



# **SAMSUNG BIOEPIS**

## Biosimilar Market Report

*3<sup>rd</sup> Edition, Q4 2023*

**SAMSUNG** BIOEPIS

# | FOREWORD

Dear Readers,

This year was a truly special year for biosimilars.

With the launch of the adalimumab biosimilars, the US healthcare market has seen various biosimilar strategies including dual pricing, interchangeability, and unbranded biologics. This new expansion of biosimilars into products categorized within specialty pharmacy benefits is expected to evolve into a fierce and competitive market that will ultimately drive down US healthcare costs.

In addition, the IRA legislation continues to roll forward with many eyes on the potential impact of this legislation on biosimilars. Medicare drug price negotiations are becoming imminent with the September 1, 2023 CMS release of the first 10 products to go through the negotiation process. Some of these products have multiple biosimilars in development, ultimately forcing biosimilar developers to strongly analyze the impact of this legislation on the future of biosimilars.

Samsung Bioepis began publishing our biosimilar market report for the first time in 2023. We are pleased to be able to successfully publish this valuable information on a quarterly basis to US stakeholders. We would like to thank our readers for their interest in our desire to broaden biosimilar knowledge within the US healthcare market in an expedited manner.

Moving forward, we can anticipate looking into more diverse topics as current markets mature and new biosimilar products enter into new therapeutic areas. Samsung Bioepis will always strive to deliver richer and timely content to our readers.

In closing, this quarterly report includes an analysis of current US biosimilar trends. Most would agree that the US healthcare market has more stakeholders and complex factors than other countries impacting market uptake. Therefore, it may not be possible to define a single correct answer to trends and changes, but in this report we strive to provide utilization and financial datapoints so our readers can make their own assessments and interpretations.



**Thomas Newcomer**

Vice President  
Head of Market Access, Samsung Bioepis US

# | SAMSUNG BIOEPIS

## Our mission

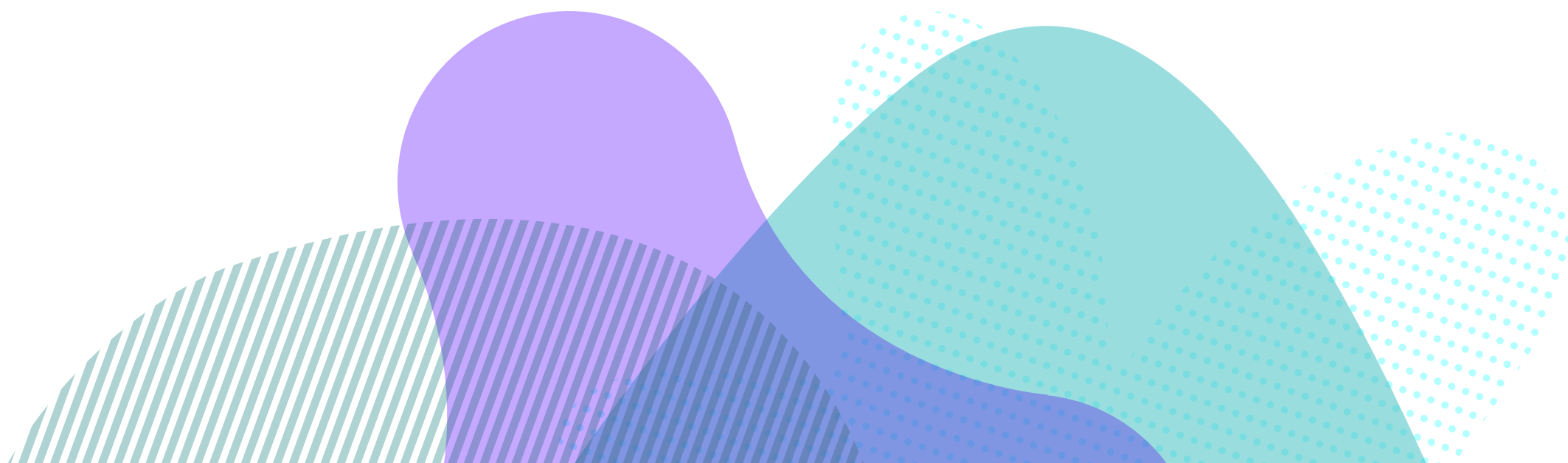
Samsung Bioepis is a biopharmaceutical company dedicated to accelerating access to biologic medicines by bringing **high-quality, clinically proven biosimilars to patients** who need them

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 October 2023, the FDA has approved a total of 42 biosimilars across 12 unique biological molecules. Of the 42 approvals, 37 biosimilars have been launched in the US market.

- In Q3, one new biosimilar was approved in the US (Tyruko for Tysabri).

Cumulative Approvals

42

Figure 1. Biosimilars Approval and Launch Status in the US<sup>1\*</sup> (As of October 2023)

TA	Oncology			Supportive Care			Immunology				Endocrinology	Ophthalmology
Molecule	Bevacizumab	Rituximab		Filgrastim	Pegfilgrastim	Epoetin alfa	Infliximab	Adalimumab	Etanercept	Natalizumab	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	Tysabri Biogen 2004	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	Tyruko Sandoz 2023	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			Hulio Mylan 2020				
				Fylnetra Amneal&Kashiv 2022			Yusimry Coherus 2021					
							Idacio Fresenius Kabi 2022					
							Yuflyma Celltrion 2023					
							Abrilada Pfizer 2019					

■ Launched ■ Not launched □ Updated brand vs. last report

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

FDA Biosimilar Approval Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Pharmacy Benefit

- Immunology & Endocrinology

Biosimilar Market Dynamics

Biosimilar Market

Adoption & Price Erosion

Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Biosimilar Deep Dive

Reference

Figure 1-1. Biosimilars Approval and Launch Status in the US<sup>1\*</sup> (As of October 2023, with Suffix)

TA	Oncology			Supportive Care			Immunology				Endocrinology	Ophthalmology
Molecule	Trastuzumab	Bevacizumab	Rituximab	Filgrastim	Pegfilgrastim	Epoetin alfa	Infliximab	Adalimumab	Etanercept	Natalizumab	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) AbbVie 2002	Enbrel (etanercept) Amgen 2003	Tysabri (natalizumab) Biogen 2004	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-szsz) Sandoz 2016	Tyruko (natalizumab-sztn) Sandoz 2023	Semglee (insulin glargine-yfgr) Mylan 2021	Byooviz (Ranibizumab-nuna) Samsung Bioepis 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-eqrm) Coherus 2022
	Ontruzant (trastuzumab-dttb) Samsung Bioepis&Organon 2019	Alymsys (bevacizumab-maly) Amneal 2022	Riabni (rituximab-arrx) Amgen 2020	Releuko (filgrastim-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					
							Yuflyma (adalimumab-aaty) Celltrion 2023					
							Abrilada (adalimumab-afzb) Pfizer 2019					

■ Launched ■ Not launched □ Updated brand vs. last report

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

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Pharmacy Benefit

- Immunology & Endocrinology

Biosimilar Market Dynamics

Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

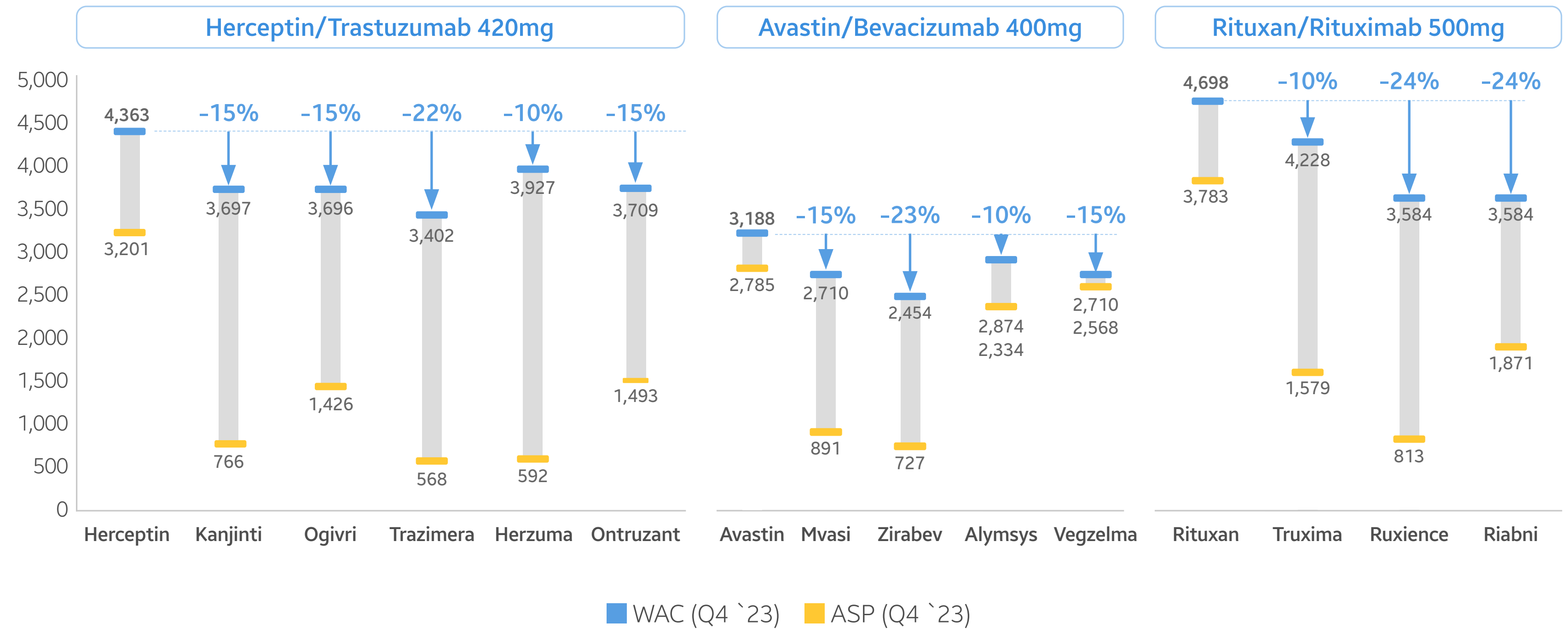
Biosimilar Deep Dive

Reference

# Oncology WAC and ASP - Q4 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 70% compared to their reference products.

Figure 3. Q4 2023 WAC and ASP<sup>2,3</sup>



Products are listed in order of launch  
 ASP: Average sales price; WAC: Wholesale acquisition cost

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Pharmacy Benefit

- Immunology & Endocrinology

Biosimilar Market Dynamics

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Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

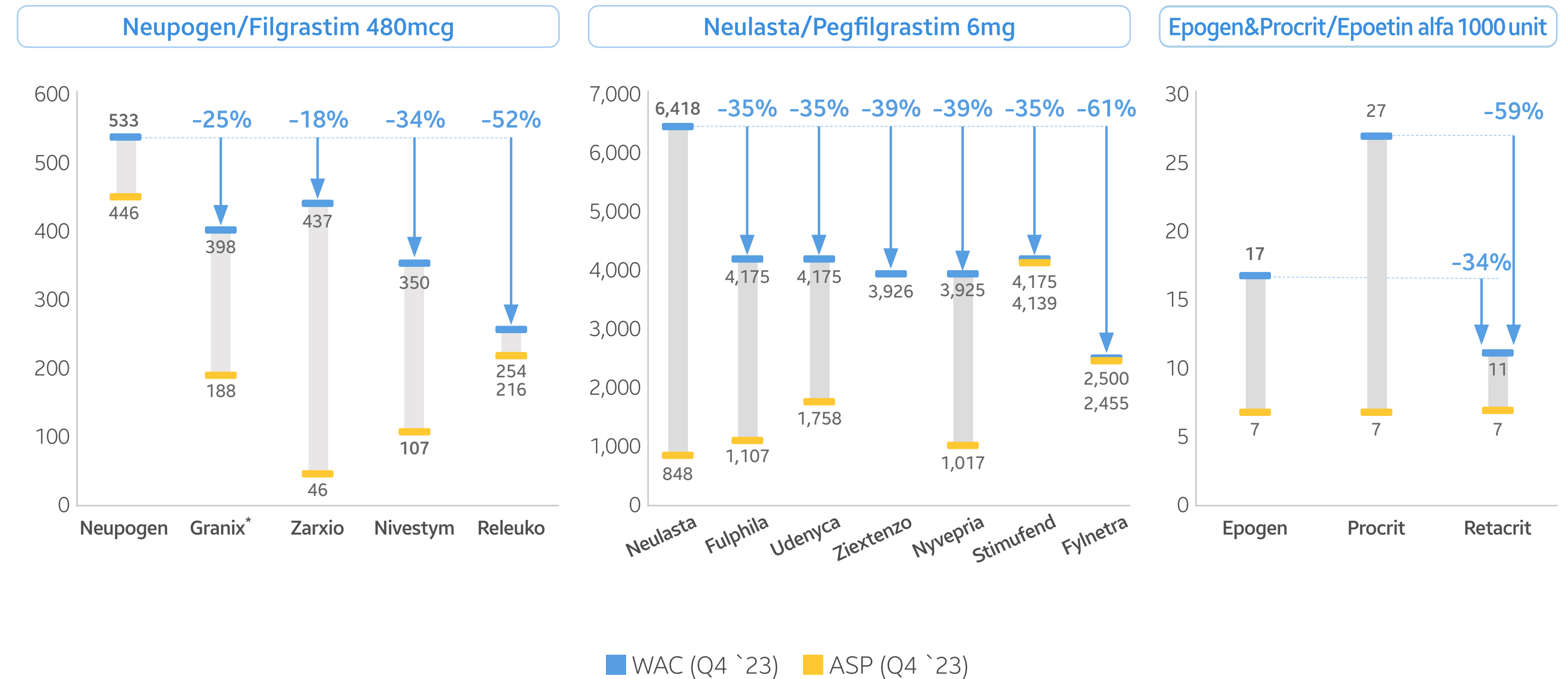
Biosimilar Deep Dive

Reference

# Supportive Care WAC and ASP - Q4 2023

- \* In Pegfilgrastim and Epoetin alfa, the reference products match biosimilars' ASP in an effort to retain market share.
- \* However, Neupogen maintains higher ASP relative to biosimilars.

Figure 4. Q4 2023 WAC and ASP<sup>2,3</sup>



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  
 † Ziextenzo ASP is not published in Q4 2023



Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Pharmacy Benefit

- Immunology & Endocrinology

Biosimilar Market Dynamics

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Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Biosimilar Deep Dive

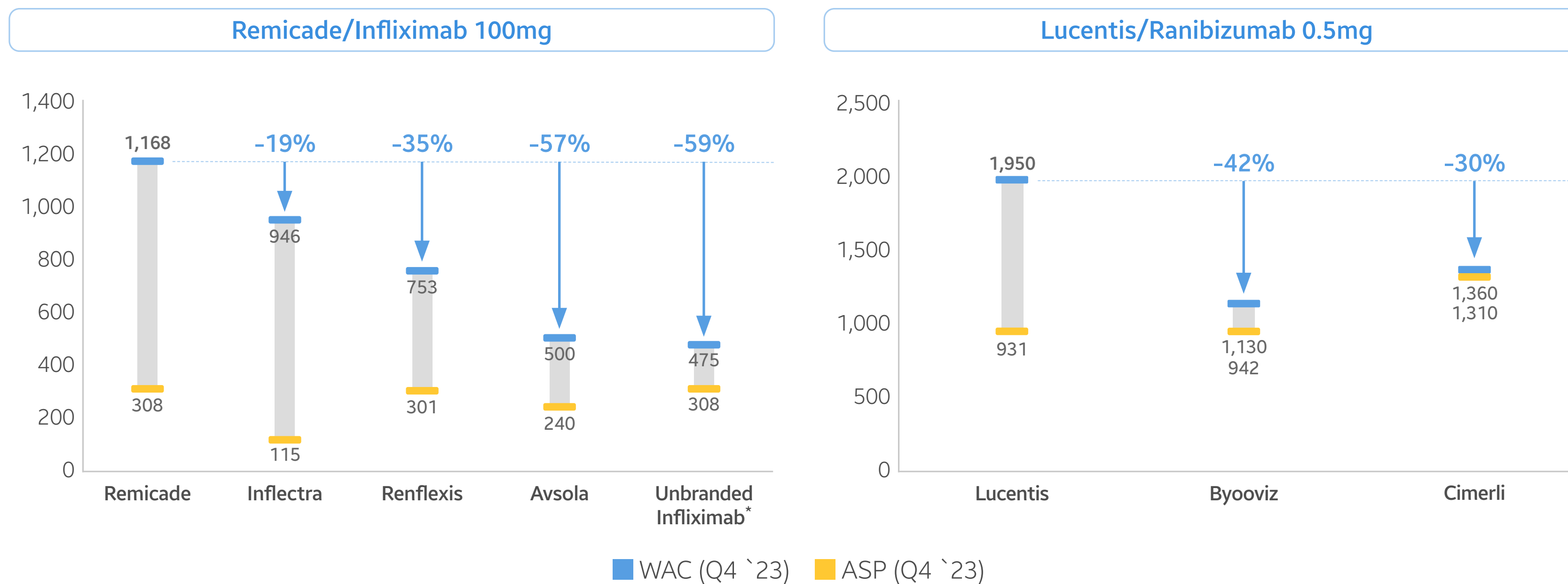
Reference

# Immunology & Ophthalmology

## WAC and ASP - Q4 2023

- ✦ Infiximab biosimilars launched with progressively lower WACs. The first biosimilar, Inflectra, only discounted 19% vs the reference product in Q3 2023, but subsequent launches of Avsola and unbranded infiximab had discounted WAC by over 50%.
- ✦ Recent ranibizumab biosimilar launches have already led to lower costs.

Figure 5. Q4 2023 WAC and ASP<sup>2,3</sup>



Products are listed in order of launch  
 ASP: Average sales price; WAC: Wholesale acquisition cost  
 \*Unbranded Infiximab is Remicade without the brand name

- Oncology
- Supportive Care
- Immunology & Ophthalmology

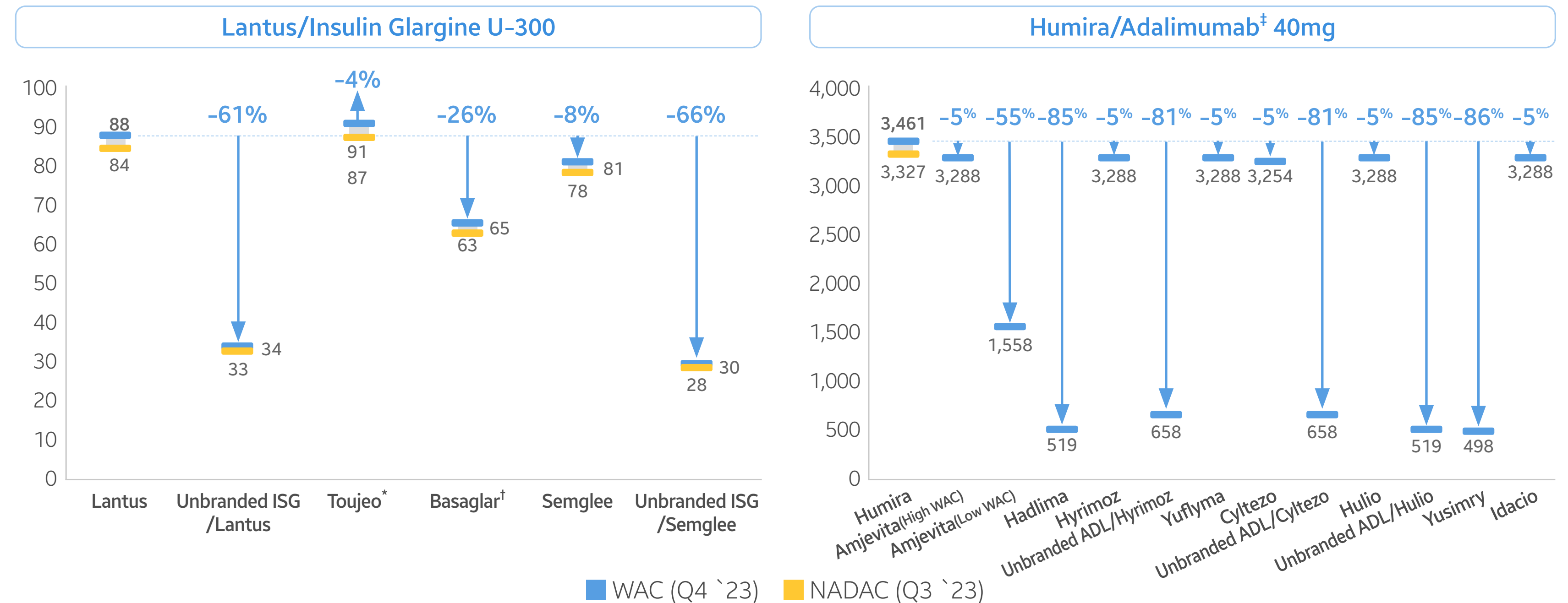
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

# Immunology & Endocrinology

## WAC and NADAC - Q3 & 4 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. Q4 2023 WAC and Q3 NADAC<sup>2,4</sup>



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

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

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- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Biosimilar Deep Dive

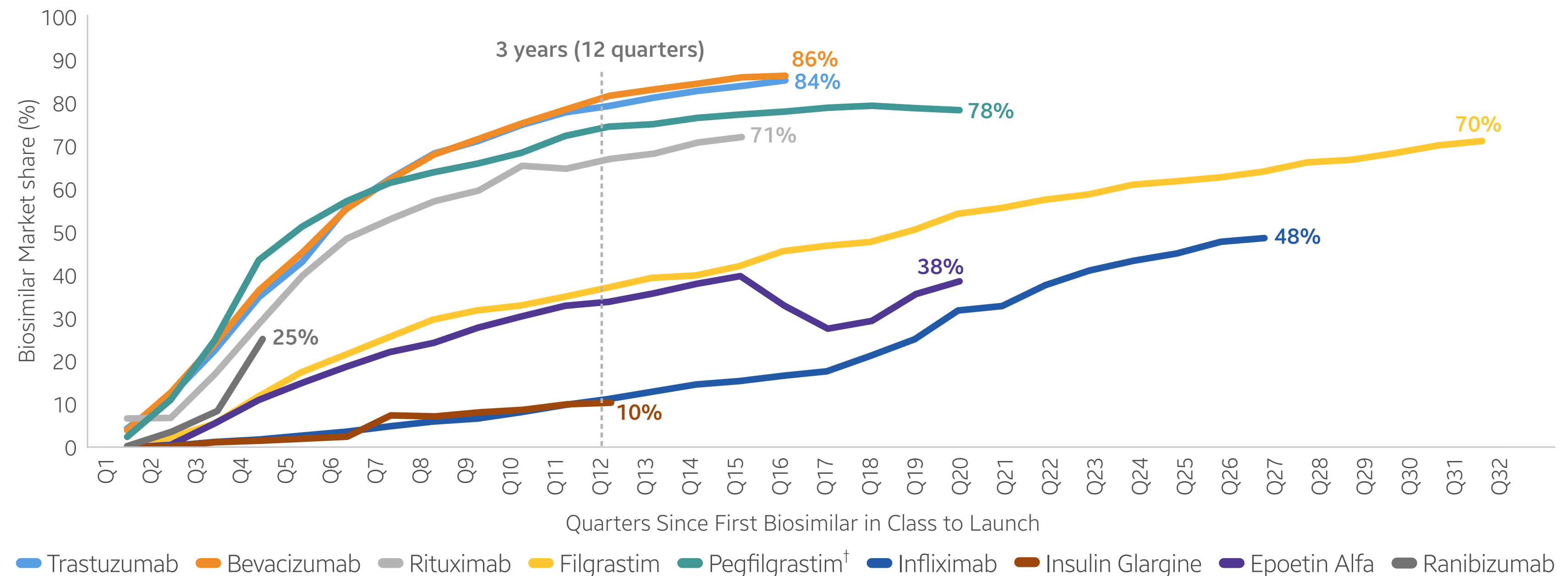
Reference

# 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 but, each molecule has demonstrated unique biosimilar uptake.

- 1) Oncology\*, and Pegfilgrastim biosimilars average 75% market share three years post launch.
- 2) Filgrastim, and Epoetin Alfa gained 35% market share in three years.
- 3) Infliximab and Insulin Glargine reached only 11% market share.

Figure 7. Biosimilar Market Share Post-Launch<sup>5</sup>



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

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

Biosimilar Market Dynamics

Biosimilar Market Adoption & Price Erosion

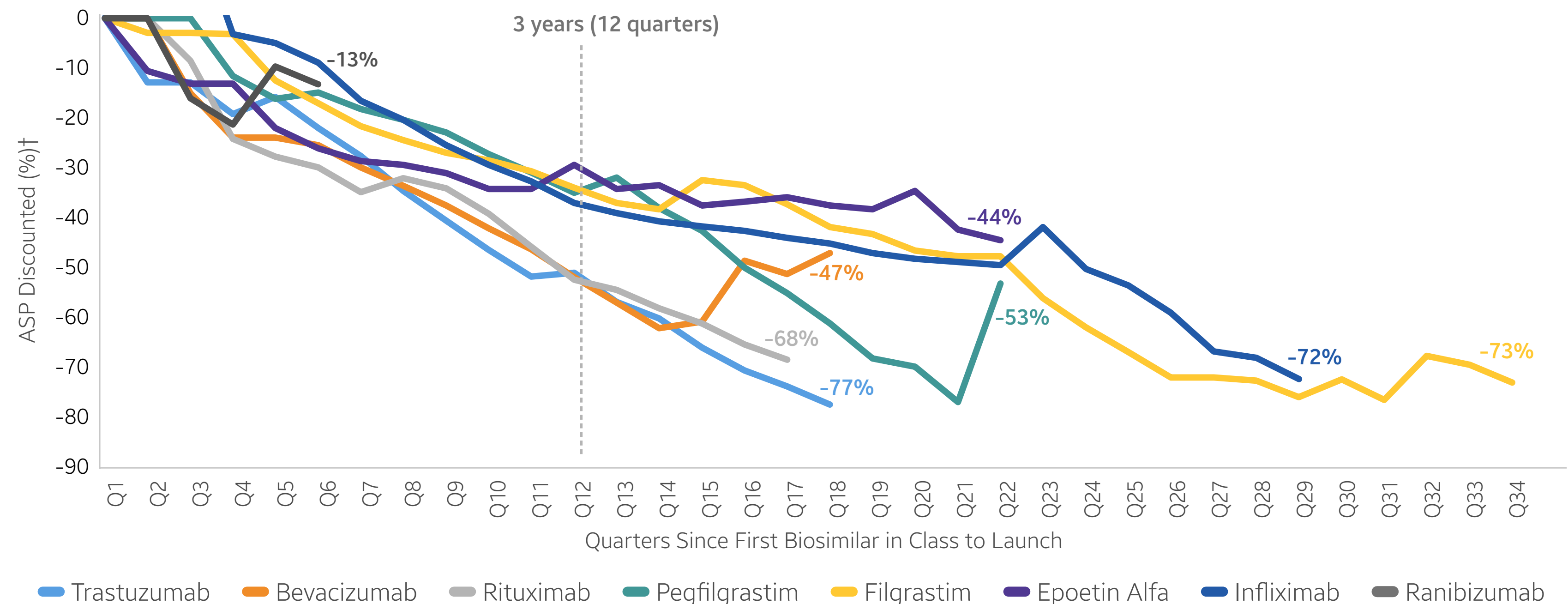
Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

# Biosimilars are Reducing 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.
- ✦ The ASP for oncology\* biosimilars experienced the steepest decline vs. others.
  - Each falling just over 50% in the first three years (12 quarters) post biosimilar launch.

Figure 8. ASP Trend by Molecule<sup>3</sup>



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

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

Biosimilar Market Dynamics

Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

# Market Share and ASP Trends - Herceptin (Trastuzumab)

- ✦ As of Q2 2023, the biosimilar share of the trastuzumab market has reached 84% .
  - The first biosimilar of trastuzumab has been the market leader since Q4 2020.
- ✦ As of Q4 2023, the average ASP of all products is \$1,341 (-68%) and the average for biosimilars alone is \$969 (-77%) vs. the reference product's ASP at the time of the first biosimilar launch.

Figure 9. Trastuzumab Volume Market Share<sup>5</sup>

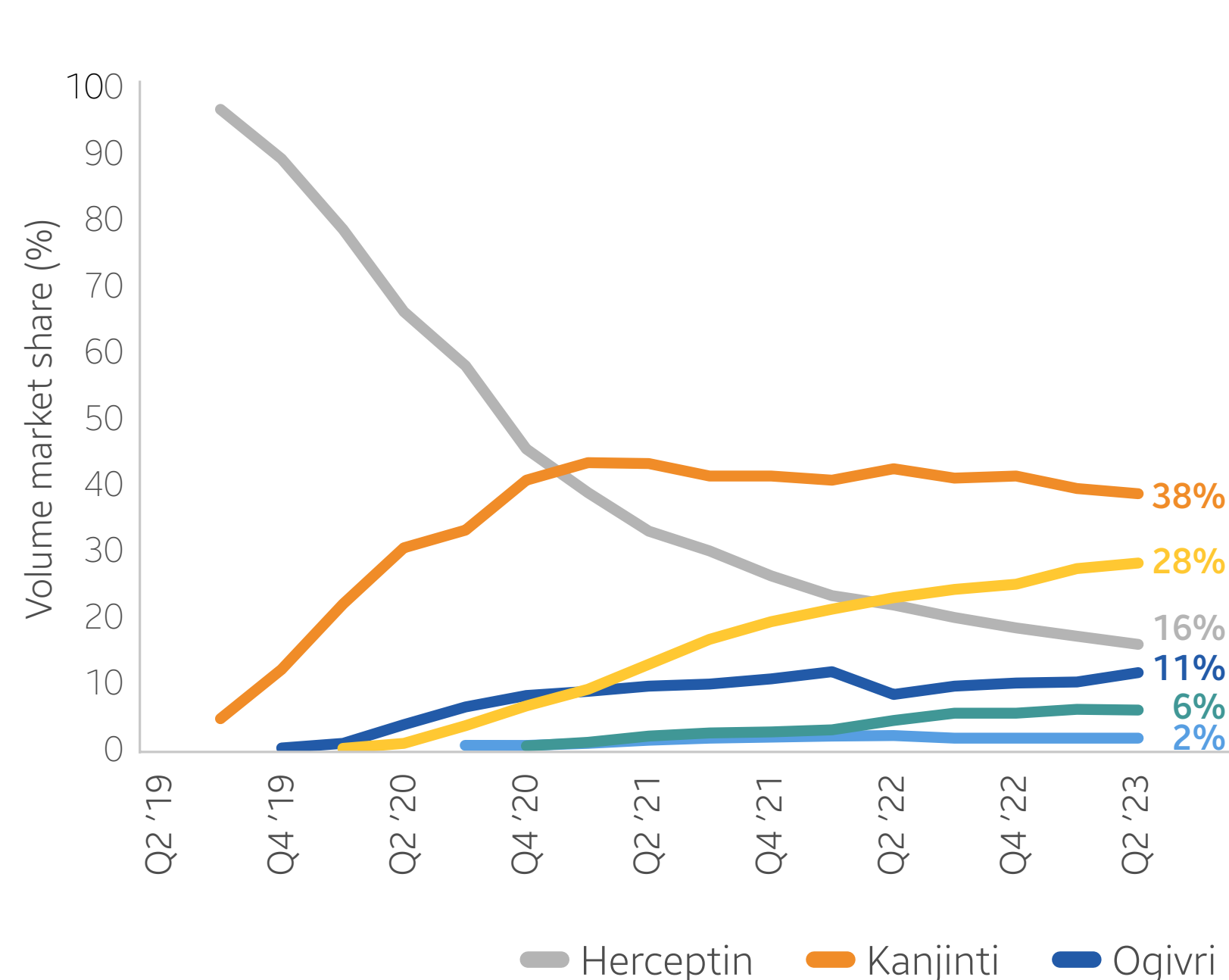
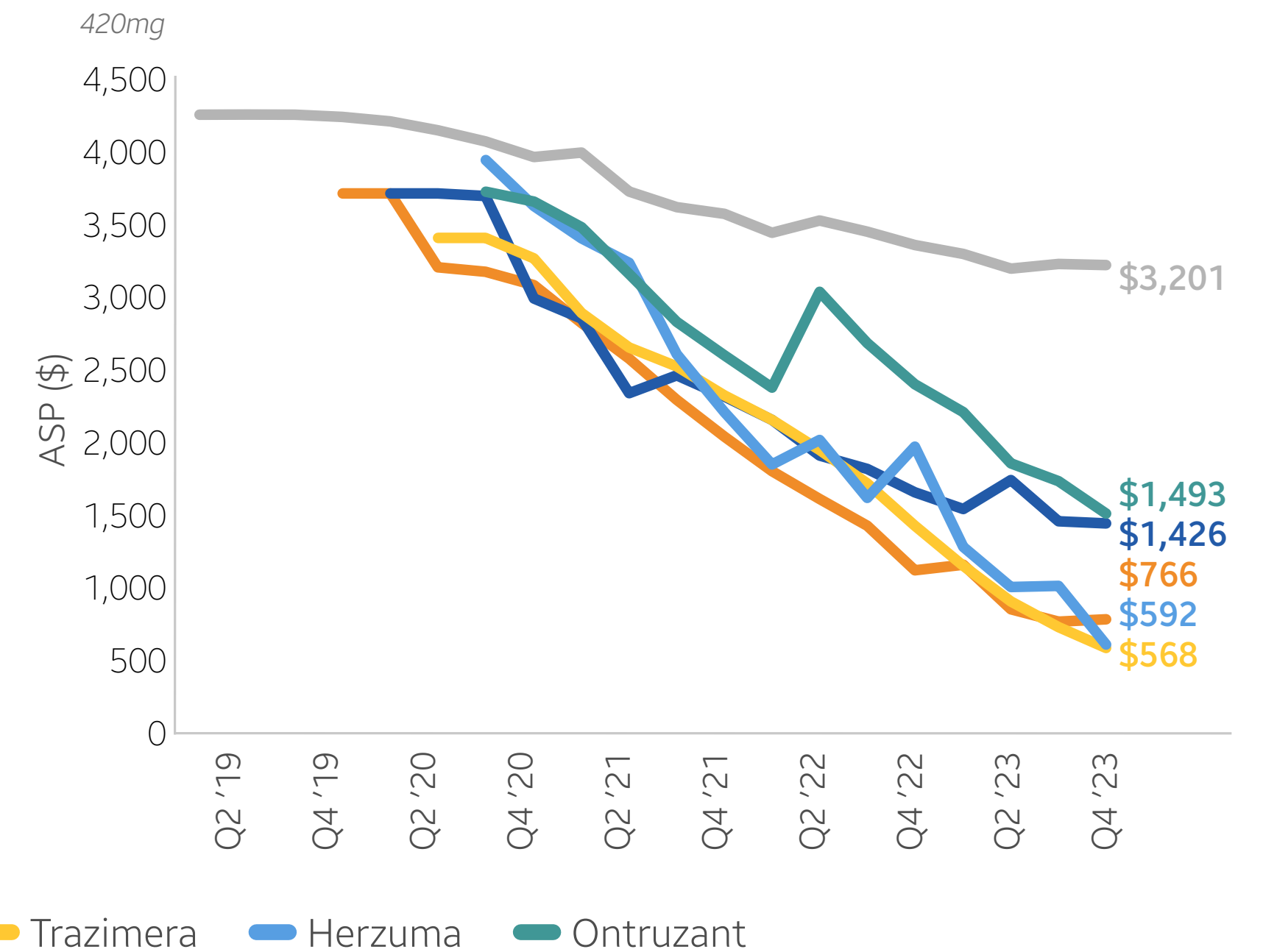
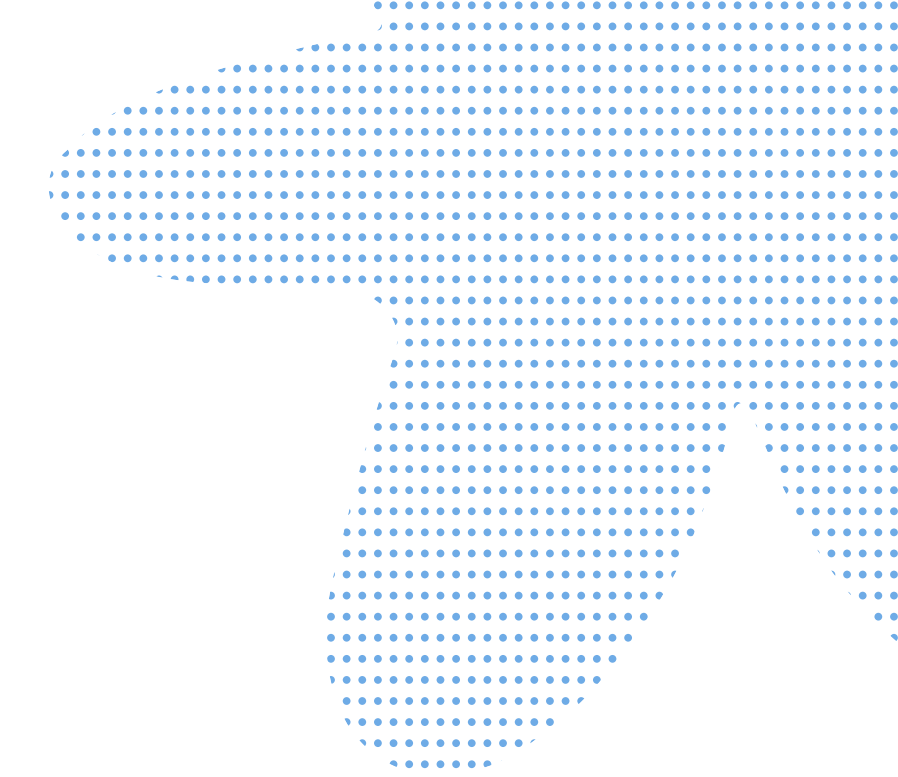


Figure 10. Trastuzumab ASP Trend<sup>3</sup>



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



FDA Biosimilar Approval Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Pharmacy Benefit

- Immunology & Endocrinology

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Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

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- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Biosimilar Deep Dive

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# Market Share and ASP Trends - Avastin (Bevacizumab)

- ✦ As of Q2 2023, the biosimilar share of the bevacizumab market was 86%.
  - Vegzelma which is 4th bevacizumab biosimilar has now been launched.
- ✦ As of Q4 2023, the average ASP of all products is \$1,861 (-39%) and the average for biosimilars alone is \$1,630 (-47%) vs the reference product's ASP at the time of the first biosimilar launch.

Figure 11. Bevacizumab Volume Market Share<sup>5</sup>

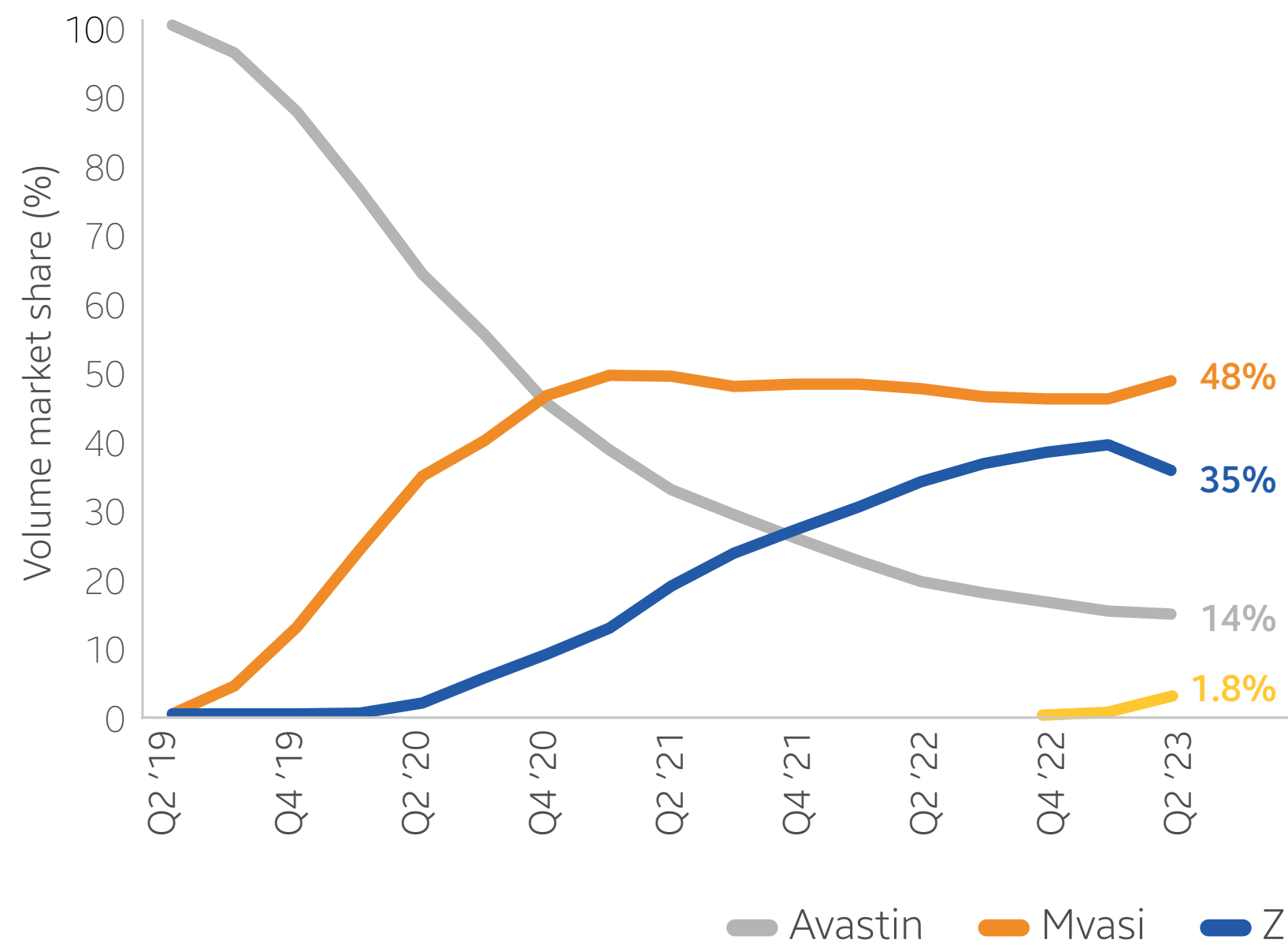
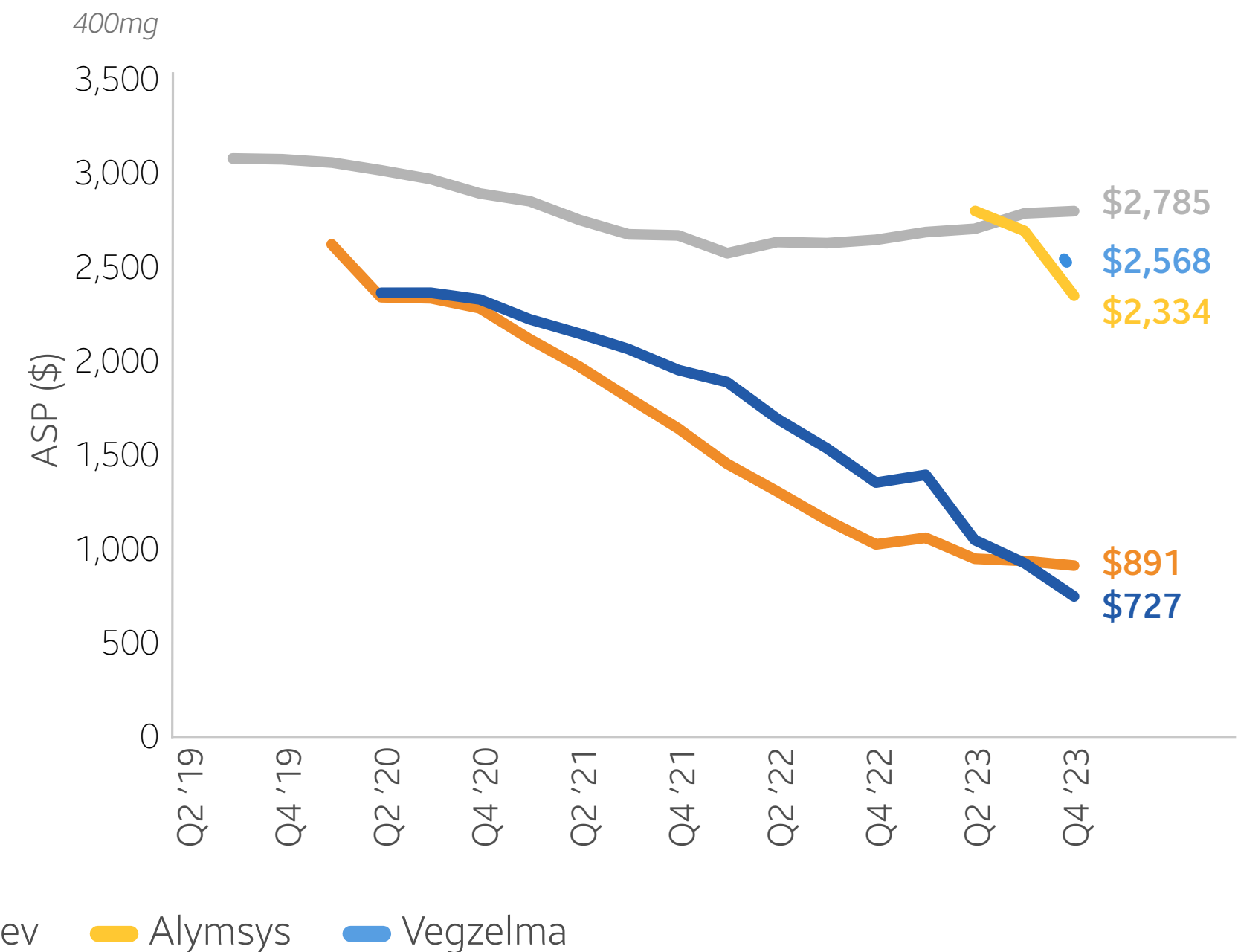


Figure 12. Bevacizumab ASP Trend<sup>3</sup>



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

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

Biosimilar Market Dynamics

Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

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- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

# Market Share and ASP Trends - Rituxan (Rituximab)

✦ As of Q2 2023, the biosimilar share of the rituximab market was 71%.

- A rituximab biosimilar has been the market leader since Q3 of 2022.

✦ As of Q4 2023, the average ASP of all products is \$2,011 (-55%) and the average for biosimilars alone is \$1,421 (-68%) vs. the reference product's ASP at the time of the first biosimilar launch.

Figure 13. Rituximab Volume Market Share<sup>5</sup>

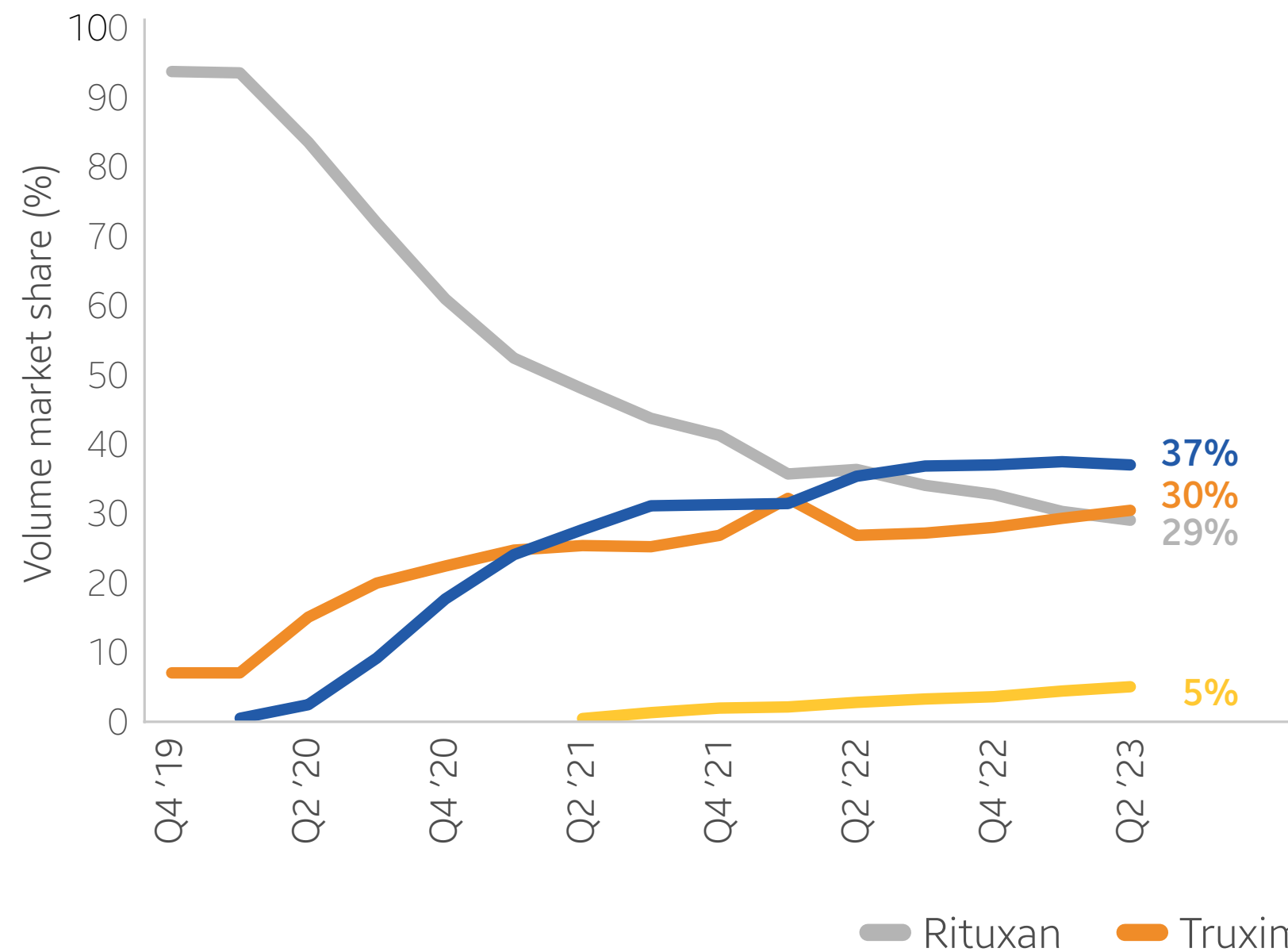
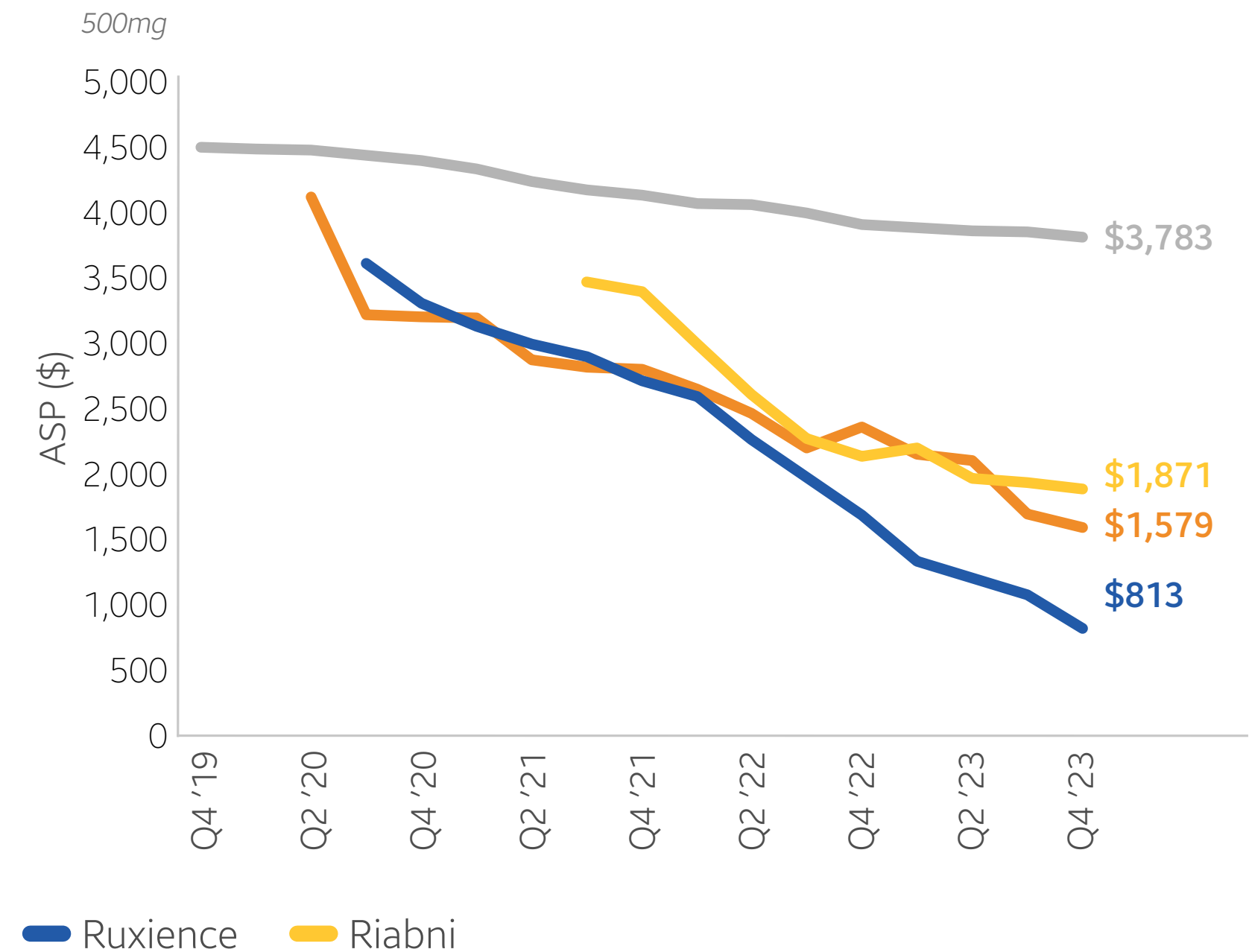


Figure 14. Rituximab ASP Trend<sup>3</sup>



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

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

Biosimilar Market Dynamics

Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

# Market Share and ASP Trends - Neupogen (Filgrastim)

- ✦ As of Q2 2023, the biosimilar share of the filgrastim market has reached 85%.
  - The first filgrastim biosimilar to launch has been the US market leader since Q3 2018.
- ✦ As of Q4 2023, the average ASP of all products is \$201 (-56%) and the average for biosimilars alone is \$123 (-73%) vs the reference product's ASP at the time of the first biosimilar launch.

Figure 15. Filgrastim Volume Market Share<sup>5</sup>

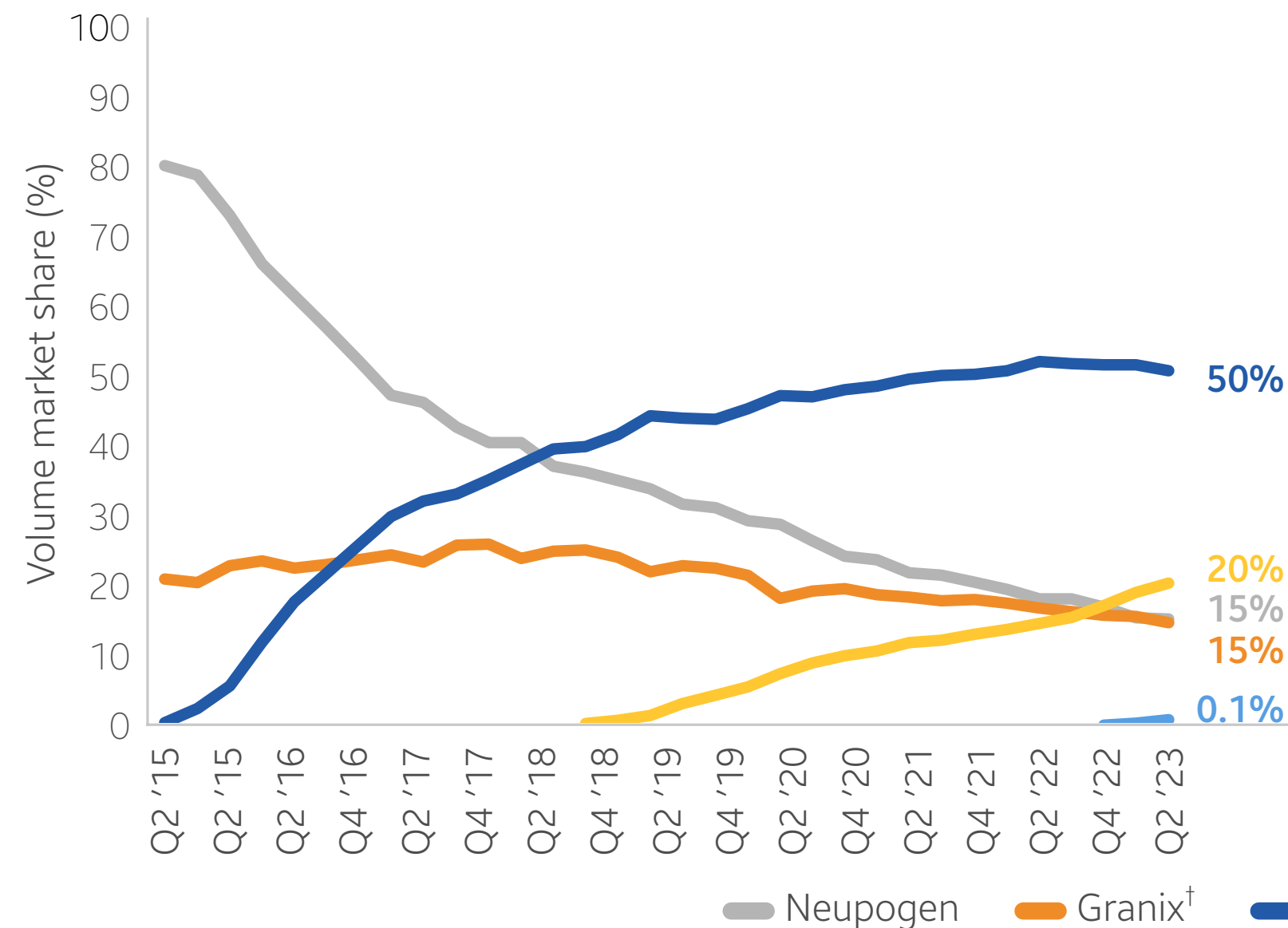
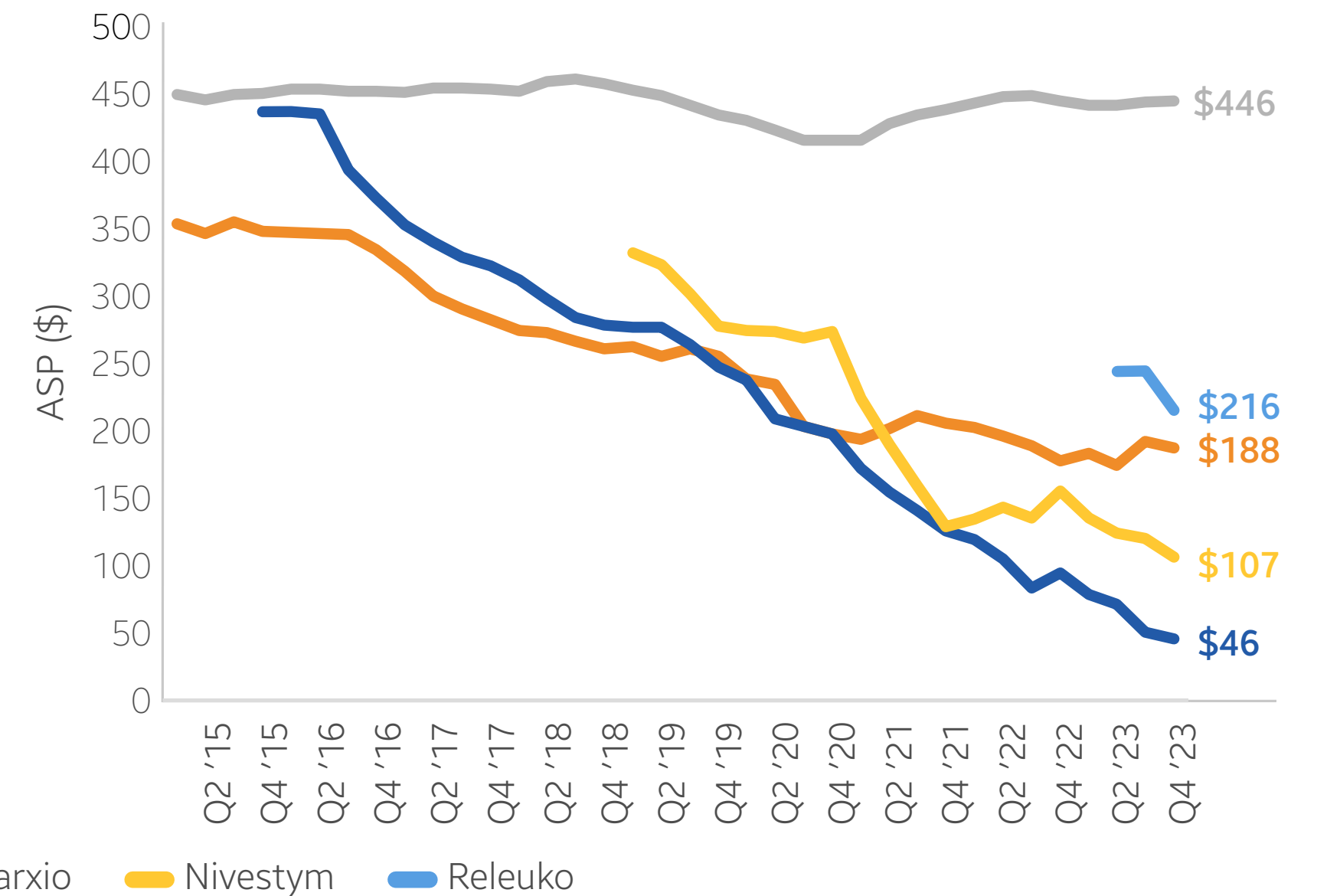


Figure 16. Filgrastim ASP Trend<sup>3</sup>



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



- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

Biosimilar Market Dynamics

Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

# Market Share and ASP Trends - Neulasta (Pegfilgrastim)

✦ As of Q2 2023, the biosimilar share of the pegfilgrastim market was 77%.

- Note that, Flyneta, the 6th Pegfilgrastim biosimilar has now launched.

✦ As of Q4 2023, the average ASP of all products is \$1,887 (-58%) and the average for biosimilars alone is \$2,095 (-53%) vs. the reference product's ASP at the time of the first biosimilar launch.

Figure 17. Pegfilgrastim Volume Market Share<sup>5</sup>

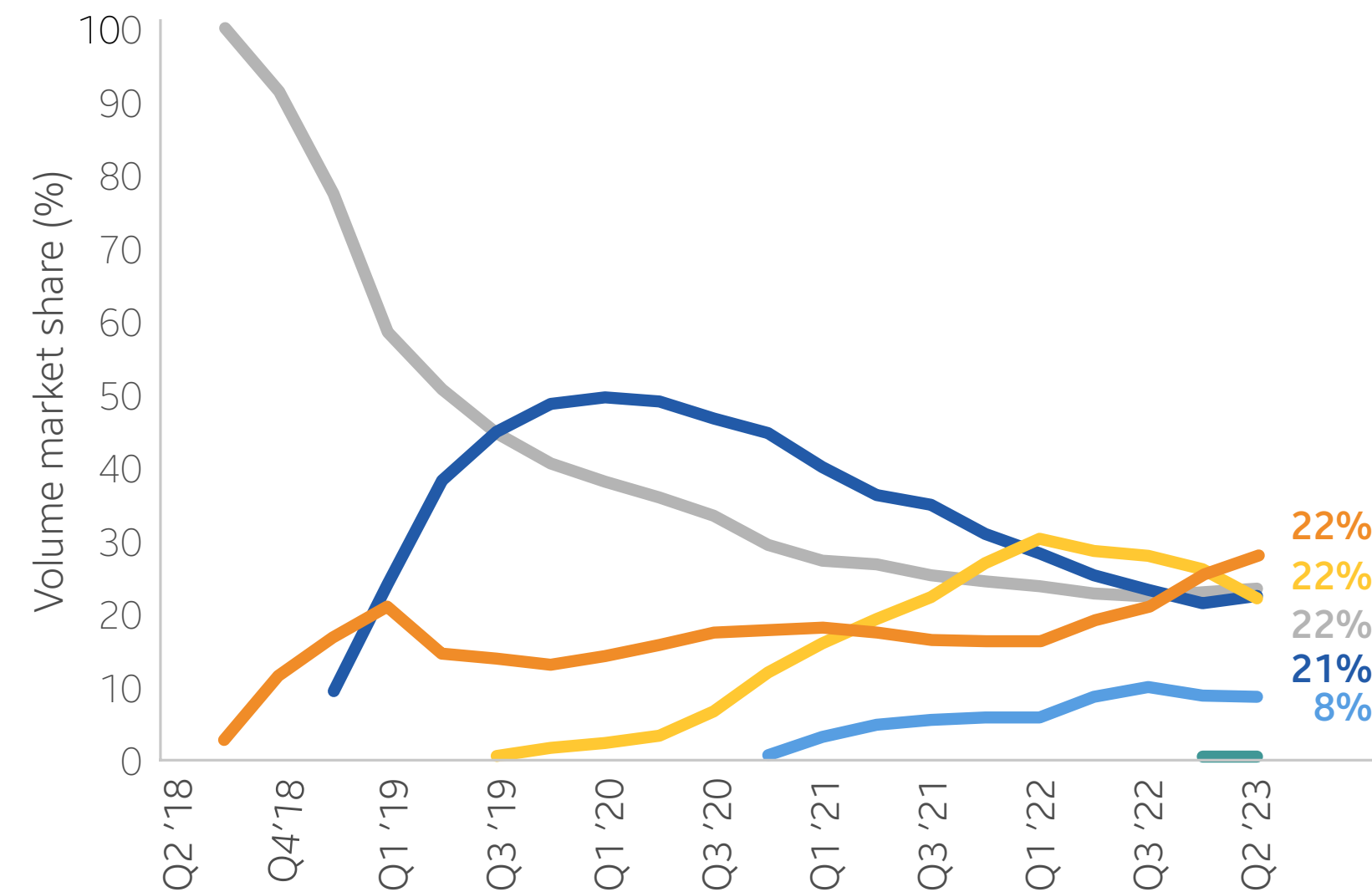
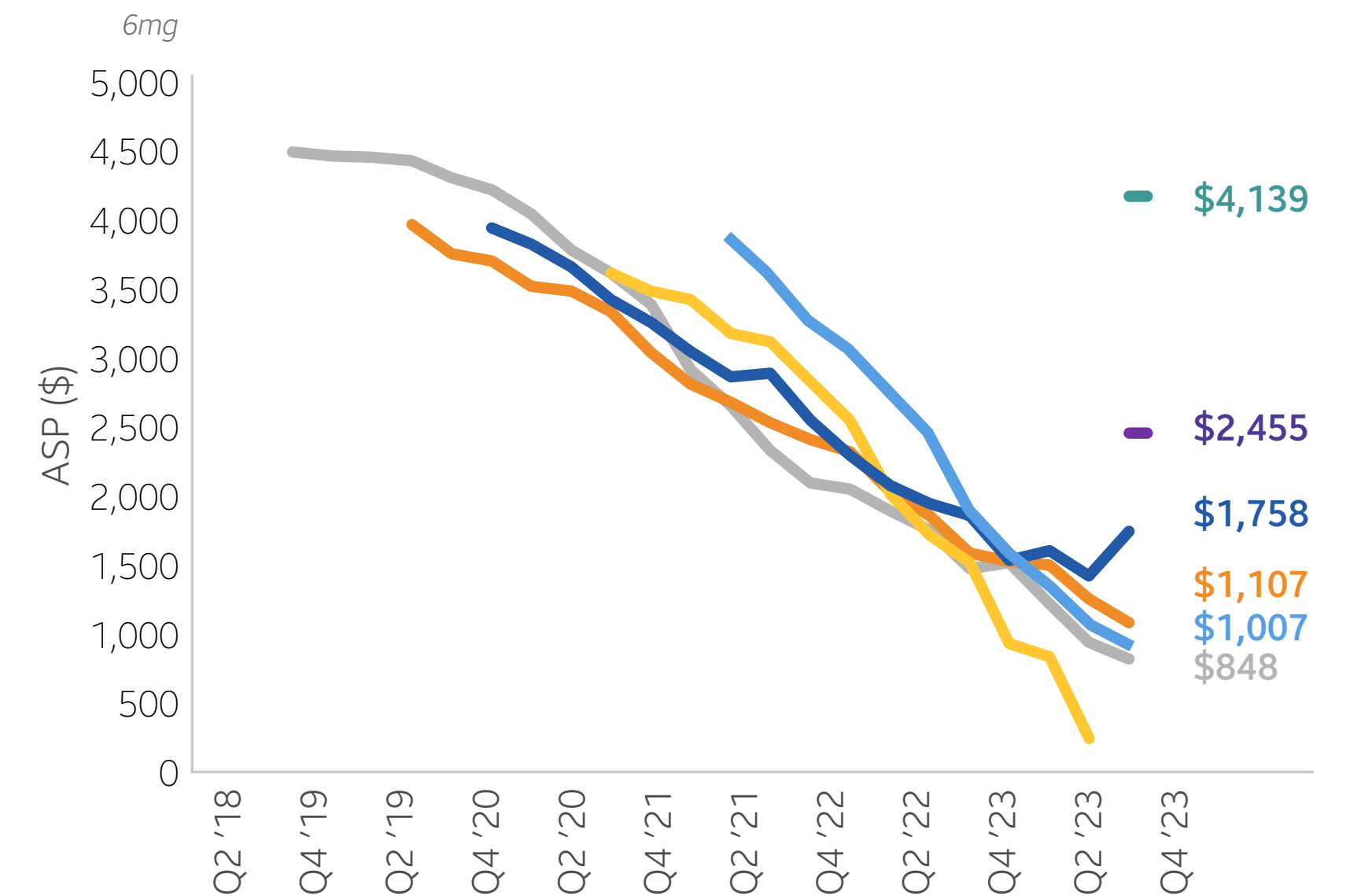


Figure 18. Pegfilgrastim ASP Trend<sup>3</sup>



— Neulasta† — Fulphila — Udenyca — Ziextenzo† — Nyvepria — Stimufend — Flyneta

Legends are listed in order of launch  
 ASP: Average sales price  
 † Ziextenzo ASP is not published in 4Q 2023 ‡ Onpro is not included.

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

Biosimilar Market Dynamics

Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

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# Market Share and ASP Trends

## - Epogen/Procrit (Epoetin alfa)

- ✦ Retacrit is only biosimilar of Epoetin alfa, which has resulted in less of a decline in ASP compared to markets with multiple biosimilars.
- ✦ By matching ASP, the two reference products have maintained a combined share of approximately 60%.

Figure 19. Epoetin Alfa Volume Market Share<sup>5</sup>

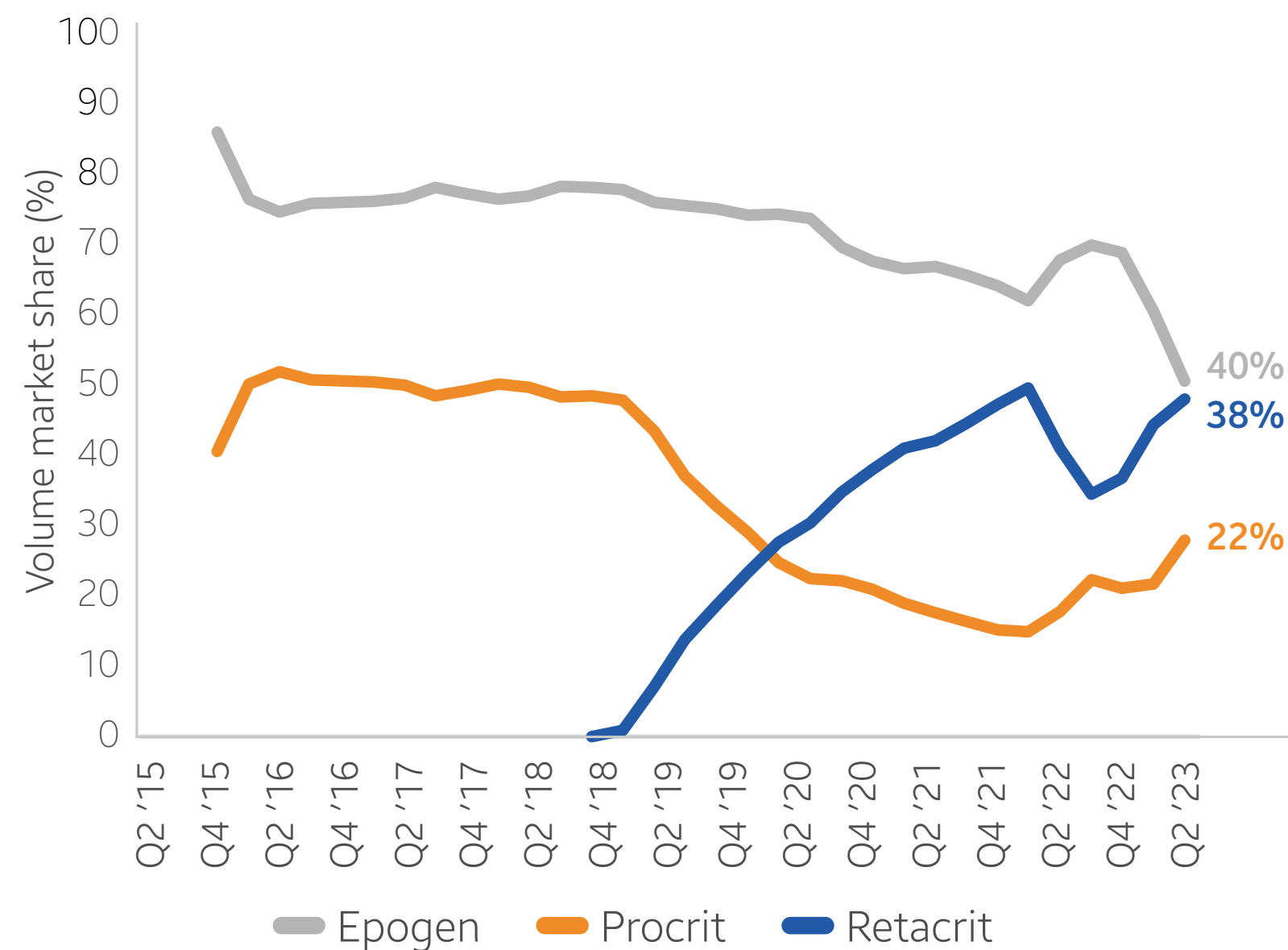
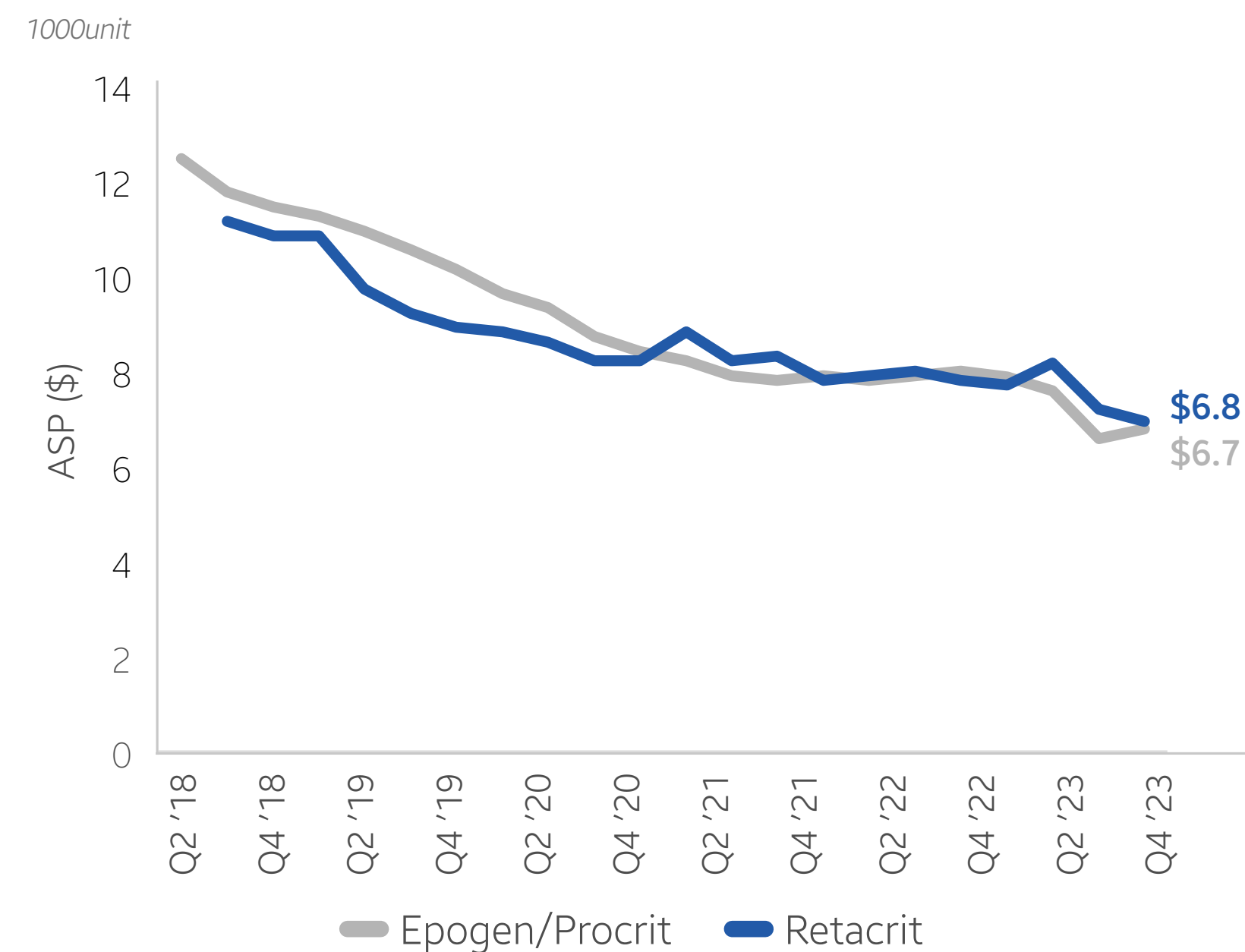


Figure 20. Epoetin alfa ASP Trend<sup>3</sup>



Legends are listed in order of launch  
ASP: Average sales price

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

Biosimilar Market Dynamics

Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

- Oncology
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- Immunology
- Endocrinology
- Ophthalmology

# Market Share and ASP Trends - Remicade (Infliximab)

- ✦ After a slow start, the Infliximab biosimilar market began to accelerate in year three.
  - As of Q2 2023, Infliximab biosimilar market share has reached 54%..
- ✦ Janssen launched an unbranded biosimilar of Remicade in Q4 2022, re-accelerating the price erosion that had slowed in 2020/21.
- ✦ As of Q4 2023, the average ASP of all products is \$241 (-69%) and the average for biosimilars alone is \$219 (-72%) vs. the reference product's ASP at the time of the first biosimilar launch.

Figure 21. Infliximab Volume Market Share<sup>5</sup>

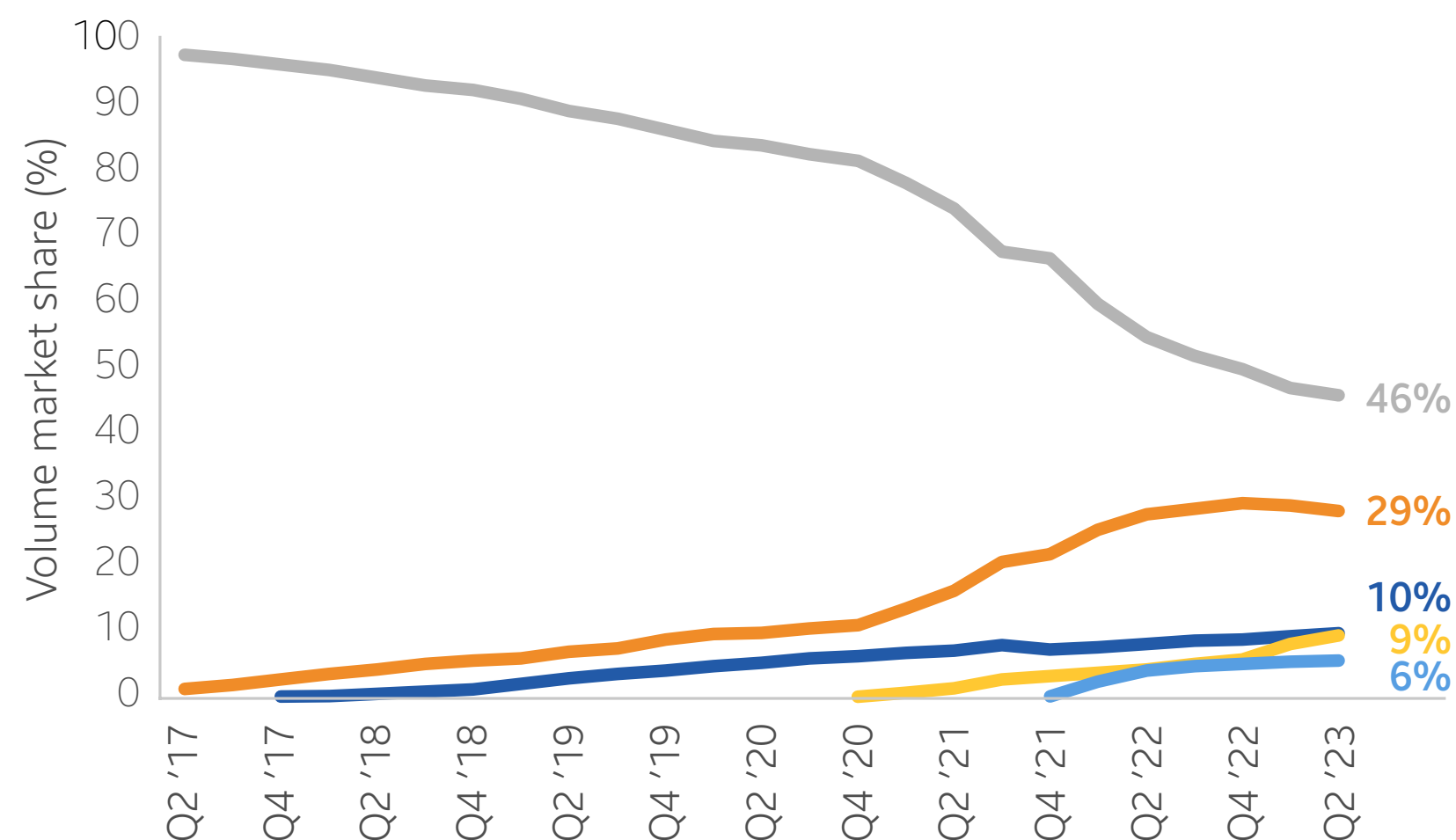
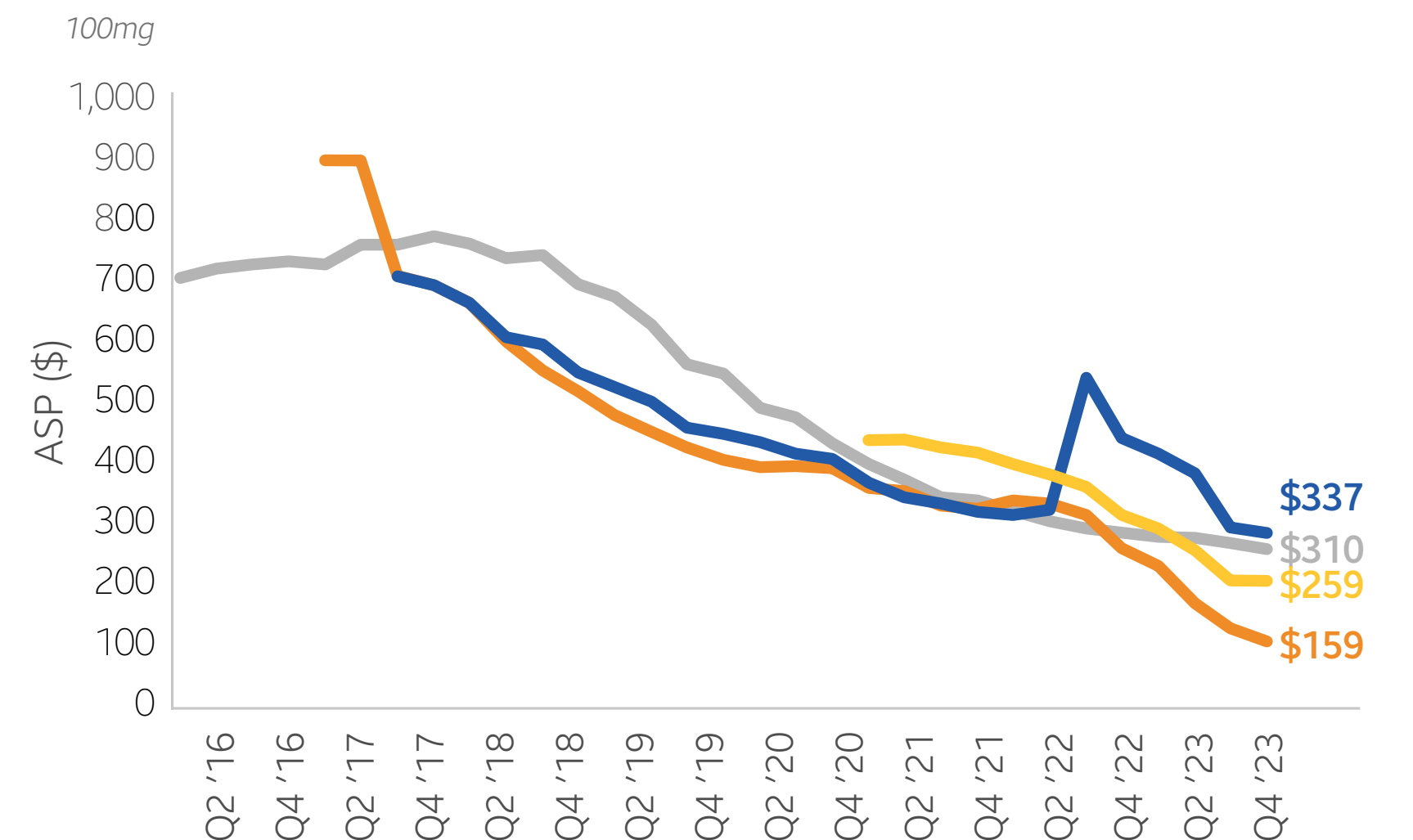


Figure 22. Infliximab ASP Trend<sup>3</sup>



— Remicade† — Inflectra — Renflexis — Avsola — Unbranded Infliximab\*

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

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

Biosimilar Market Dynamics

Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

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- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

# Market Share and WAC Trends - Humira (Adalimumab)

- ✦ As of July, a total of 8 Humira biosimilars have launched in the US market.
  - Seven Humira biosimilars launched in early July, joining Amjevita that was already in market since January.
- ✦ These brands are providing customers with a wide range of pricing options,
  - 1) Hadlima, Yusimry are offering a low WAC: ~85-86% less than Humira
  - 2) Yuflyma and Idacio are offering a high WAC just ~5-7% below Humira
  - 3) Amjevita, Hyrimoz, Cyltezo, and Hulio are offering two pricing options including both a low and a high WAC

Figure 23. Adalimumab Volume Market Share<sup>5</sup>

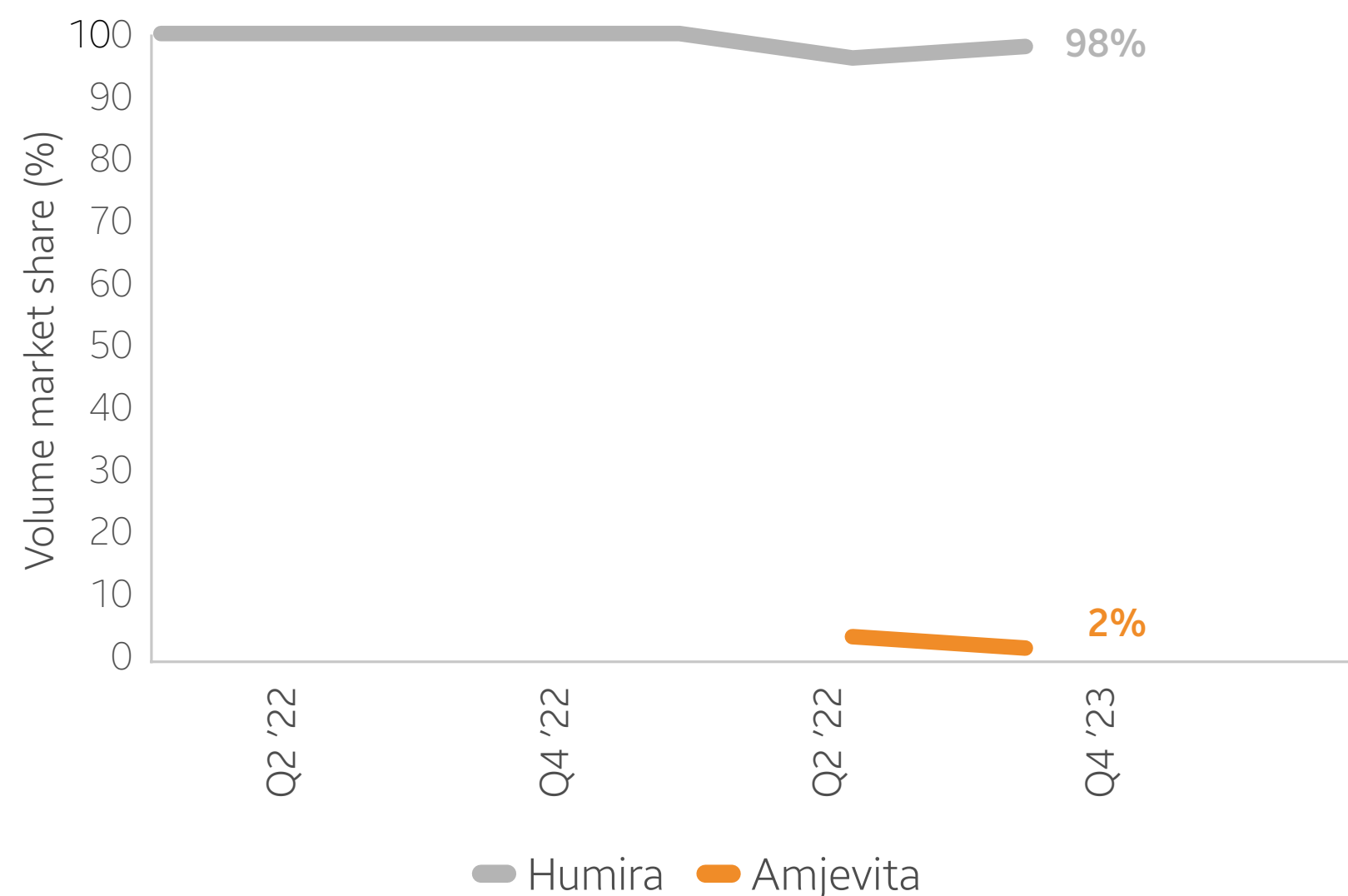
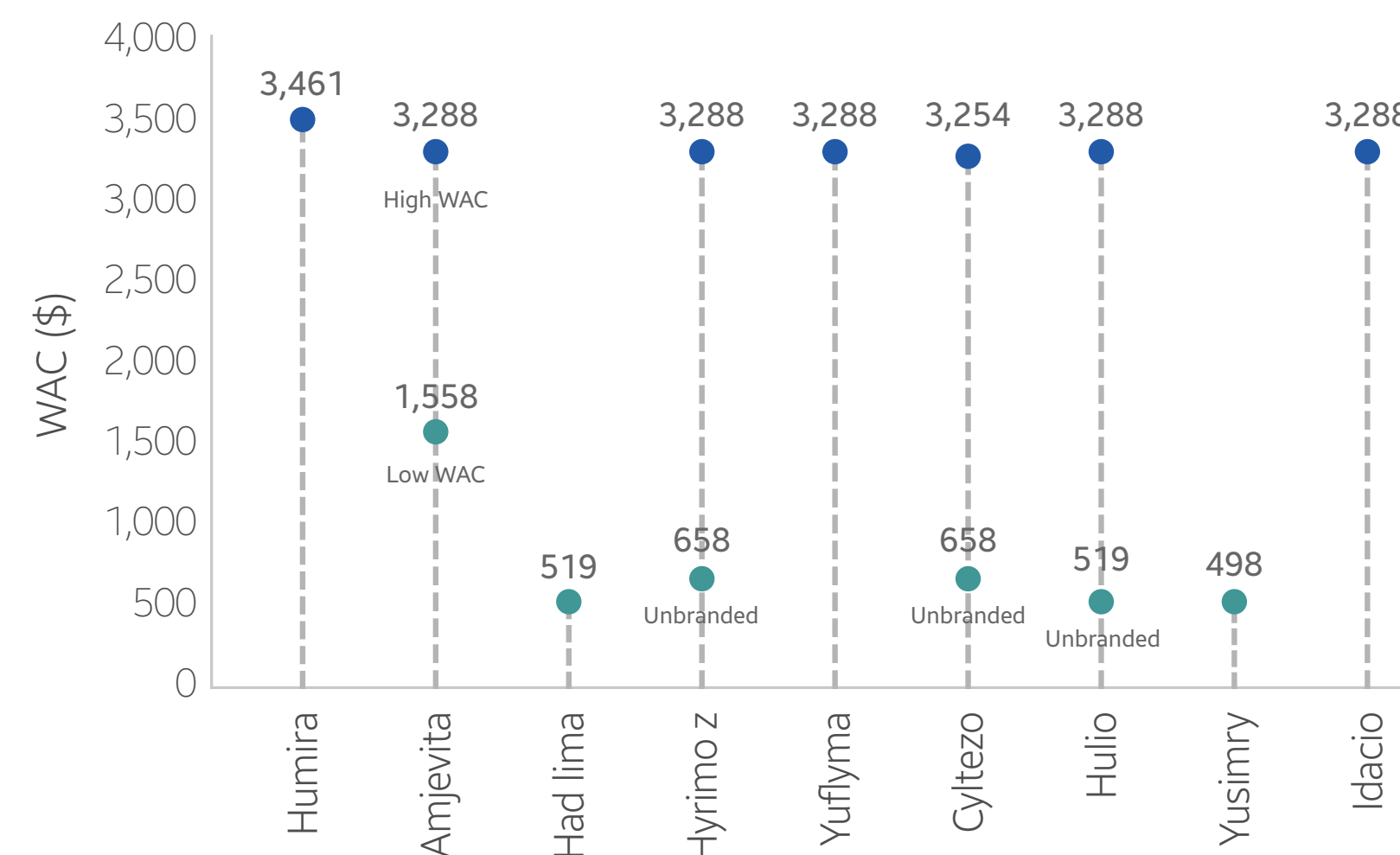


Figure 24. Adalimumab WAC Trend<sup>2</sup>



WAC: Wholesale acquisition cost

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

Biosimilar Market Dynamics

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- Immunology
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# 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.
  - Basaglar is a version of insulin glargine that is not considered a Lantus biosimilar due to it's approval under FDA, via 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 25. Insulin Glargine Volume Market Share<sup>5</sup>

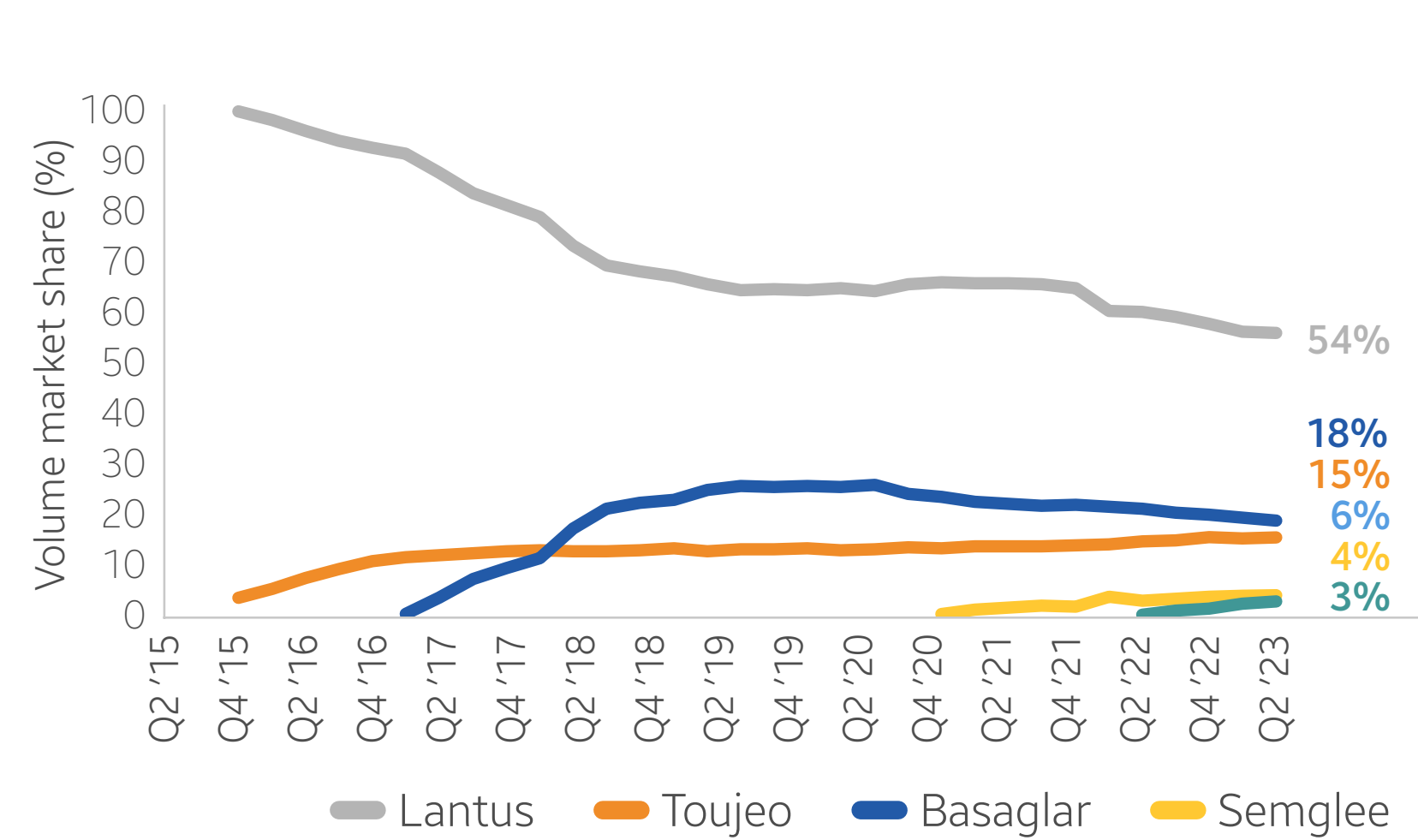
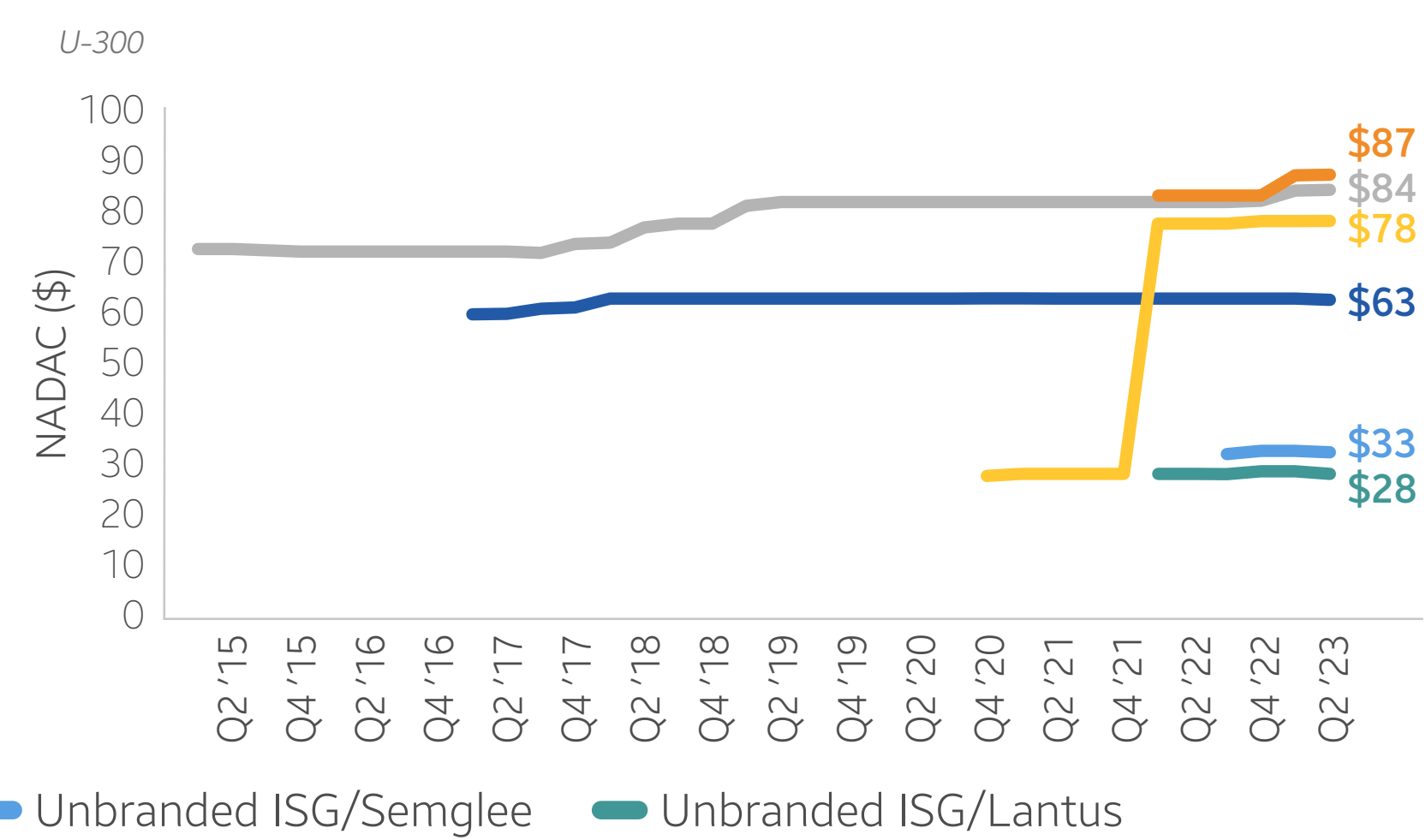


Figure 26. Insulin Glargine NADAC Trend<sup>4</sup>



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

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

**Biosimilar Market Dynamics**

Biosimilar Market Adoption & Price Erosion

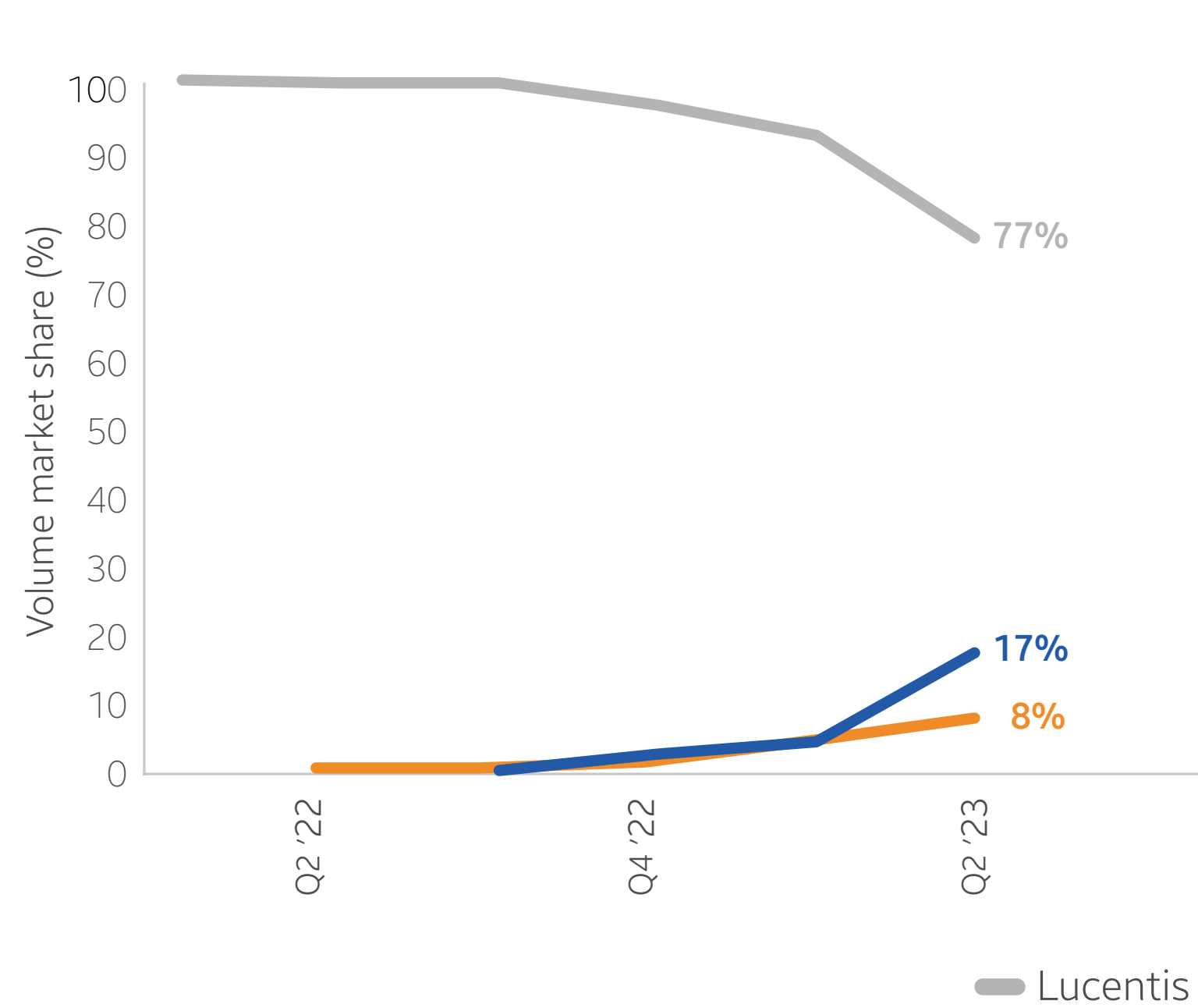
**Market Share & Price Trends**

- Oncology
- Supportive Care
- Immunology
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- Ophthalmology

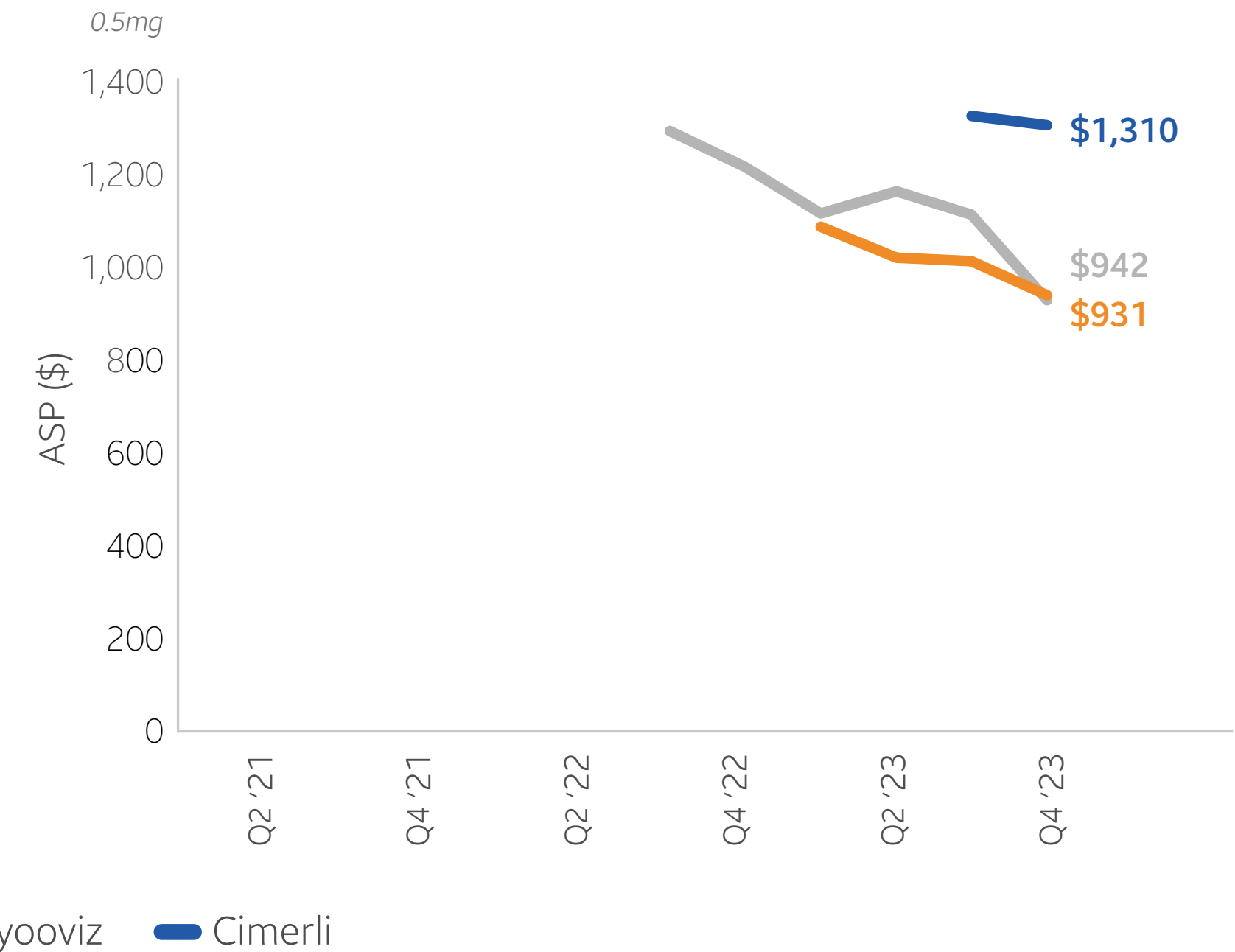
# Market Share and ASP Trends - Lucentis (Ranibizumab)

- ✦ As of Q2 2023, two biosimilars have launched and their market share is 25%.
- ✦ As of Q4 2023, the average ASP of all products is \$1,154 (-11%) and the average for biosimilars alone is \$1,173 (-10%) vs. the reference product's ASP at the time of the first biosimilar launch.

**Figure 27. Ranibizumab Volume Market Share<sup>5</sup>**



**Figure 28. Ranibizumab ASP Trend<sup>3</sup>**



Legends are listed in order of launch  
ASP: Average sales price

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

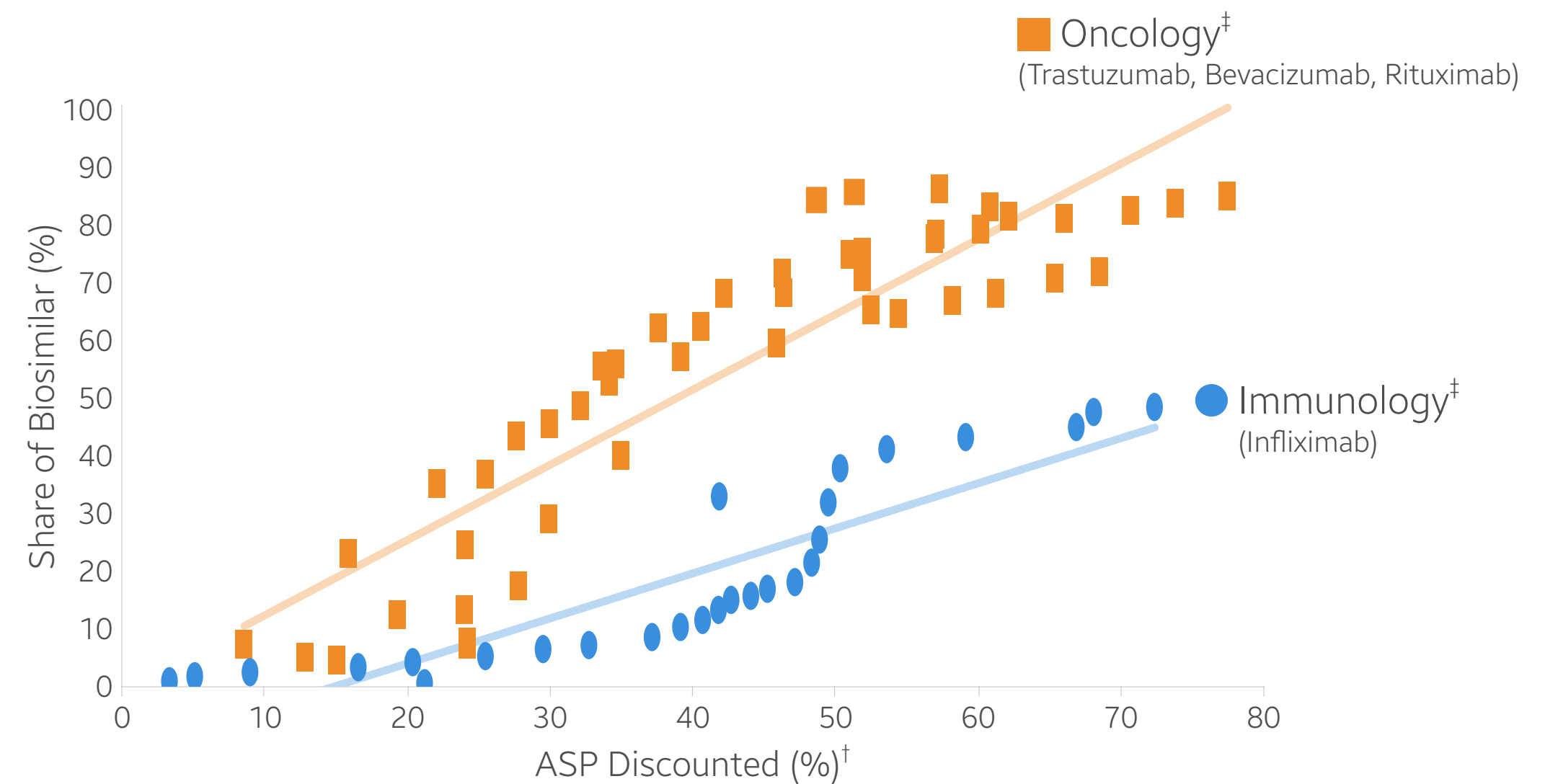
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

# Understanding the Factors that Determine Biosimilar Uptake (1/3)

- The landscape of biosimilar uptake in the United States is a multifaceted puzzle, with seemingly contradictory variances apparent across different therapeutic areas and products.
- The 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, demonstrating that the oncology category is likely more price-sensitive than immunology.
- While cost and the number of available biosimilar options significantly impact acceptance, several underlying factors shape this complex scenario. In this analysis, we explore three key determinants influencing the degree of biosimilar utilization:

1. Independent Medical Guidelines
2. Duration of Treatment: Acute vs. Chronic Conditions
3. Access and Rebate Walls

Figure 29. 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:  $y = 1.3069x - 0.0098$   $R^2 = 0.8169$ ; Immunology equation:  $y = 0.7825x - 0.1193$   $R^2 = 0.796$ ;

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Oncology
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- Immunology
- Endocrinology
- Ophthalmology

# Understanding the Factors that Determine Biosimilar Uptake (2/3)

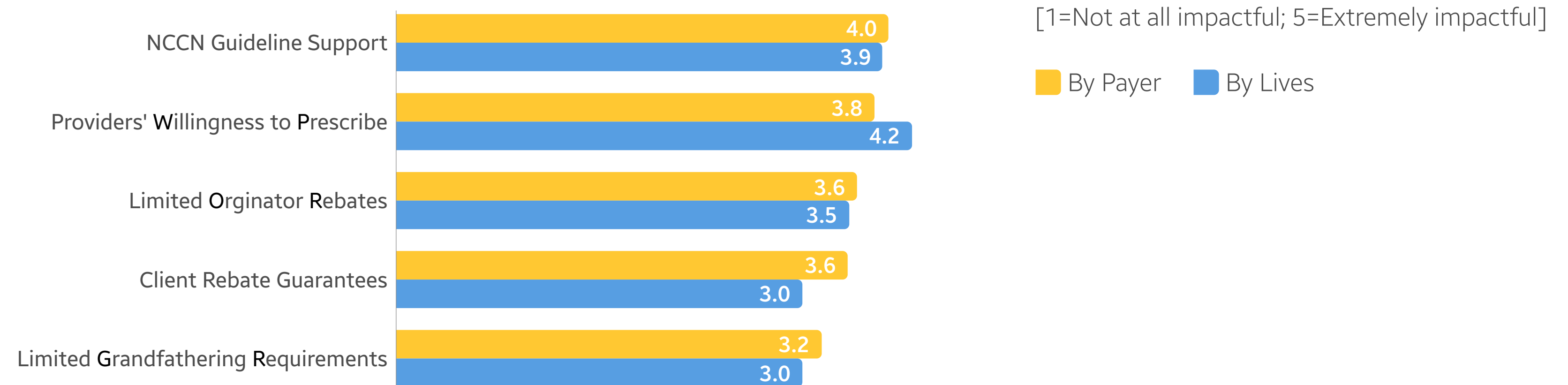
## \* 1. Independent Medical Guidelines

The influence of respected medical societies on biosimilar usage cannot be overstated. Guidance provided by these organizations plays a pivotal role in shaping healthcare professionals' (HCPs) decisions. For instance, the National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines are instrumental in oncology.

Following Samsung Bioepis commissioned research to 20 PBMs/payers, they responded that the NCCN guideline support is a most impactful factor that the reason why oncology has experience faster growth than inflammatory.

The NCCN explicitly states that "An FDA-approved biosimilar is an appropriate substitute." In contrast, immunology faces a more cautious landscape. The American College of Rheumatology (ACR) and the American College of Gastroenterology (ACG) have published position statements that are guarded in their recommendations. While the ACR generally favors biosimilars for new starts, it firmly opposes insurer-mandated forced switching. These varying stances underscore the importance of medical society endorsements in driving or impeding biosimilar adoption.

**Figure 30.** Impact of the factors on why oncology has experienced disproportionate growth in biosimilar uptake relative to inflammatory<sup>6</sup>





- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Oncology
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- Ophthalmology

# Understanding the Factors that Determine Biosimilar Uptake (3/3)

## \* 2. Duration of Treatment: Acute vs. Chronic Conditions

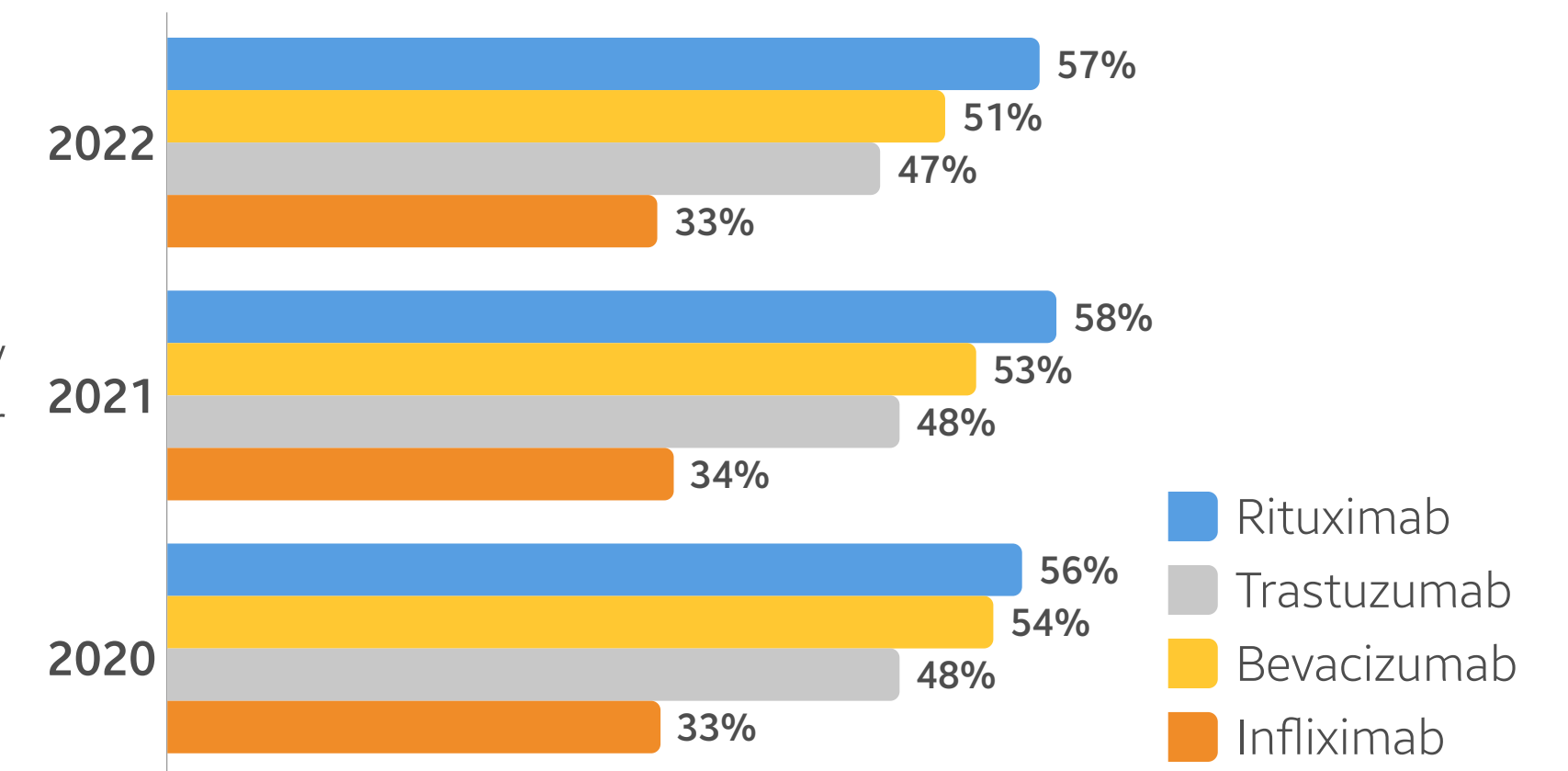
Treatment duration plays a pivotal role in determining biosimilar utilization. In chronic conditions, patients tend to remain on therapy for more extended periods, and HCPs are often reluctant to initiate changes when patients are well controlled on a medicine. This hesitation aligns with the ACR's opposition to forced switching. Conversely, oncology presents a different dynamic. Due to disease progression, patients typically receive therapy for shorter durations, and new patients constitute a larger portion of total treatments. This dynamic contributes to higher biosimilar usage in oncology compared to other therapeutic areas.

## \* 3. Access and Rebate Walls

Access is a paramount factor influencing pharmaceutical product usage in the US. The concept of "grandfathering" allows many patients to continue their existing treatment, even when biosimilar manufacturers achieve access victories. This phenomenon is particularly pronounced in therapeutic areas where new patient starts represent a small fraction of total prescriptions. Moreover, the reliance of payers on rebate streams from originators often results in the creation of "rebate walls." These walls occur when the projected initial loss of rebates negates the potential for overall savings offered by biosimilars. Such conditions are well-known in immunology, where the market share for originator products have endured in the face of biosimilars with lower unit costs.

The journey towards enhanced biosimilar uptake in the United States is a multifaceted one, characterized by variations across therapeutic areas and products. While cost and competition undoubtedly impact acceptance, the interplay of factors such as independent medical guidelines, treatment duration, and access dynamics creates a complex landscape. Recognizing and understanding these determinants is essential for healthcare professionals as they navigate the evolving biosimilar landscape, ultimately striving to optimize patient care while promoting cost-efficiency in the healthcare system.

Figure 31. Portion of New Patient by Molecule<sup>7</sup>



- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

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