SAMSUNG BIOEPIS

Biosimilar Market Report

1st Edition, Q2 2023

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FOREWORD

Since 2013, biosimilars have already generated $56 Billion in savings for the US healthcare system. Moving forward over the next five years, that total is expected to reach $181 Billion in savings, as newly approved biosimilars launch and existing biosimilars see continued uptake in utilization.[1]

Biosimilars continue to play a crucial role in driving down healthcare costs in the US and a collaborative approach is fundamental for the sustainable growth of the US biosimilar market. To support all the stakeholders involved in the exciting journey of biosimilars in the US, Samsung Bioepis will bring you this Biosimilar Market Report every quarter after the Center of Medicare, Medicaid Services (CMS) publishes updated ASP values for each product. We hope to offer this resource as useful context in order to bring up to date information to the forefront of the biosimilar market landscape.

In this first edition of the Samsung Bioepis Biosimilar Market Report, we have included the most recent price trends of all molecules for which biosimilar(s) have launched in addition to insights around interpretations and misconceptions related to the interchangeability of biosimilars.

Each report moving forward will consist of comprehensive updates on pricing and market penetration for all marketed biosimilars currently available in the US. Additionally, every report we will include an article on a current biosimilar topic or trend that is particularly relevant to US market.

Samsung Bioepis is a global pharmaceutical company that is focused on the development and commercialization of biosimilars and we warmly invite you to explore the latest trend of biosimilars in this series.

Thomas Newcomer
Vice President
Head of Market Access, 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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FDA Approval and Launch Status of US Biosimilars

As of April 2023, the FDA has approved a total of 40 biosimilars across 11 unique biological molecules. Of the 40 approvals, 28 biosimilars have been launched in the US market.

- In 2021, Semglee became the first biosimilar to obtain an interchangeability designation from the FDA. Subsequently, three more biosimilars (Cyltezo, Rezvoglar, and Cimerli) have been granted such a designation.
- In January, Amjevita became the first Humira (adalimumab) biosimilar to hit the US Market. Several additional biosimilar competitors are expected to launch later this year into what is likely to be the largest biosimilar market in the US.

Cumulative Approvals
40

Figure 1. Biosimilars Approval and Launch Status in the US[2*]

TA	Oncology			Supportive Care			Immunology			Endocrinology	Ophthalmology
Molecule	Trastuzumab	Bevacizumab	Rituximab	Filgrastim	Pegfilgrastim	Epoetin alfa	Infliximab	Adalimumab	Etanercept	Insulin Glargine	Ranibizumab
Reference Product	Herceptin Roche 1998	Avastin Roche 2004	Rituxan Genentech&Biogen 1997	Neupogen Amgen 1991	Neulasta Amgen 2002	Epogen/Procrit Amgen 1989	Remicade Janssen 1998	Humira AbbVie 2002	Enbrel Amgen 2003	Lantus Sanofi 2000	Lucentis Novartis 2006
Biosimilar	Ogivri Mylan 2017	Mvasi Amgen 2017	Truxima Celltrion&Teva 2018	Zarxio Sandoz 2015	Fulphila Mylan 2018	Retacrit Hospira&Pfizer 2018	Inflectra Celltrion&Pfizer 2016	Amjevita Amgen 2016	Erelzi Sandoz 2016	Semglee Mylan 2021	Byooviz Samsung Bioepis &Biogen 2021
	Herzuma Celltrion&Teva 2018	Zirabev Pfizer 2019	Ruxience Pfizer 2019	Nivestym Hospira&Pfizer 2018	Udenyca Coherus 2018		Renflexis Samsung Bioepis &Organon 2017	Cyltezo Boehringer Ingelheim 2017	Eticovo Samsung Bioepis 2019	Rezvoglar Eli Lilly 2021	Cimerli Coherus 2022
	Ontruzant Samsung Bioepis &Organon 2019	Alymsys Amneal 2022	Riabni Amgen 2020	Releuko Amneal&Kashiv 2022	Ziextenzo Sandoz 2019		Avsola Amgen 2019	Hyrimoz Sandoz 2018			
	Trazimera Pfizer 2019	Vegzelma Celltrion 2022			Nyvepria Hospira&Pfizer 2020		Ixifi Pfizer 2017	Hadlima Samsung Bioepis &Organon 2019			
	Kanjinti Amgen 2019				Stimufend Fresenius Kabi 2022			Abrilada Pfizer 2019			
					Fylnetra Amneal&Kashiv 2022			Hulio Mylan 2020			
								Yusimry Coherus 2021			
								Idacio Fresenius Kabi 2022			

Launched Not launched Interchangeability

FDA: Food and Drug Administration; TA: Therapeutic area
*Trade marks are not described to all brands

Figure 1-1. Biosimilars Approval and Launch Status in the US[2*] (with Suffix)

TA	Oncology			Supportive Care			Immunology			Endocrinology	Ophthalmology
Molecule	Trastuzumab	Bevacizumab	Rituximab	Filgrastim	Pegfilgrastim	Epoetin alfa	Infliximab	Adalimumab	Etanercept	Insulin Glargine	Ranibizumab
Reference Product	Herceptin (trastuzumab) Roche 1998	Avastin (bevacizumab) Roche 2004	Rituxan (rituximab) Genentech&Biogen 1997	Neupogen (Filgrastim) Amgen 1991	Neulasta (pegfilgrastim) Amgen 2002	Epogen (epoetin alfa) Amgen 1898	Remicade (infliximab) Janssen 1998	Humira (adalimumab) AbbvVie 2002	Enbrel (etanercept) Amgen 2003	Lantus (insulin glargine) Sanofi 2000	Lucentis (ranibizumab) Novartis 2006
Biosimilar	Ogivri (trastuzumab-dkst) Mylan 2017	Mvasi (bevacizumab-awwb) Amgen 2017	Truxima (rituximab-abbs) Celltrion&Teva 2018	Zarxio (filgrastim-sndz) Sandoz 2015	Fulphila (pegfilgrastim-jmdb) Mylan 2018	Retacrit (epoetin alfa-epbx) Hospira&Pfizer 2018	Inflectra (infliximab-dyyb) Celltrion&Pfizer 2016	Amjevita (adalimumab-atto) Amgen 2016	Erelzi (etanercept-szzs) Sandoz 2016	Semglee (insulin glargine-yfgn) Mylan 2021	Byooviz (Ranibizumab-nuna) Samsung Bioepis &Biogen 2021
	Herzuma (trastuzumab-pkrb) Celltrion&Teva 2018	Zirabev (bevacizumab-bvzr) Pfizer 2019	Ruxience (rituximab-pvvr) Pfizer 2019	Nivestym (filgrastim-aafi) Hospira&Pfizer 2018	Udenyca (pegfilgrastim-cbqv) Coherus 2018		Renflexis (infliximab-abda) Samsung Bioepis &Organon 2017	Cyltezo (adalimumab-adbm) Boehringer Ingelheim 2017	Eticovo (etanercept-ykro) Samsung Bioepis 2019	Rezvoglar (insulin glargine-aglr) Eli Lilly 2021	Cimerli (Ranibizumab-eqrn) Coherus 2022
	Ontruzant (trastuzumab-dttb) Samsung Bioepis &Organon 2019	Alymsys (bevacizumab-maly) Amneal 2022	Riabni (rituximab-arrx) Amgen 2020	Releuko (filgrstim-ayow) Amneal&Kashiv 2022	Ziextenzo (pegfilgrastim-bmez) Sandoz 2019		Avsola (infliximab-axxq) Amgen 2019	Hyrimoz (adalimumab-adaz) Sandoz 2018			
	Trazimera (trastuzumab-qyyp) Pfizer 2019	Vegzelma (Bevacizumab-adcd) Celltrion 2022			Nyvepria (pegfilgrastim-apgf) Hospira&Pfizer 2020		Ixifi (infliximab-qbtx) Pfizer 2017	Hadlima (adalimumab-bwwd) Samsung Bioepis &Organon 2019			
	Kanjinti (trastuzumab-anns) Amgen 2019				Stimufend (pegfilgrastim-fpgk) Fresenius Kabi 2022			Abrilada (adalimumab-afzb) Pfizer 2019			
					Fylnetra (pegfilgrastim-pbbk) Amneal&Kashiv 2022			Hulio (adalimumab-fkjp) Mylan 2020			
								Yusimry (adalimumab-aqvh) Coherus 2021			
								Idacio (adalimumab-aacf) Fresenius Kabi 2022			

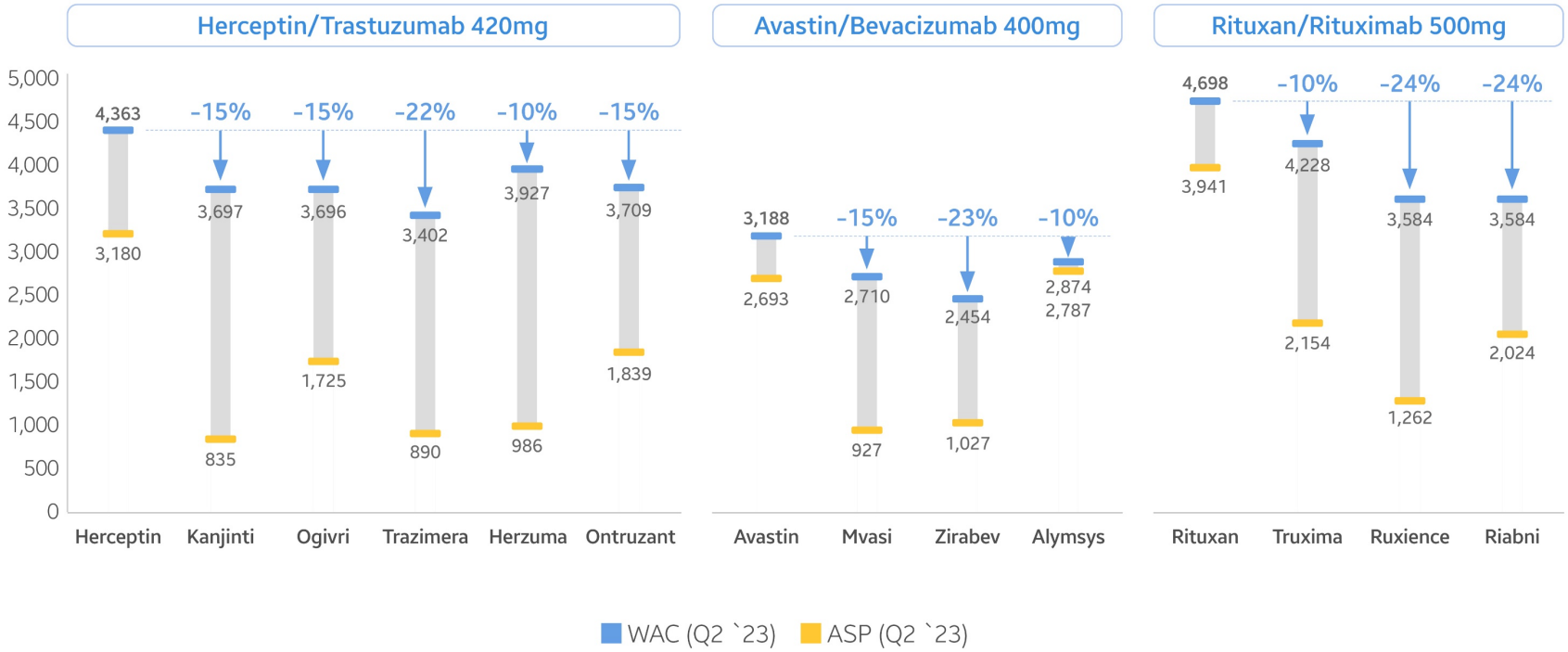
Launched Not launched Interchangeability

FDA: Food and Drug Administration; TA: Therapeutic area
*Trade marks are not described to all brands

Oncology WAC and ASP – As of Q2 2023

- Across oncological biosimilars, the stated WAC represents a modest discount (between 10-25%) compared to the reference product.
- Savings are seen in ASP where oncology biosimilars can save the health care system more than 60% compared to their reference products.

Figure 3. Q2 2023 WAC and ASP[3,4]

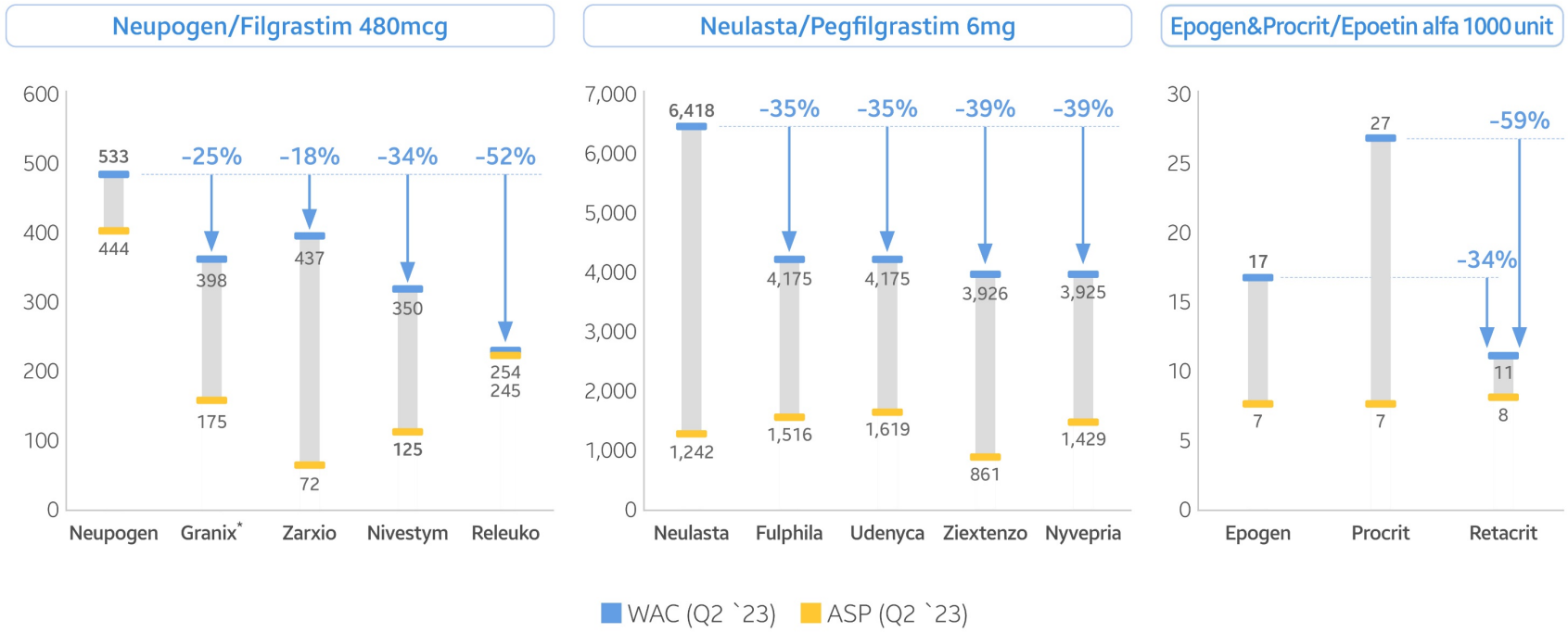


ASP: Average sales price; WAC: Wholesale acquisition cost

Supportive Care WAC and ASP - As of Q2 2023

- Neulasta and Epogen/Procrit match biosimilars' ASP in an effort to retain market share.
- However, Neupogen maintains higher ASP relative to biosimilars.

Figure 4. Q2 2023 WAC and ASP[3,4]

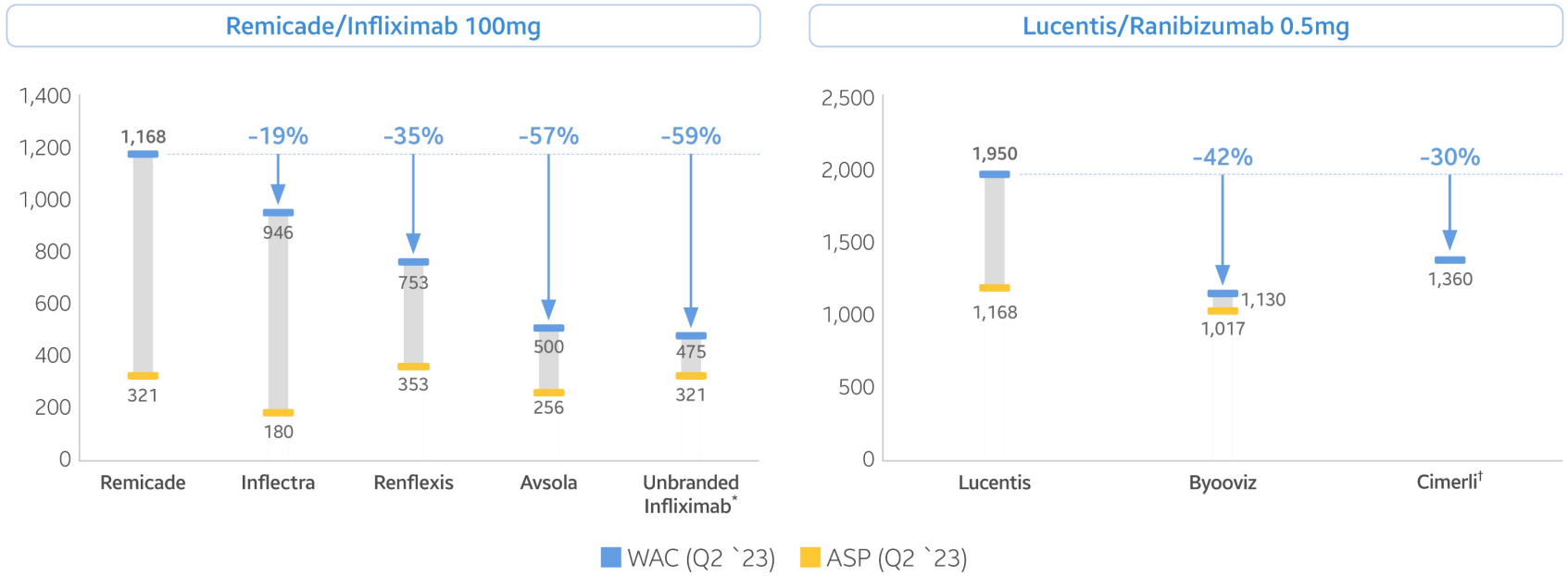


Products are listed in order of launch
ASP: Average sales price; WAC: Wholesale acquisition cost
*Granix is not a biosimilar. It's approved under FDA, a new drug application pathway

Immunology & Ophthalmology WAC and ASP - As of Q2 2023

- Infliximab biosimilars launched with progressively lower WACs. The first biosimilar, Inflectra, only discounted 19% vs the reference product in Q2 2023, but subsequent launches of Avsola and unbranded infliximab had discounted WAC by over 50%.
- Recent ranibizumab biosimilar launches have already led to lower costs.

Figure 5. Q2 2023 WAC and ASP[3,4]

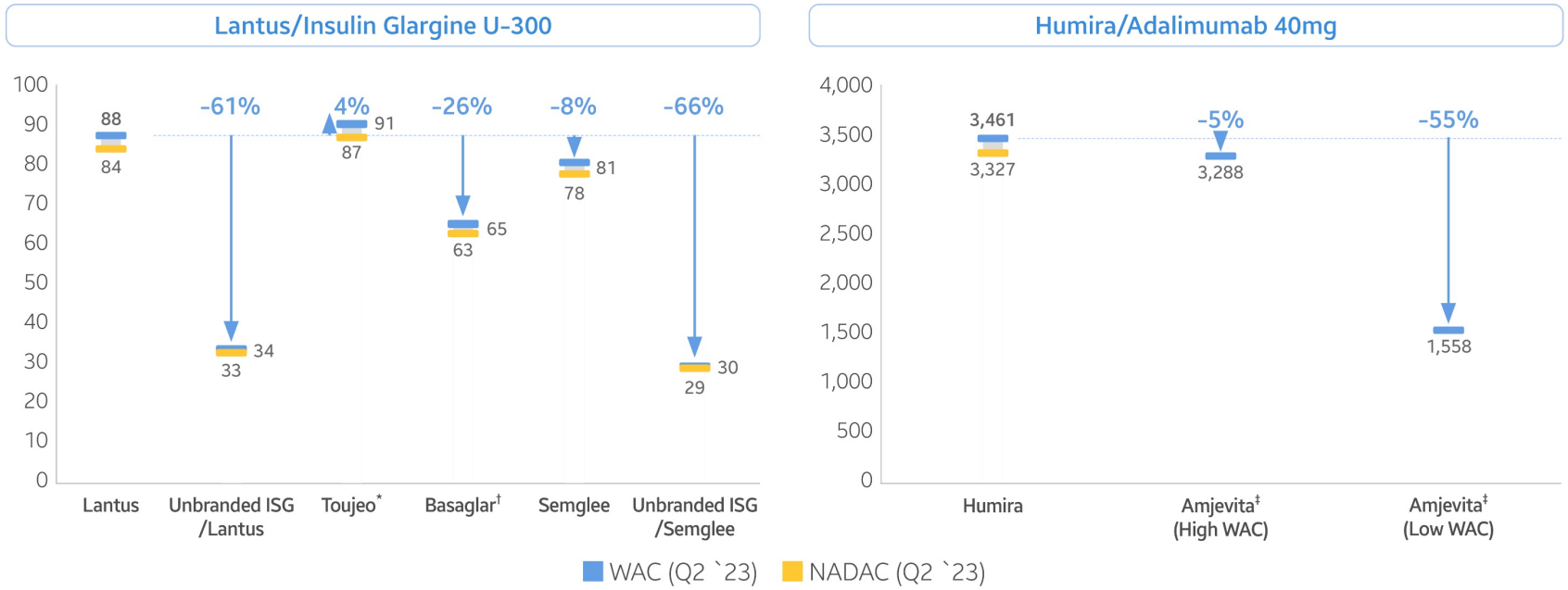


Products are listed in order of launch
ASP: Average sales price; WAC: Wholesale acquisition cost
*Unbranded Infliximab is Remicade without the brand name
†Cimerli ASP is not published yet

Immunology & Endocrinology WAC and NADAC - As of Q2 2023

- Insulin glargine & adalimumab categories reflect recent pricing practices such as "Unbranded biologics" and high/low WAC options
- With no published ASP for products under the pharmacy benefit it is difficult to ascertain the true net price, but NADAC comparisons show the potential for deep discounts and savings in insulin and adalimumab classes.

Figure 6. Q2 2023 WAC and NADAC[3,5]

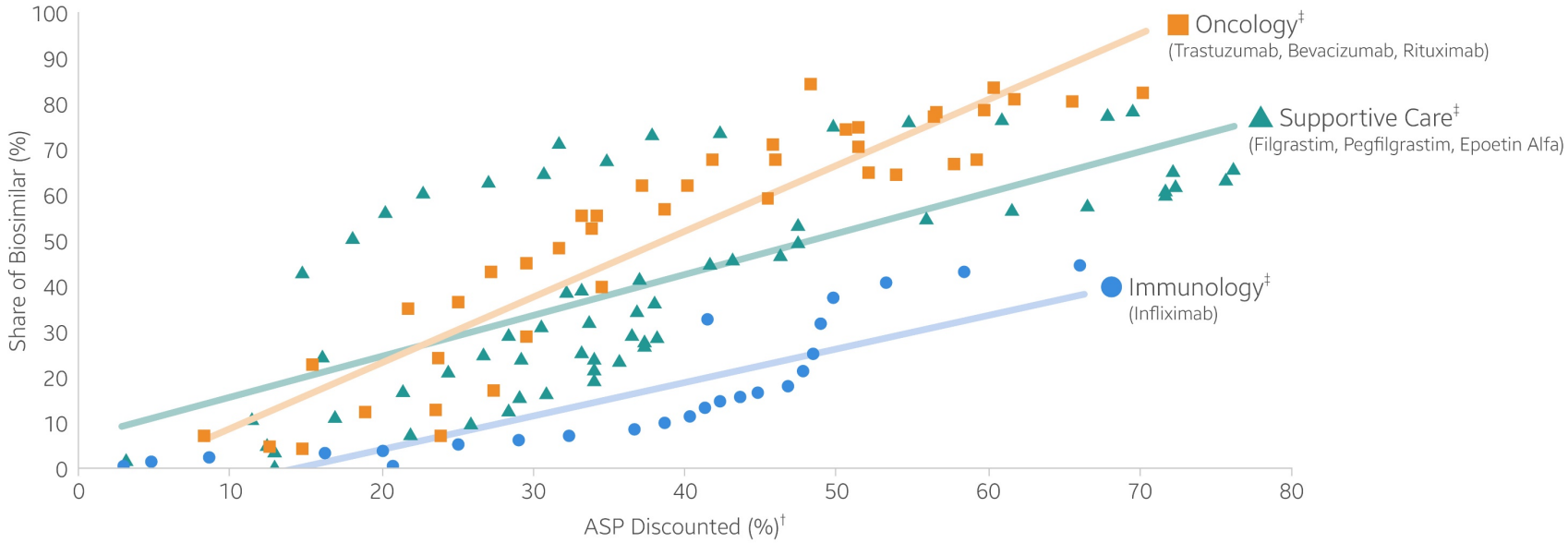


Products are listed in order of launch
WAC: Wholesale acquisition cost; NADAC:National average drug acquisition cost; ISG: Insulin glargine
*Toujeo is high dose version of Lantus
†Basaglar is not a biosimilar because it's approved under FDA, a new drug application pathway
‡Amjevita NADAC price is not published yet

Increased Biosimilar Usage Shows Correlation to Lower Costs

- The below scatter chart shows a positive correlation between biosimilar usage (market share) and price erosion (ASP discount) which indicates a strong relationship between lower biosimilar prices and the higher shares.
- The slope of oncology line is steeper than others, demonstrating that the oncology category is likely more price-sensitive than supportive care or immunology.

Figure 7. Scatter Chart of Price Discount vs. Share of Biosimilar*

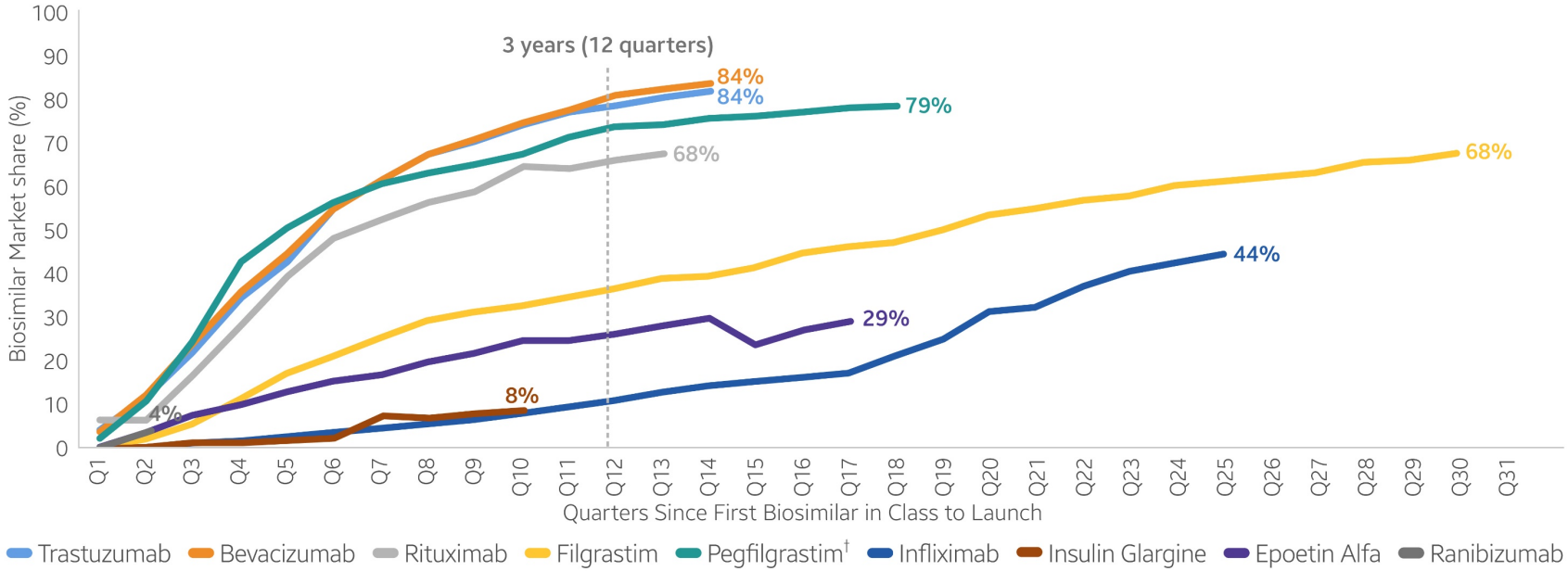


*Ranibizumab is not included due to price data is not enough to see correlation and molecules in which ASP does not exist are also excluded
†Biosimilar ASP discounted % vs. reference product ASP when the first biosimilar launched
‡ Oncology linear equation: y = 1.4451x - 0.0575, R^2 = 0.8486; Supportive Care linier equation: y = 0.8986x + 0.0661, R^2 = 0.5151; Immunology equation: y = 0.736x - 0.1061, R^2 = 0.7336

Biosimilar Uptake Varies by Molecule, but Acceptance has been Greater in Oncology than other TAs

- **On average biosimilars gain 53% market share in three years (12 quarters) post initial launch.**
- **The oncology TA* and pegfilgrastim have seen faster acceptance of biosimilars compared to other TAs and molecules.**
  - After 3 years, the average biosimilar share was 75%, while the biosimilar share in other TAs was only 25% in the same time period.

Figure 8. Biosimilar Market Share Post-Launch[6]

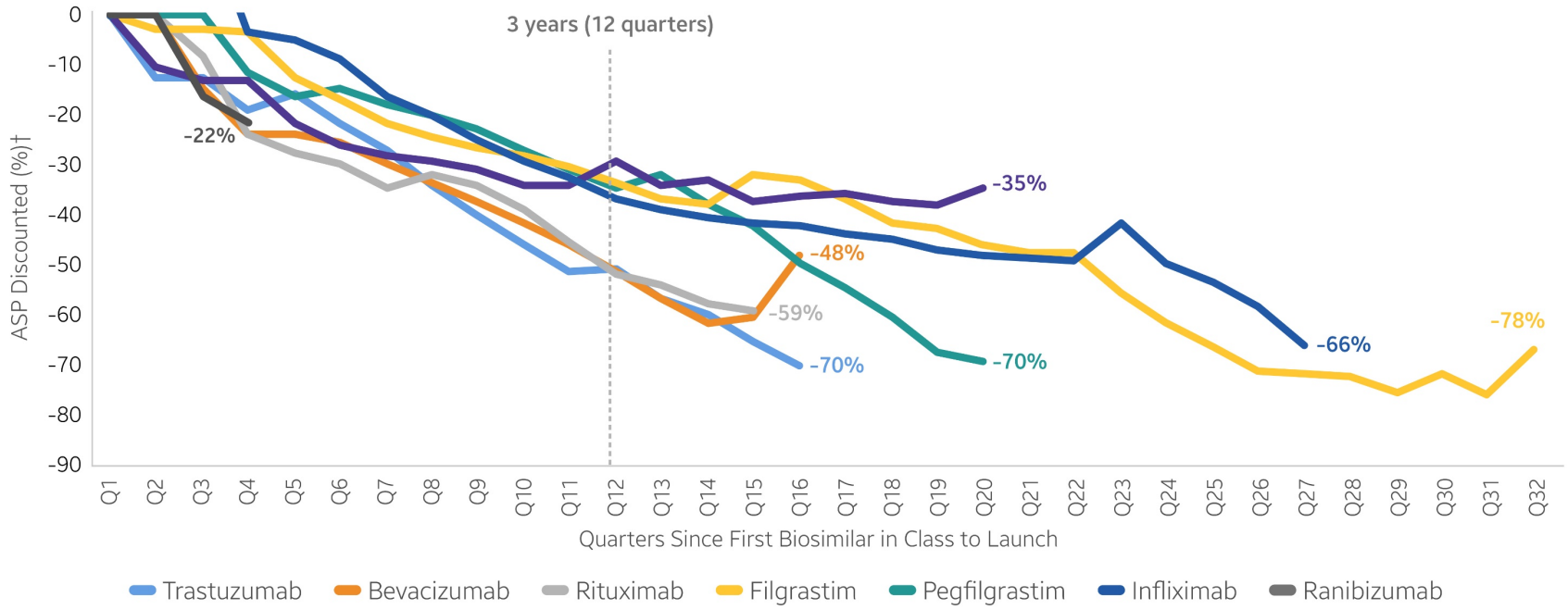


TA: Therapeutic area
*: Trastuzumab, bevacizumab, and rituximab are included
†Onpro is not included

Biosimilars have Reduced Drug Costs across Multiple TAs by Lowering Prices

- **Biosimilar launches have led to significant price decreases over time. ASP declined 41% on average three years (12 quarters) post first biosimilar launch.**
- **Bevacizumab and filgrastim ASPs have seen increases following new competitive launches.**
  - Bevacizumab and filgrastim ASPs have seen increases following new biosimilar launches.

Figure 9. ASP Trend by Molecule[4]



TA: Therapeutic area; ASP: Average sales price
*: Trastuzumab, bevacizumab, and rituximab are included
†: ASP discounted % vs. reference product ASP when first biosimilar in class launch

Market Share and ASP Trends - Herceptin (Trastuzumab)

- **As of Q4 2022, the biosimilar share of the trastuzumab market has reached 82% .**
  - The first biosimilar of trastuzumab has been the market leader since Q4 2020.
- **As of Q2 2023, the average ASP of all products is $1,576 (-63%) and the average for biosimilars alone is $1,255 (-70%) vs. the reference product's ASP at the time of the first biosimilar launch.**

Figure 10. Trastuzumab Volume Market Share[6]

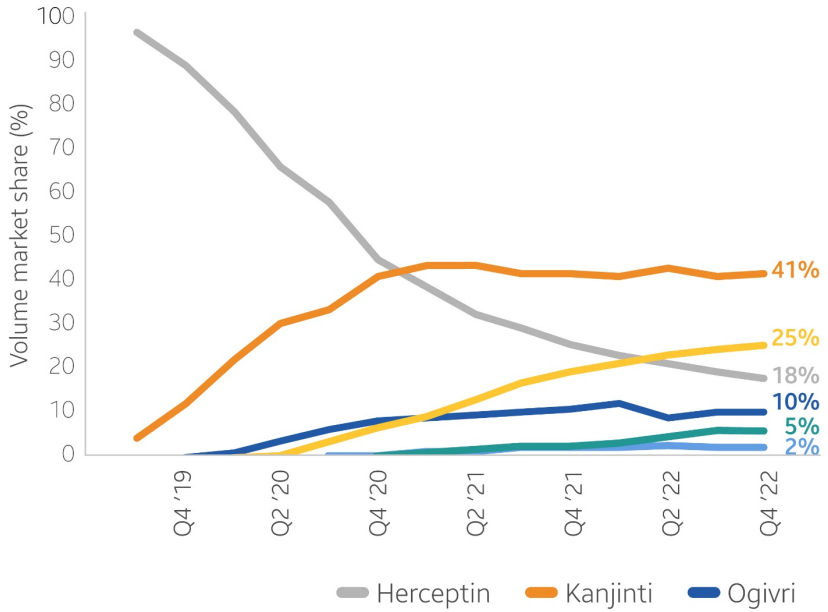
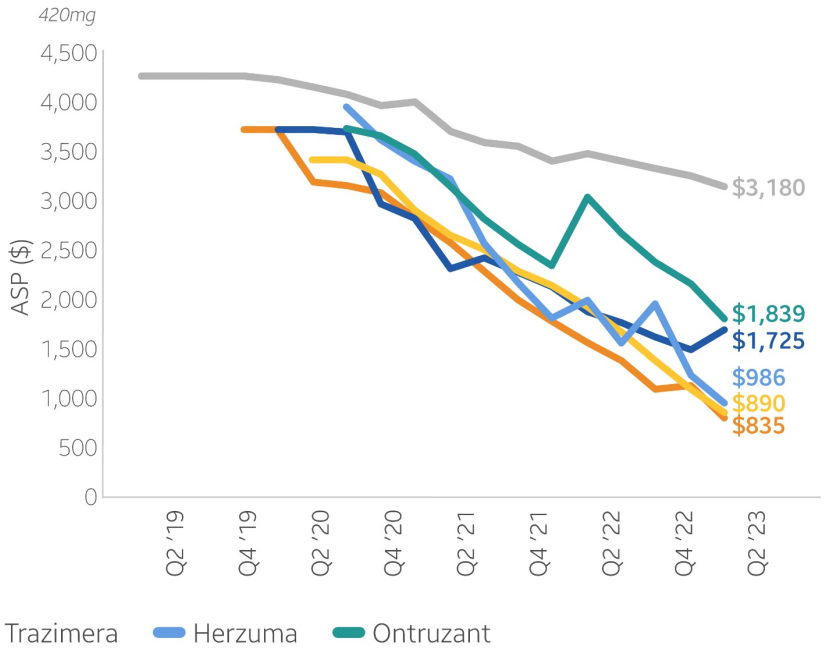


Figure 11. Trastuzumab ASP Trend[4]



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 2022, the biosimilar share of the bevacizumab market was 84%.**
  - Both biosimilars have surpassed the bevacizumab reference product in market share.
- **As of Q2 2023, the average ASP of all products is $1,858 (-39%) and the average for biosimilars alone is $1,580 (-48%) vs the reference product's ASP at the time of the first biosimilar launch.**

Figure 12. Bevacizumab Volume Market Share[6]

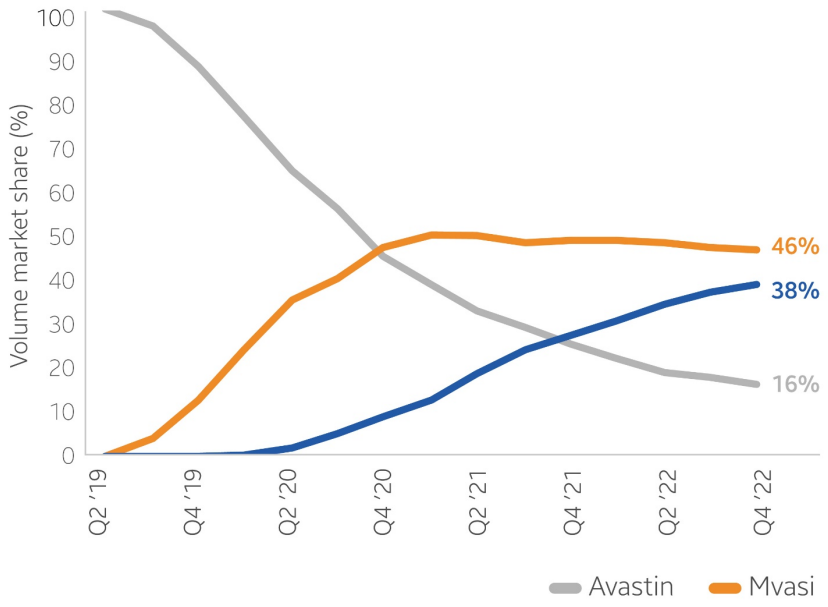
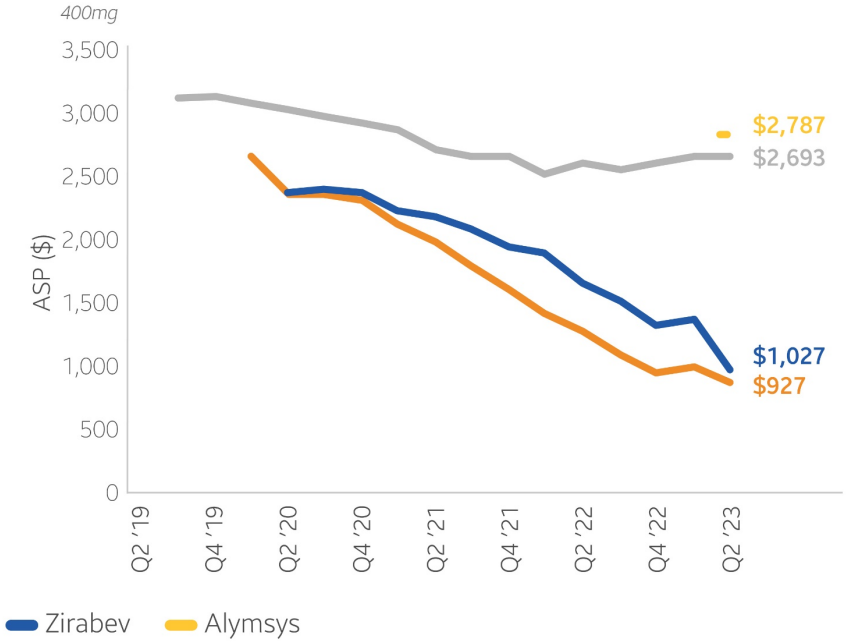


Figure 13. Bevacizumab ASP Trend[4]



Products are listed in legends in order of launch
ASP: Average sales price

Market Share and ASP Trends - Rituxan (Rituximab)

- **As of Q4 2022, the biosimilar share of the rituximab market was 68%.**
  - A rituximab biosimilar has been the market leader since Q3 of 2022.
- **As of Q2 2023, the average ASP of all products is $2,345 (-47%) and the average for biosimilars alone is $1,813 (-59%) vs. the reference product's ASP at the time of the first biosimilar launch.**

Figure 14. Rituximab Volume Market Share[6]

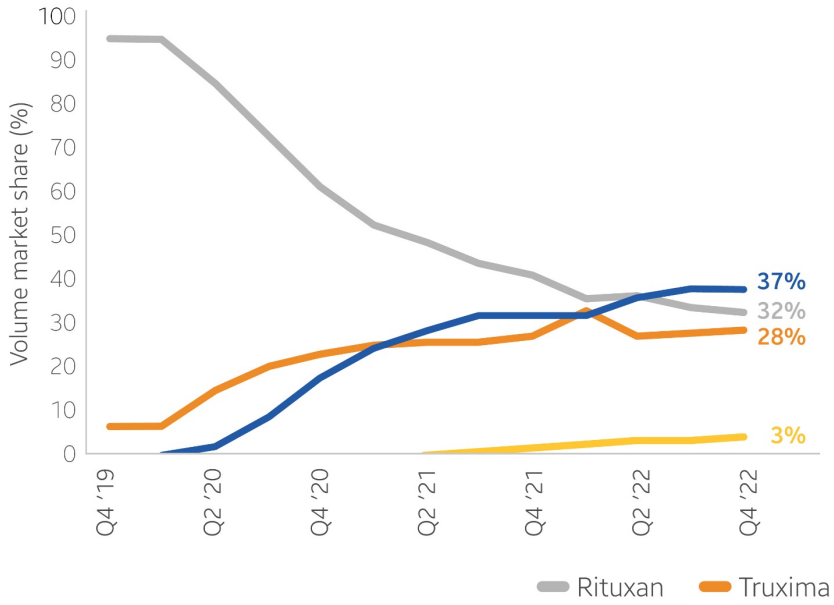
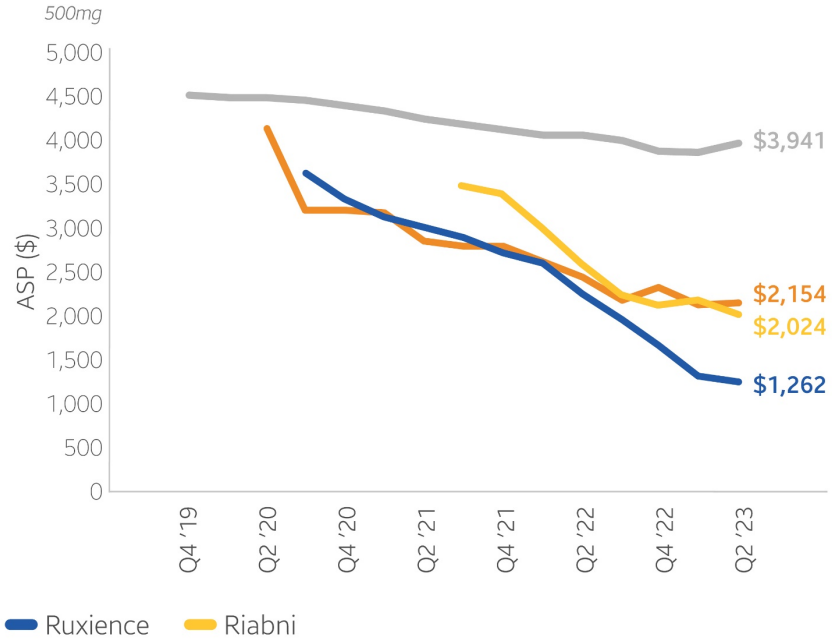


Figure 15. Rituximab ASP Trend[4]



Rituxan Truxima Ruxience Riabni

Products are listed in legends in order of launch
ASP: Average sales price

Market Share and ASP Trends - Neupogen (Filgrastim)

- **As of Q4 2022, the biosimilar share of the filgrastim market has reached 68%.**
  - The first filgrastim biosimilar to launch has been the US market leader since Q3 2018.
  - The other three brands, including the reference product, each trail with about 17% of the market.
- **As of Q2 2023, the average ASP of all products is $212 (-53%) and the average for biosimilars alone is $147 (-67%) vs. the reference product's ASP at the time of the first biosimilar launch.**

Figure 16. Filgrastim Volume Market Share[6]

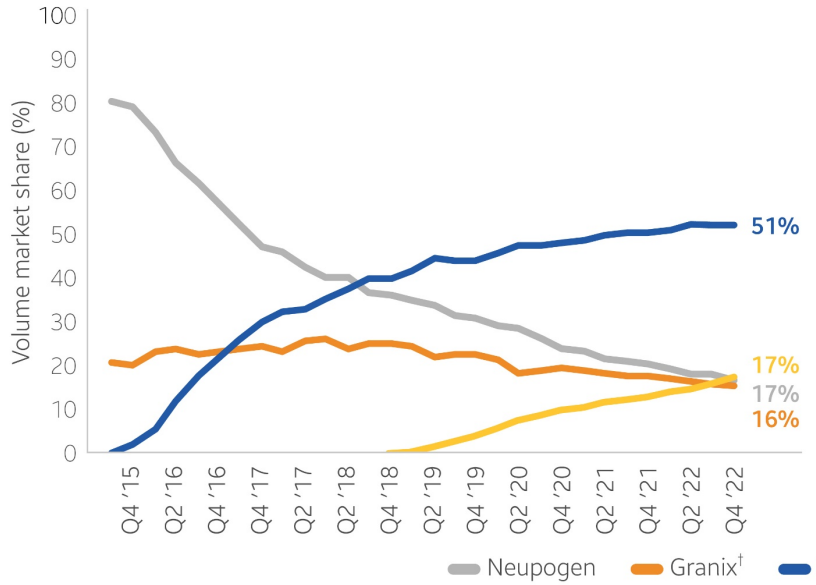
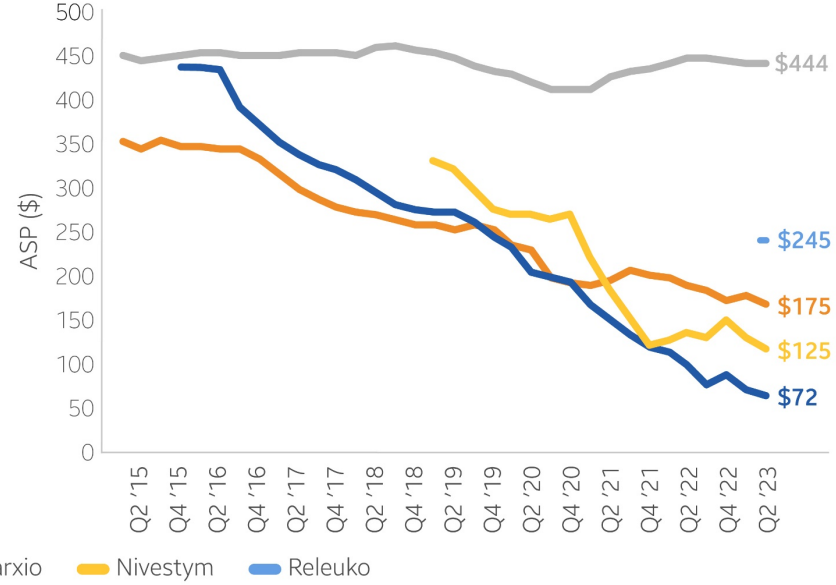


Figure 17. Filgrastim ASP Trend[4]



Products are listed in legends in order of launch
ASP: Average sales price
† Granix is not abiosimilar; It's approved under FDA, a new drug application pathway

Market Share and ASP Trends - Neulasta (Pegfilgrastim)

- **As of Q4 2022, the biosimilar share of the pegfilgrastim market was 79%.**
  - Note that, Stimufend, the 5th Pegfilgrastim biosimilar has now launched, but is not yet captured in the market share or ASP data.
- **As of Q2 2023, the average ASP of all products is $1,334 (-70%) and the average for biosimilars alone is $1,356 (-70%) vs. the reference product's ASP at the time of the first biosimilar launch.**

Figure 18. Pegfilgrastim Volume Market Share[6]

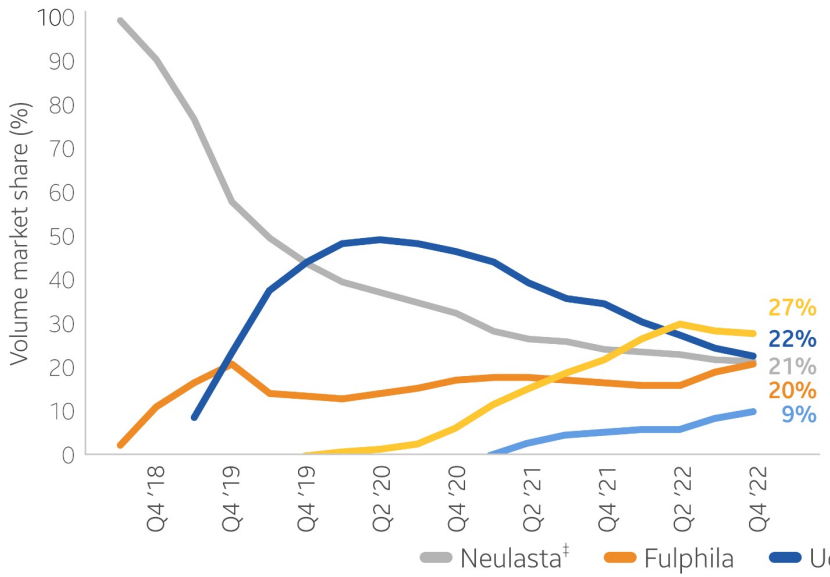
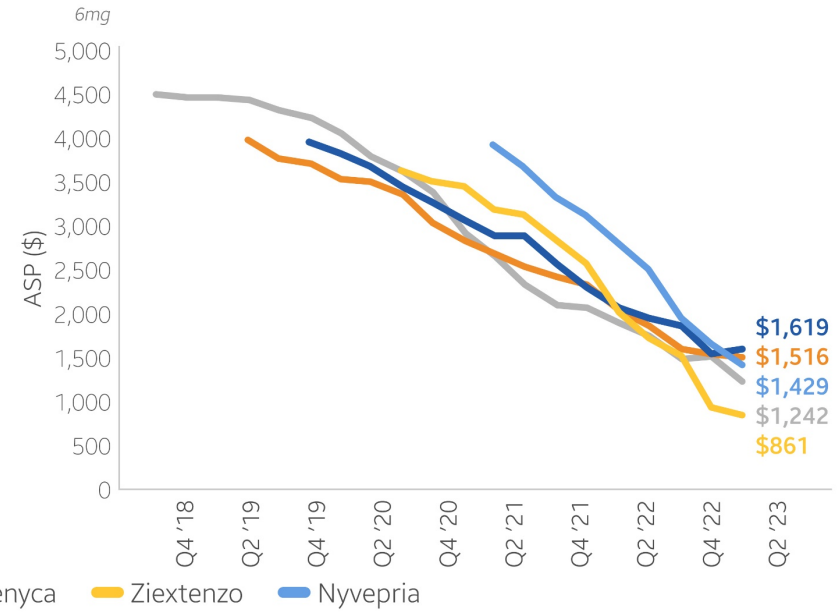


Figure 19. Pegfilgrastim ASP Trend[4]



Products are listed in legends in order of launch
ASP: Average sales price
‡: Onpro is not included

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

- Retracrit is only biosimilar in Epoetin alfa and its launch has led to an ASP decline of 35% which is less than other molecules that have more than two biosimilars.
- By matching ASP, the two reference products have maintained a combined 72% share.

Figure20. Epoetin Alfa Volume Market Share[6]

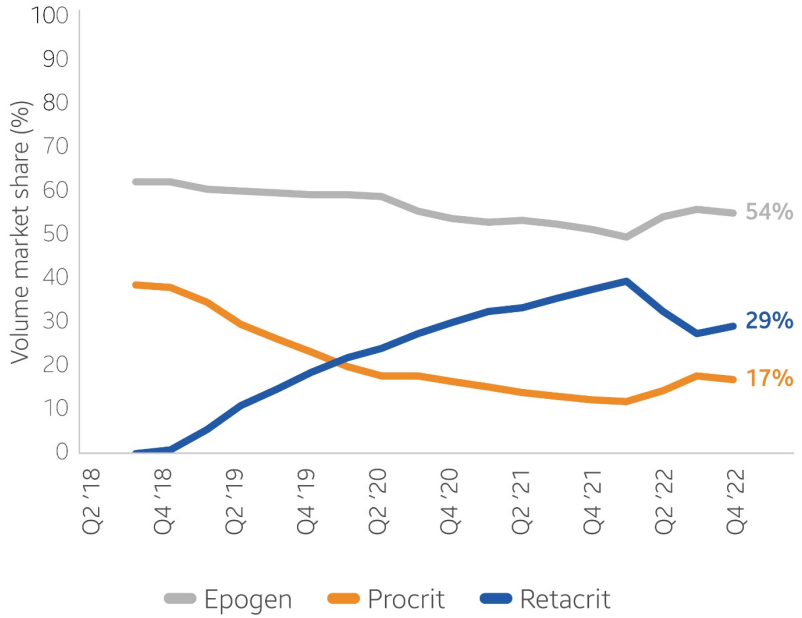
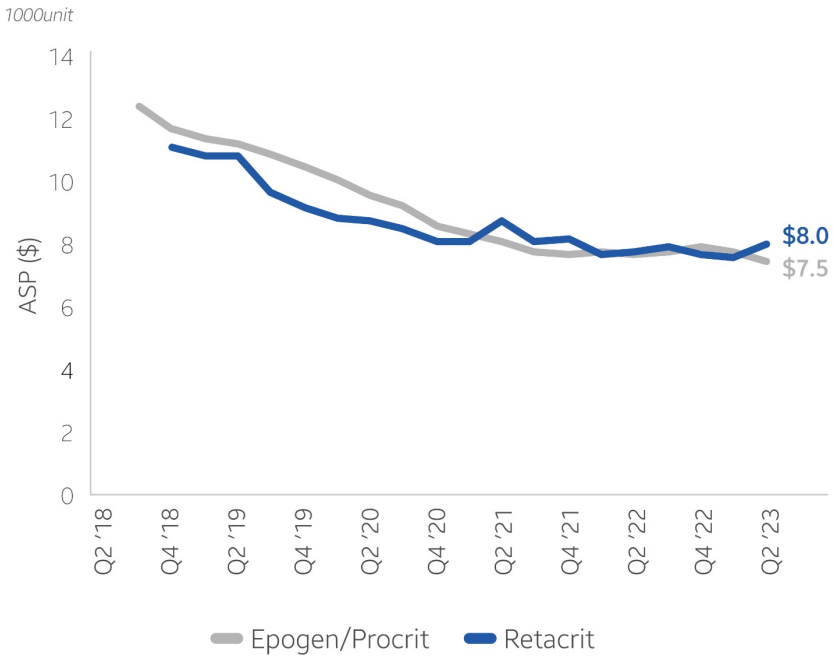


Figure 21. Epoetin Alfa ASP Trend[4]



Products are listed in legends in order of launch
ASP: Average sales price

Market Share and ASP Trends - Remicade (Infliximab)

- **After a slow start, the Infliximab biosimilar market began to accelerate in year three.**
  - As of Q4 2022, Infliximab biosimilar market share has reached 44%.
- **Janssen launched an unbranded biosimilar of Remicade in Q4 2022, re-accelerating the price erosion that had slowed in 2020/21.**
- **As of Q2 2023, the average ASP of all products is $278 (-64%) and the average for biosimilars alone is $263 (-66%) vs. the reference product's ASP at the time of the first biosimilar launch.**

Figure 22. Infliximab Volume Market Share[6]

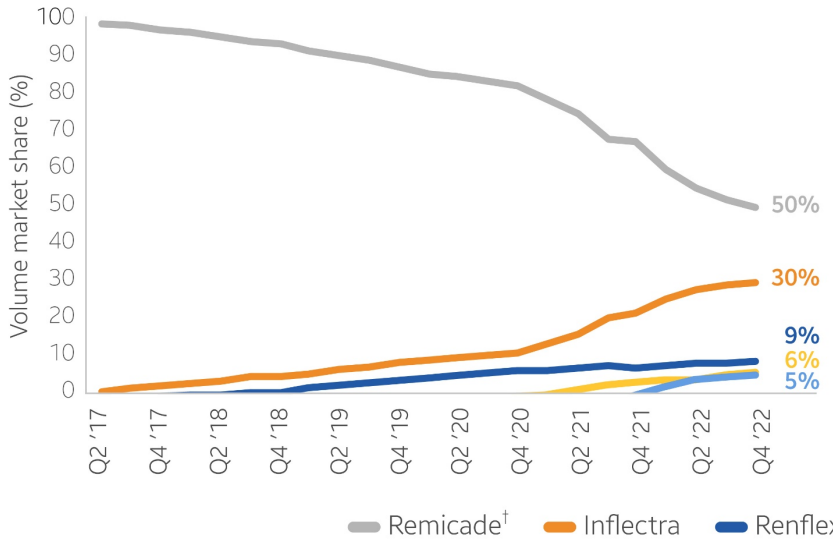
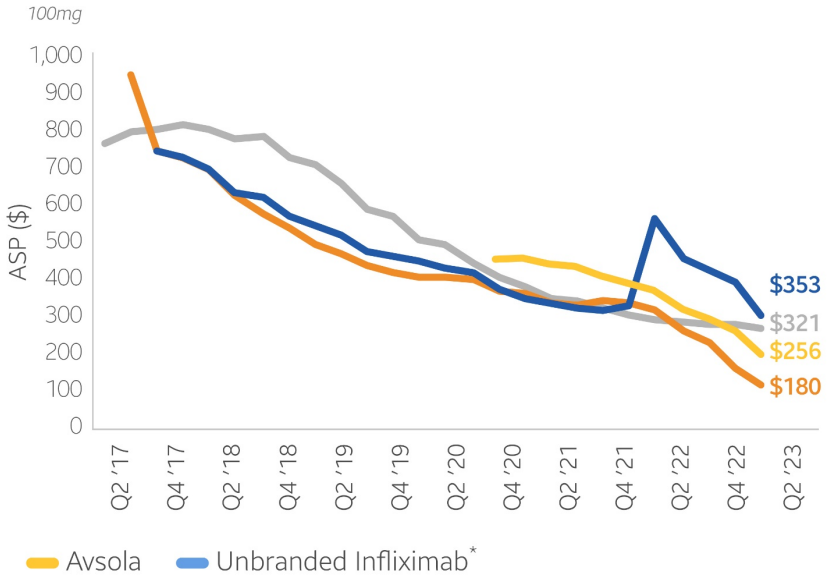


Figure 23. Infliximab ASP Trend[4]



Remicade† Inflectra Renflexis Avsola Unbranded Infliximab*

Products are listed in legends in order of launch
ASP: Average sales price
*Unbranded Infliximab is Remicade without the brand name
†Remicade and Unbranded Infliximab share their J code

Market Trends - Humira (Adalimumab)

- **With annual revenue approaching $20B – and still growing at 7% -- Humira (adalimumab) represents the largest opportunity for US biosimilar manufacturers.**
  - Launched in 2018, the high concentration formulation of adalimumab now accounts for over 85% of total sales.
- **Amjevita was the first Humira biosimilar to enter the US Market in January. While share data is not yet available, it has offered customers two pricing options:**
  - One with a higher WAC, just 5% less the Humira but with significant rebate opportunities and the other with a much lower WAC that is discounted by 55% compared to Humira WAC ($3,461).
- **An additional seven biosimilars have gained FDA approval and are expected launch later this year.**

Figure 24. Humira Sales and Strength Portion[6,7]

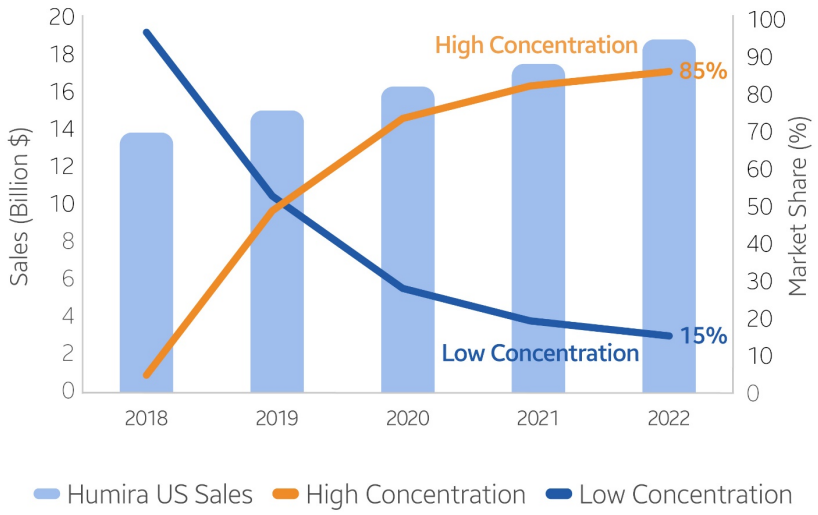
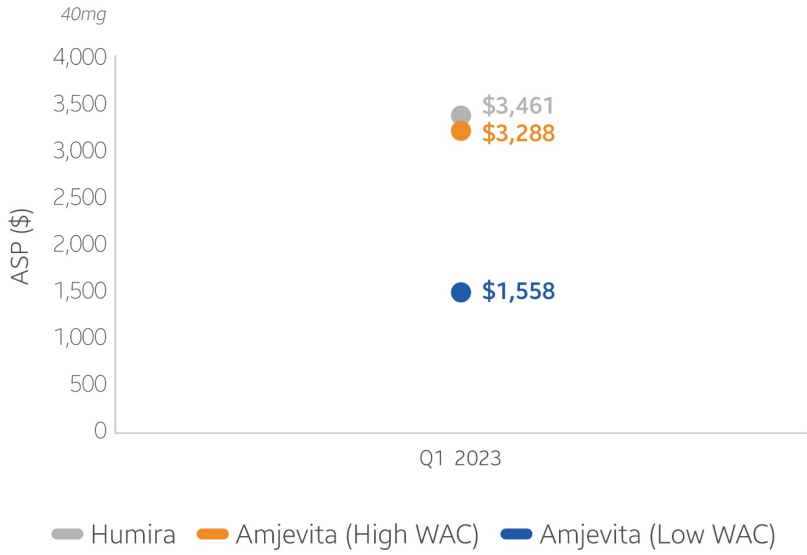


Figure 25. Adalimumab WAC Trend[3]



WAC: Wholesale acquisition cost

Market Share and NADAC Trends - Lantus (Insulin glargine)

- **Sanofi currently markets three versions of insulin glargine(ISG): the reference product, Lantus; Toujeo (a higher dose ISG); and an unbranded ISG, which can be thought as the biologic version of an 'authorized generic.'**
- **Semglee, which launched in 2020, is the only biosimilar in this market.**
  - Semglee also has launched its unbranded ISG in 2022.
  - Basaglar is a version of insulin glargine that is not considered a Lantus biosimilar due to it's approved under FDA, a new drug application pathway.
- **By analyzing NADAC, we can see that the unbranded ISGs are discounted by as much as 66%, compared to Lantus.**
  - Semglee, after initially launching at a similar discount, increased its price to within 10% of Lantus' in 2022 when it received an interchangeability designation and launched an unbranded ISG as a lower priced alternative.

Figure 26. Insulin Glargine Volume Market Share[6]

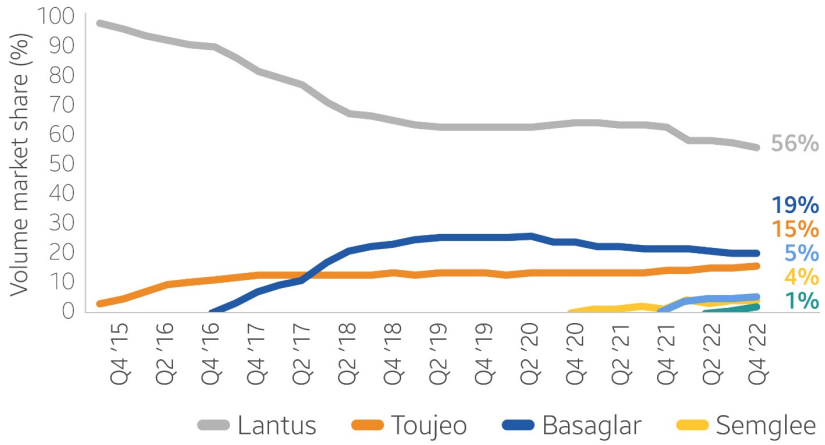
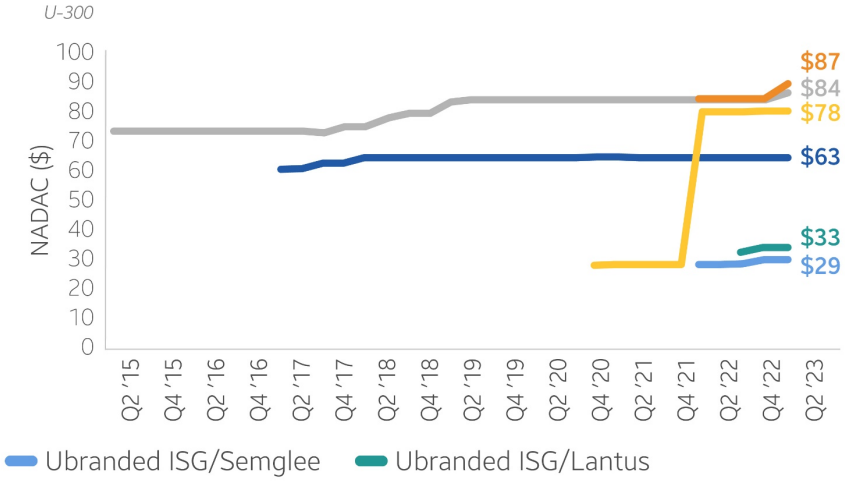


Figure 27. Insulin Glargine NADAC Trend[5]



Products are listed in legends in order of launch
ISG: Insulin Glargine; NADAC: National average drug acquisition cost

Market Share and ASP Trends - Lucentis (Ranibizumab)

- As of Q4 2022, the biosimilar share of the ranibizumab market was only 4%, as the first biosimilar, Byooviz, had launched two quarter previously and Cimerli entered in next quarter.
- As of Q2 2023, the average ASP of all products is $1,092 (-16%). Byooviz, the only biosimilar on the market has an ASP of $1,017 (-22%) vs. the reference product's ASP at the time of the first biosimilar launch.

Figure 28. Ranibizumab Volume Market Share[6]

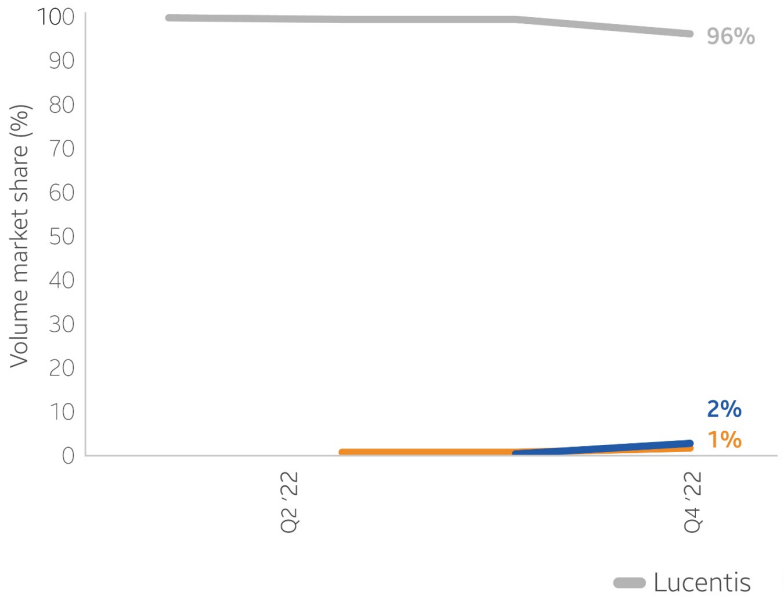
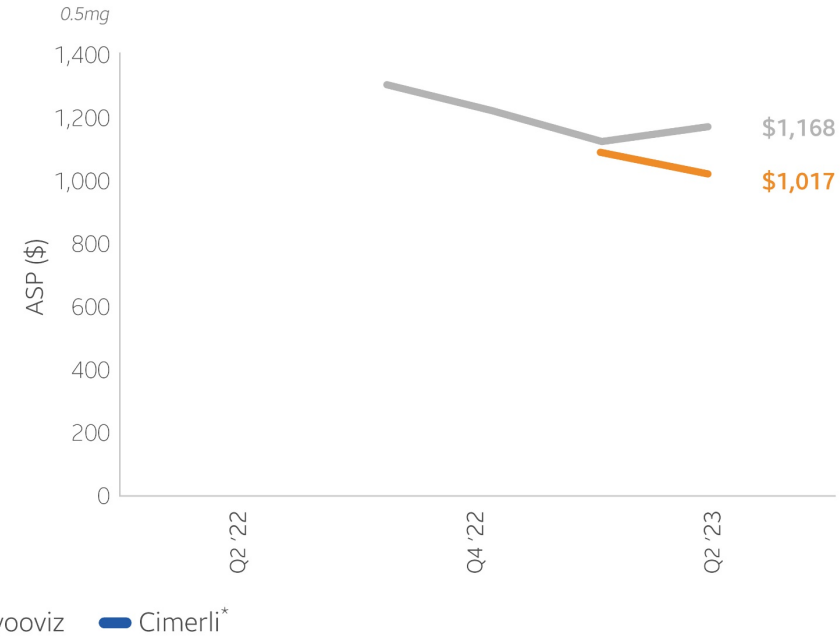


Figure 29. Ranibizumab ASP Trend[4]



Lucentis Byooviz Cimerli*

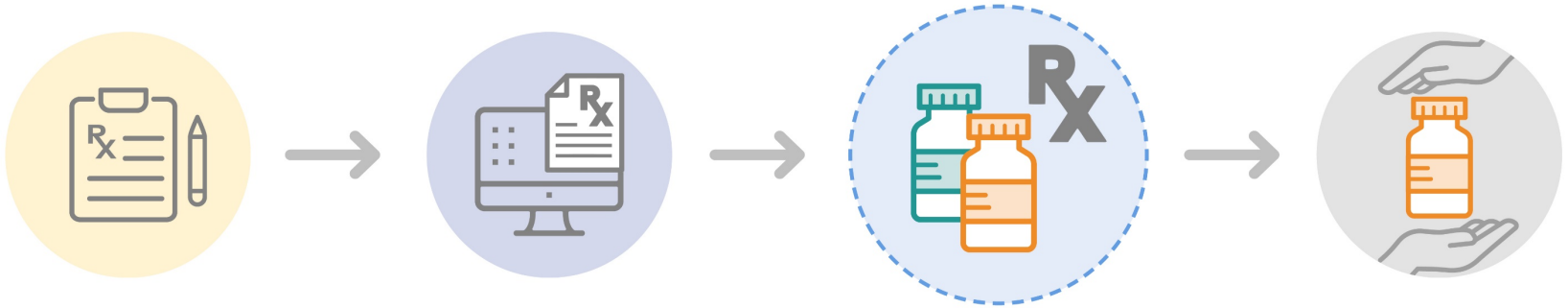
Products are listed in legends in order of launch
ASP: Average sales price
*Cimerli ASP is not published yet

What is FDA Interchangeability Designation?

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) was enacted on March 23, 2010 and granted the FDA the authority to designate certain biologics as interchangeable. Subsequently, the FDA defined interchangeable as a product that "may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product".

The interchangeability designation is unique to biosimilars and simply indicates that a patient may be switched between the interchangeable biosimilar and its reference product by a pharmacist without the approval of the prescribing HCP. A subsequent interchangeability designation does not change product's safety or efficacy and should not be used to infer that interchangeable biosimilars are in any way superior to other biosimilars.

Pharmacy-Level Substitution[8]



Doctor prescribes the reference product

Script goes to the Pharmacy

Pharmacist substitutes the interchangeable biosimillar for the reference product

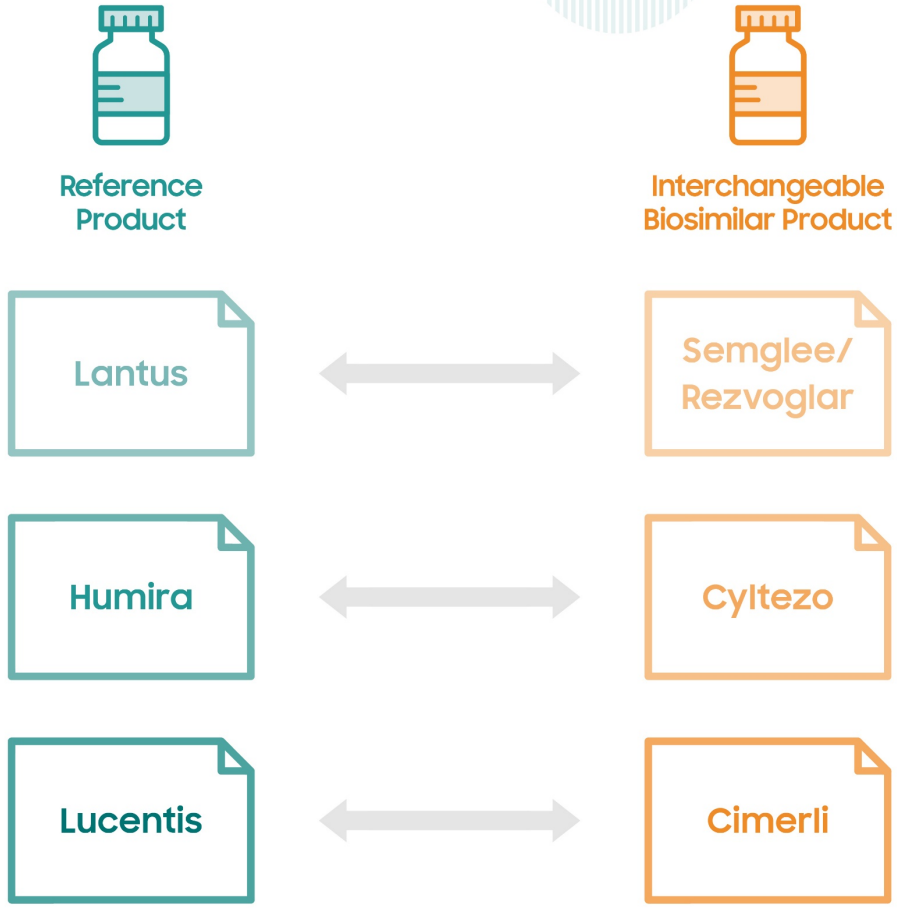
Patient can receive the Interchangeable biosimilar

Why Pursue Interchangeability?

Manufacturers may pursue an interchangeability designation for a variety of reasons. This is usually done to allow greater utilization when the medicine is dispensed at a pharmacy and to appeal to payers, who, according to research, view interchangeability as a means of reducing costs.

While most biologics are administered in the provider's office by the prescribing HCP, others are distributed at retail or specialty pharmacies. When biologics are dispensed at a pharmacy, an interchangeability designation allows a pharmacist to freely substitute a biosimilar for its reference product (subject to state law), in much the same way AB* rated generics are substituted for small molecule pharmaceuticals. This in turn can lead to greater utilization for the biosimilar.

An interchangeable designation does not interfere with a physician's ability to prescribe whichever approved medicine is most appropriate for their patient.



*AB is one of the codes that indicate bioequivalence of the generic drug to the reference listed drug used to gain FDA approval and it means the product meets necessary bioequivalence requirements

Interchangeable designation creates confusion[9]

The introduction of an Interchangeability designation has led to some confusion among HCPs. Some of this is because biosimilars are still fairly new in the US market, but confusion also stems from the fact that the FDA interchangeability designation is a narrow term that only applies to switching at pharmacies. While, in common usage, interchangeability might be used to refer more broadly to prescribers switching from a reference product to a biosimilar. In creating the interchangeable designation, Congress and the FDA were attempting to create a pathway to allow biosimilar substitutions for reference products in the same way that pharmacists are able to switch AB* rated generics for branded small-molecule medications.

As a result, the FDA designation of interchangeability should have little or no impact on HCP prescribing decisions. HCPs may continue to change Rx's from reference products to all biosimilars with confidence knowing that biosimilars provide equivalent safety and efficacy with their reference products for patients, whether or not the biosimilar has an interchangeable designation.

In the EU, which has more than 80 approved biosimilars, the EMA has stated 'that biosimilar medicines approved in the European Union (EU) are interchangeable with their reference medicine or with an equivalent biosimilar.' The UK's Medicines and Healthcare products Regulatory Agency has issued similar guidance.

Switching

Any biosimilar can be used instead of its reference product (or vice versa) or as a substitute for another biosimilar of the same reference product.

Interchangeability

Interchangeability designation enables substitution at the pharmacy level without the intervention of the prescribing healthcare provider.

*AB is one of the codes that indicate bioequivalence of the generic drug to the reference listed drug used to gain FDA approval and it means the product meets necessary bioequivalence requirements

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   Based on internal analysis by SAMSUNG BIOEPIS CO., LTD. using data from the following source: IQVIA MIDAS® in Standard Units for the period Jan 2017 – Dec 2022 (in the United States and Puerto Rico) reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved.
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