Coherus 2018	
	Stoboclo/Osenvelt (denosumab-bmwo) Celltrion 2025				Ahzantive (aflibercept-mrbb) Formycon&Klinge 2024		Releuko (filgrstim-ayow) Amneal&Kashiv 2022	Ziextenzo (pegfilgrastim-bmez) Sandoz 2019	
	Conexxence/Bomyntra (denosumab-bnht) Fresenius Kabi 2025				Enzeevu (aflibercept-abzv) Sandoz 2024		Nypozi (filgrastim-txid) Tanvex 2024	Nyvepria (pegfilgrastim-apgf) Hospira&Pfizer 2020	
					Pavblu (aflibercept-ayyh) Amgen 2024			Stimufend (pegfilgrastim-fpgk) Fresenius Kabi 2022	
								Fylnetra (pegfilgrastim-pbbk) Amneal&Kashiv 2022	

Launched Not launched

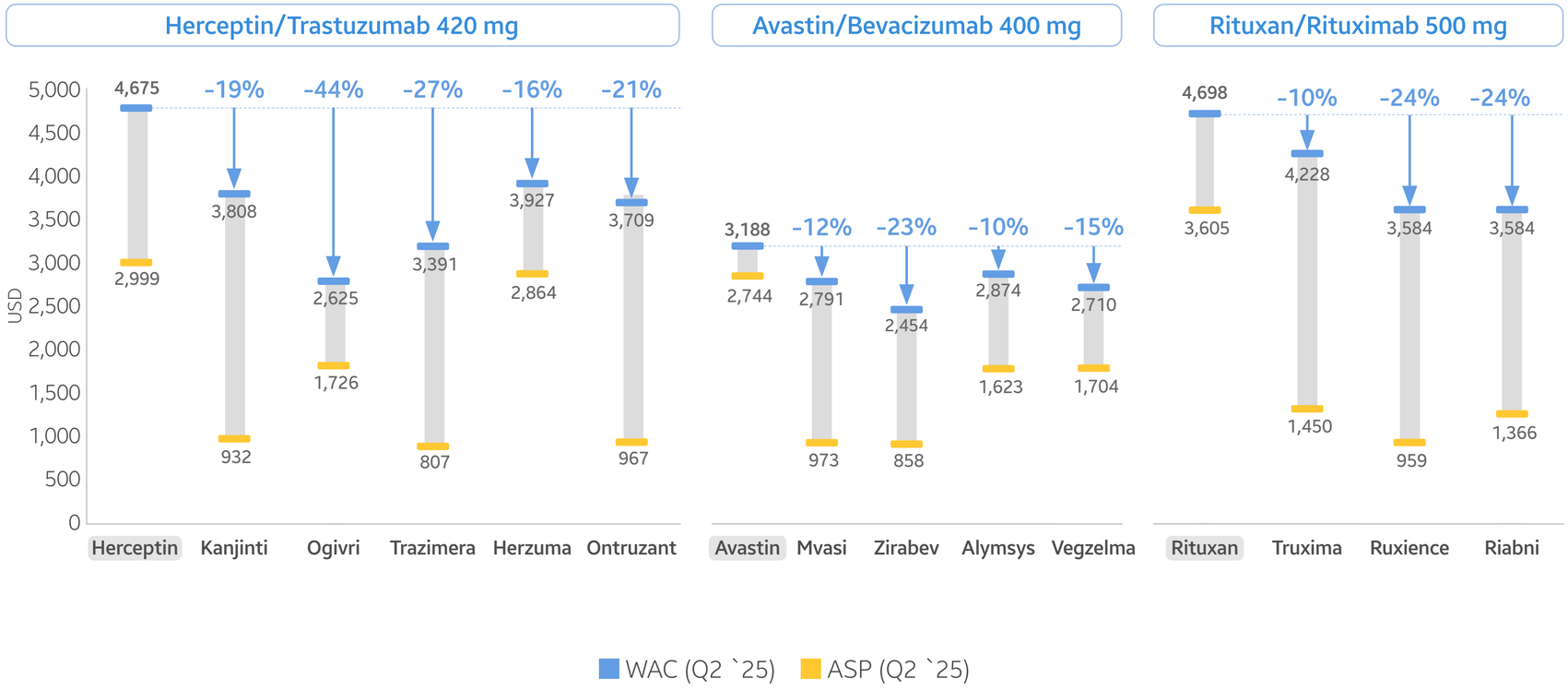
*Trade marks are not described to all brands

II. Biosimilar Price
(Medical Benefit & Pharmacy Benefit)

Oncology WAC and ASP - Q2 2025

- Across oncology biosimilars, WAC prices discounted between 10-44% compared to reference products.
- Biosimilar Q2 2025 ASP discounts as compared to the reference product ASP average -51%, -53%, and -65% for the trastuzumab, bevacizumab, and rituximab markets, respectively.

Figure 4. Q2 2025 WAC and ASP[2,3]

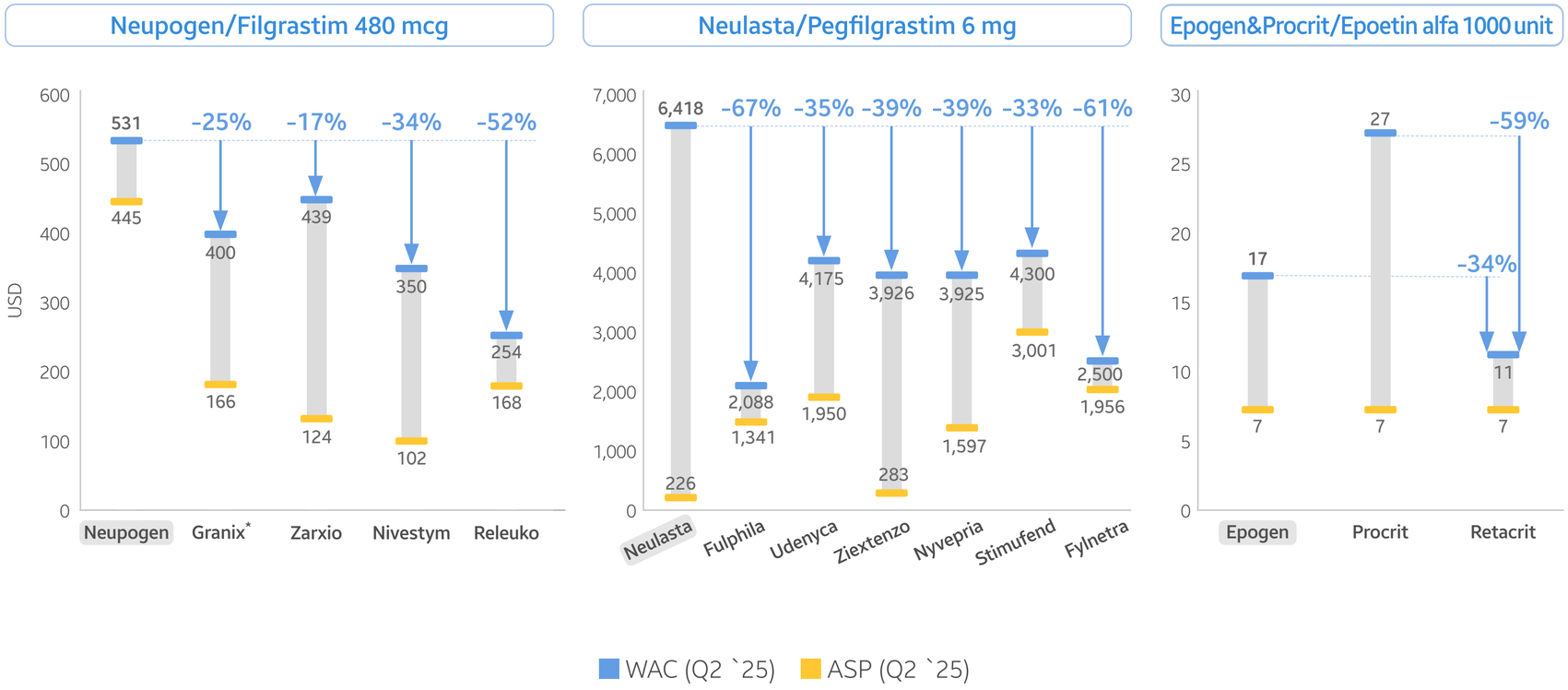


Products are listed in order of launch
ASP: Average Sales Price; **WAC**: Wholesale Acquisition Cost

Supportive Care WAC and ASP - Q2 2025

- Across supportive care biosimilars, WAC prices discounted between 17-67% compared to reference products.
- Amgen, the manufacturer for reference biologics filgrastim (Neupogen) and pegfilgrastim (Neulasta), only provides competitive ASP pricing in the pegfilgrastim market.

Figure 5. Q2 2025 WAC and ASP[2,3]

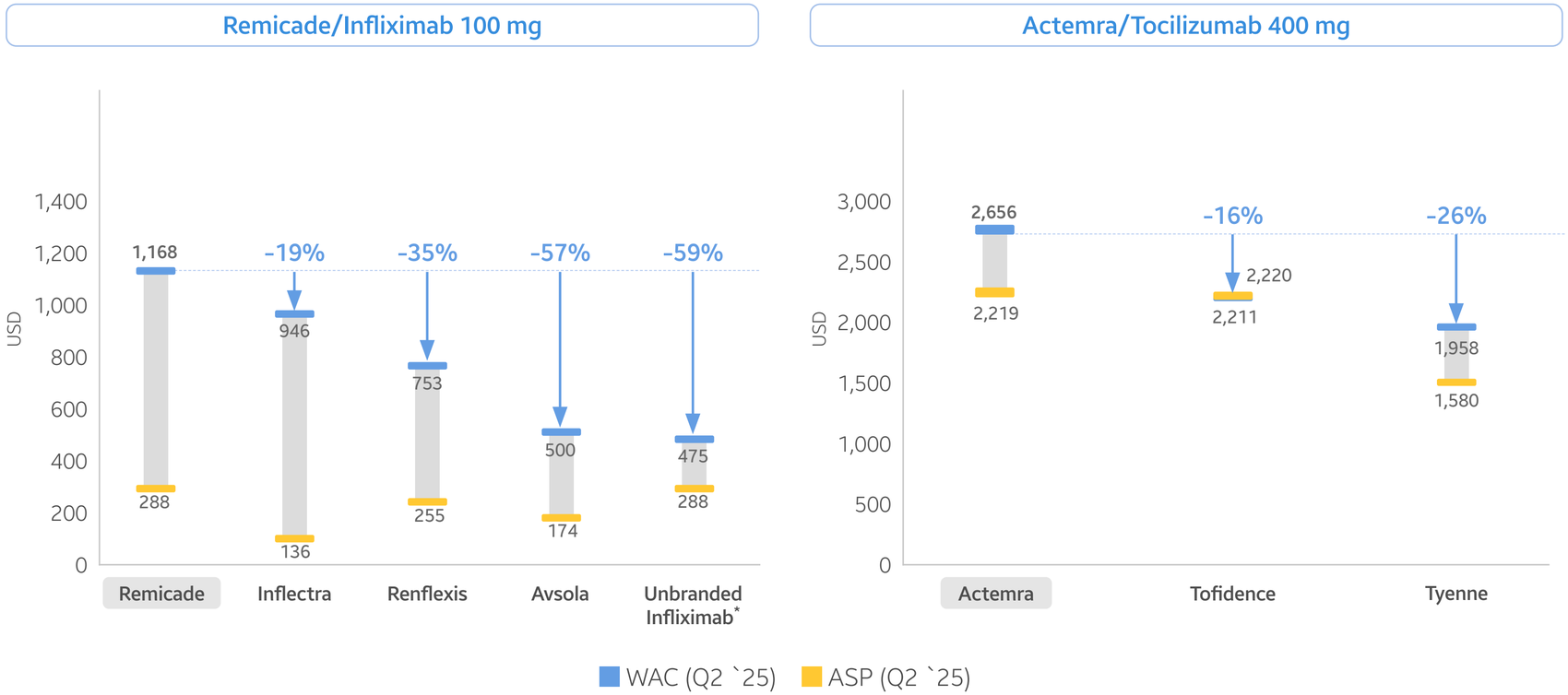


Products are listed in order of launch
ASP: Average Sales Price; **WAC**: Wholesale Acquisition Cost
*Granix is not a biosimilar; approved under the FDA's New Drug Application pathway

Immunology WAC and ASP - Q2 2025

- Infliximab biosimilars launched with progressively lower WACs, ranging from -19% to -59% in discounts.
- The two tocilizumab biosimilars demonstrate distinct ASP pricing strategies: Tofidence is priced at just 0.3% below the reference product's ASP, while Tyenne offers a significantly deeper discount of 29% compared to the originator.

Figure 6. Q2 2025 WAC and ASP[2,3]

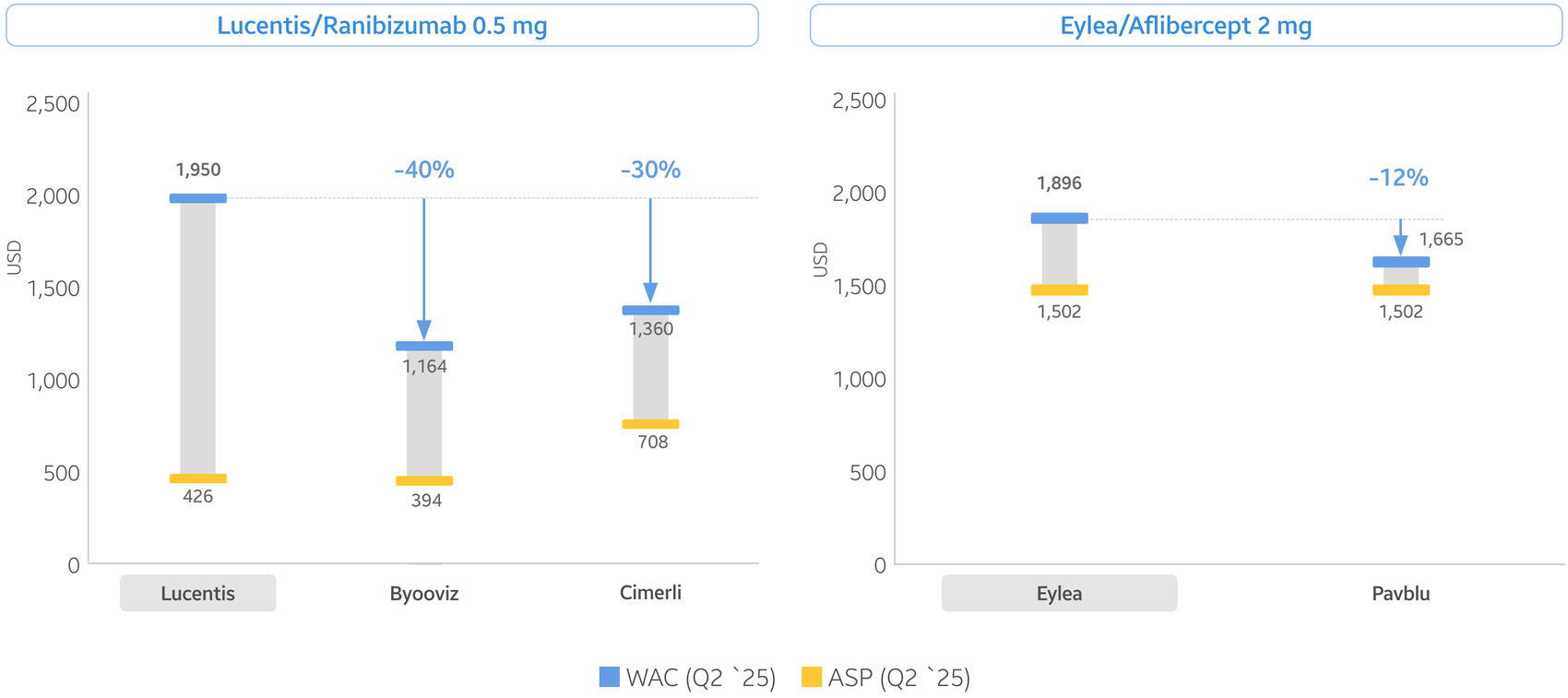


Products are listed in order of launch
ASP: Average Sales Price; **WAC**: Wholesale Acquisition Cost
*Janssen's Remicade without the brand name

Ophthalmology WAC and ASP – Q2 2025

- With only two competing biosimilars on the market, ranibizumab WACs represent -30% to -40% WAC discounts as compared to the reference product.
- Pavblu, the only Aflibercept biosimilar available in the US, launched with WAC 12% lower than the reference product WAC.

Figure 7. Q2 2025 WAC and ASP[2,3]

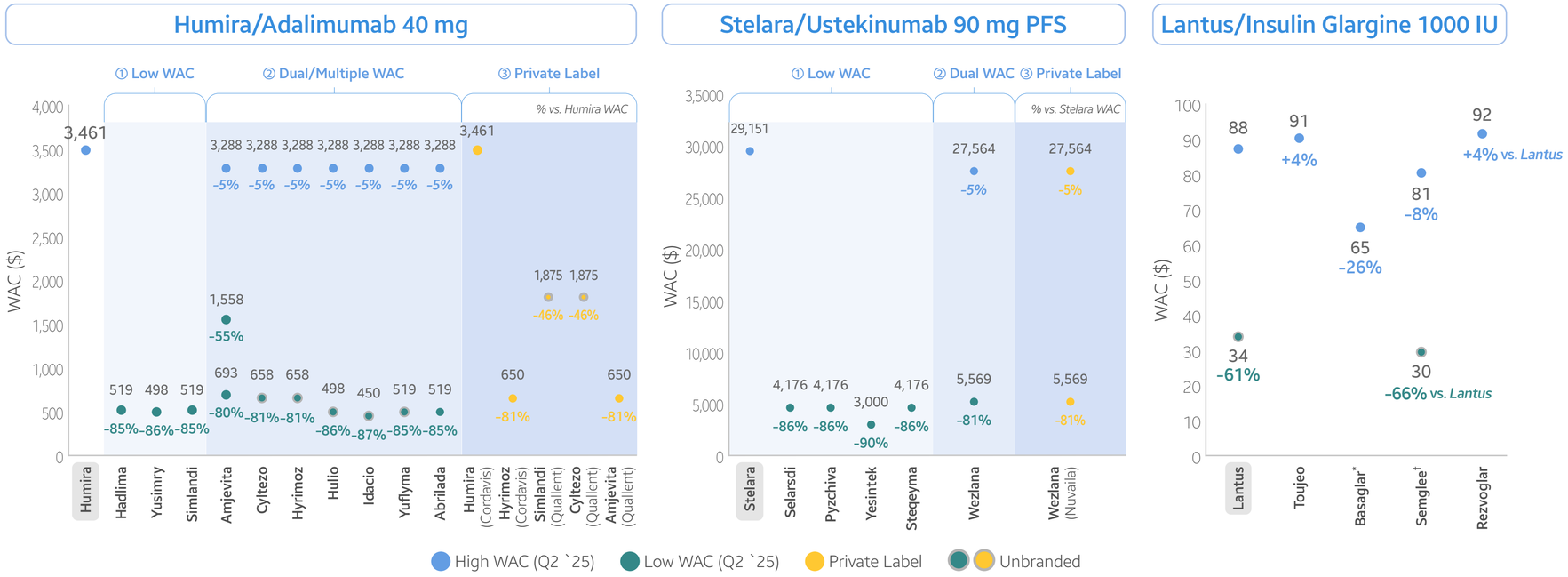


Products are listed in order of launch
ASP: Average Sales Price; **WAC**: Wholesale Acquisition Cost

Immunology & Endocrinology WAC - Q2 2025

- Adalimumab & Insulin glargine categories reflect recent pricing practices such as multiple WAC options and unbranded biologics.
- In the adalimumab market, private label brands offer alternative WAC prices.
- The beginning of 2025 marked the entrance of Stelara's biosimilar, ustekinumab; upon Stelara's loss of exclusivity, entrants provided steep WAC discounts of greater than 80%.

Figure 8. Q2 2025 WAC[2]



Products are listed in order of launch
WAC: Wholesale Acquisition Cost
*Toujeo is high dose version of Lantus †Basaglar is not a biosimilar, approved under the FDA's New Drug Application pathway

III. Biosimilar Market Dynamics

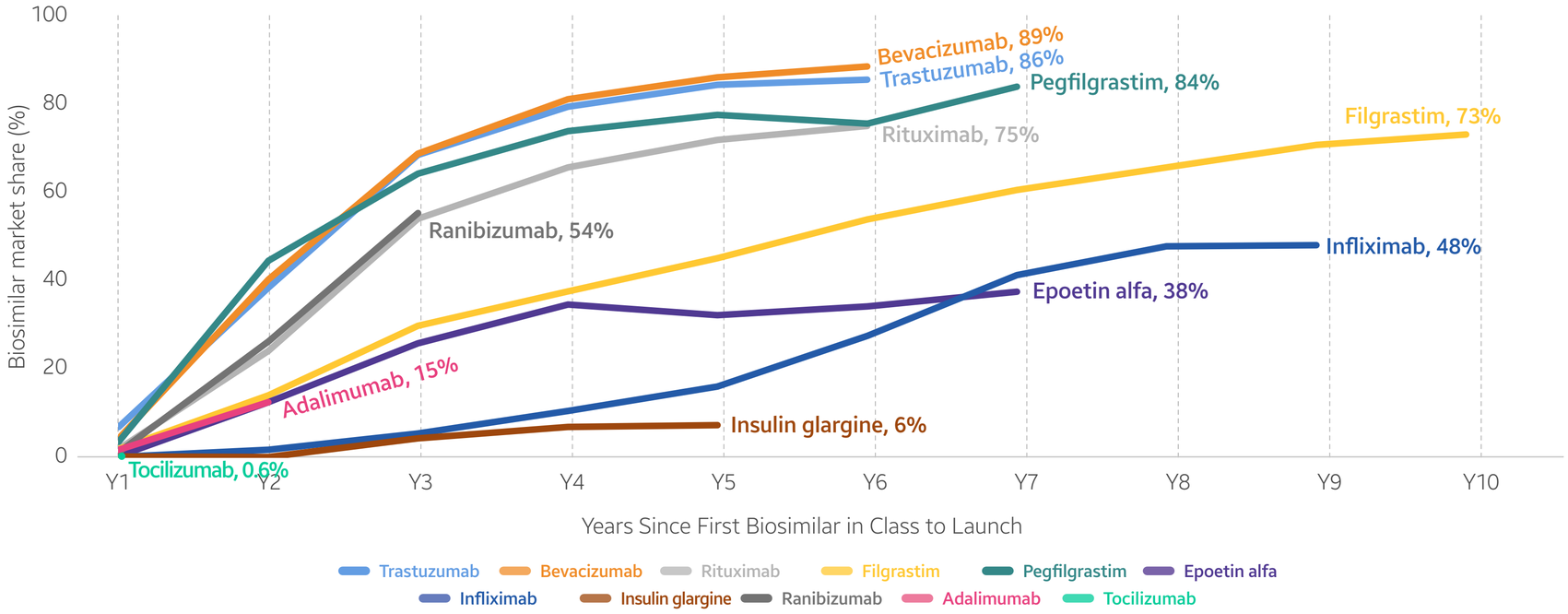
Biosimilar Volume Uptake Varies by Molecule

On average, biosimilars have gained 52% market share within 5 years post initial launch.[†] Each molecule has demonstrated unique biosimilar uptake and can be categorized into fast or slow uptake markets.

1) **Fast Uptake Speed**: Oncology[*], ophthalmology, and pegfilgrastim biosimilars. Five years post launch, average biosimilar market share reached 81%.[†]

2) **Slow Uptake Speed:** Immunology[‡], filgrastim, epoetin alfa, and insulin glargine biosimilars. On average, only a 25% biosimilar market share was achieved by Year 5.[†]

Figure 9. Biosimilar Market Share Post-Launch[4§]

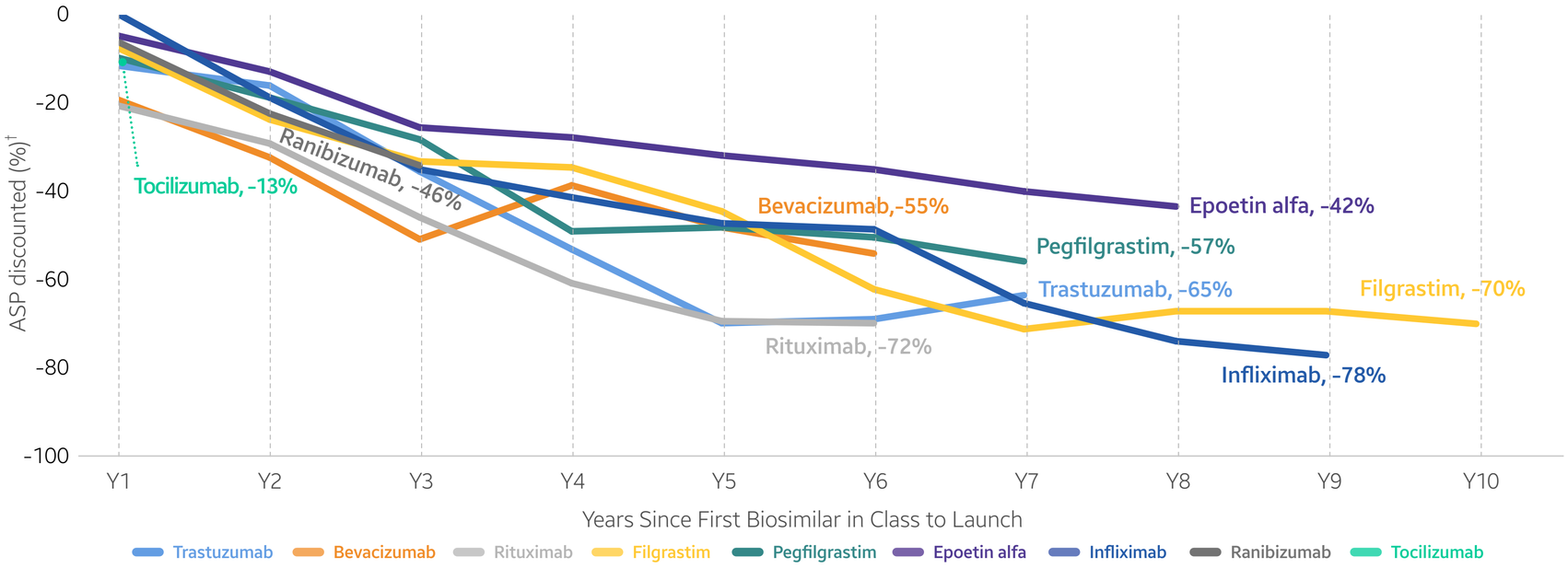


[*] Trastuzumab, bevacizumab, and rituximab [†] Averages include products that are 5 years or older [‡] Infliximab and adalimumab [§] Calculated based on calendar year

Biosimilars are Reducing Drug Costs across Multiple TAs by Lowering Prices

- Biosimilar launches have led to significant price decreases over time. On average, ASP decreased by 53% within five years of the first biosimilar launch, with more mature markets achieving even greater price reductions over time.
- Recently observed increases in ASP for some markets (e.g. trastuzumab, bevacizumab, pegfilgrastim and filgrastim) may be due to 1) artifacts of newly-launched, low-market share biosimilars with ASPs that reflect WAC pricing and 2) intentional ASP repositioning of some biosimilars.

Figure 10. ASP Trend by Molecule[3]



TA: Therapeutic Area; ASP: Average Sales Price
† ASP discounted % vs. reference product ASP when first biosimilar in class launch

Market Share and ASP Trends - Herceptin (Trastuzumab)

- As of Q4 2024, the biosimilar share of the trastuzumab market was 87% (+1% vs. last quarter).
- As of Q2 2025, the average ASP of all biosimilar products is $1,459 (-1% vs. last quarter).
- Over the last few quarters, many trastuzumab biosimilars have shown ASP increases in a highly competitive market.

Figure 11. Trastuzumab Volume Market Share[4]

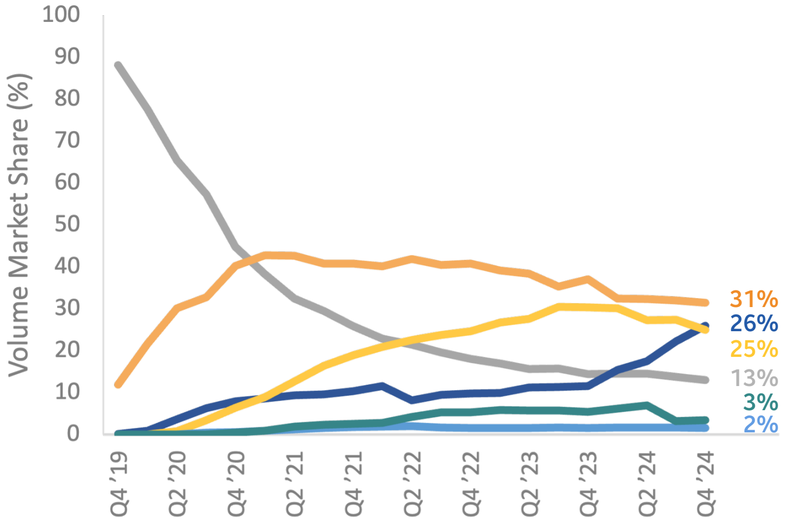
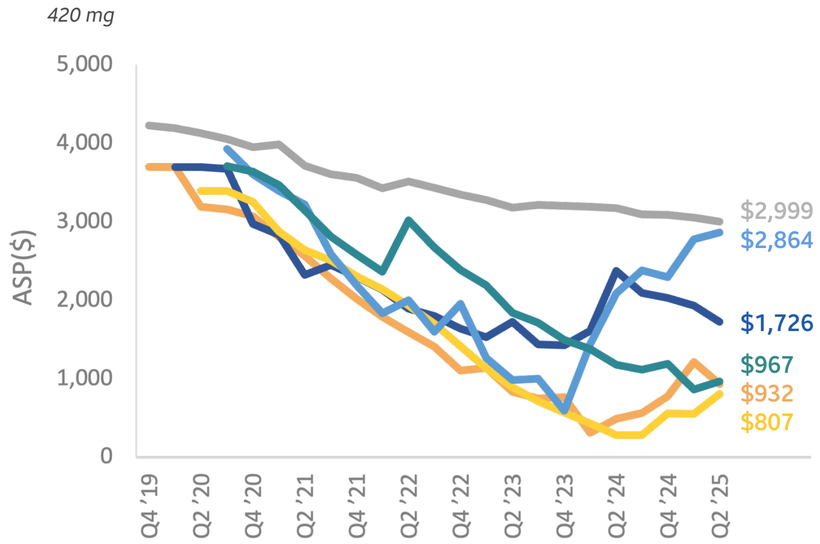


Figure 12. Trastuzumab ASP Trend[3]



Herceptin Kanjinti Ogivri Trazimera Herzuma Ontruzant

Products are listed in legends in order of launch
ASP: Average Sales Price

Market Share and ASP Trends - Avastin (Bevacizumab)

- As of Q4 2024, the biosimilar share of the bevacizumab market was 90% (Unchanged vs. last quarter).
- As of Q2 2025, the average ASP of all biosimilar products is $1,289 (-8% vs. last quarter).
- In Q4 2024, overall bevacizumab volume declined partly due to a Zirabev shortage that persisted until early February 2025. Mvasi share increased as a result of these dynamics.
- Market share for the more recent biosimilar entrants (i.e. Almysys and Vegzelma) continues to steadily grow.

Figure 13. Bevacizumab Volume Market Share[4]

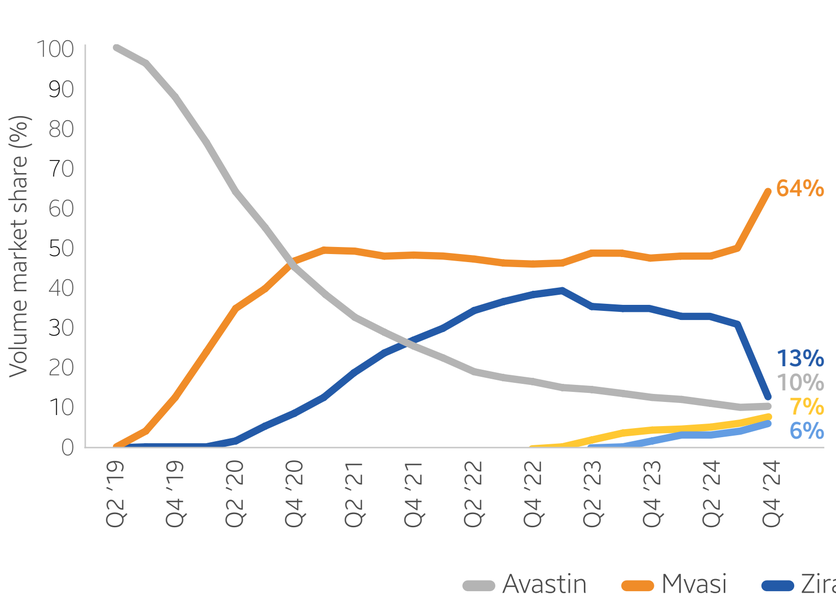
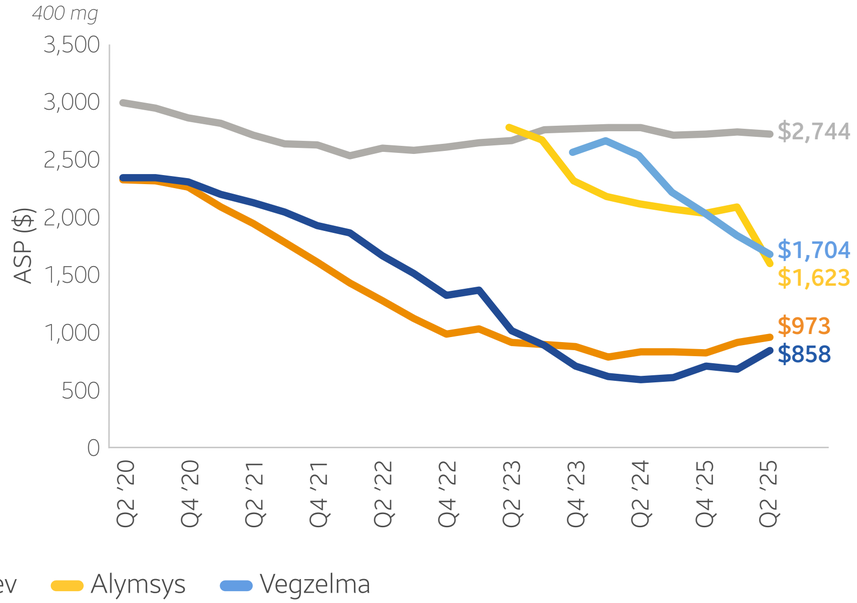


Figure 14. Bevacizumab ASP Trend[3]



Avastin Mvasi Zirabev Alymsys Vegzelma

Products are listed in legends in order of launch
ASP: Average Sales Price

Market Share and ASP Trends - Rituxan (Rituximab)

- As of Q4 2024, the biosimilar share of the rituximab market was 76% (Unchanged vs. last quarter).
- As of Q2 2025, the average ASP of all biosimilar products is $1,258 (+1% vs. last quarter).
- In the rituximab market, lower priced biosimilars are dominating the market. The most recent entrant, Riabni, has started to grow in market share and its ASP continues to trend downward.

Figure 15. Rituximab Volume Market Share[4]

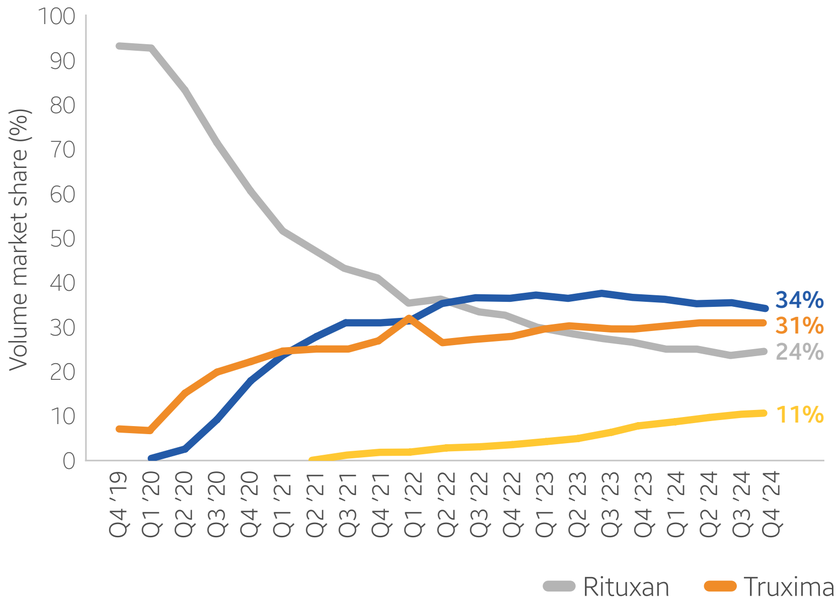
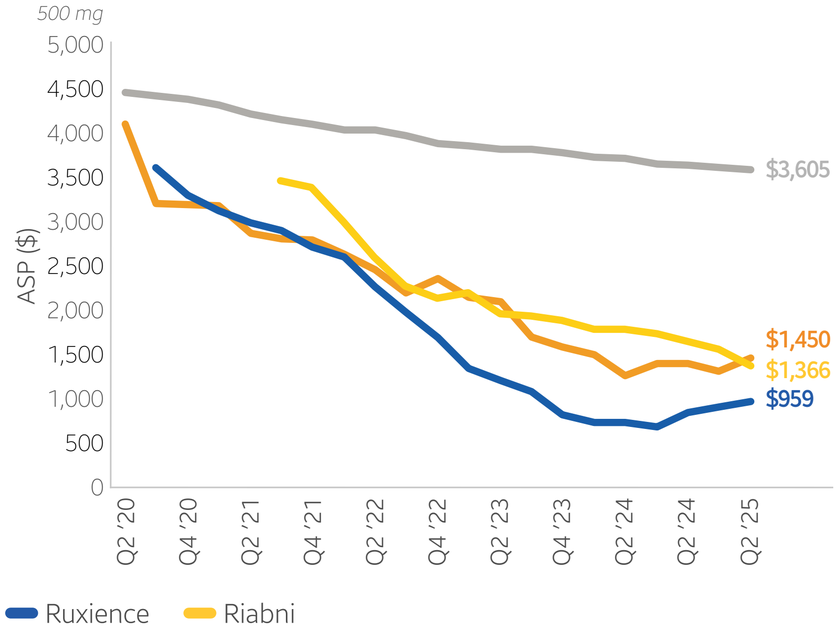


Figure 16. Rituximab ASP Trend[3]



Products are listed in legends in order of launch
ASP: Average Sales Price

Market Share and ASP Trends - Neupogen (Filgrastim)

- As of Q4 2024, the biosimilar share of the filgrastim market has reached 88% (+1% vs. last quarter).
- As of Q2 2025, the average ASP of all biosimilar products is $140 (-1% vs. last quarter).
- In the filgrastim market, lower priced biosimilars are dominating the market.

Figure 17. Filgrastim Volume Market Share[4]

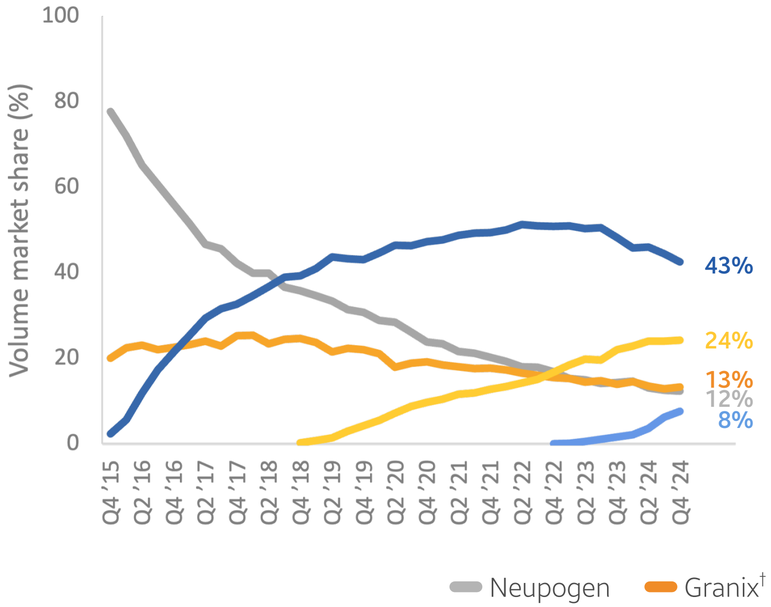
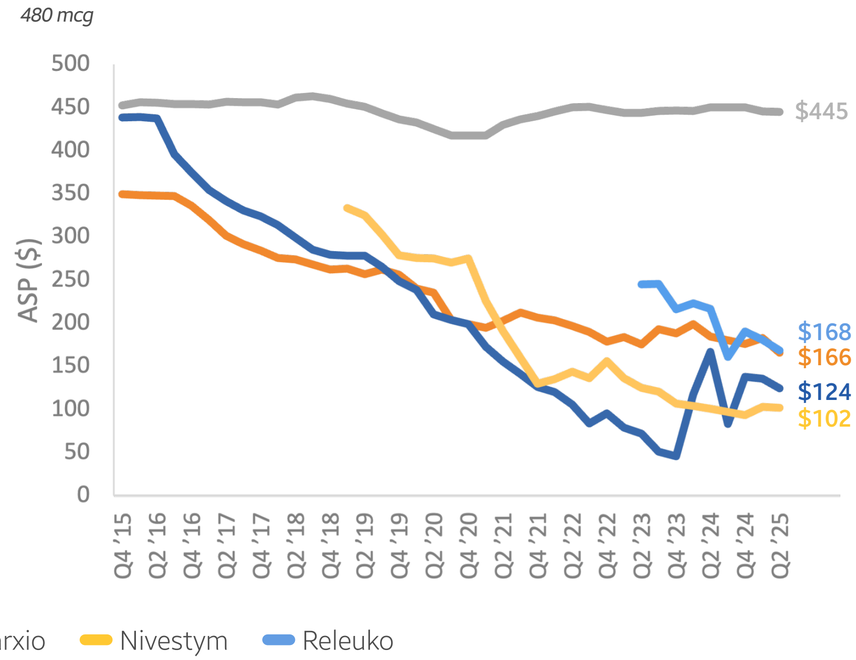


Figure 18. Filgrastim ASP Trend[3]



Neupogen Granix† Zarxio Nivestym Releuko

Legends are listed in order of launch
ASP: Average Sales Price
† Granix is not a biosimilar; it's approved under FDA, a new drug application pathway

Market Share and ASP Trends - Neulasta (Pegfilgrastim)

- As of Q4 2024, the biosimilar share of the pegfilgrastim market has reached 82% (-3% vs. last quarter).
- As of Q2 2025, the average ASP of all biosimilar products is $1,688 (-5% vs. last quarter).
- The pegfilgrastim biosimilar market is competitive with narrow differences in market share and two recent entrants (i.e. Flynetra and Stimufend).
  - In Q4 of 2024, other pegfilgrastim products saw market share increases secondary due to Udenyca experiencing temporary supply issue due to manufacturer capacity constraints.

Figure 19. Pegfilgrastim Volume Market Share[4]

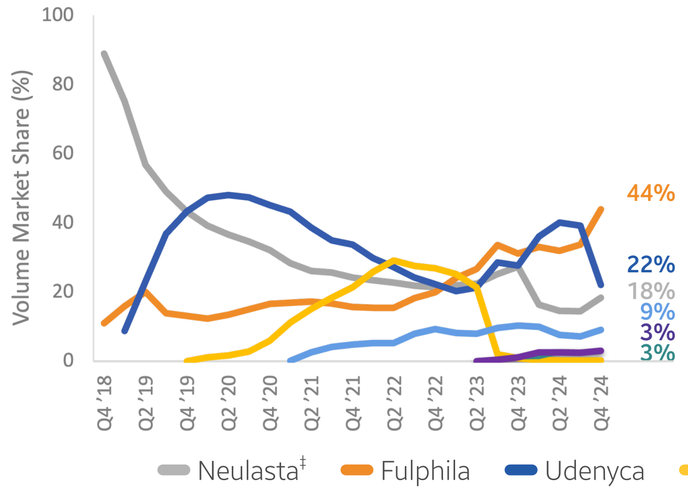
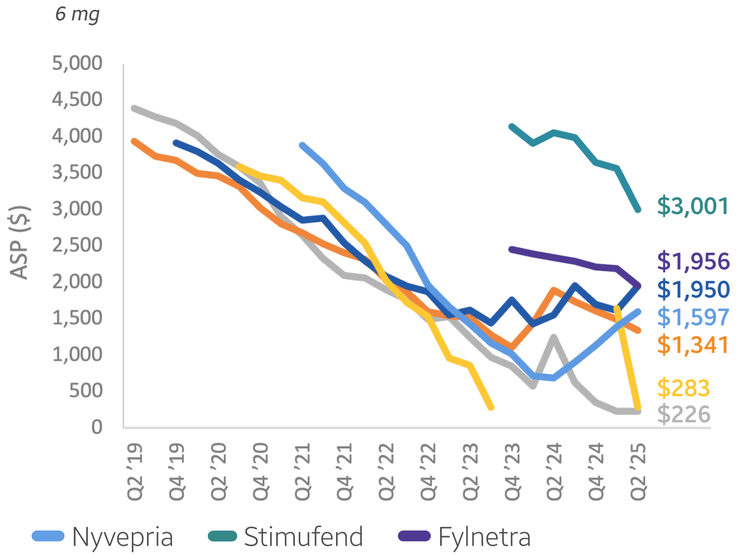


Figure 20. Pegfilgrastim ASP Trend[3]



Neulasta‡ Fulphila Udenyca Ziextenzo† Nyvepria Stimufend Fylnetra

Legends are listed in order of launch **ASP**: Average Sales Price
‡ Onpro is not included † Ziextenzo ASP republished in Q1 2025

Market Share and ASP Trends - Epogen/Procrit (Epoetin alfa)

* Matching the Retacrit ASP has led to a market share decline for the reference products, but they still maintain the majority of market share (58%).

Figure21. Epoetin Alfa Volume Market Share[4]

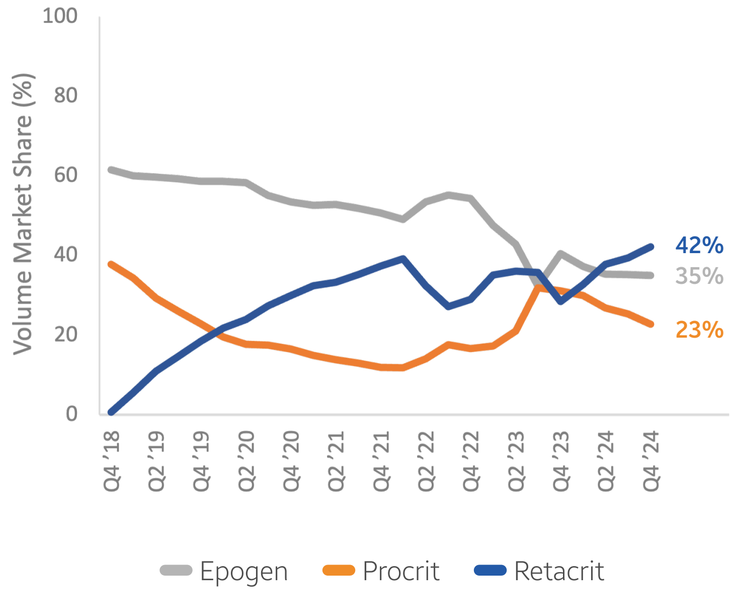
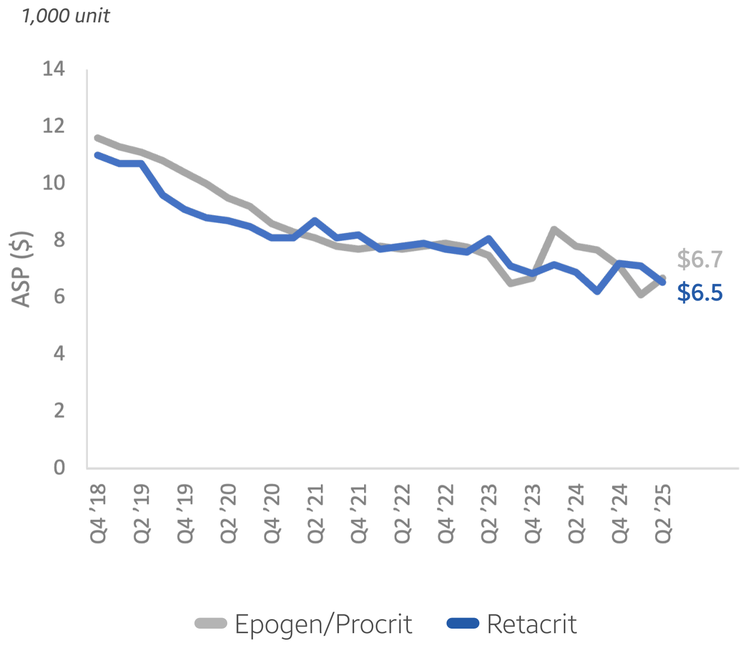


Figure 22. Epoetin alfa ASP Trend[3]



Legends are listed in order of launch
ASP: Average Sales Price

Market Share and ASP Trends - Remicade (Infliximab)

- As of Q4 2024, infliximab biosimilar market share has reached 49% (+1% vs. last quarter).
- As of Q2 2025, the average ASP of all biosimilar products is $189 (+12% vs. last quarter).
- Janssen's competitive ASP pricing and launch of unbranded infliximab of Remicade in Q4 2021 have allowed the reference product to hold onto the market leading position.

Figure 23. Infliximab Volume Market Share[4]

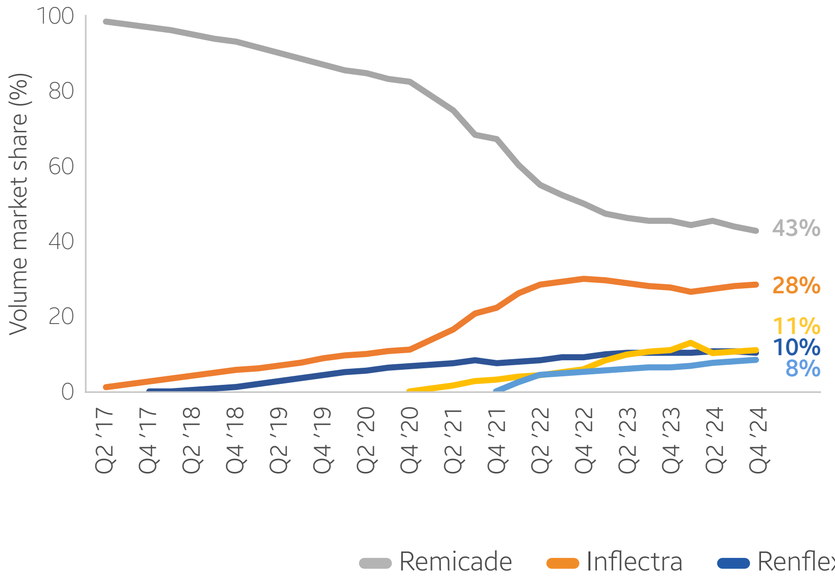
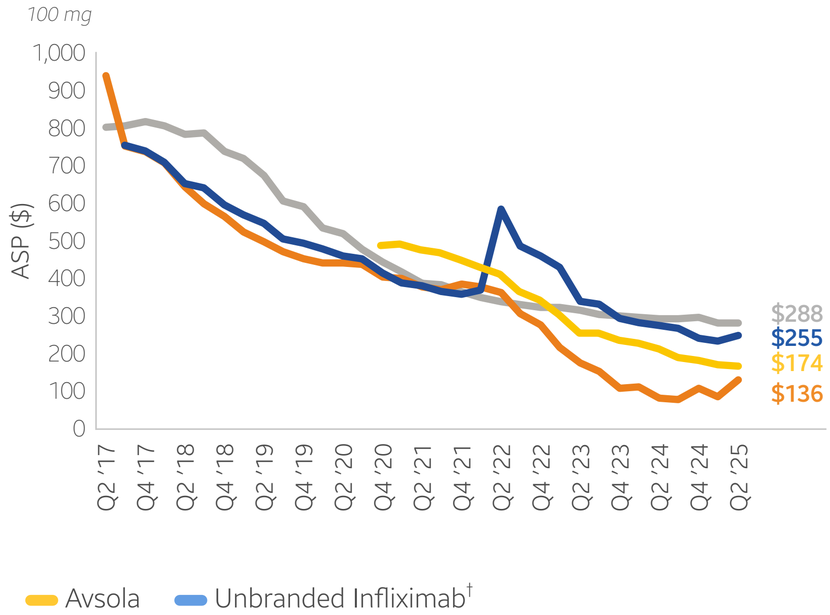


Figure 24. Infliximab ASP Trend[3]



Remicade Inflectra Renflexis Avsola Unbranded Infliximab†

Legends are listed in order of launch
ASP: Average Sales Price
†Janssen's Remicade without the brand name ‡Remicade and Unbranded Infliximab share a J code

Market Share and WAC Trends - Humira (Adalimumab)

- **Excluding Cordavis product dynamics, adalimumab biosimilars' market share has modestly increased in 2025 as Humira's market share continues to slowly erode.**
- **Biosimilar brands provided the market with diverse WAC pricing options.**

1) Hadlima, Yusimry, and Simlandi offer a low WAC: ~85-86% less than Humira.
2) Cyltezo, Amjevita, Hyrimoz, Hulio, Idacio, Yuflyma, and Abrilada offer dual/multiple pricing options (i.e. high and low WAC).
3) Optum Rx entered the adalimumab private-label business through its wholly owned subsidiary, Nuvaila, contracting with Amgen's Amjevita.

Figure 25. Adalimumab Volume Market Share[5]

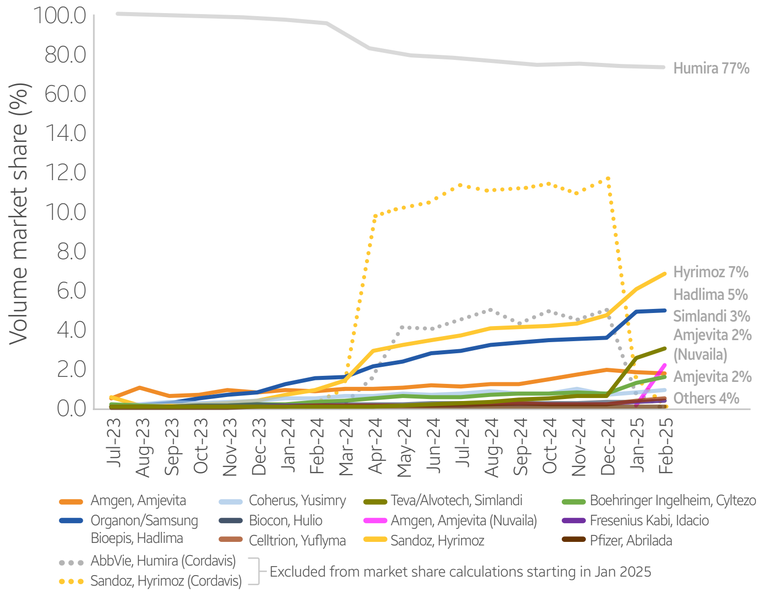
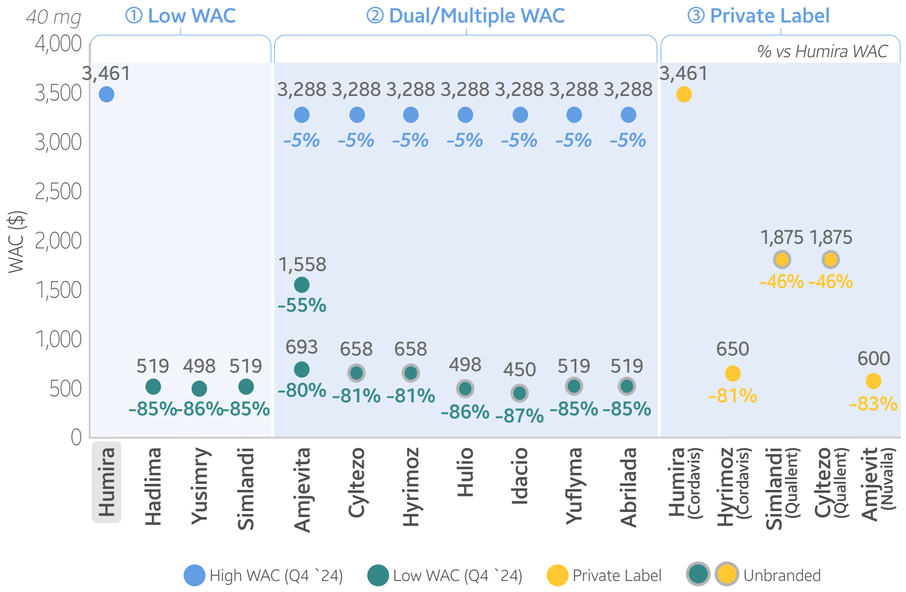


Figure 26. Adalimumab WAC Trend[2]



CVS Health's private label biosimilars, Humira (Cordavis) and Hyrimoz (Cordavis), do not have any published market share data available as of Jan 2025 and thus market share calculations do not reflect these two products.
WAC: Wholesale acquisition cost

Market Share and ASP Trends - Actemra (Tocilizumab)

- As of Q4 2024, tocilizumab biosimilars still hold a low market share, accounting for 1.7% of the total market. However, Tyenne, a tocilizumab biosimilar priced approximately 29% lower than the reference product (based on ASP), is beginning to gain traction and show notable growth in market share.
- As of Q2 2025, the average ASP of all biosimilar products is $1,896 (+3% vs. last quarter).

Figure 27. Tocilizumab Volume Market Share[4]

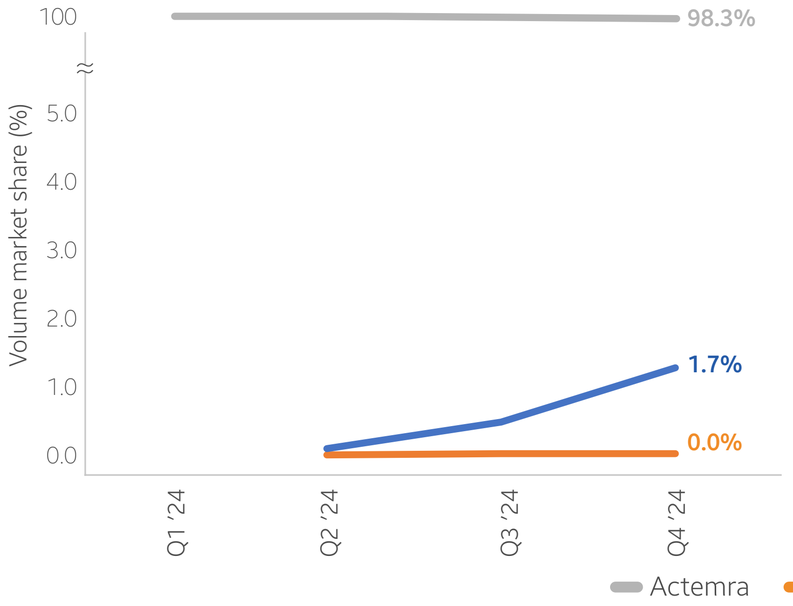
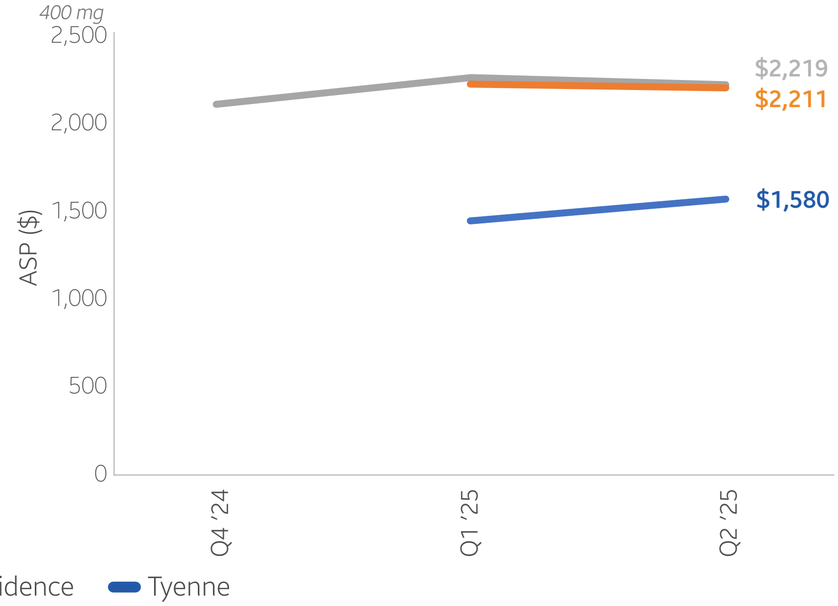


Figure 28. Tocilizimab ASP Trend[3]



WAC: Wholesale acquisition cost
*The WAC price of Actemra Subcutaneous Solution Prefilled Syringe 162 MG/0.9 ML and Subcutaneous Solution Auto-injector 162 MG/0.9 ML

Market Share and WAC Trends - Lantus (Insulin glargine)

- **As of Q4 2024, insulin glargine biosimilar market share is 36% (+1% vs. last quarter)**
- **Sanofi's dual pricing strategy and competitive rates have helped to maintain Lantus' position as the market leader**
- ***Insulin Glargine Market Background***
  - Lantus (Sanofi): reference product, available unbranded
  - Toujeo (Sanofi): higher dose insulin glargine product
  - Rezvoglar (Eli Lilly): Lantus biosimilar, interchangeable
  - Semglee (Biocon): Lantus biosimilar, available unbranded
  - Basaglar (Eli Lilly): ISG product approved via New Drug Application pathway

Figure 29. Insulin Glargine Volume Market Share[4]

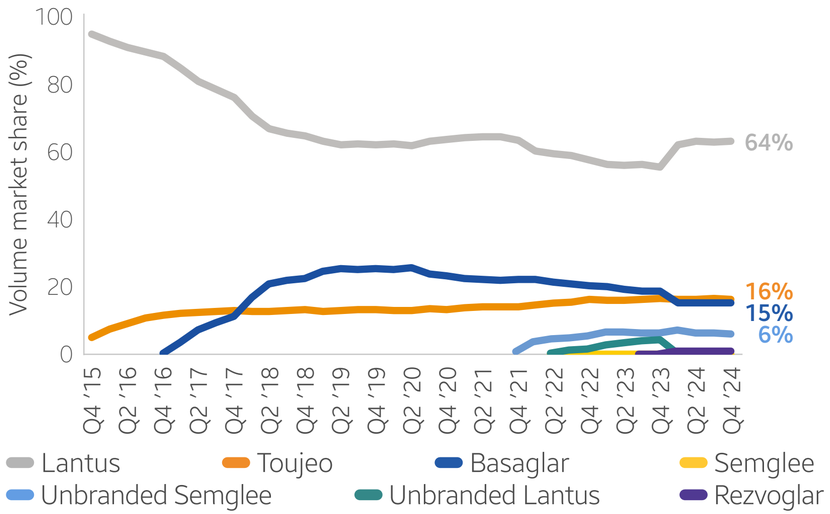
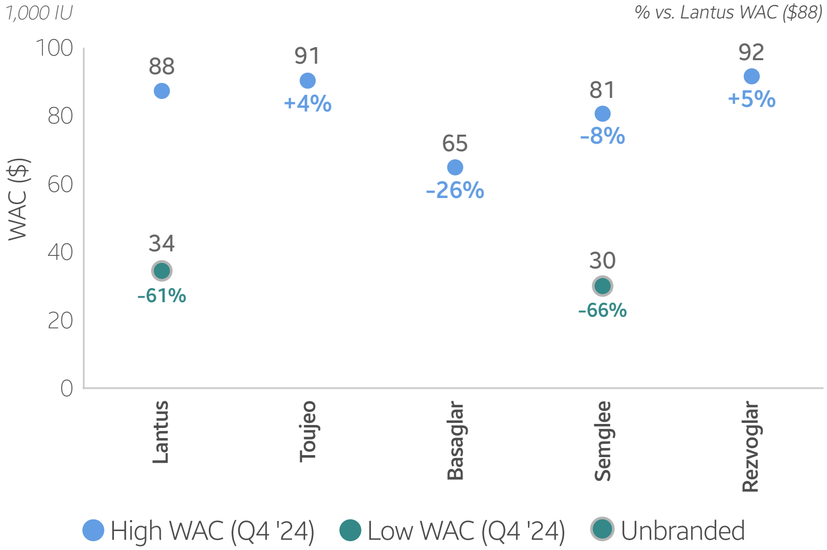


Figure 30. Insulin Glargine WAC Trend[2]



Legends are listed in order of launch
ISG: Insulin glargine; **WAC**: Wholesale Acquisition Cost

Market Share and ASP Trends - Lucentis (Ranibizumab)

* As of Q4 2024, ranibizumab biosimilar market share has reached 49% (-8% vs. last quarter).
* As of Q2 2025, the average ASP of all biosimilar products is $551 (-32% vs. last quarter), with Byooviz showing the greatest decrease in ASP of -51%.

Figure 31. Ranibizumab Volume Market Share[4]

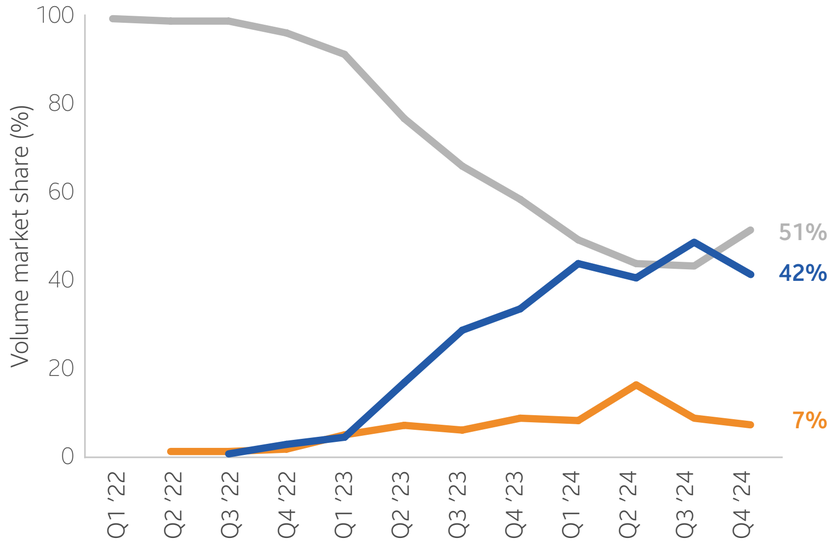
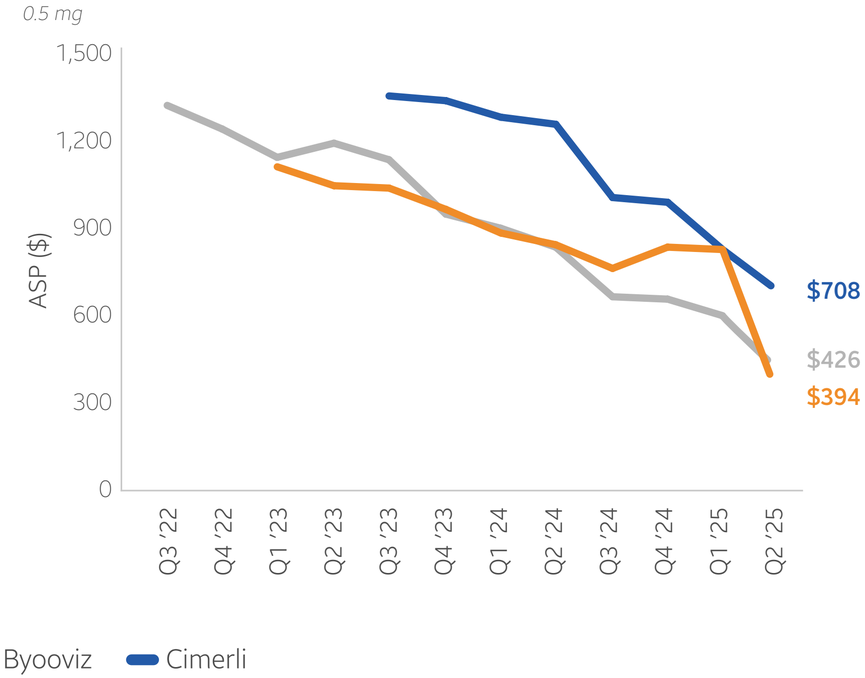


Figure 32. Ranibizumab ASP Trend[3]



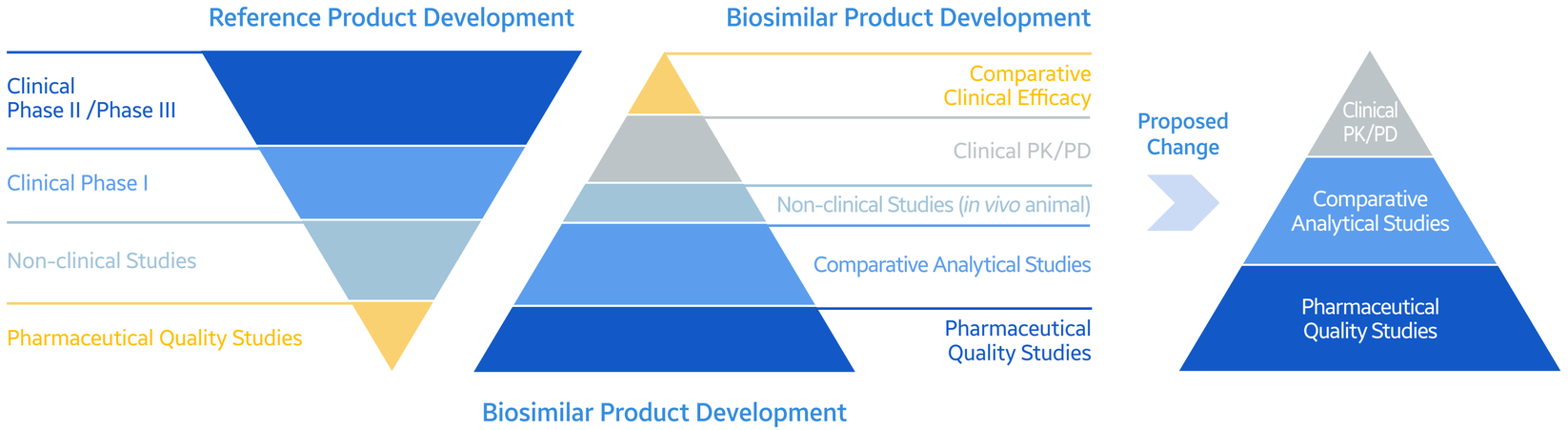
Lucentis Byooviz Cimerli

Legends are listed in order of launch
ASP: Average Sales Price

IV. Biosimilar Deep Dive

Streamlining development helps mitigate biosimilar barriers to entry

- Currently, biosimilar development costs range between **$100 million and $300 million,** with development timelines spanning **seven to eight years**[6].
- Initially regulators leaned on the side of caution by requiring extensive clinical and non-clinical studies to allow for biosimilar regulatory approval, generate a large body of evidence to support understanding of biosimilars, and help to ensure clinician confidence and comfort with biosimilar products.
- Since the approval of the first biosimilars in 2006 in the EU and 2015 in the US, regulatory agencies and the biosimilar industry have accumulated extensive experience in developing, evaluating, and approving biosimilars. As such, the amount of data needed to demonstrate that the biosimilar is highly similar to the reference product is being re-assessed.
- Streamlined biosimilar development will allow more cost-effective and timely biosimilar development, and may allow biosimilars to be developed to a broader array of originator products[7].



Evidence and Opportunities for Streamlining Biosimilar Development

- Two opportunities for streamlining biosimilar development under review by regulatory agencies include:

Clinical Comparative Effectiveness Studies (CES)

- CES are clinical trials that directly compare efficacy and safety of biosimilars with that of the reference product. There is a growing consensus that such studies often do not provide additional meaningful information for regulatory decision-making.
- In September 2023, International Pharmaceutical Regulators Programme Biosimilars Working Group hosted a workshop "Increasing the Efficiency of Biosimilar Development Programs-Reevaluating the Need for Comparative Clinical Efficacy Studies". At this workshop, regulators and industry experts recognized the limitations of CES as they are not likely to be additionally informative with respect to the small differences typically observed in analytical comparisons, particularly if comparative PK show similar profiles[8].
- In April 2025, the EMA released a reflection paper aimed at identifying opportunities to waive CES requirements for biosimilars. For biosimilars where high similarity to the reference product is established through analytical and functional data, and where the mechanism of action is well-understood, CES may be deemed unnecessary[9].

"Considering the advances in the analytical sciences and the extensive regulatory experience gained, *in vivo* non-clinical data and, at least for some less complex biologicals with a straightforward mechanism of action, the importance of dedicated clinical efficacy and safety data should be re-evaluated. Currently, the need for Comparative Efficacy Studies (CES) is increasingly questioned in general." (EMA)

Interchangeable Switching Studies

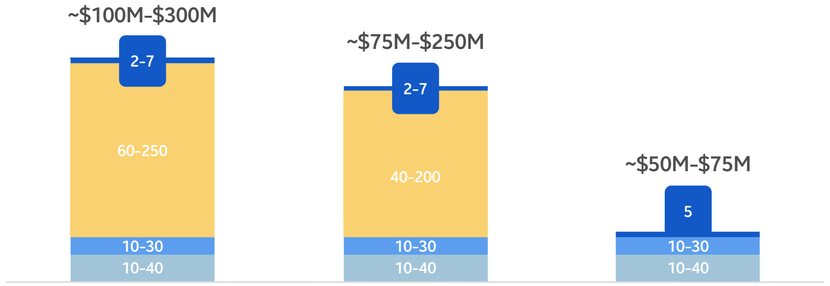
- Unique to the US, the FDA's interchangeability designation sets a higher bar for biosimilars, requiring additional clinical switching studies to earn the right to automatic substitution at the pharmacy level.
- In June 2024, the FDA released an updated guidance that suggests a shift toward a more streamlined approach, acknowledging that robust analytical, functional, and pharmacokinetic (PK) data may, in some cases, provide sufficient evidence without the need for large-scale switching studies[10].

"Experience has shown that for the products approved as biosimilars to date, the risk in terms of safety or diminished efficacy is insignificant following single or multiple switches between a reference product and a biosimilar product. Accordingly, FDA's scientific approach to when a switching study or studies may be needed to support a demonstration of interchangeability has evolved" (FDA 2024 Guidance)

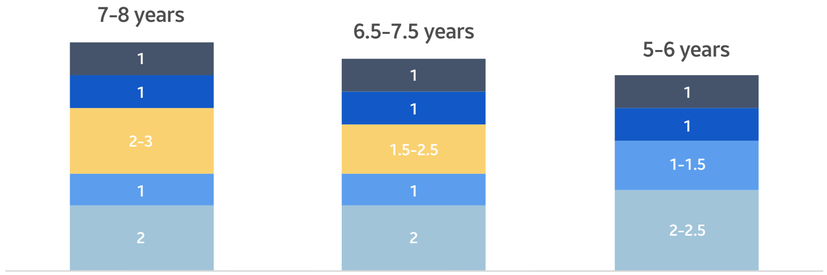
Optimizing Biosimilar Development for Greater Access

- Analyses suggest development streamlining proposals could reduce the US cost of biosimilar development by $50-$225M and shorten the development timeline by 1-2 years[11].
- A globally coordinated approach to streamlined biosimilar development would enhance access and affordability by eliminating redundant clinical studies while maintaining rigorous standards for quality, safety, and efficacy.
- Currently, 90% of biologics facing patent expiry over the next decade lack biosimilar candidates, limiting potential savings[7]. By shortening development timelines, reducing research and development costs, and expediting regulatory reviews, a more efficient framework could enable developers to pursue biosimilars for biologics previously deemed unfeasible.
- Streamlined development will never reduce the development costs of a biosimilar to those of generic small molecule drugs, but nonetheless remains urgent if biosimilars are to fulfil their role in the virtuous cycle. By doing so, biosimilars can both stimulate innovation and enable new originator biologics to find headroom in the healthcare dollar.

Biosimilar Development Cost[11]



Biosimilar Development Timeline[11]



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