

SAMSUNG BIOEPIS

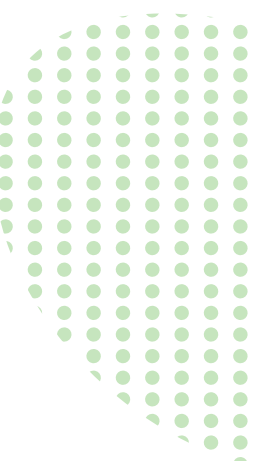
SAMSUNG BIOEPIS

Biosimilar Market Report

4th Edition, Q1 2024



| FOREWORD



Happy New Year!

This is our 4th edition of the Biosimilar Market Report.

The goal of this report is to provide you with convenient, timely information on the status of biosimilars in the U.S.

We look forward to covering all of the competitive market dynamics in 2024 and beyond. In the immunology pipeline, several originator products face loss of exclusivity in the next few years (e.g. ustekinumab, golimumab, certolizumab pegol, and tocilizumab). In other therapeutic areas, many biologics, such as aflibercept, denosumab, and eculizumab, are also expected to face competition from multiple biosimilar companies, including Samsung Bioepis.

We continue to closely monitor Humira and its biosimilar market. The underutilization of Humira biosimilars is a missed opportunity for cost savings, not only for healthcare systems but also for patients. Some of the biosimilars have pricing models that are designed to provide direct cost savings, but patients cannot benefit from these lower-cost options if the biosimilars are not made available to them.

Samsung Bioepis is proud to be a competitor in the biosimilar market for as long as our high-quality, safe, and effective biosimilars have a route to improve access and benefit patients.



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 January 2024, the FDA has approved a total of 45 biosimilars across 14 unique biological molecules. Of the 45 approvals, 38 biosimilars have been launched in the US market.

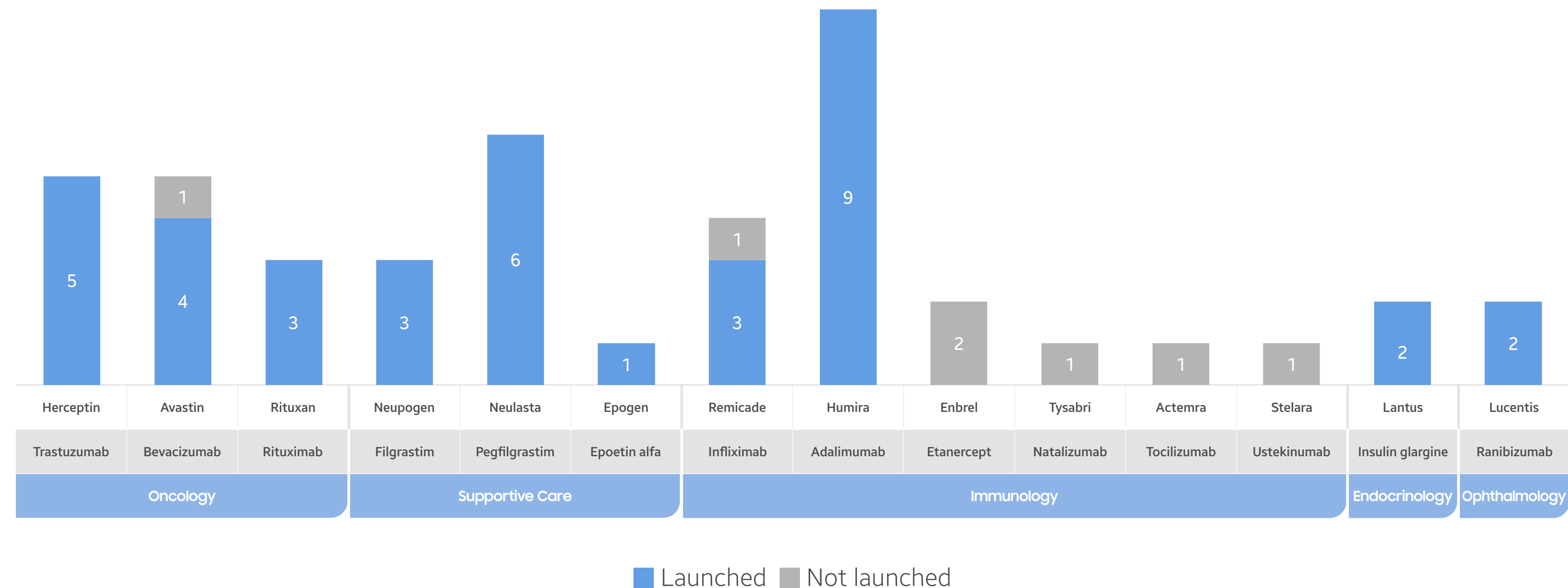
In Q4 last year, three new biosimilars were approved in the US (See Figure 2 in next slide)

- Avzivi for Avastin (bevacizumab) biosimilar
- Tofidence for Actemra (tocilizumab) biosimilar
- Wezlana for Stelara (ustekinumab) biosimilar

Cumulative Approvals

45

Figure 1. Biosimilars Approval and Launch Status in the US^{1*} (As of January 2024)



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

US Biosimilars Approval & Launch Status

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Figure 2. Biosimilars Approval and Launch Status in the US^{1*} (As of January 2024, with Suffix)

TA	Oncology			Supportive Care			Immunology						Endocrinology	Ophthalmology
Molecule	Trastuzumab	Bevacizumab	Rituximab	Filgrastim	Pegfilgrastim	Epoetin alfa	Infliximab	Adalimumab	Etanercept	Natalizumab	Tocilizumab	Ustekinumab	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	Epoen (epoetin alfa) Amgen 1898	Remicade (infliximab) Janssen 1998	Humira (adalimumab) AbbVie 2002	Enbrel (etanercept) Amgen 2003	Tysabri (natalizumab) Biogen 2004	Actemra (tocilizumab) Genetech 2010	Stelara (ustekinumab) Janssen 2009	Lantus (insulin glargine) Sanofi 2000	Lucentis (ranibizumab) Novartis 2006
Biosimilar	Ogivri (trastuzumab-dkst) Biocon 2017	Mvasi (bevacizumab-awwb) Amgen 2017	Truxima (rituximab-abbs) Celltrion&Teva 2018	Zarxio (filgrastim-sndz) Sandoz 2015	Fulphila (pegfilgrastim-jmdb) Biocon 2018	Retacrit (epoetin alfa-epbx) Hospira&Pfizer 2018	Inflectra (infliximab-dyyb) Celltrion&Pfizer 2016	Amjevita (adalimumab-atto) Amgen 2016	Erelzi (etanercept-szss) Sandoz 2016	Tyruko (natalizumab-sztn) Sandoz 2023	Tofidence (tocilizumab-bavi) Biogen&Bio-Thera 2023	Wezlana (ustekinumab-auub) Amgen 2023	Semglee (insulin glargine-yfgr) Biocon 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 (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	Avzivi (bevacizumab-tnjn) Sandoz&Bio-Thera 2023			Stimufend (pegfilgrastim-fpgk) Fresenius Kabi 2022			Abrilada (adalimumab-afzb) Pfizer 2019						
				Fylnetra (pegfilgrastim-pbbk) Amneal&Kashiv 2022			Hulio (adalimumab-fkjp) Biocon 2020							
								Yusimry (adalimumab-aqvh) Coherus 2021						
								Idacio (adalimumab-aacf) Fresenius Kabi 2022						
								Yufflyma (adalimumab-aaty) Celltrion 2023						

■ 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

Biosimilar Price - Pharmacy Benefit

- Immunology & Endocrinology

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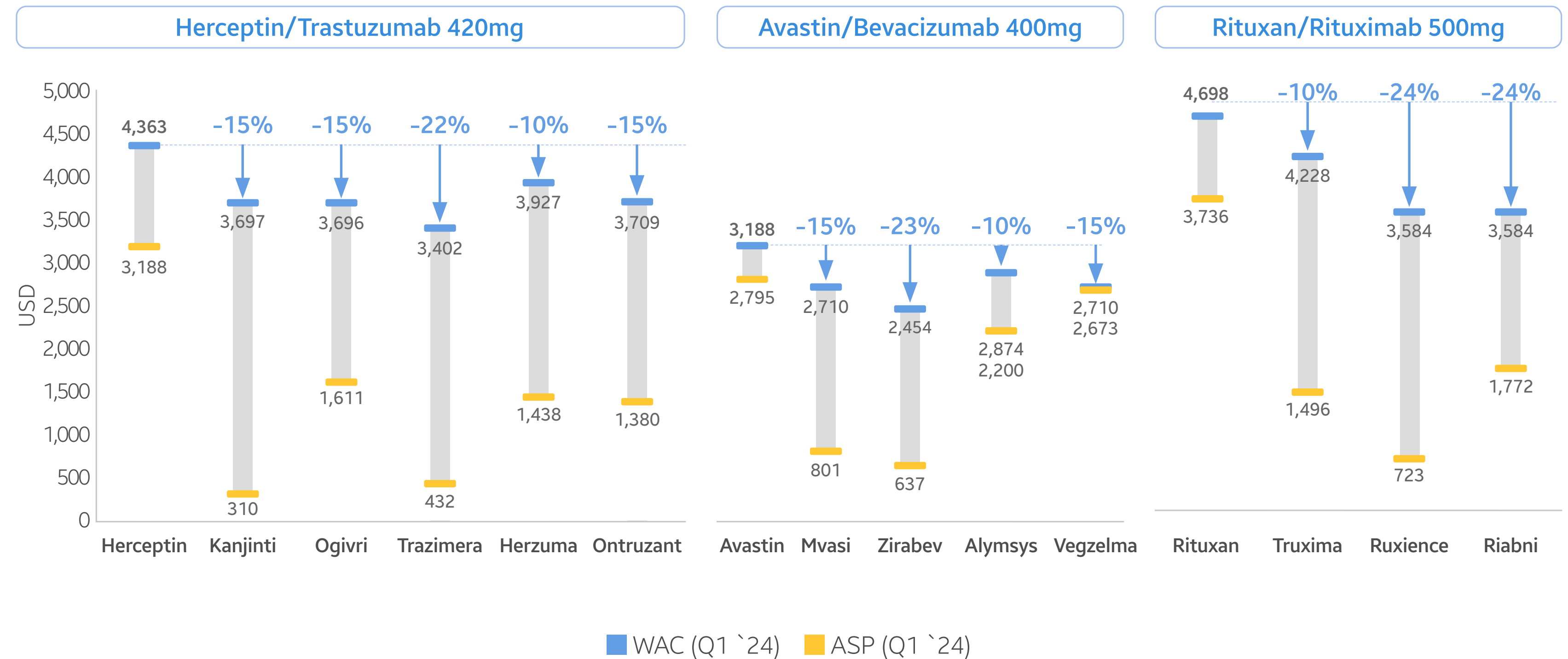
Biosimilar Deep Dive

Reference

Oncology WAC and ASP - Q1 2024

- * 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 up to 90% compared to their reference products.

Figure 3. Q1 2024 WAC and ASP^{2,3}



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

Biosimilar Price - Medical Benefit

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Biosimilar Price - Pharmacy Benefit

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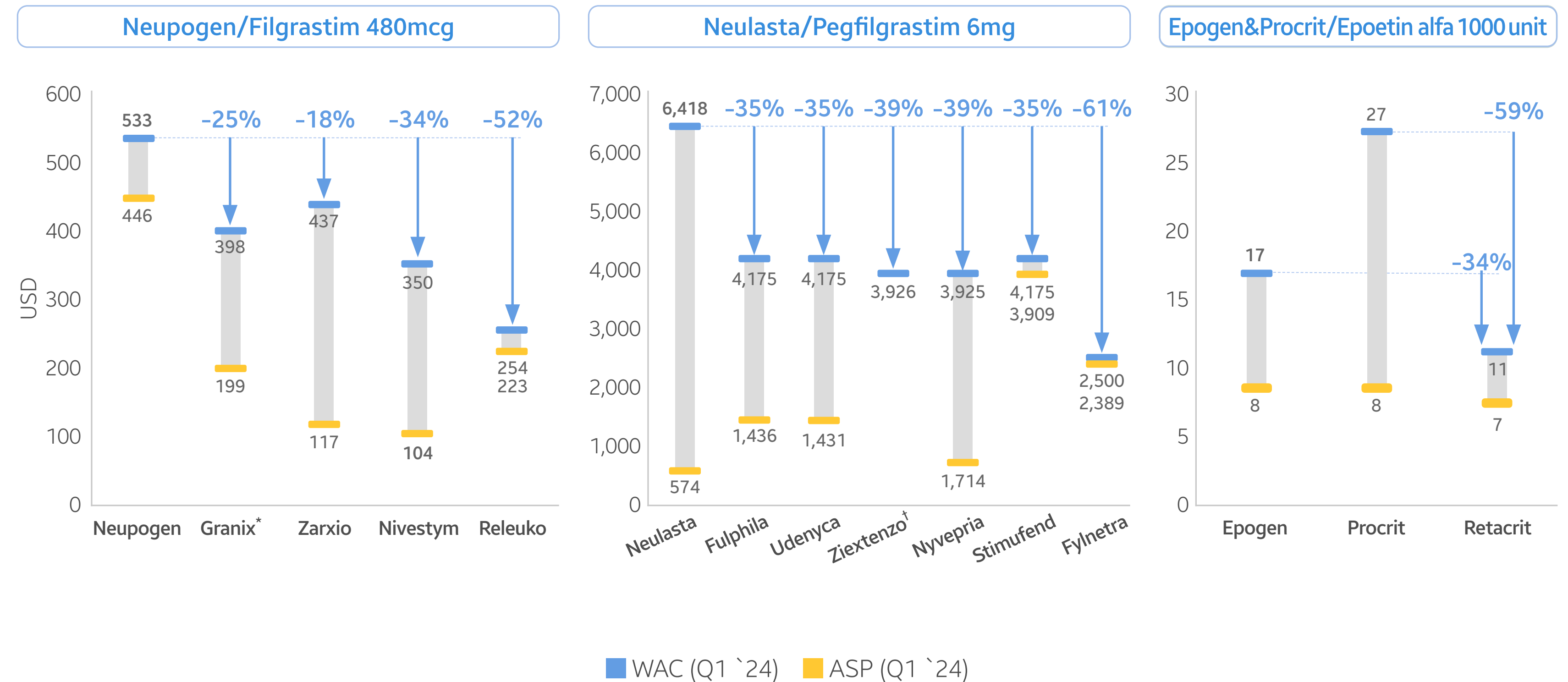
Biosimilar Deep Dive

Reference

Supportive Care WAC and ASP - Q1 2024

- * 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. Q1 2024 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. It's approved under FDA, a new drug application pathway
 † Ziextenzo ASP is not published in Q4 2023

Biosimilar Price - Medical Benefit

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Biosimilar Price - Pharmacy Benefit

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Biosimilar Deep Dive

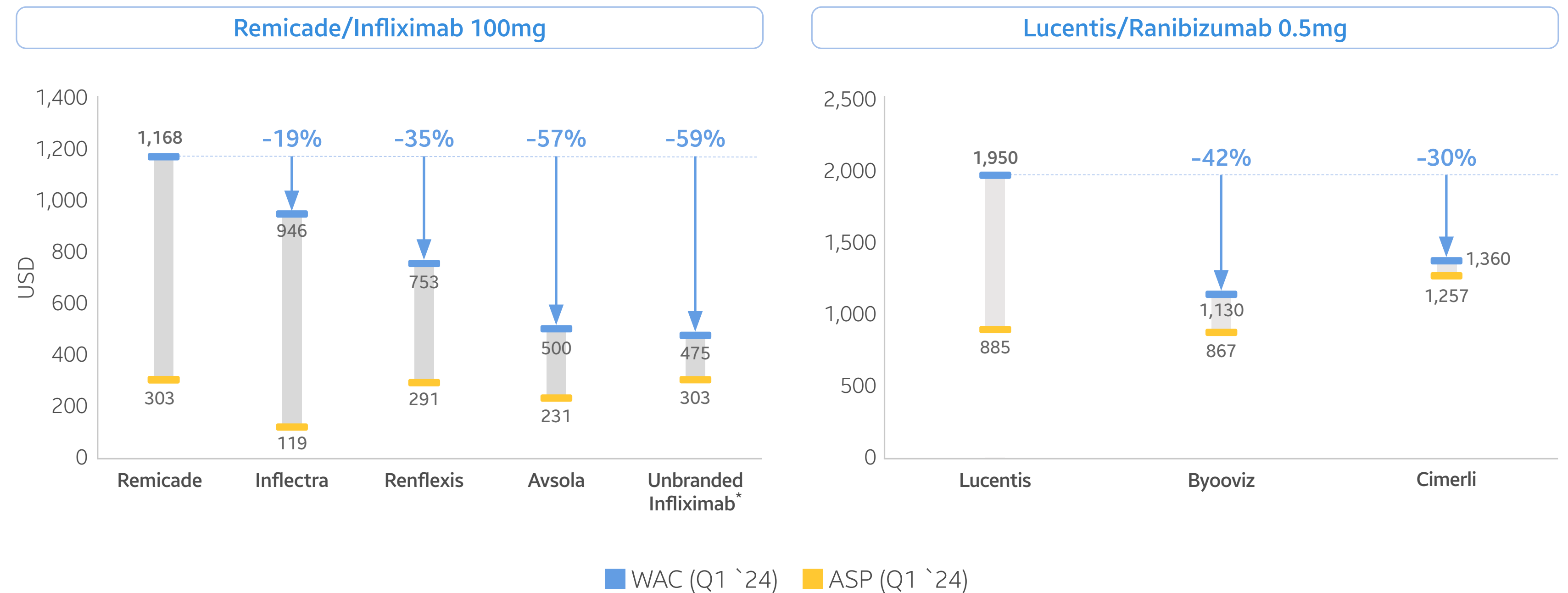
Reference

Immunology & Ophthalmology

WAC and ASP - Q1 2024

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

Figure 5. Q1 2024 WAC and ASP^{2,3}



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

Biosimilar Price - Medical Benefit

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Biosimilar Price - Pharmacy Benefit

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- Endocrinology
- Ophthalmology

Biosimilar Deep Dive

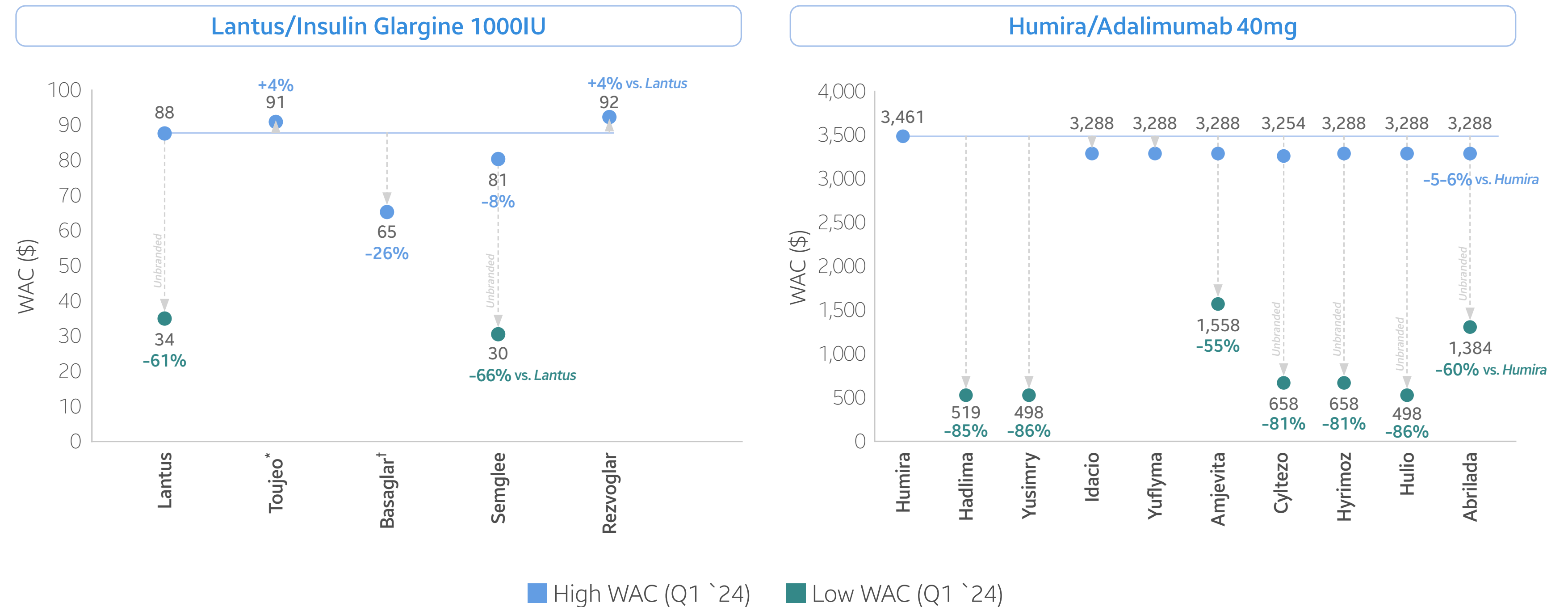
Reference



Immunology & Endocrinology WAC and NADAC - Q1 2024

- * 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 true net prices.

Figure 6. Q1 2024 WAC²



Products are listed in order of launch
WAC: Wholesale 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

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

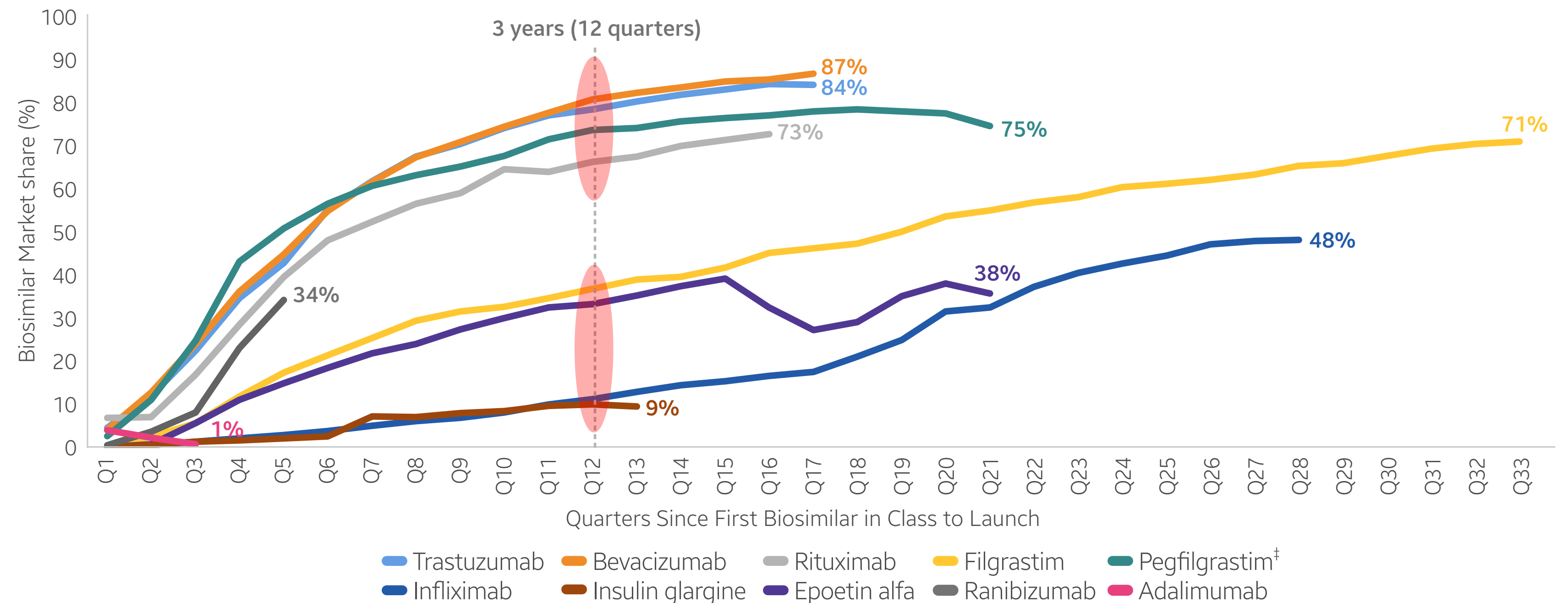
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Biosimilar Volume Uptake Varies by Molecule

✦ On average, biosimilars gain 53% market share within three years (12 quarters) post initial launch. However, each molecule has demonstrated unique biosimilar uptake and can be categorized into fast or slow uptake speed.

- 1) **Fast Uptake Speed:** Oncology*, pegfilgrastim and ophthalmology biosimilars.
Three years post launch, average biosimilar market share reached 75%. (Only products that are more than 3 years)
- 2) **Slow Uptake Speed:** Immunology†, filgrastim, epoetin alfa, and insulin glargine.
On average, only a 23% biosimilar market share was achieved by Year 3. (Only products that are more than 3 years)

Figure 7. Biosimilar Market Share Post-Launch⁵



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

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

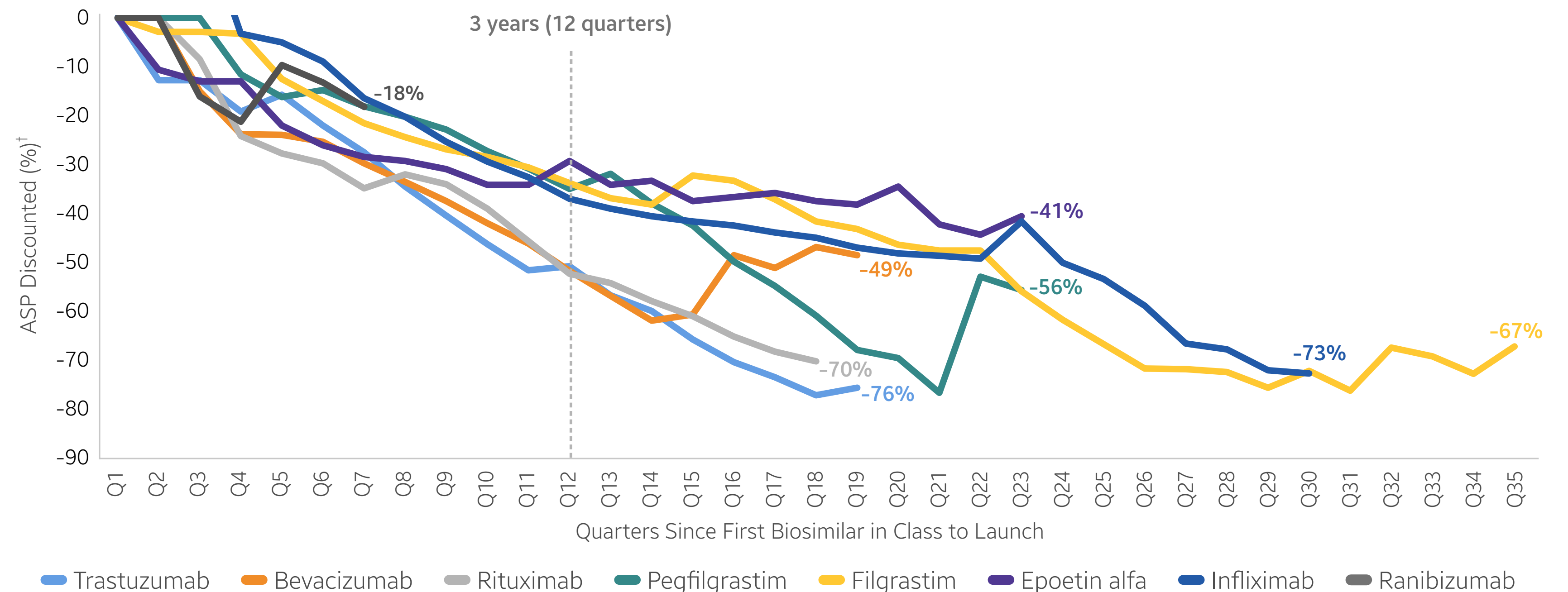
- Biosimilar Market Adoption & Price Erosion

- 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. On average, ASP declined by 41% three years (12 quarters) post first biosimilar launch with more mature markets demonstrating increasing price concessions.
- ✦ Recent observed increases in ASP for some markets (e.g. bevacizumab, pegfilgrastim) are an artifact of newly-launched, low-market share biosimilars with ASPs that reflect WAC pricing.

Figure 8. ASP Trend by Molecule³



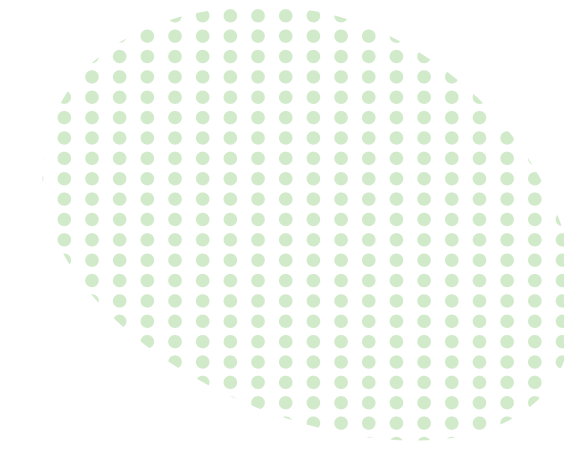
TA: Therapeutic area; ASP: Average sales price
 *: Trastuzumab, bevacizumab, and rituximab are included
 †: ASP discounted % vs. reference product ASP when first biosimilar in class launch

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

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- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology



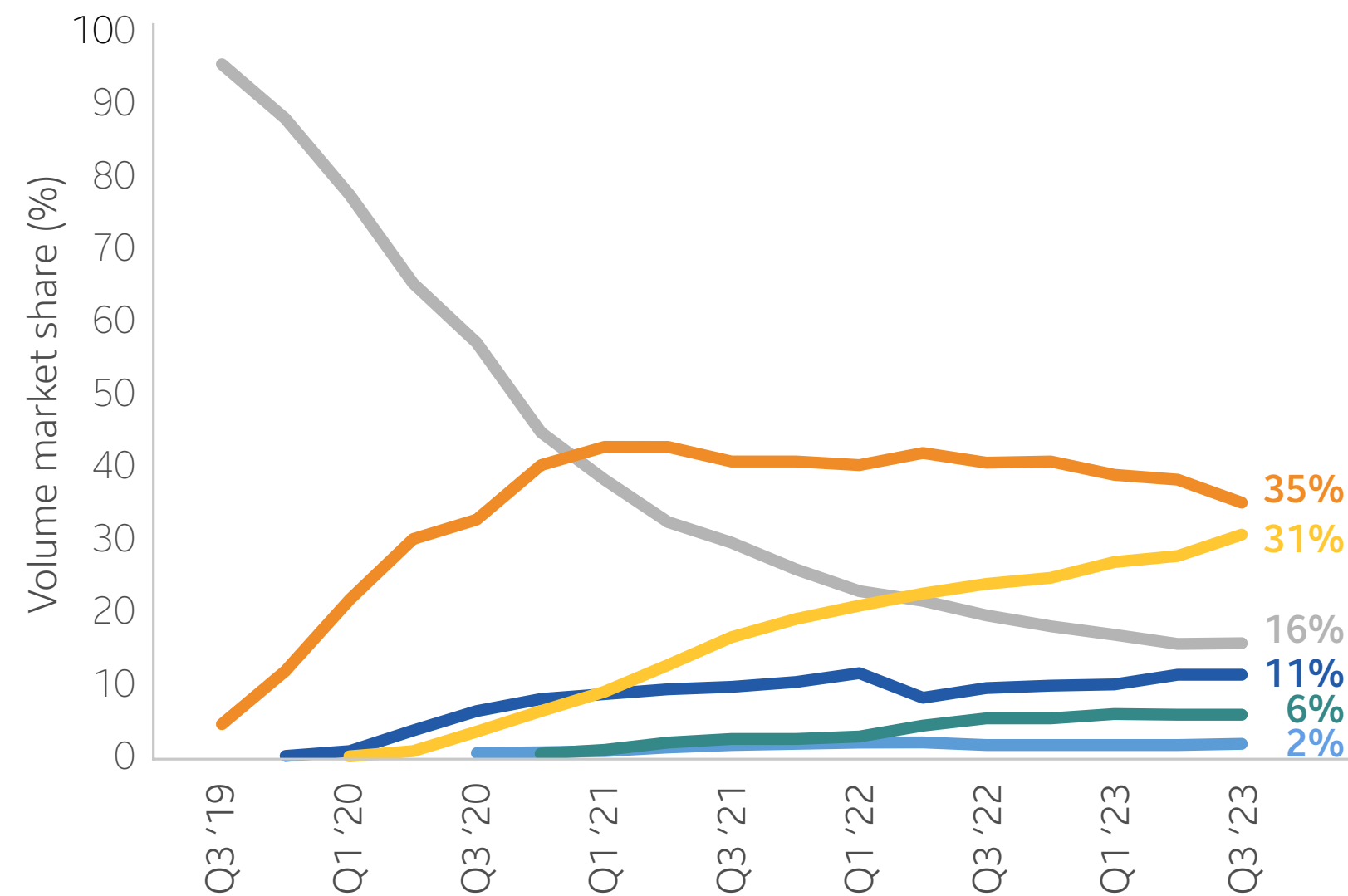
Market Share and ASP Trends - Herceptin (Trastuzumab)

✦ As of Q3 2023, the biosimilar share of the trastuzumab market has reached 84%.

- First-to-market biosimilar, Kanjinti, has been the market leader since Q4 2020.

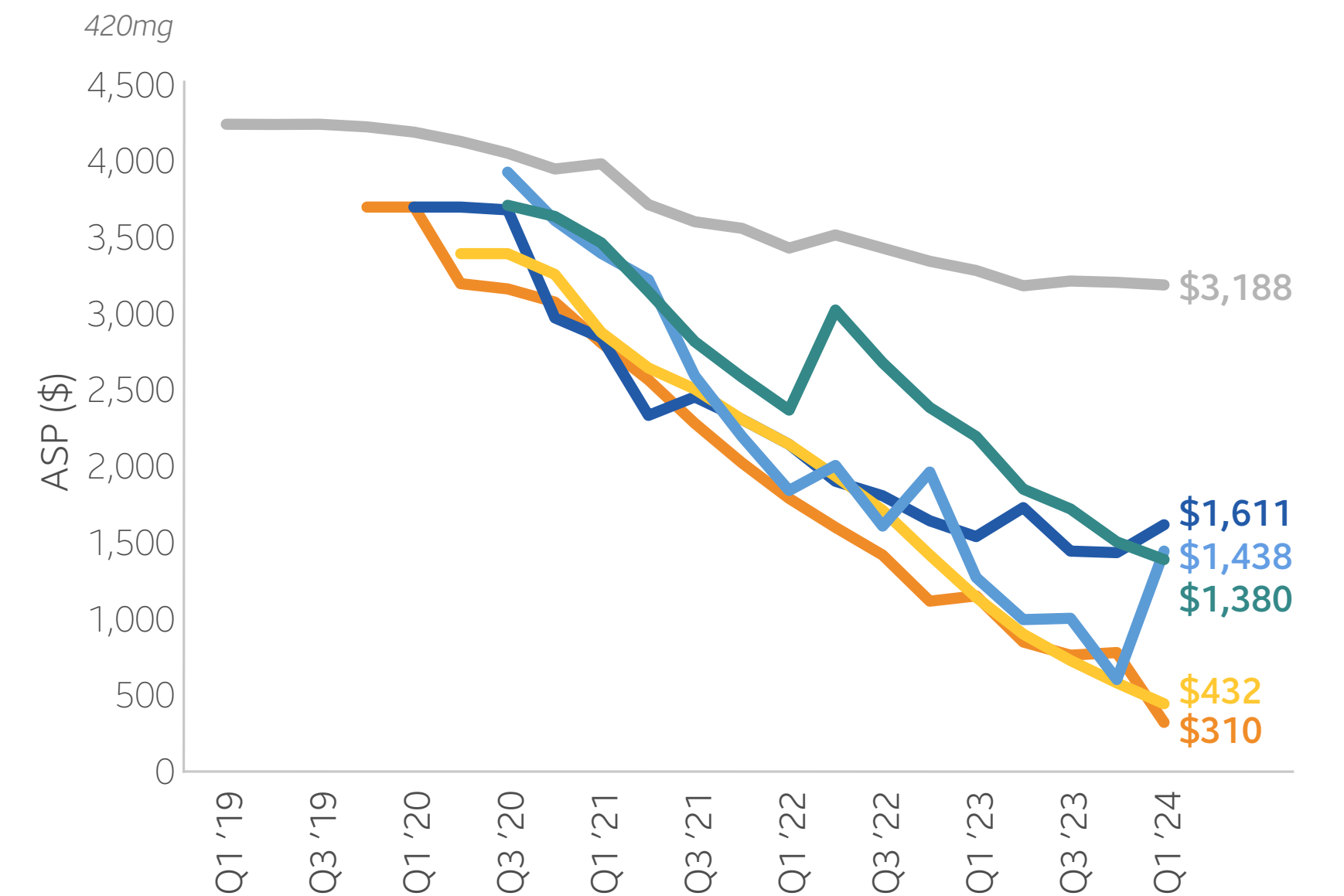
✦ As of Q1 2024, average ASP of all products is \$1,393 (-67%)* and the average for biosimilars alone is \$1,034 (-76%)*.

Figure 9. Trastuzumab Volume Market Share⁵



— Herceptin — Kanjinti — Ogivri — Trazimera — Herzuma — Ontruzant

Figure 10. Trastuzumab ASP Trend³



Products are listed in legends in order of launch
 ASP: Average sales price
 *Percentages reflect the change from the reference product's ASP at the time of the first biosimilar launch.

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

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- Ophthalmology

Market Share and ASP Trends - Avastin (Bevacizumab)



✦ As of Q3 2023, the biosimilar share of the bevacizumab market was 87%.

- Biosimilars achieved a higher marketshare than the originator as of Q4 2020.
- A 5th bevacizumab biosimilar Avzivi was recently approved in Q4 2023.

✦ As of Q4 2024 average ASP of all products is \$1,821 (-41%)* and the average for biosimilars alone is \$1,578 (-49%)*.

Figure 11. Bevacizumab Volume Market Share⁵

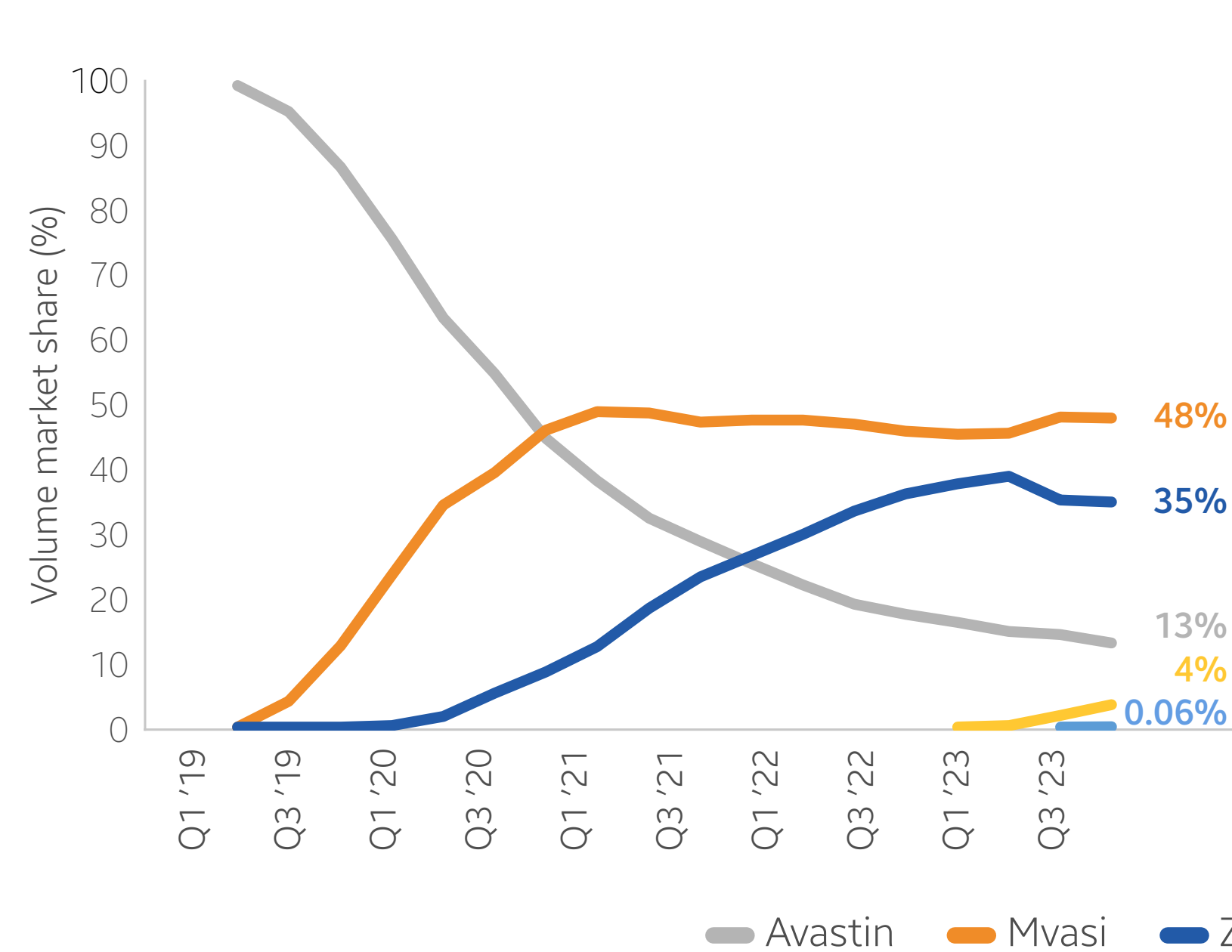
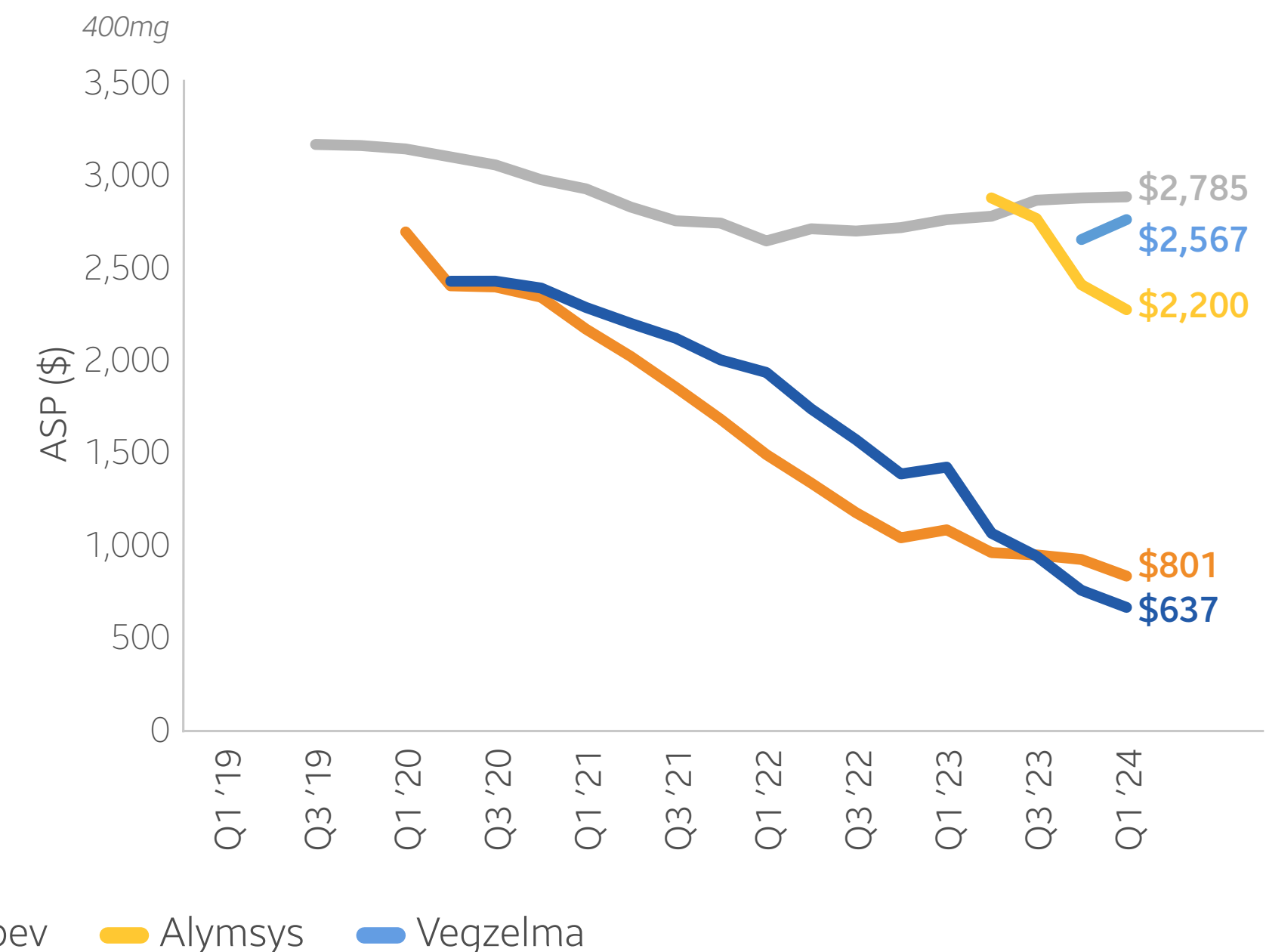


Figure 12. Bevacizumab ASP Trend³



Products are listed in legends in order of launch
 ASP: Average sales price
 *Percentages reflect the change from the reference product's ASP at the time of the first biosimilar launch.

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Market Share and ASP Trends - Rituxan (Rituximab)



✦ As of Q3 2023, the biosimilar share of the rituximab market was 73%.

- A rituximab biosimilar, Ruxience, has become the market leader since Q3 2022.

✦ As of Q1 2024, the average ASP of all products is \$1,932 (-57%)* and the average for biosimilars alone is \$1,330 (-70%)*.

Figure 13. Rituximab Volume Market Share⁵

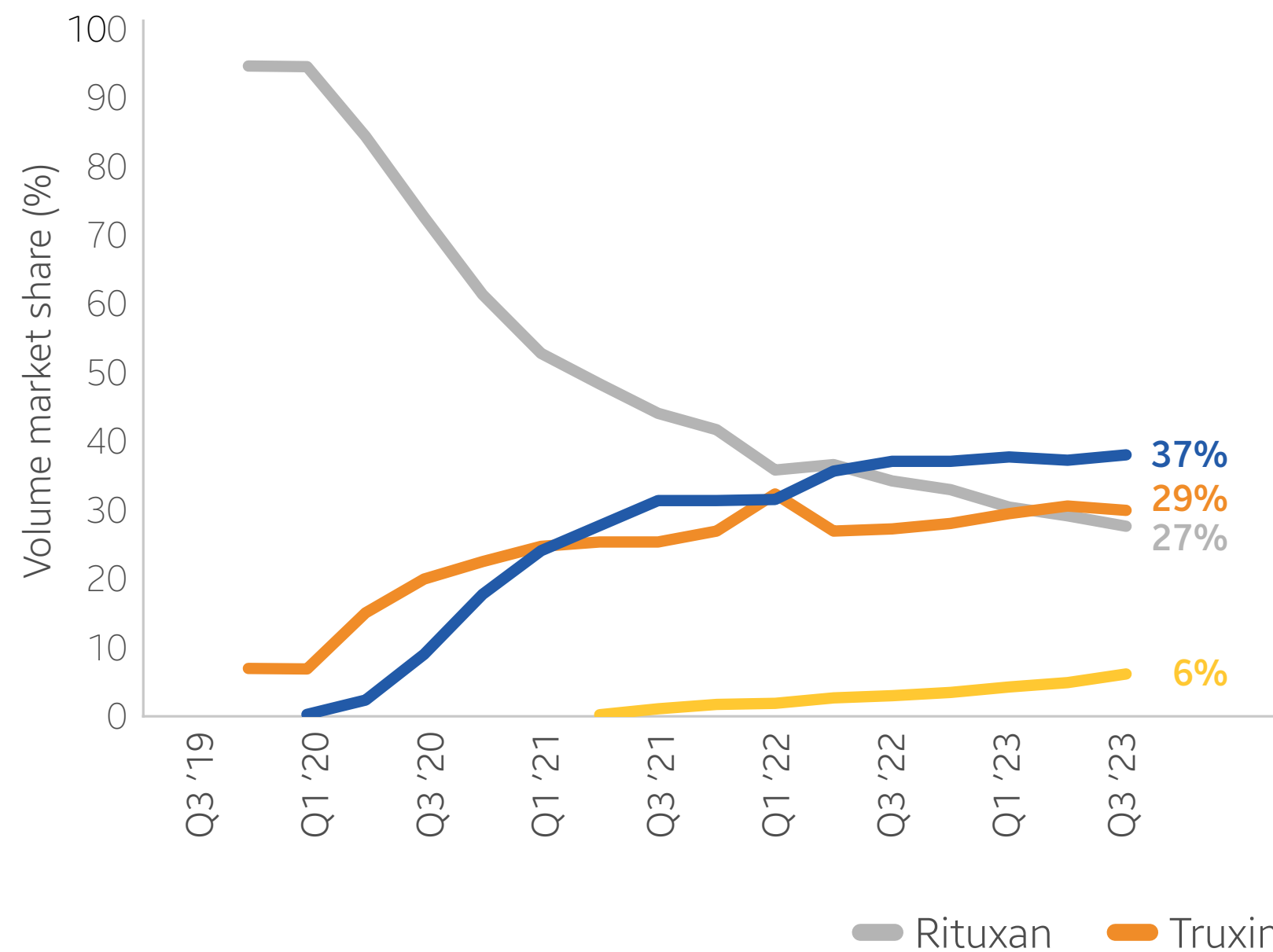
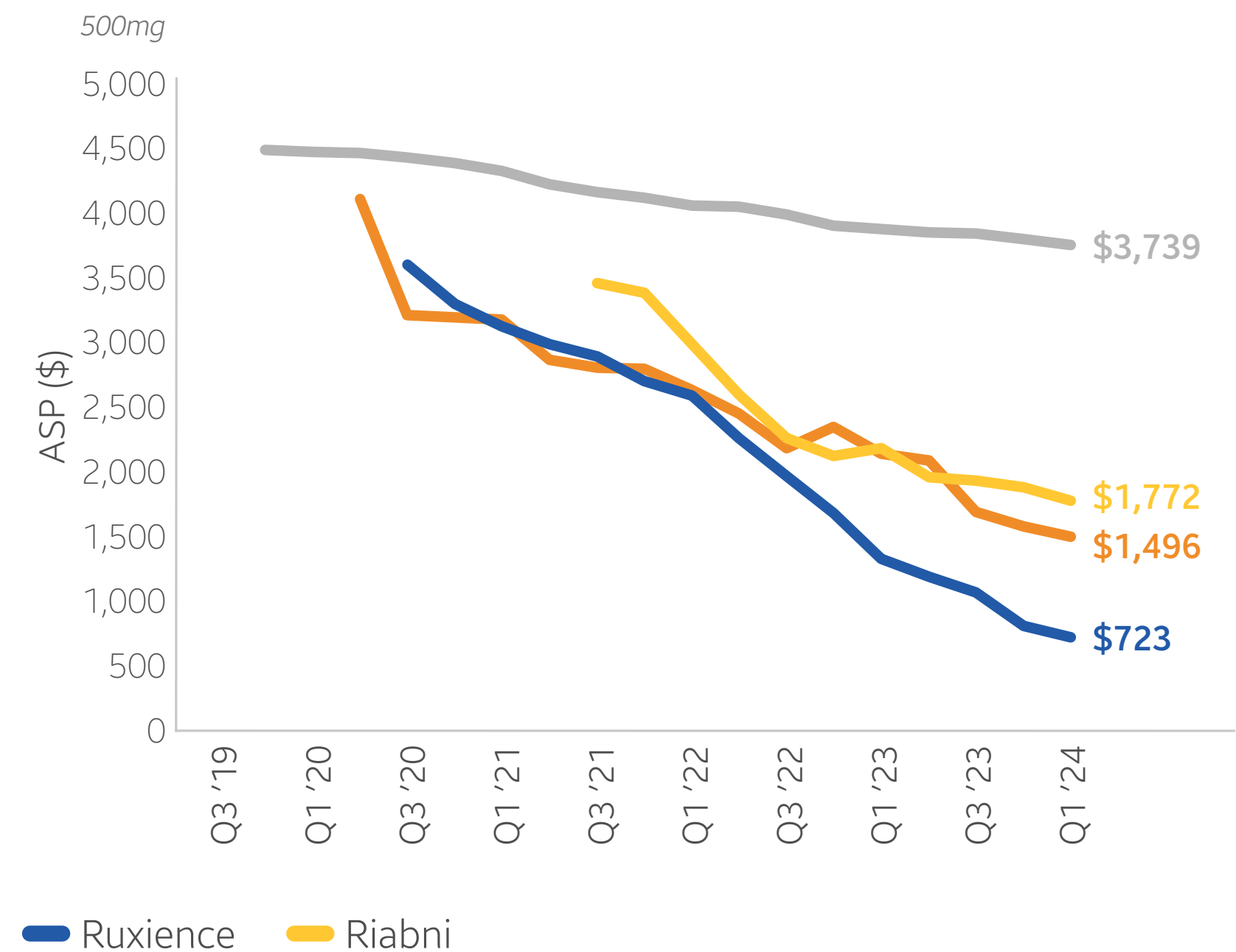


Figure 14. Rituximab ASP Trend³



Products are listed in legends in order of launch
 ASP: Average sales price
 *Percentages reflect the change from the reference product's ASP at the time of the first biosimilar launch.

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Market Share and ASP Trends - Neupogen (Filgrastim)

✦ As of Q3 2023, the biosimilar share of the filgrastim market has reached 86%.

- The first filgrastim biosimilar to launch has been the US market leader since Q3 2018.

✦ As of Q1 2024, the average ASP of all products is \$218 (-52%)* and the average for biosimilars alone is \$148 (-67%)*.

Figure 15. Filgrastim Volume Market Share⁵

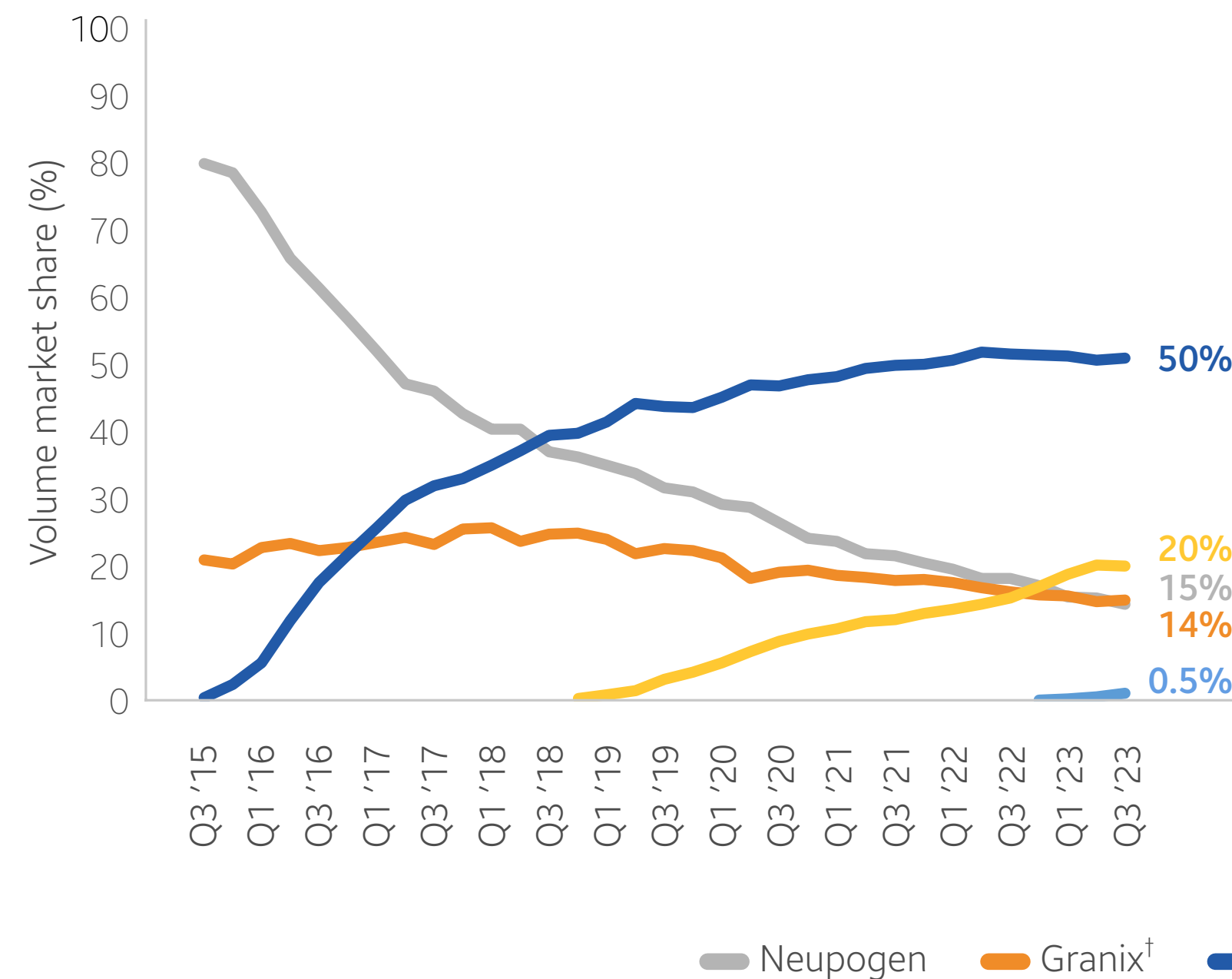
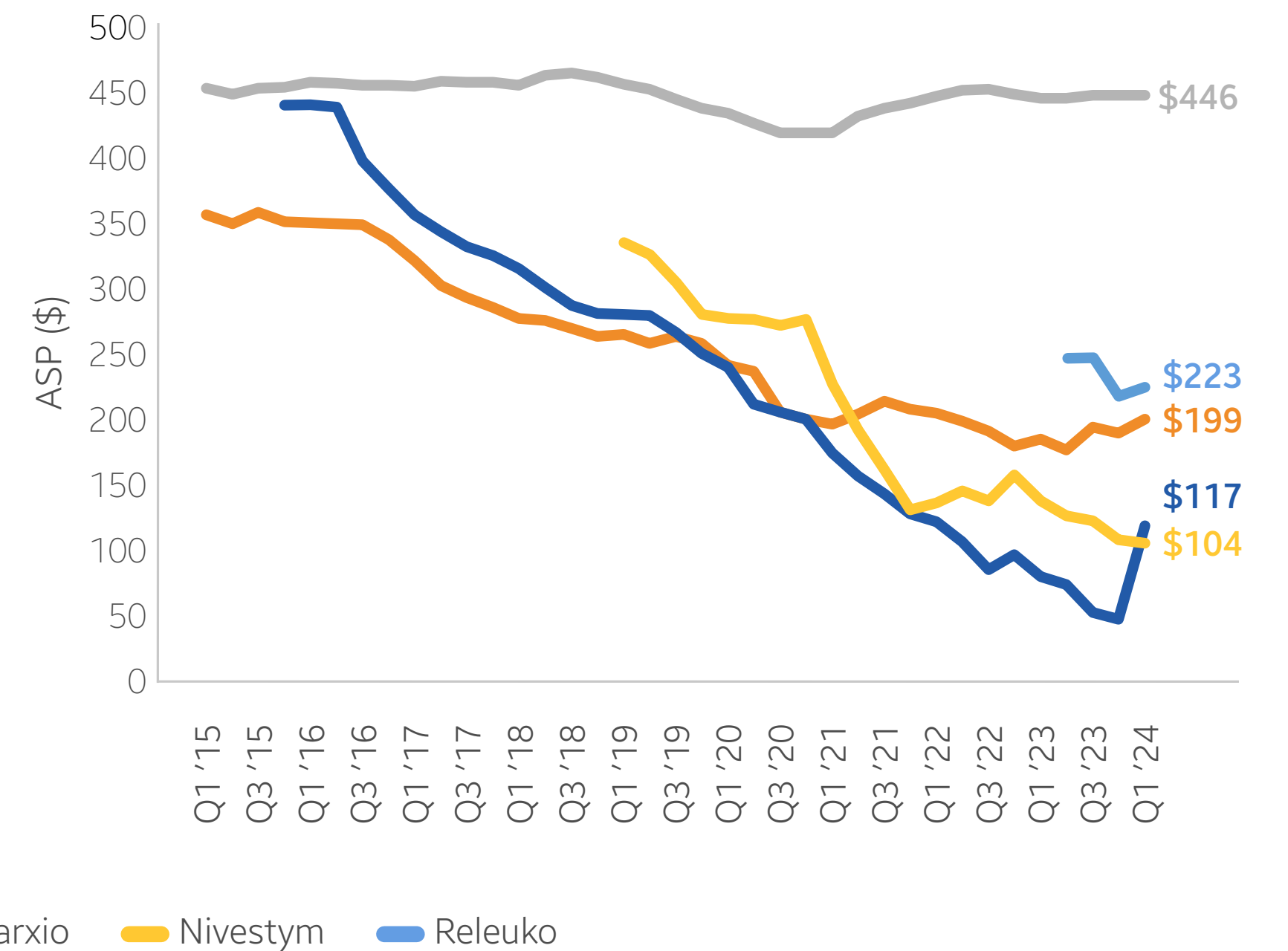


Figure 16. Filgrastim ASP Trend³



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
 *Percentages reflect the change from the reference product's ASP at the time of the first biosimilar launch.

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
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- Endocrinology
- Ophthalmology

Market Share and ASP Trends - Neulasta (Pegfilgrastim)

✦ As of Q3 2023, the biosimilar share of the pegfilgrastim market was 75%.

✦ As of Q1 2024, the average ASP of all products is \$1,742 (-61%)* and the average for biosimilars alone is \$1,976 (-56%)*.

Figure 17. Pegfilgrastim Volume Market Share⁵

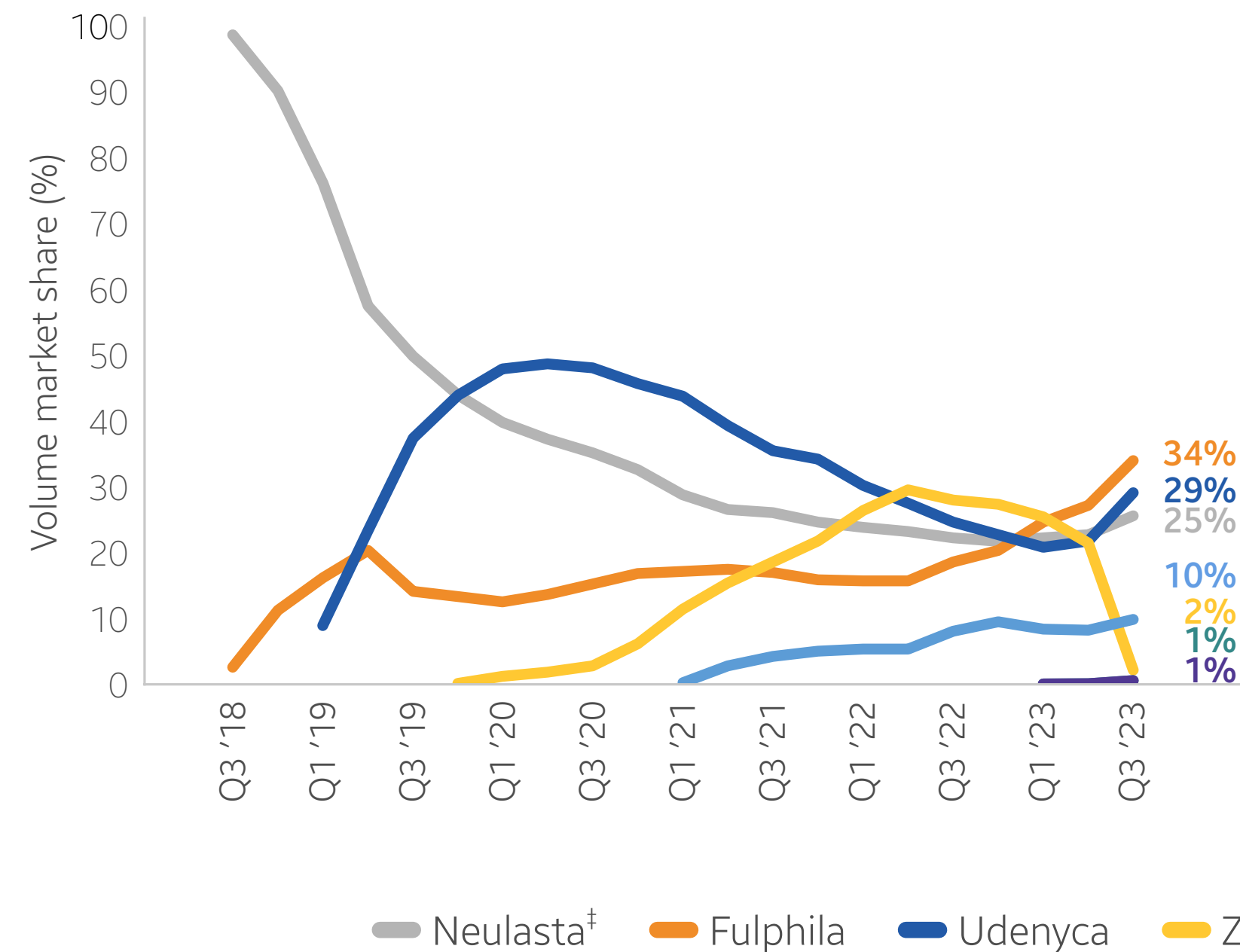
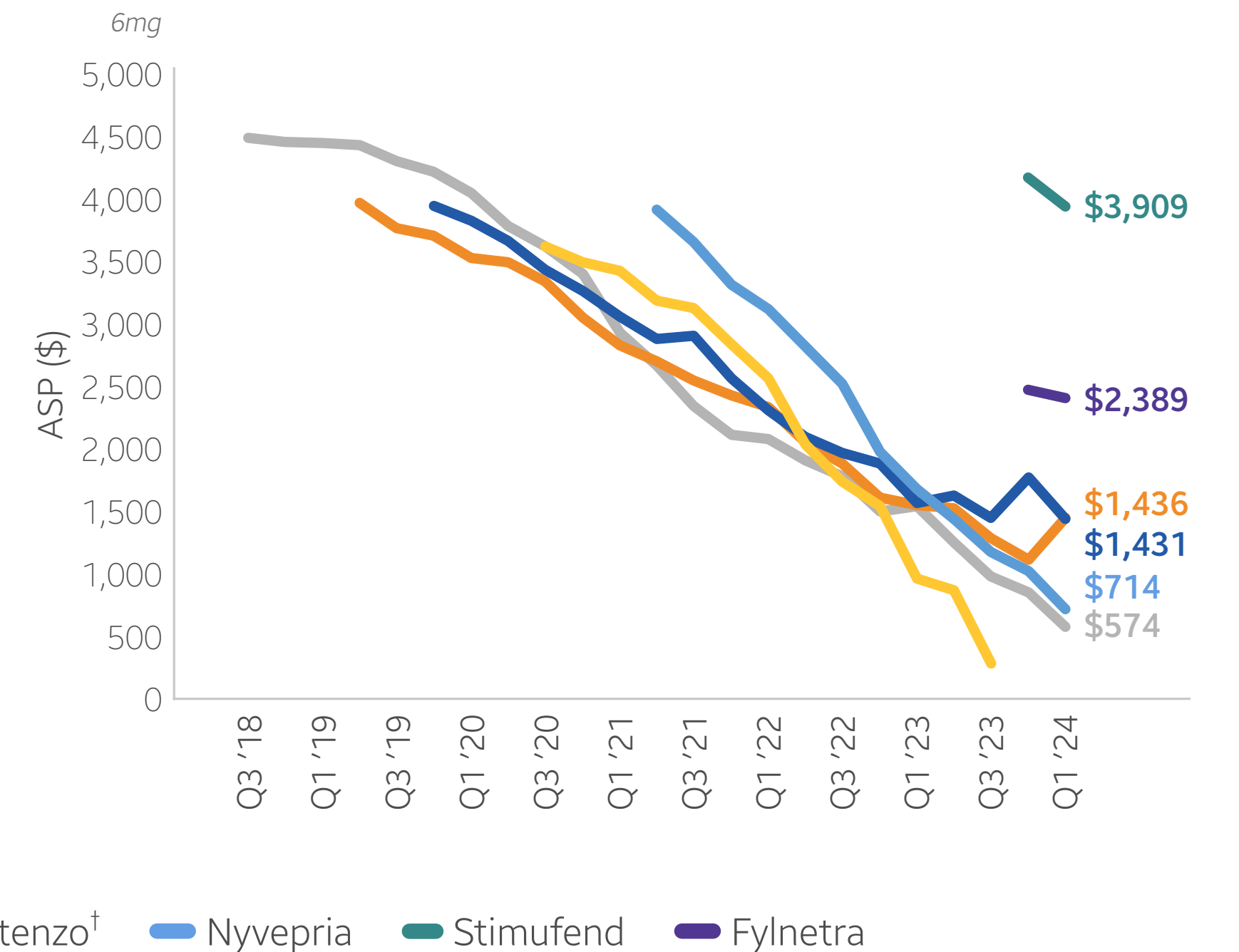


Figure 18. Pegfilgrastim ASP Trend³



Legends are listed in order of launch
 ASP: Average sales price
 *Percentages reflect the change from the reference product's ASP at the time of the first biosimilar launch.
 † Ziextenzo ASP is not published in 4Q 2023
 ‡ Onpro is not included.

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

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

- ✦ Retacrit, the only biosimilar of Epoetin alfa, surpassed the originator and became the market leader in Q3 2023.
- ✦ By matching ASP, the two reference products have maintained a combined share of approximately about 55%.

Figure 19. Epoetin Alfa Volume Market Share⁵

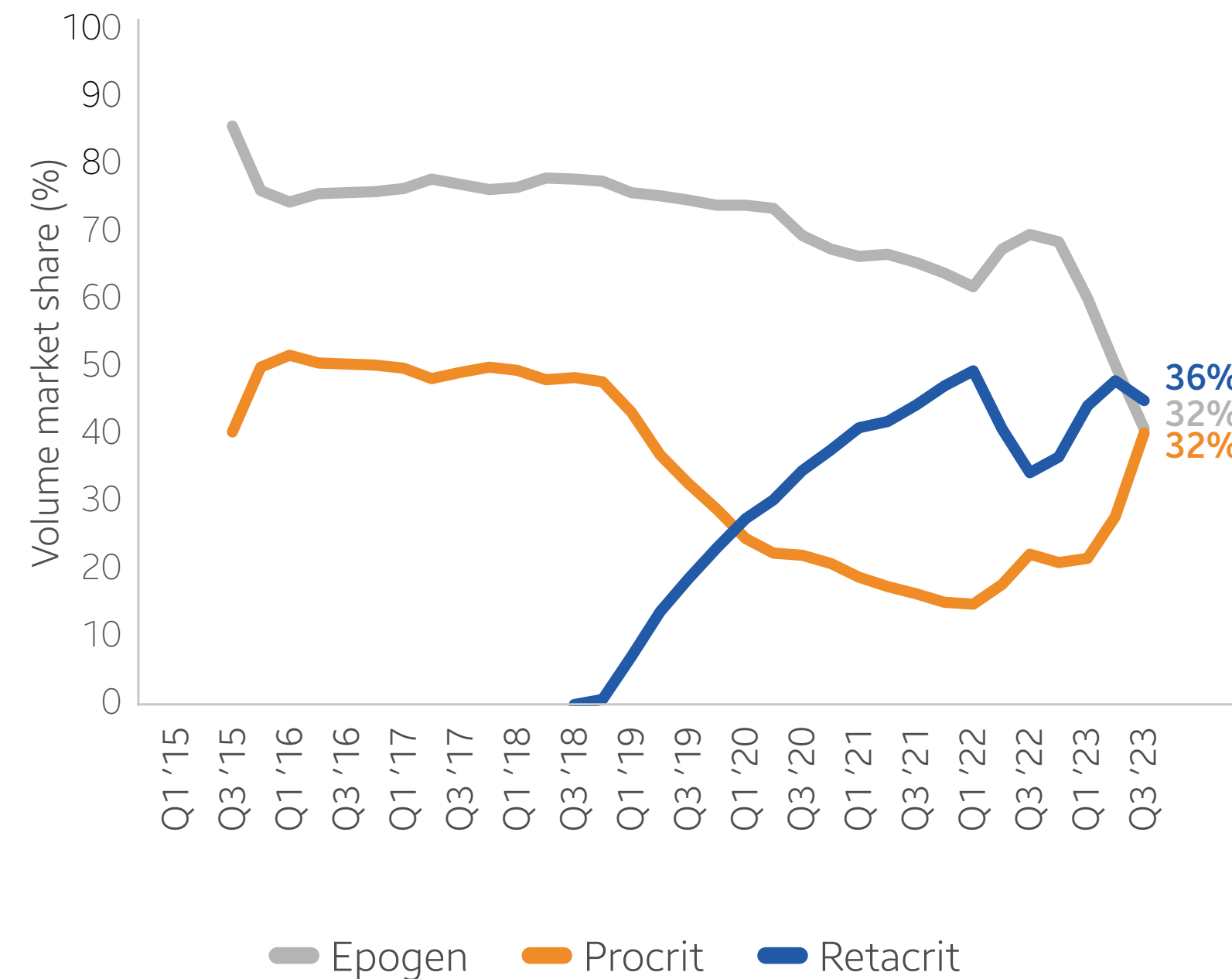
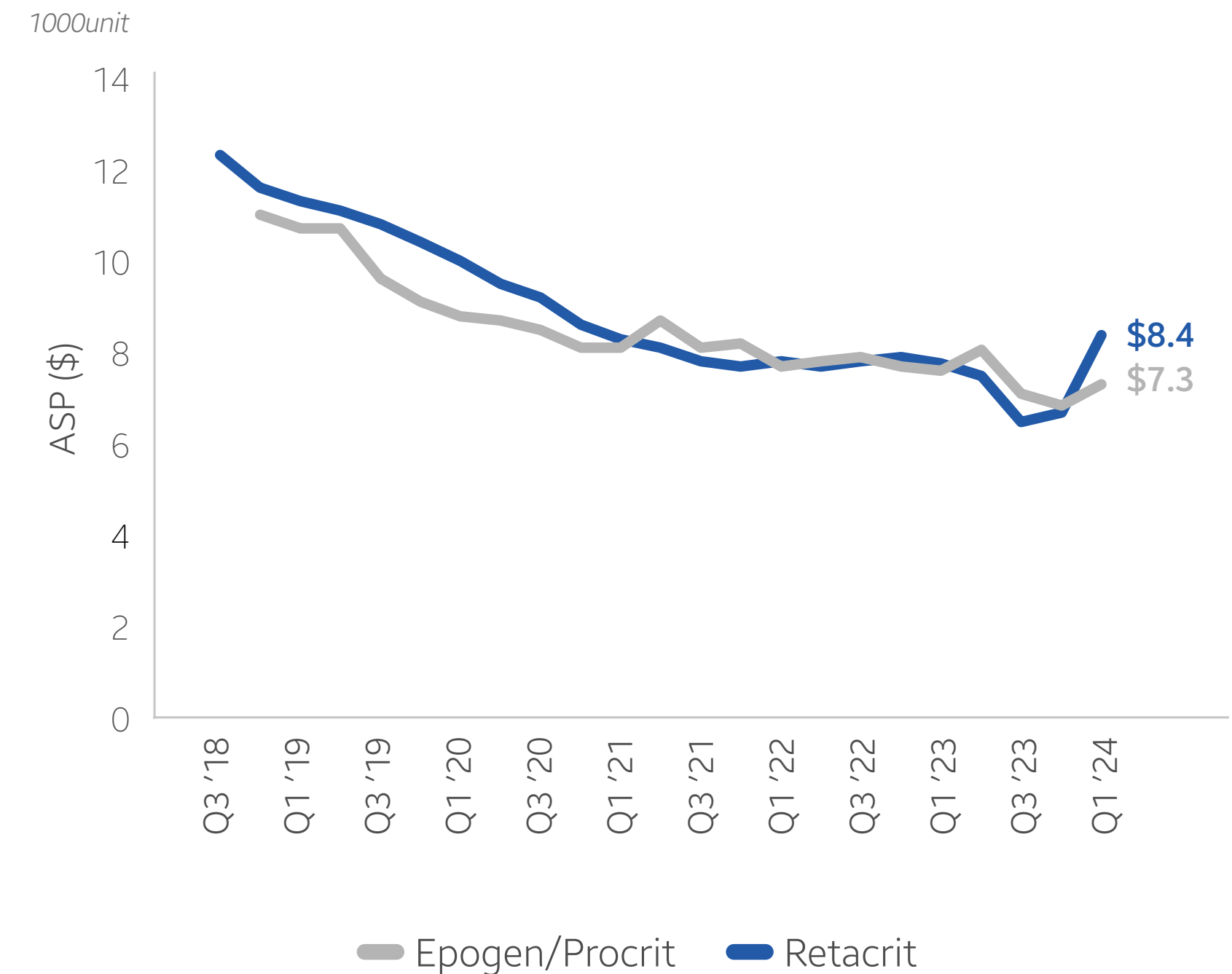


Figure 20. Epoetin alfa ASP Trend³



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

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

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Market Share and ASP Trends - Remicade (Infliximab)

- ✦ After a slow start, the Infliximab biosimilar market began to accelerate in year three.
 - As of Q3 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 Q1 2024, the average ASP of all products is \$236 (-70%)* and the average for biosimilars alone is \$214 (-73%)*.

Figure 21. Infliximab Volume Market Share⁵

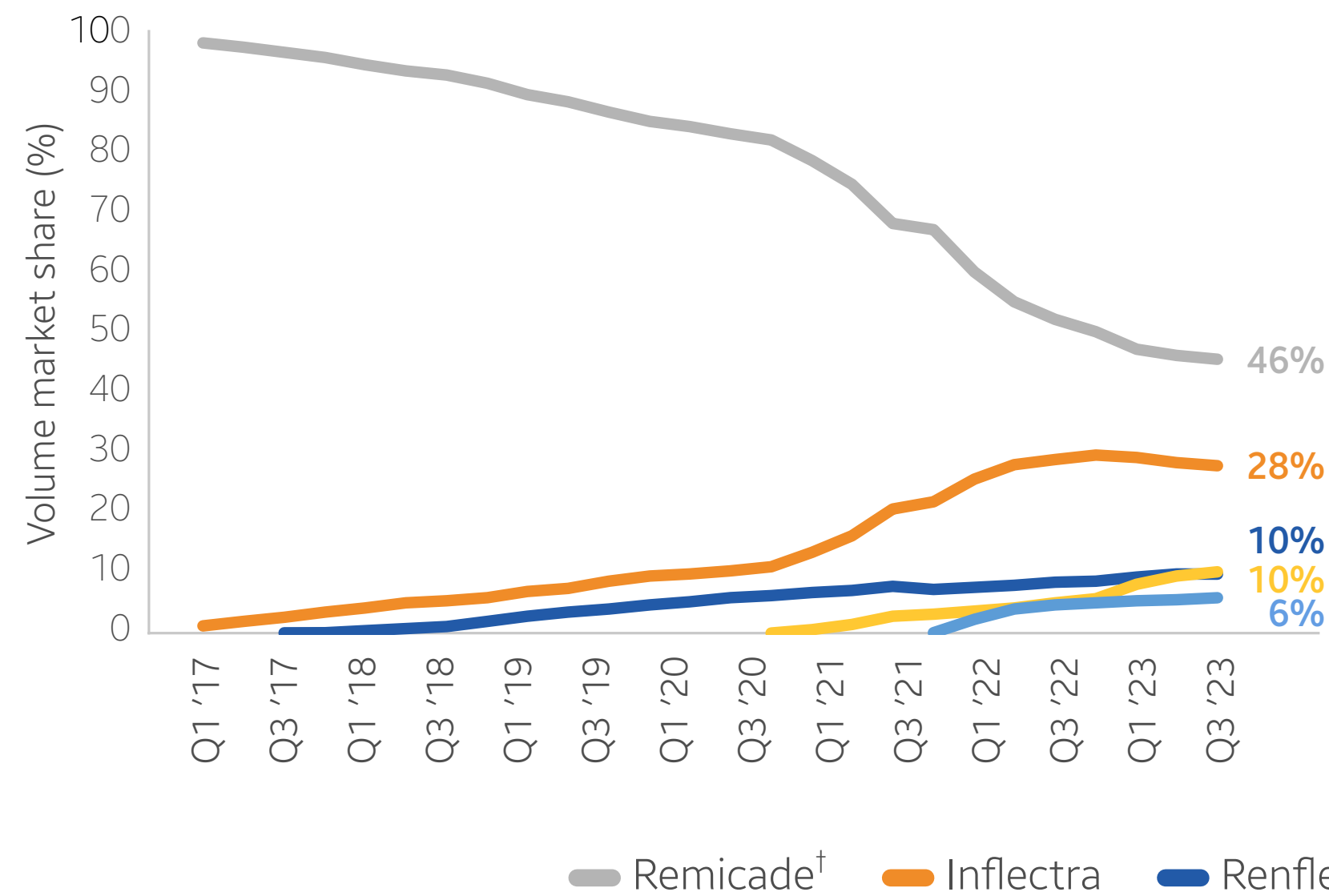
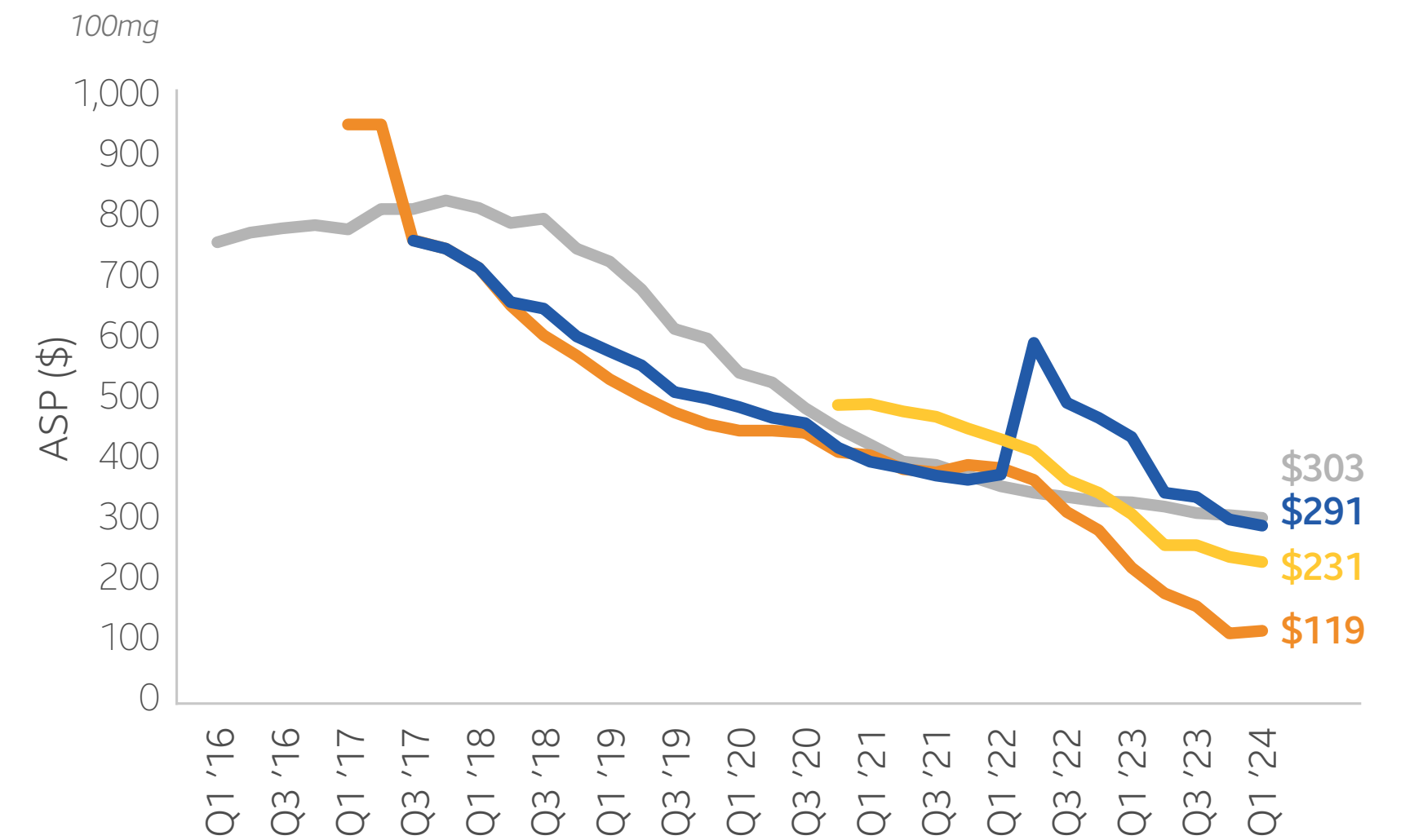


Figure 22. Infliximab ASP Trend³



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
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- Immunology & Endocrinology

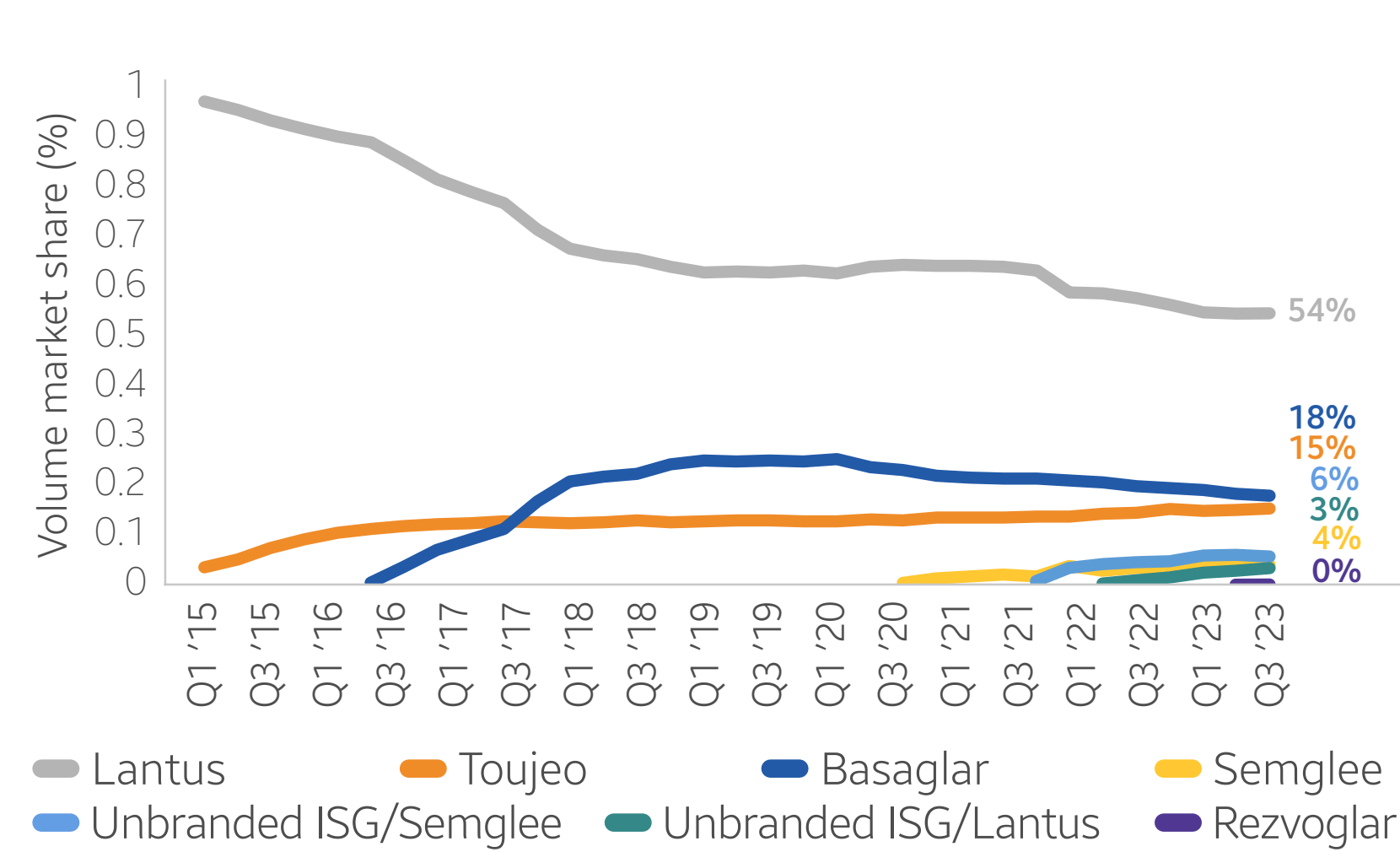
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Market Share and NADAC Trends - Lantus (Insulin glargine)

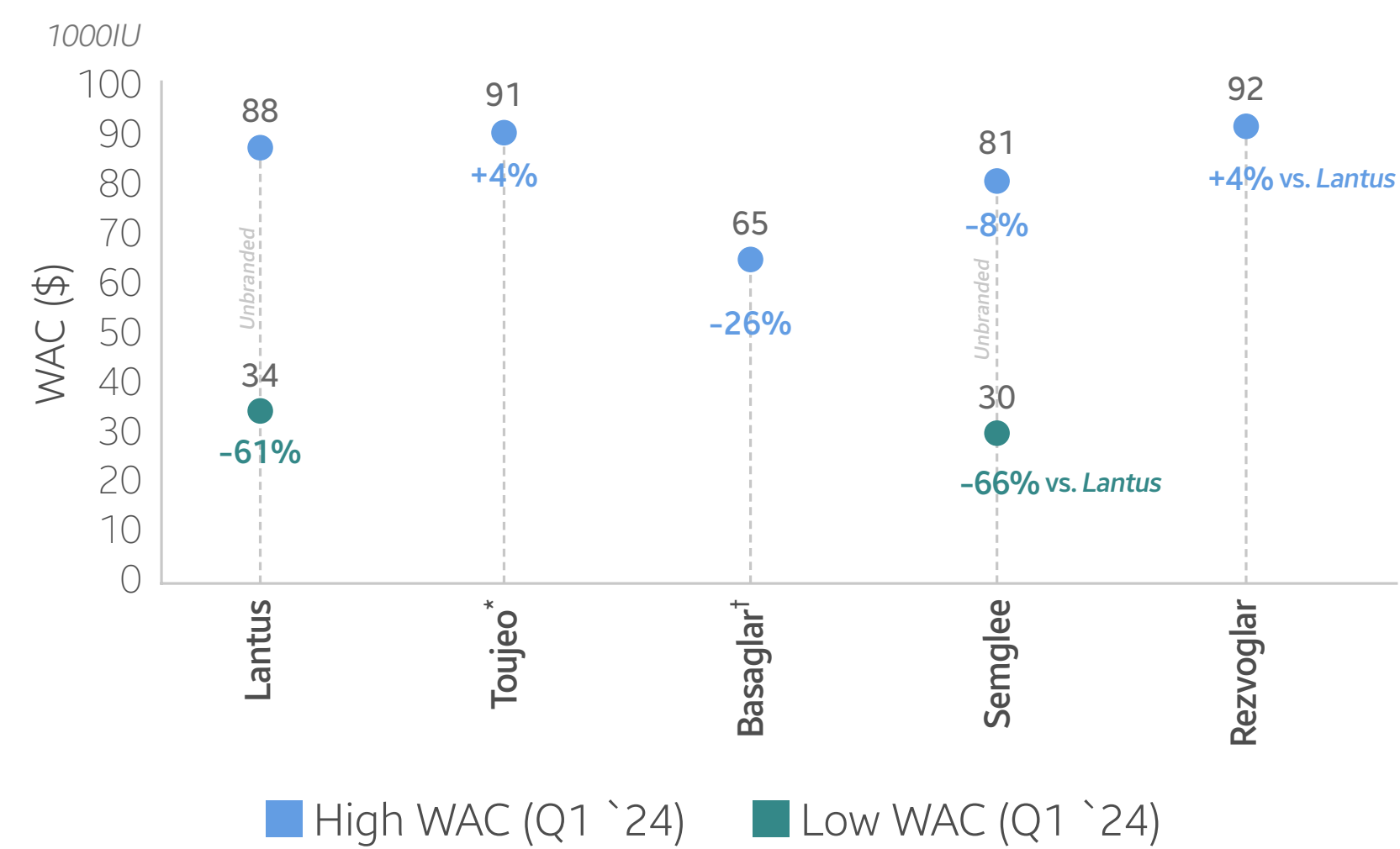
- ✦ Sanofi currently markets three versions of insulin glargine(ISG): 1) the reference product, Lantus; 2) Toujeo (a higher dose ISG); and an 2) unbranded Lantus, which can be viewed as the biologic version of an 'authorized generic.'
- ✦ Biocon has two Lantus biosimilars, Semglee (insulin glargine-yfgn) and unbranded Semglee (insulin glargine-yfgn).
- ✦ Lilly has launched two insulin glargine products, Basaglar and Rezvoglar (insulin glargine-aglr).
 - Basaglar (insulin glargine) was FDA-approved under a New Drug Application pathway, therefore is not considered a Lantus biosimilar.
 - Rezvoglar (insulin glargine-aglr) is an interchangeable, Lantus biosimilar.
- ✦ By analyzing NADAC, we can see that the unbranded ISGs are discounted by as much as 66%, compared to Lantus.

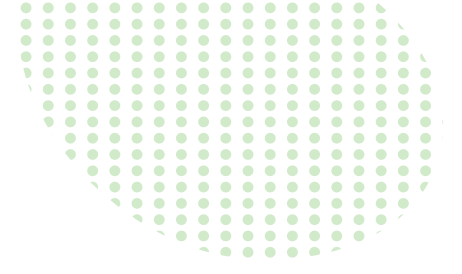
Figure 25. Insulin Glargine Volume Market Share⁵



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

Figure 26. Insulin Glargine WAC Trend²





US Biosimilars Approval & Launch Status

Biosimilar Price - Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Biosimilar Price - 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

Market Share and ASP Trends - Lucentis (Ranibizumab)

✦ As of Q3 2023, two biosimilars have launched with accounting for a combined market share of 34%.

✦ As of Q1 2024, the average ASP of all products is \$1,003 (-23%)* and the average for biosimilars alone is \$1,062 (-18%)*.

Figure 27. Ranibizumab Volume Market Share⁵

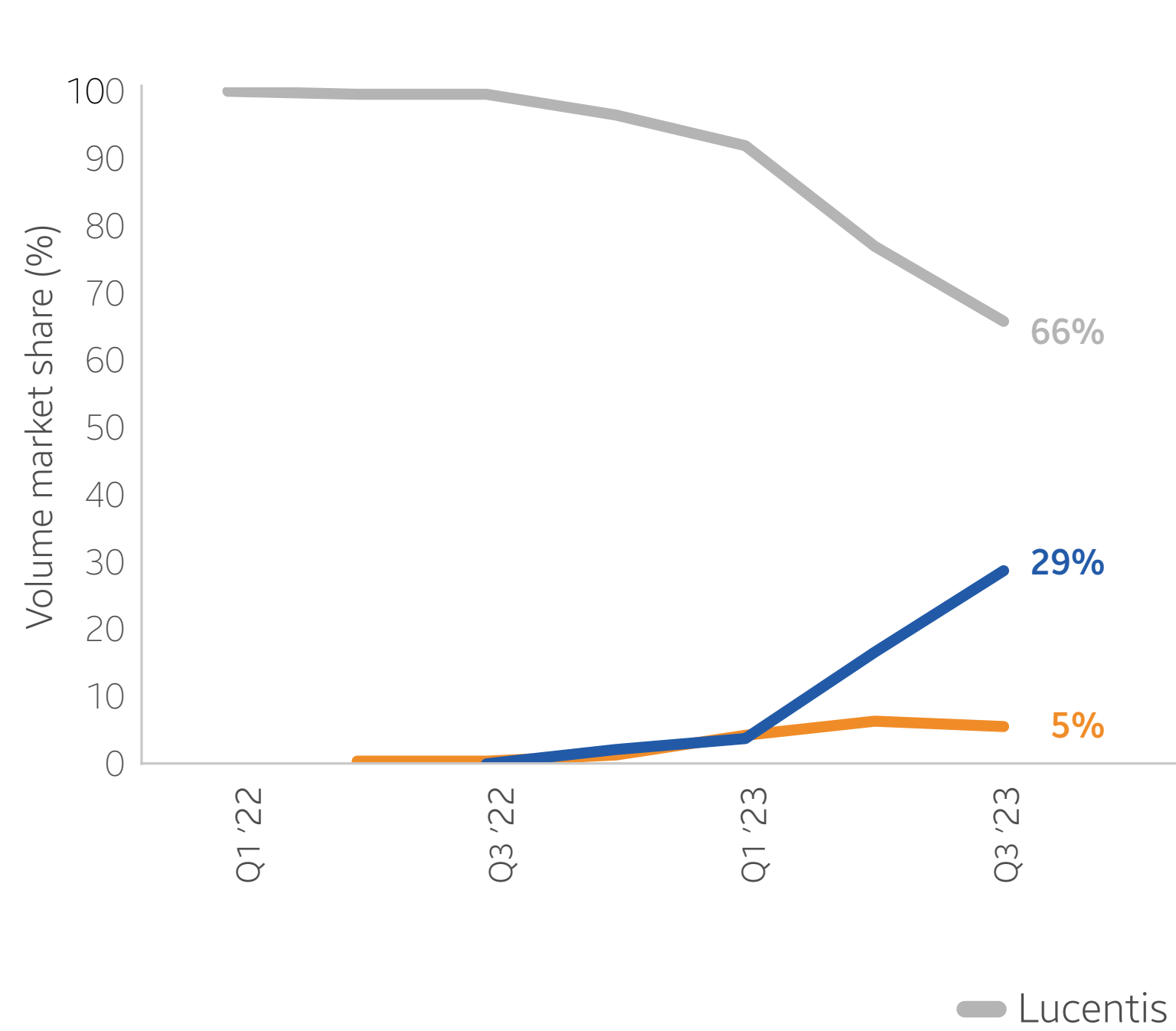
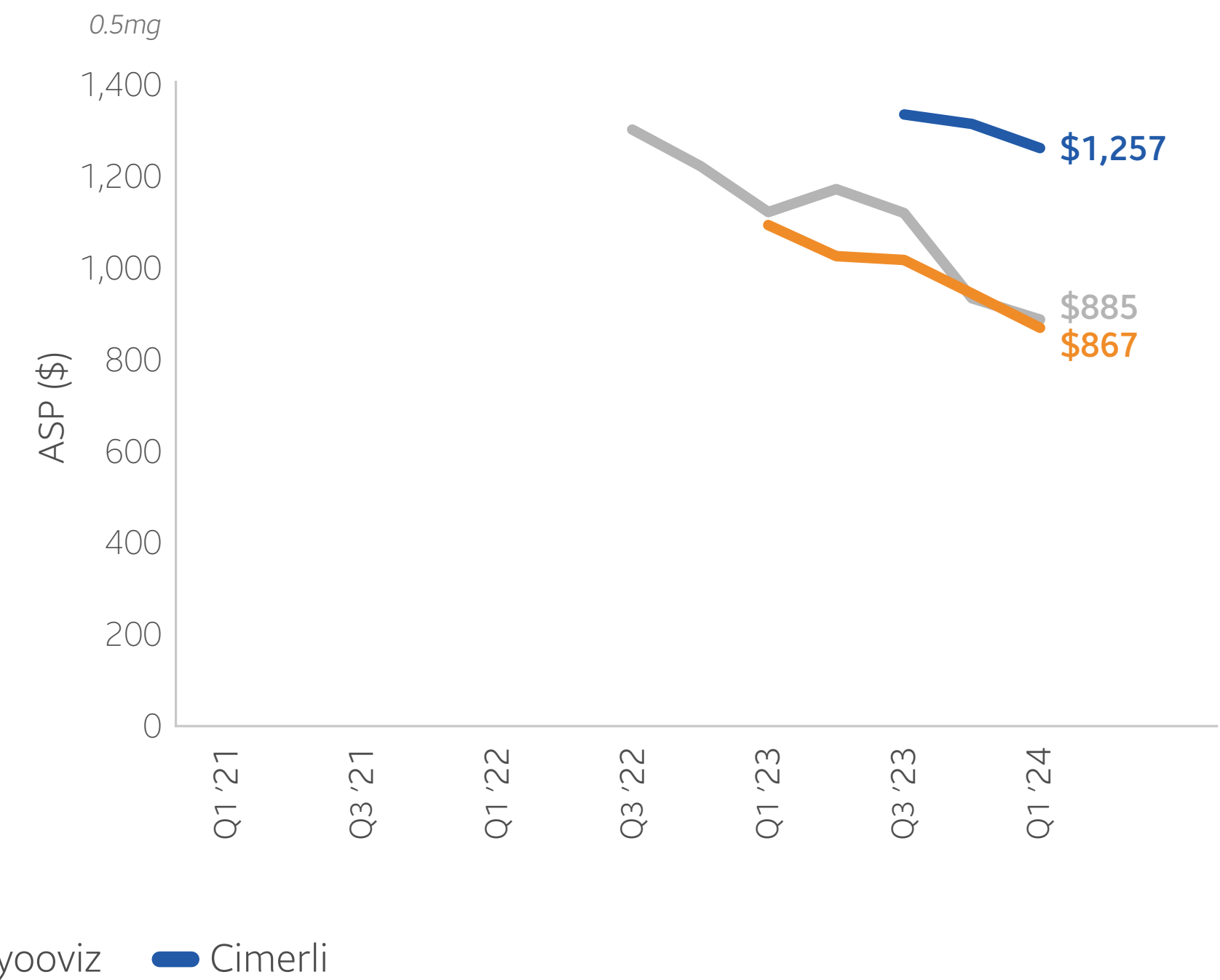


Figure 28. Ranibizumab ASP Trend³



Legends are listed in order of launch
 ASP: Average sales price
 *Percentages reflect the change from the reference product's ASP at the time of the first biosimilar launch.

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Slow Adalimumab Biosimilar Adoption Delays Opportunity for Major Financial Relief to the US Healthcare System

Despite introduction of adalimumab biosimilars priced at significant discounts, a major savings opportunity remains unrealized.

- * Six months after the July 2023 launch of seven additional biosimilar products, biosimilar adoption remains stagnant at 2.0%.⁶
 - Despite of stagnant biosimilar uptake, Amjevita has shown stable sales and Hadlima is rapidly growing vs. other biosimilars.
 - Interchangeability has not yet been demonstrated as a distinguishing factor with Cyltezo market share at 2% within biosimilars. This may change with approval of high-concentration interchangeable products on the horizon.
- * Most major PBMs have announced parity access to one or more adalimumab biosimilars, initiating a first step in access for these products.
- * Slow adoption to date may suggest that prescribers and specialty pharmacies have not yet determined the best practices to navigate payer biosimilar preferences and may favor the originator to avoid treatment delays.
- * Strategies requiring biosimilar use over the originator product may be needed for acceleration of biosimilar adoption.
- * Although it is too early to determine the fate of the US adalimumab market, these realities delay biosimilars from playing a pivotal role in alleviating the financial burden the US healthcare system and patients currently face.

Figure 29. US Adalimumab Biosimilar Uptake (~23.7~)⁶

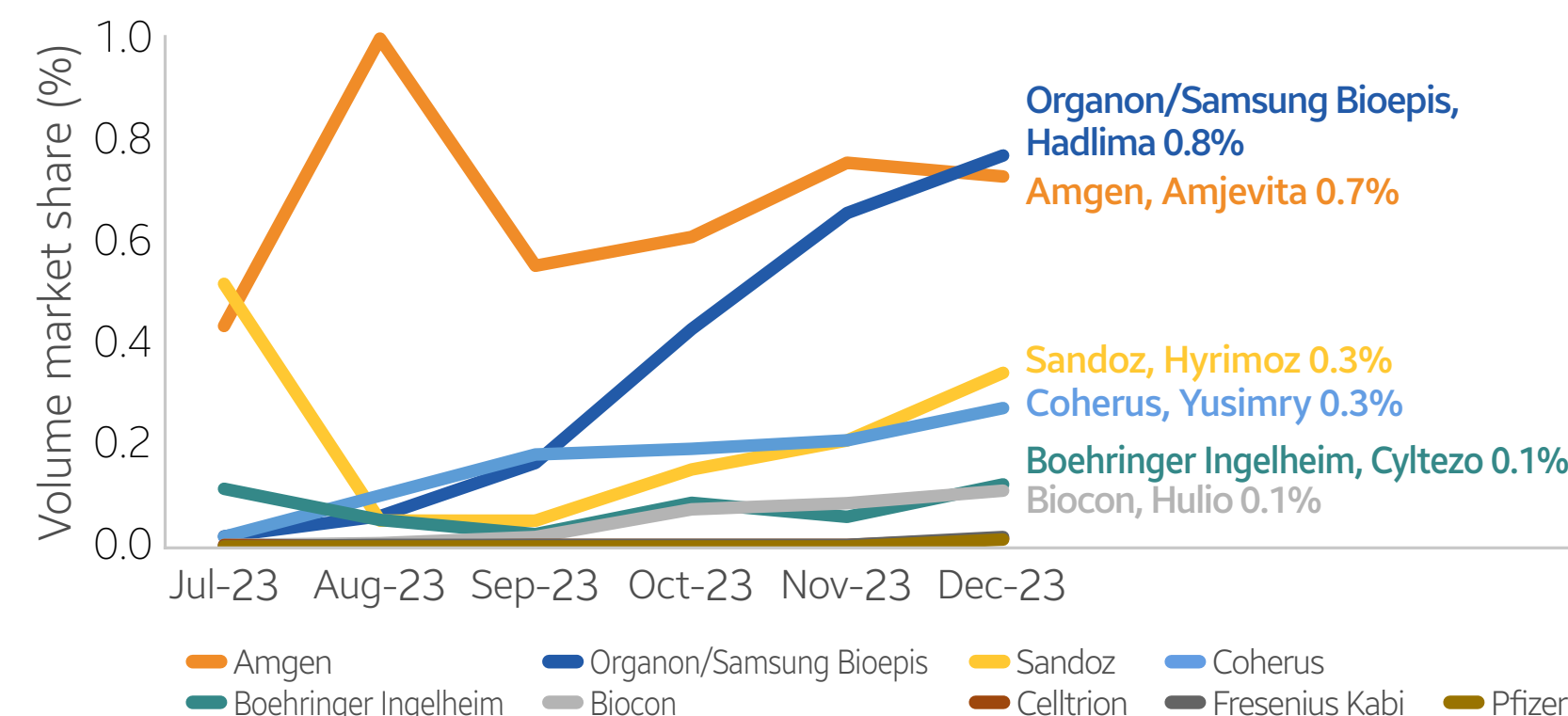
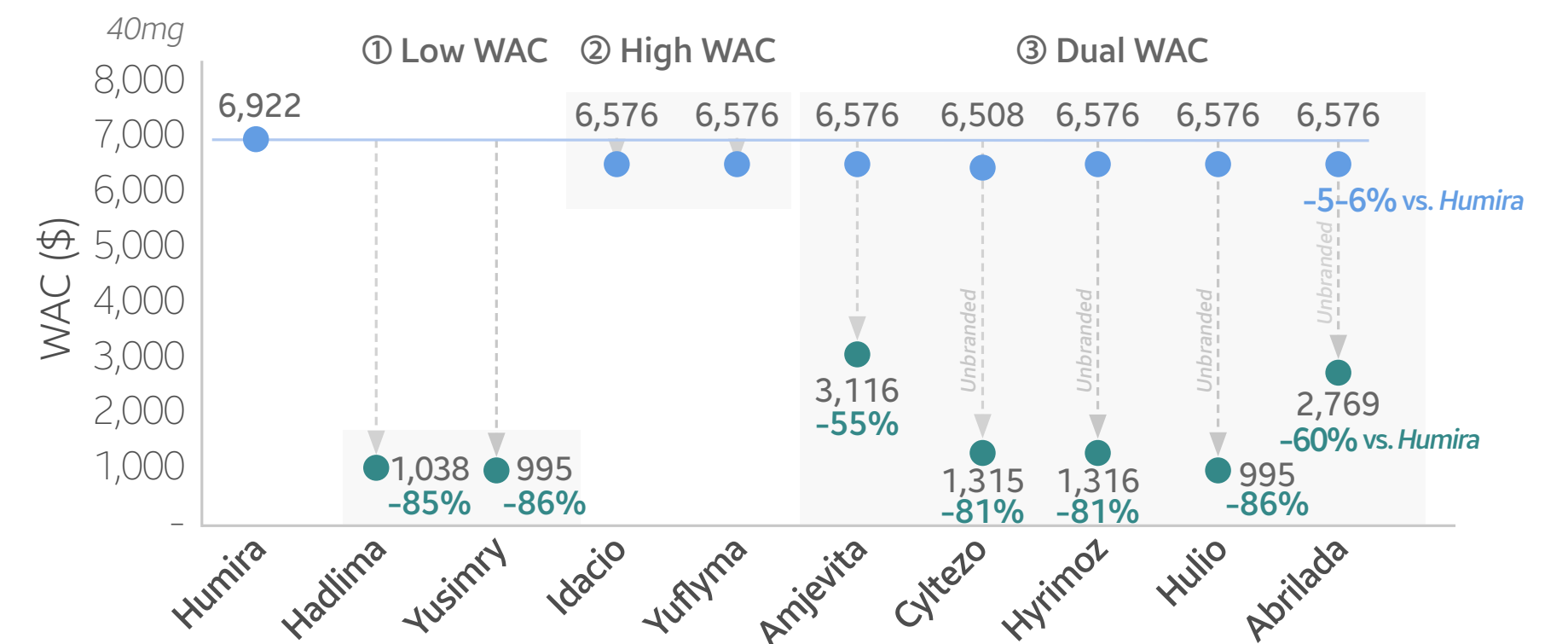


Figure 30. Monthly WAC of Adalimumab Products²



- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Patients Benefit from Lower Cost Options

In some instances, patient out-of-pocket costs remain high and have accumulated during their treatment time horizon.

✦ **Beneficiaries with certain plan designs will continue to have larger out of pocket costs on the originator than with biosimilars such as:**

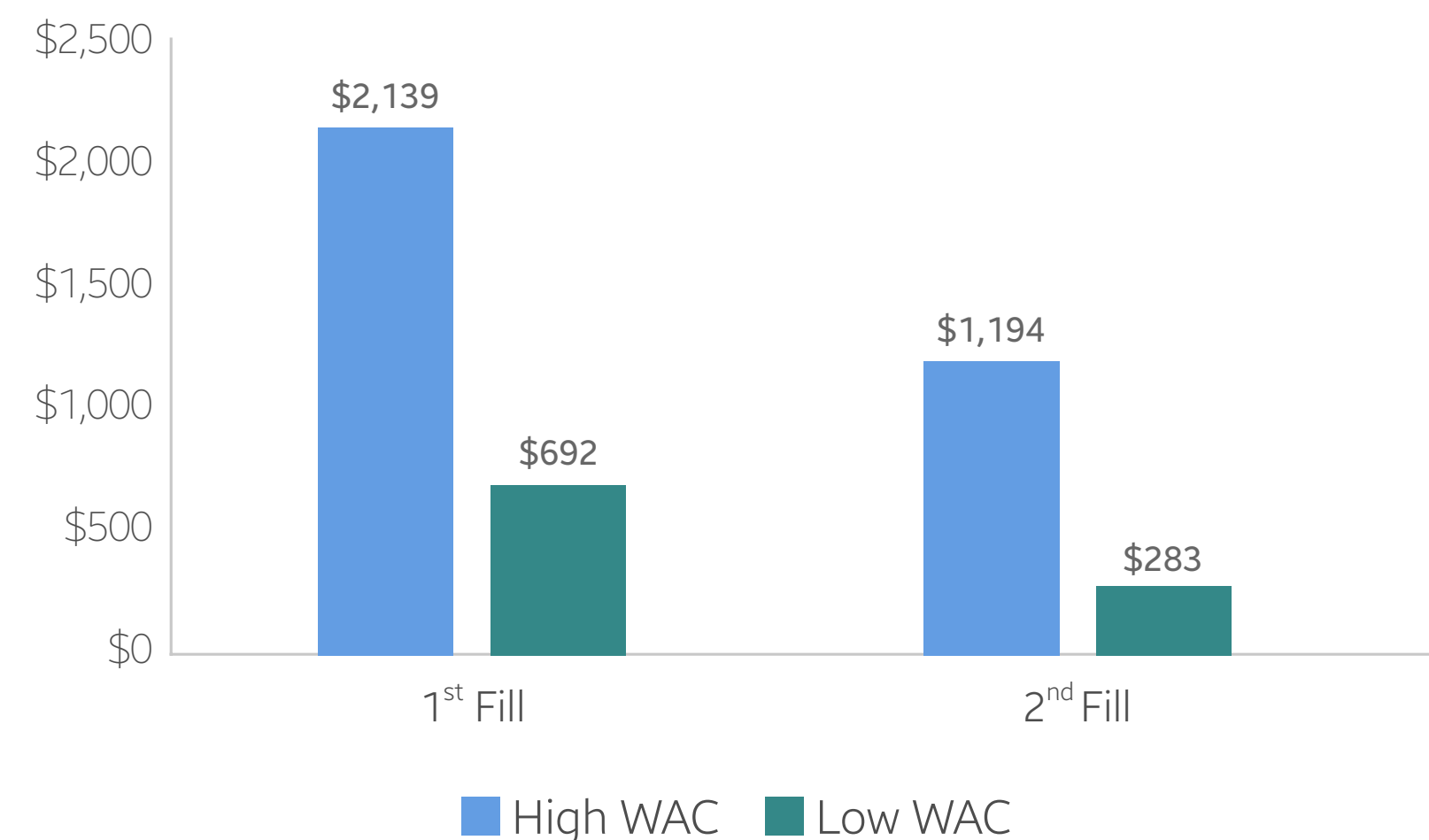
- Medicare beneficiaries where out-of-pocket costs are calculated based on the list price rather than the net price and coupon assistance cannot apply.
- Commercial beneficiaries in plan designs with coinsurance, high deductibles, and high maximum out of pocket limits*.
- Commercial beneficiaries in plan designs where rebates are not passed through at the point of sale*.

*Note: Additional benefit design factors such as coupon assistance, copay maximizer programs, and point-of-sale rebates may affect patient out-of-pocket costs at the pharmacy counter.

In the following illustration of a Medicare beneficiary using the 2024 CMS benefit phase thresholds, the beneficiary will have significantly high up-front costs with Humira as compared to Biosimilar X.

✦ **Within the first two fills of the year, Medicare beneficiaries taking Humira are exposed to extremely high out-of-pocket payments (>\$3,000) with no opportunity for coupon assistance.**

Figure 31. Member Out-of-Pocket Costs for First and Second Rx Fill



Key Assumptions:

- Part D benefit phase thresholds for 2024
- Humira Avg Monthly Cost: \$6,922
- Biosimilar X Avg Monthly Cost: \$1,132

(Calculated as the average WAC price of 5 biosimilars available with over 80% discount off of originator WAC as of Dec 04, 2023)

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

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6. Weekly Sales Perspectives. IQVIA. (Jan 2023-Dec 2023). Retrieved Jan 2024.

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