

SAMSUNG BIOEPIS

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Biosimilar Market Dynamics

7th Edition, Q4 2024



| FOREWORD

The growing biosimilar market plays a critical role in improving patient access to affordable treatments, presenting both challenges and opportunities for stakeholders across the US healthcare system.

In this report, we explore the potential savings for stakeholders through the adoption of biosimilars, examine the varying challenges by line of business, and discuss strategies that can maximize these benefits.

Biosimilars have already contributed \$36 billion in savings to the US healthcare market, but there is still significant room for growth. Our hope is that stakeholders will become more familiar with biosimilars and continue to embrace their potential.

As this is our final report of the year, we reaffirm our commitment to providing high-quality insights. We have continued to refine and enhance our analyses and sincerely appreciate your trust in our work. We look forward to delivering even more valuable perspectives in the coming year.

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 Sep 2024, the FDA has approved a total of 61 biosimilars across 17 unique biological molecules. Of the 61 approvals, 41 biosimilars have launched in the US market.

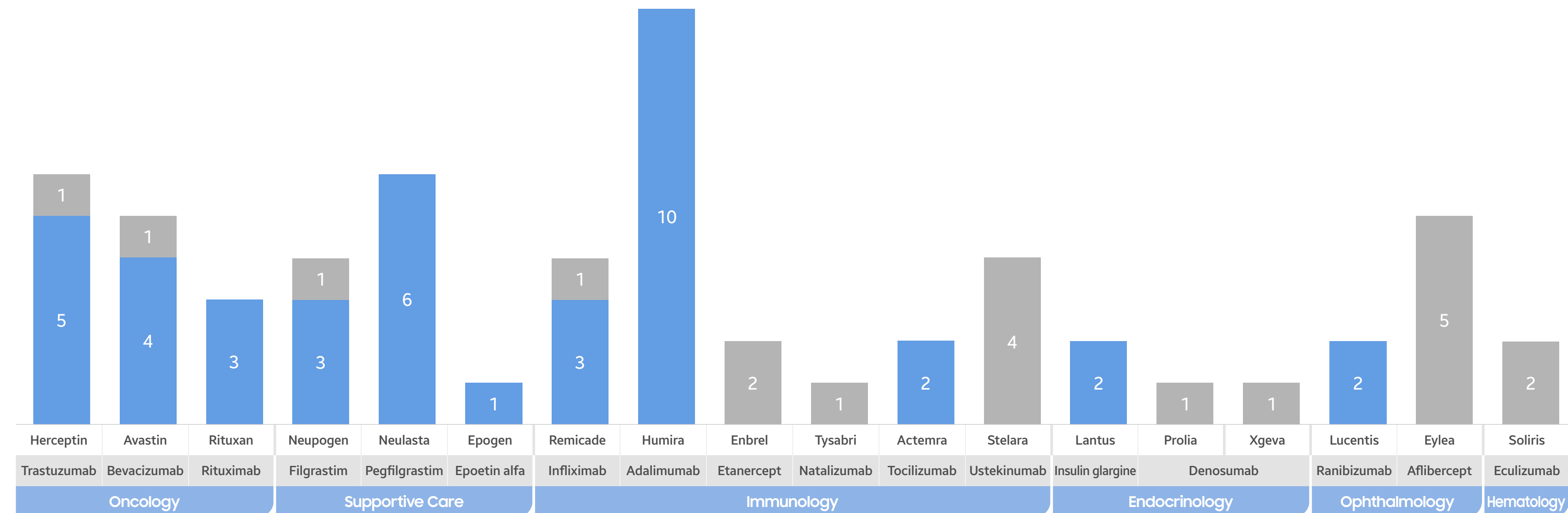
Cumulative Approvals

61

✦ In last quarter, four new biosimilars were approved in the US. (See Figure 2, 2-1)

- Epysqli for Soliris (eculizumab) biosimilar
- Enzeevu and Pavblu for Eylea (afibercept) biosimilar
- Otulfi for Stelara (ustekinumab) biosimilar

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



FDA: Food and Drug Administration
¹Trade marks are not described to all brands

■ Launched ■ Not launched

US Biosimilars Approval & Launch Status

Biosimilar Price - Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Biosimilar Price - Pharmacy Benefit

- Immunology & Endocrinology

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

TA	Oncology			Supportive Care			Immunology					
Molecule	Trastuzumab	Bevacizumab	Rituximab	Filgrastim	Pegfilgrastim	Epoetin alfa	Infliximab	Adalimumab	Etanercept	Natalizumab	Tocilizumab	Ustekinumab
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	Actemra (tocilizumab) Genetech 2010	Stelara (ustekinumab) Janssen 2009
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-szsz) Sandoz 2016	Tyruko (natalizumab-sztn) Sandoz 2023	Tofidence (tocilizumab-bavi) Biogen&Bio-Thera 2023	Wezlana (ustekinumab-auub) Amgen 2023
	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		Tyenne (tocilizumab-aazg) Fresenius Kabi 2024	Selarsdi (ustekinumab-aekn) Alvotect&Teva 2024
	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				Pyzchiva (ustekinumab-ttwe) Samsung Bioepis&Sandoz 2024
	Trazimera (trastuzumab-qyyp) Pfizer 2019	Vegzelma (bevacizumab-adcd) Celltrion 2022		Nypozi (filgrastim-txid) Tanvex 2024	Nyvepria (pegfilgrastim-apgf) Hospira&Pfizer 2020		Ixifi (infliximab-qbtx) Pfizer 2017	Hadlima (adalimumab-bwwd) Samsung Bioepis&Organon 2019				Otulfi (ustekinumab-aaaz) Formycon&Fresenius Kabi 2024
	Kanjinti (trastuzumab-anns) Amgen 2019	Avzivi (bevacizumab-tnjn) Sandoz&Bio-Thera 2023			Stimufend (pegfilgrastim-fpgk) Fresenius Kabi 2022			Abrilada (adalimumab-afzb) Pfizer 2019				
	Hercessi (trastuzumab-strf) Accord BioPharma&Henlius 2024				Fylnetra (pegfilgrastim-pbbk) Amneal&Kashiv 2022			Hulio (adalimumab-fkjp) Biocon 2020				
								Yusimry (adalimumab-aqvh) Coherus 2021				
							Idacio (adalimumab-aacf) Fresenius Kabi 2022					
							Yuflyma (adalimumab-aaty) Celltrion 2023					
							Simlandi (adalimumab-ryvk) Alvotect&Teva 2024					

■ Launched ■ Not launched

Continued on next page →

¹Trade marks are not described to all brands

US Biosimilars Approval & Launch Status

Biosimilar Price - Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Biosimilar Price - Pharmacy Benefit

- Immunology & Endocrinology

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- Immunology
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- Ophthalmology

Biosimilar Deep Dive

Reference

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

TA	Endocrinology		Ophthalmology		Hematology/Nephrology
Molecule	Denosumab	Insulin glargine	Ranibizumab	Aflibercept	Eculizumab
Reference Product	Prolia/Xgeva (denosumab) Amgen 2010	Lantus (insulin glargine) Sanofi 2000	Lucentis (ranibizumab) Novartis 2006	Eylea (aflibercept) Regeneron 2011	Soliris (eculizumab) Alexion 2007
Biosimilar	Jubbonti/Wyost (denosumab-bbdz) Sandoz 2024	Semglee (insulin glargine-yfqn) Biocon 2021	Byooviz (ranibizumab-nuna) Samsung Bioepis&Biogen 2021	Opuviz (aflibercept-yszy) Samsung Bioepis&Biogen 2024	Bkemv (eculizumab-aeeb) Amgen 2024
		Rezvoglar (insulin glargine-aglr) Eli Lilly 2021	Cimerli (ranibizumab-eqrn) Sandoz 2022	Yesafili (aflibercept-jbvff) Biocon 2024	Epysqli (eculizumab-aagh) Samsung Bioepis 2024
				Ahzantive (aflibercept-mrbb) Formycon&Klinge 2024	
				Enzeevu (aflibercept-abzv) Sandoz 2024	
				Pavblu (aflibercept-ayyh) Amgen 2024	

Legend: ■ Launched ■ Not launched

¹Trade marks are not described to all brands



II. Biosimilar Price

(Medical Benefit & Pharmacy Benefit)

Biosimilar Price - Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Biosimilar Price - Pharmacy Benefit

- Immunology & Endocrinology

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- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

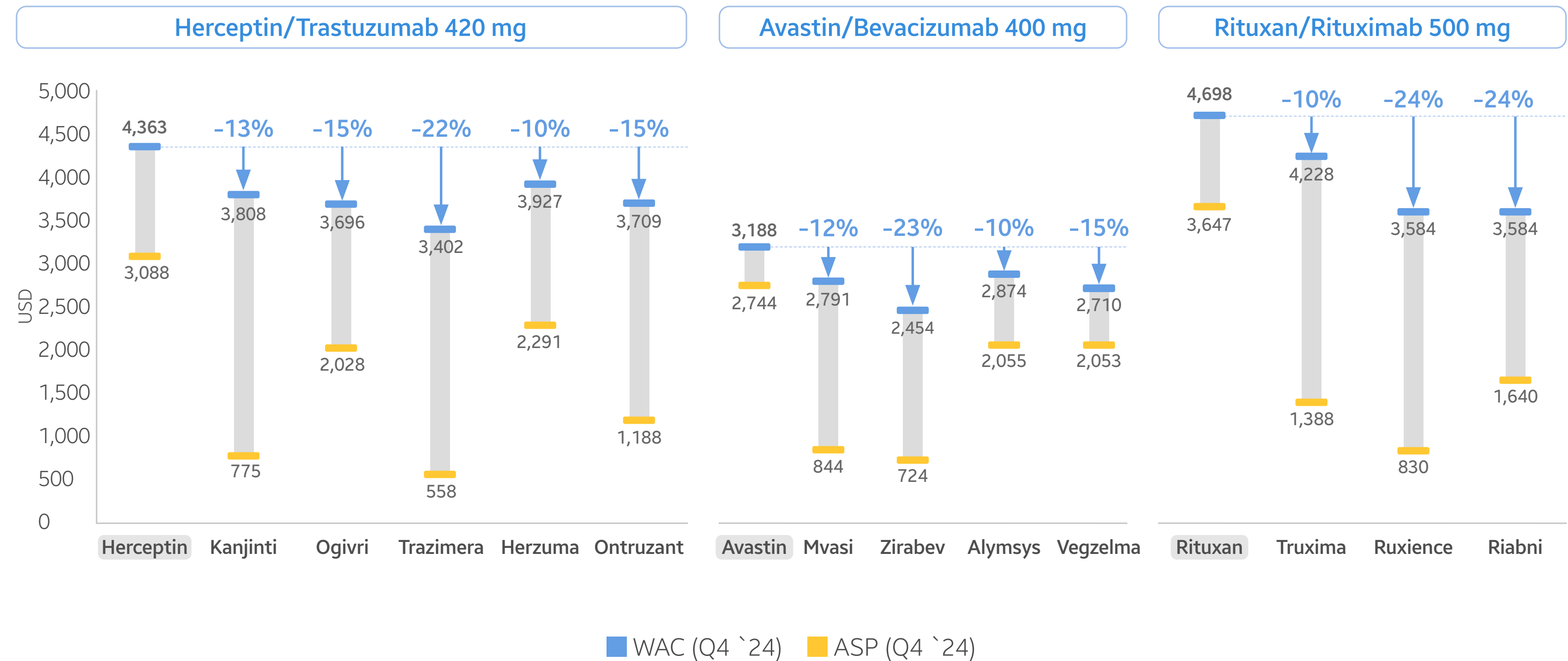
Biosimilar Deep Dive

Reference

Oncology WAC and ASP - Q4 2024

- ✦ Across oncology biosimilars, WAC prices represent a modest discount (between 10-25%) compared to reference products.
- ✦ Biosimilar Q4 2024 ASP discounts as compared to the reference product ASP average -56%, -48%, and -65% for the trastuzumab, bevacizumab, and rituximab markets, respectively.

Figure 3. Q4 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

- 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
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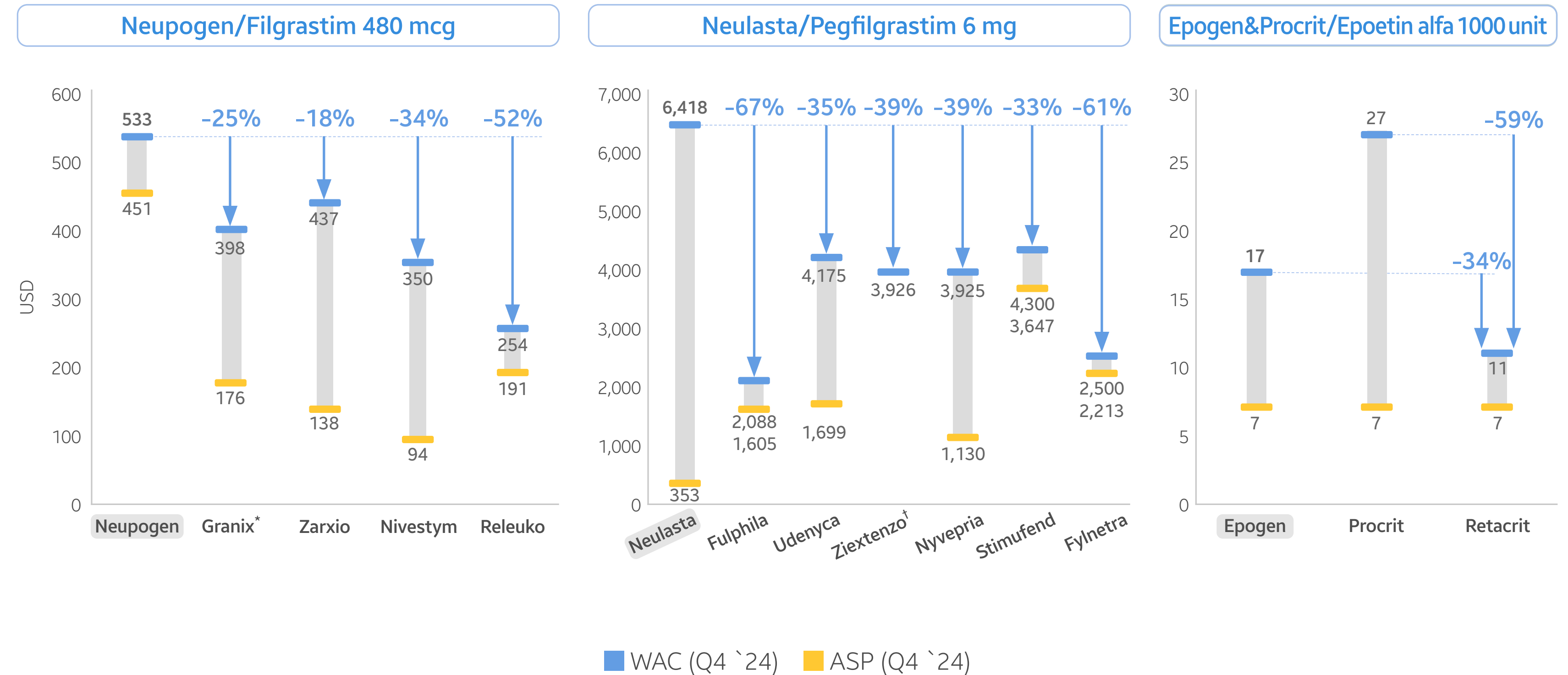
Biosimilar Deep Dive

Reference

Supportive Care WAC and ASP - Q4 2024

- * Across supportive care biosimilars, WAC prices discounted between 18-67% compared to reference products.
- * Amgen, the manufacturer for originator filgrastim (Neupogen) and pegfilgrastim (Neulasta), only provides competitive ASP pricing in the pegfilgrastim market.

Figure 4. Q4 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; approved under the FDA's New Drug Application pathway †Ziextenzo ASP has unpublished since Q4 2023

Biosimilar Price - Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Biosimilar Price - Pharmacy Benefit

- Immunology & Endocrinology

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Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Biosimilar Deep Dive

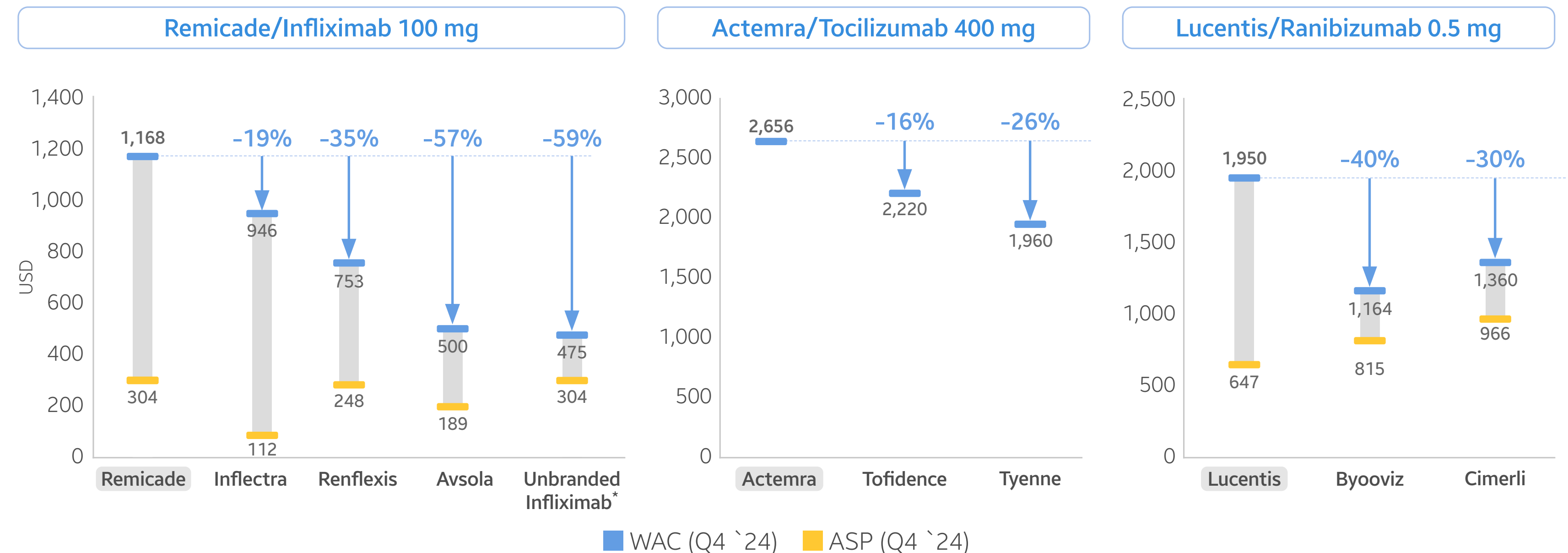
Reference

Immunology & Ophthalmology

WAC and ASP - Q4 2024

- ✦ Infliximab biosimilars launched with progressively lower WACs, ranging from -19% to -59% in discounts.
- ✦ Two tocilizumab biosimilars, Tofidence and Tyenne, newly launched last quarter with -16% and -26% WAC discounts respectively.
- ✦ With only two competing biosimilars on the market, ranibizumab WACs represent -30% to -40% WAC discounts as compared to the reference product.

Figure 5. Q4 2024 WAC and ASP^{2,3}



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

Biosimilar Price - Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Biosimilar Price - Pharmacy Benefit

- Immunology & Endocrinology

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- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

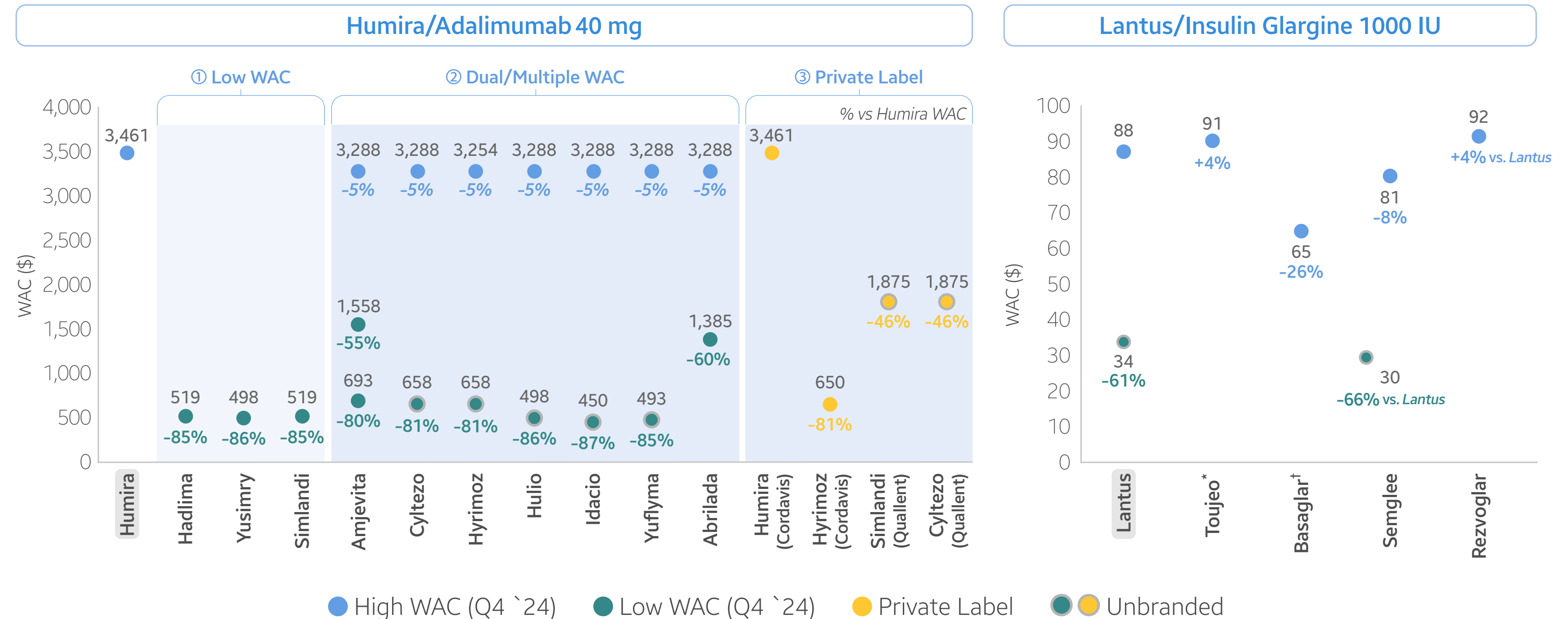
Biosimilar Deep Dive

Reference

Immunology & Endocrinology WAC and NADAC - Q4 2024

- * Adalimumab & Insulin glargine categories reflect recent pricing practices such as multiple WAC options and unbranded biologics.
- * In the adalimumab market, Private Label brands offer alternative WAC prices.

Figure 6. Q4 2024 WAC²



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



III. Biosimilar Market Dynamics

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

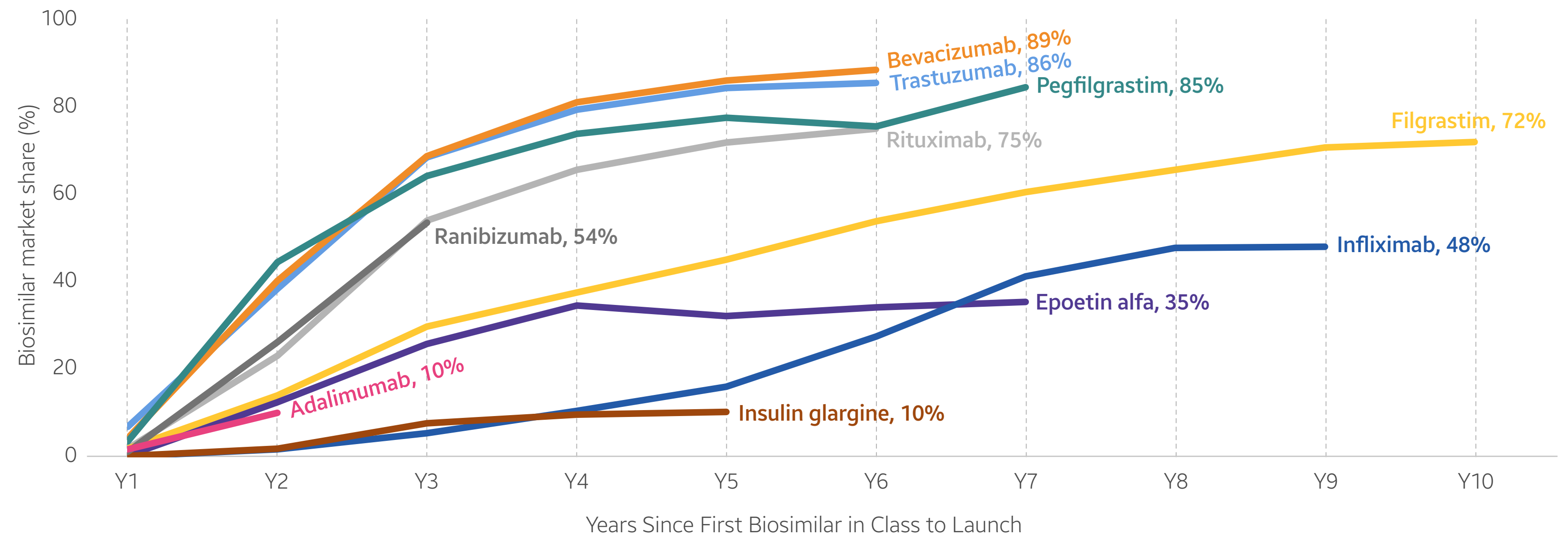
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Biosimilar Volume Uptake Varies by Molecule

✦ On average, biosimilars have gained 53% market share within 5 years post initial launch.[†] Each molecule has demonstrated unique biosimilar uptake and can be categorized into fast or slow uptake speed markets.

- 1) **Fast Uptake Speed:** Oncology*, ophthalmology, and pegfilgrastim biosimilars. Five years post launch, average biosimilar market share reached 81%.[†]
- 2) **Slow Uptake Speed:** Immunology[‡], filgrastim, epoetin alfa, and insulin glargine biosimilars. On average, only a 26% biosimilar market share was achieved by Year 5.[†]

Figure 7. Biosimilar Market Share Post-Launch^{4§¶}



*Trastuzumab, bevacizumab, and rituximab

[†]Averages include products that are 5 years or older [‡]Infiximab and adalimumab

[§]Calculated based on calendar year

[¶]Tocilizumab is not marked in this chart as its penetration is below 1% and it's been less than a year since launch

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

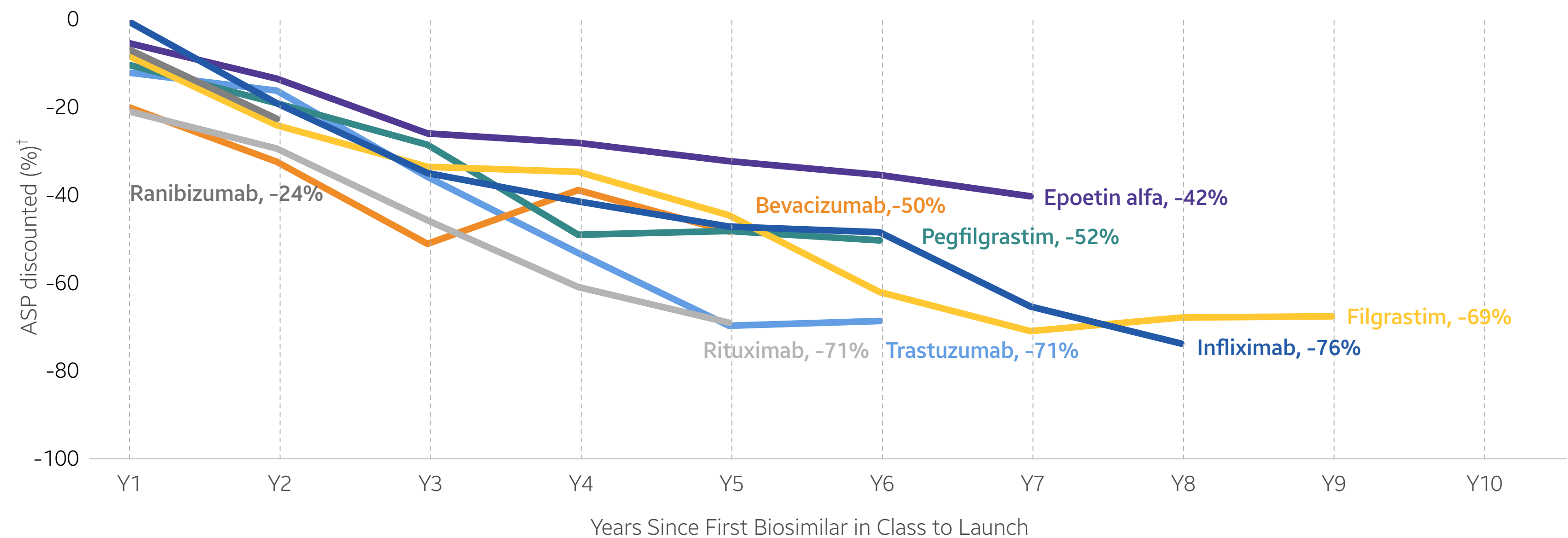
- Biosimilar Market Adoption & Price Erosion

- 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 53% 5 years post first biosimilar launch with more mature markets demonstrating increasing price concessions.
- ✦ Recent observed increases in ASP for some markets (e.g. trastuzumab, bevacizumab, pegfilgrastim and filgrastim) may be due to 1) artifacts of newly-launched, low-market share biosimilars with ASPs that reflect WAC pricing and 2) intentional ASP repositioning of some biosimilars.

Figure 8. ASP Trend by Molecule³



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

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
- Supportive Care
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- Ophthalmology

Market Share and ASP Trends - Herceptin (Trastuzumab)

- ✦ As of Q2 2024, the biosimilar share of the trastuzumab market has reached 86% (unchanged vs. last quarter).
- ✦ As of Q4 2024, average ASP of all biosimilar products is \$1,368 (+6% vs. last quarter).
- ✦ Since 2024, all trastuzumab biosimilar brands have increased their ASP.

Figure 9. Trastuzumab Volume Market Share⁴

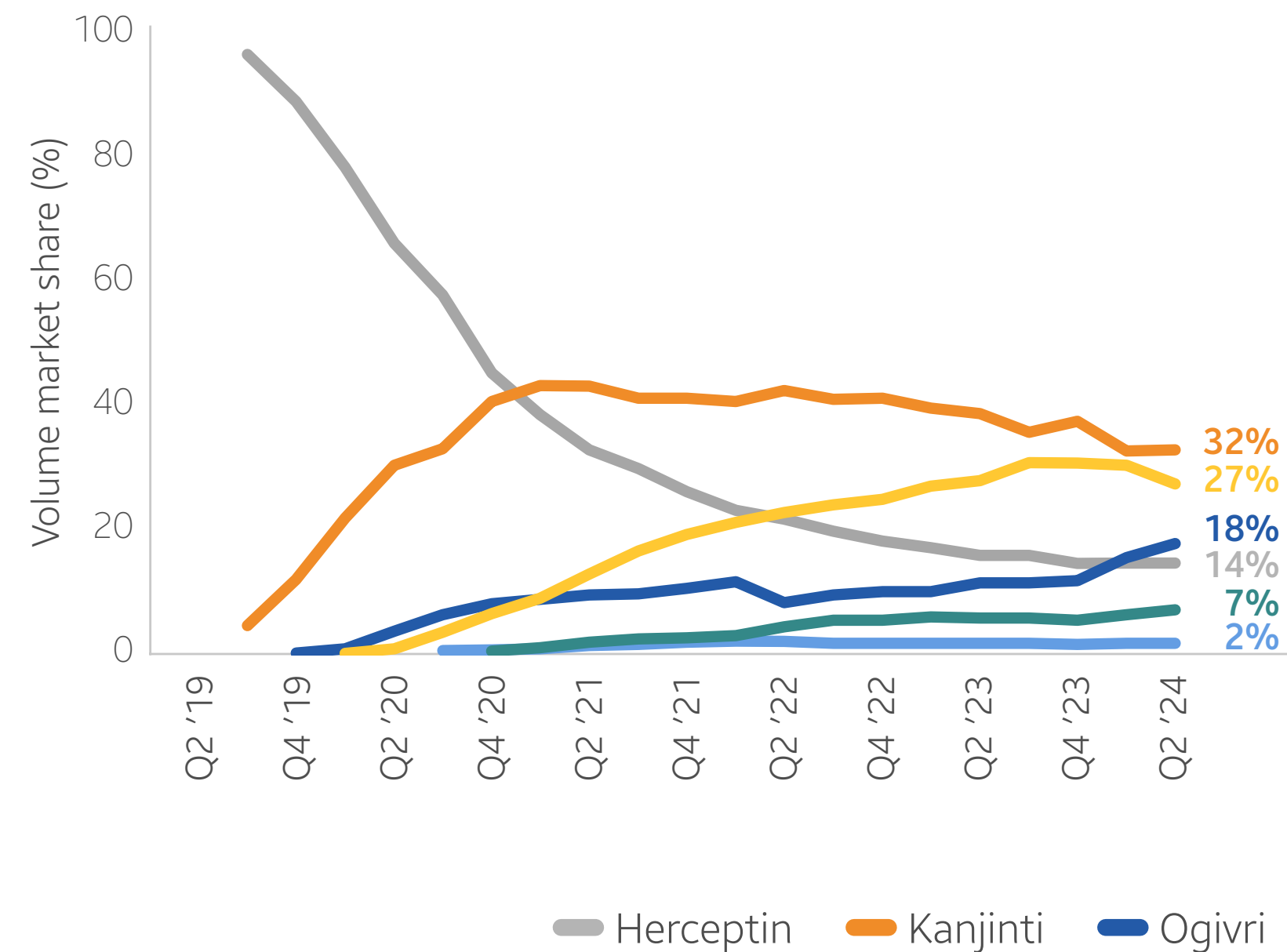
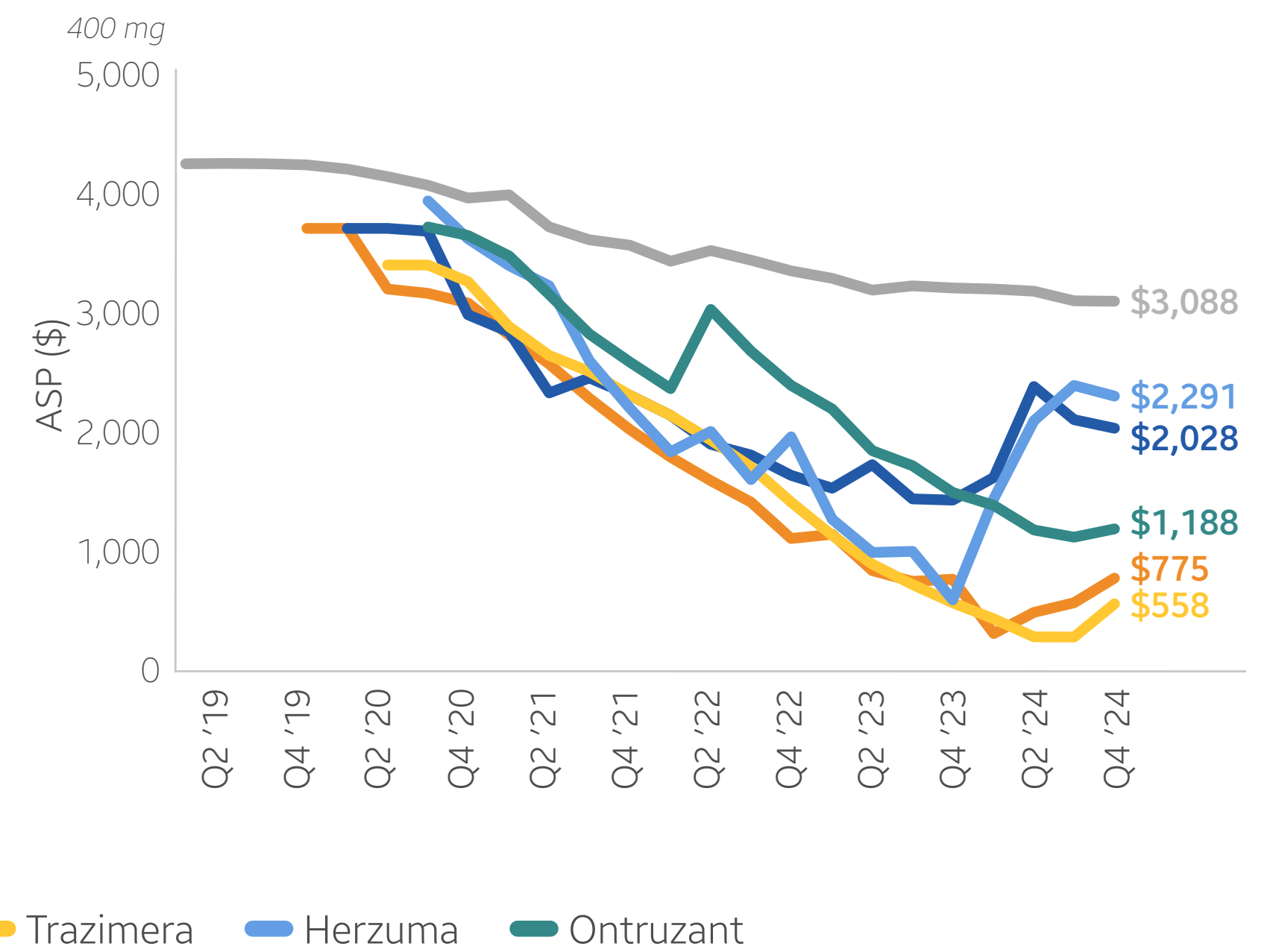


Figure 10. Trastuzumab ASP Trend³



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

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Market Share and ASP Trends - Avastin (Bevacizumab)

- ✦ As of Q2 2024, the biosimilar share of the bevacizumab market was 89% (+1% vs. last quarter).
- ✦ As of Q4 2024, average ASP of all biosimilar products is \$1,419 (-2% vs. last quarter).
- ✦ Earlier-to-market bevacizumab biosimilars with lower established ASPs (i.e. Mvasi and Zirabev) continue to make up the majority of market share (81%). However, market share for the more recent biosimilar entrants (i.e. Almysys and Vegzelma) is starting to grow.

Figure 11. Bevacizumab Volume Market Share⁴

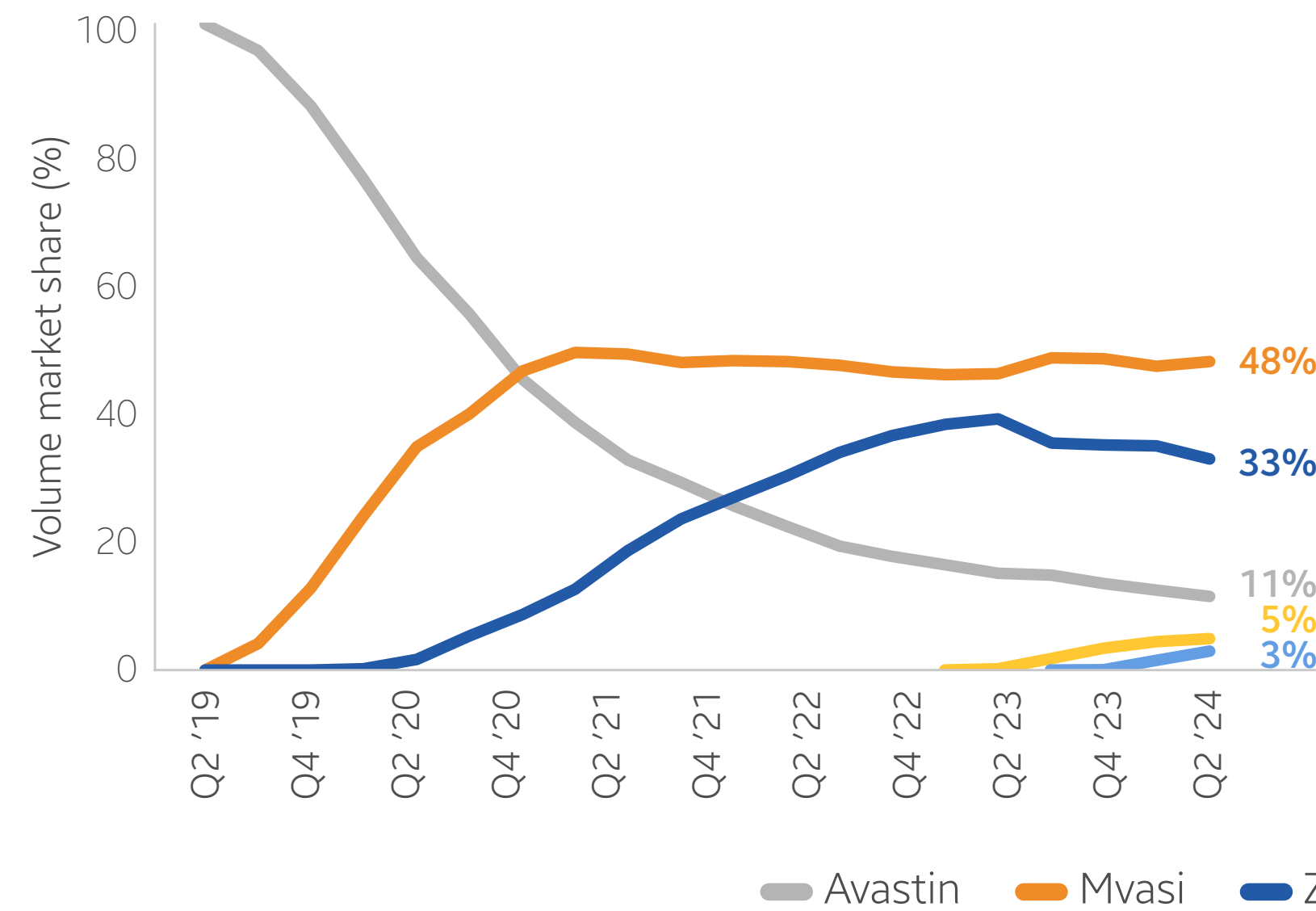
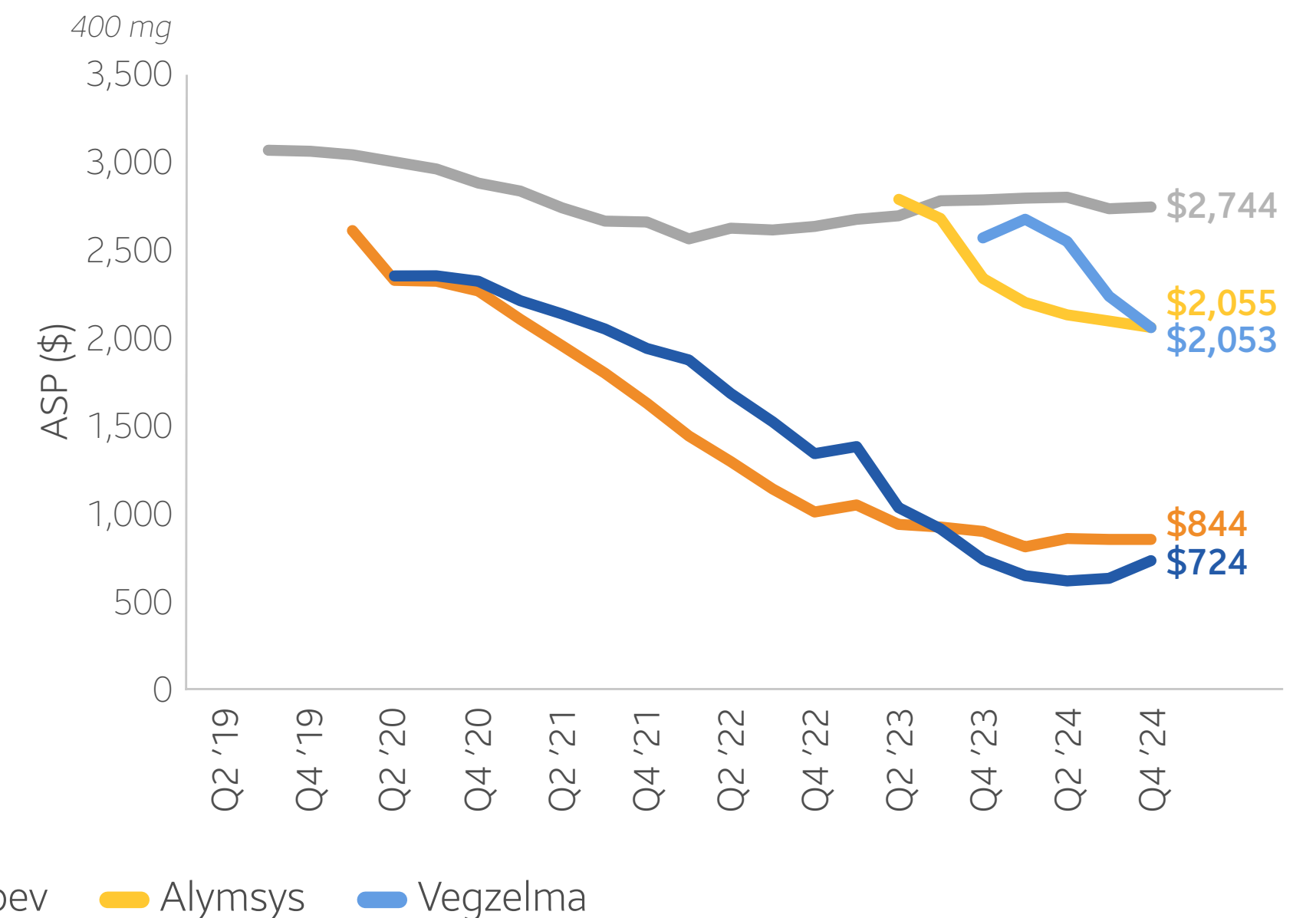


Figure 12. Bevacizumab ASP Trend³



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

- 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 Q2 2024, the biosimilar share of the rituximab market was 75% (unchanged vs. last quarter).
- ✦ As of Q4 2024, the average ASP of all biosimilar products is \$1,286 (+2% vs. last quarter).
- ✦ In the rituximab market, lower priced biosimilars are dominating the market. The later entrant, Riabni, has started to grow in market share as its ASP declines.

Figure 13. Rituximab Volume Market Share⁴

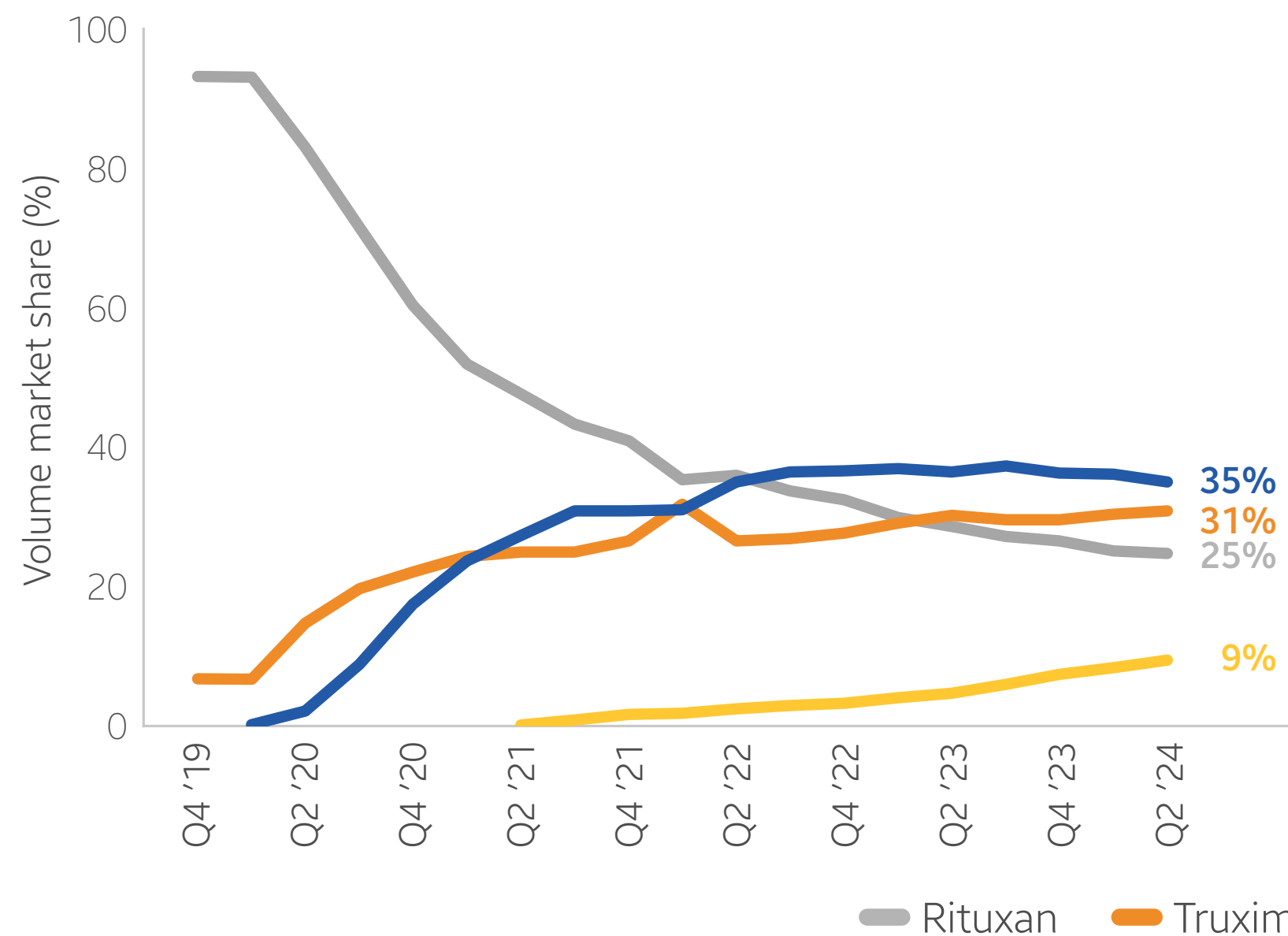
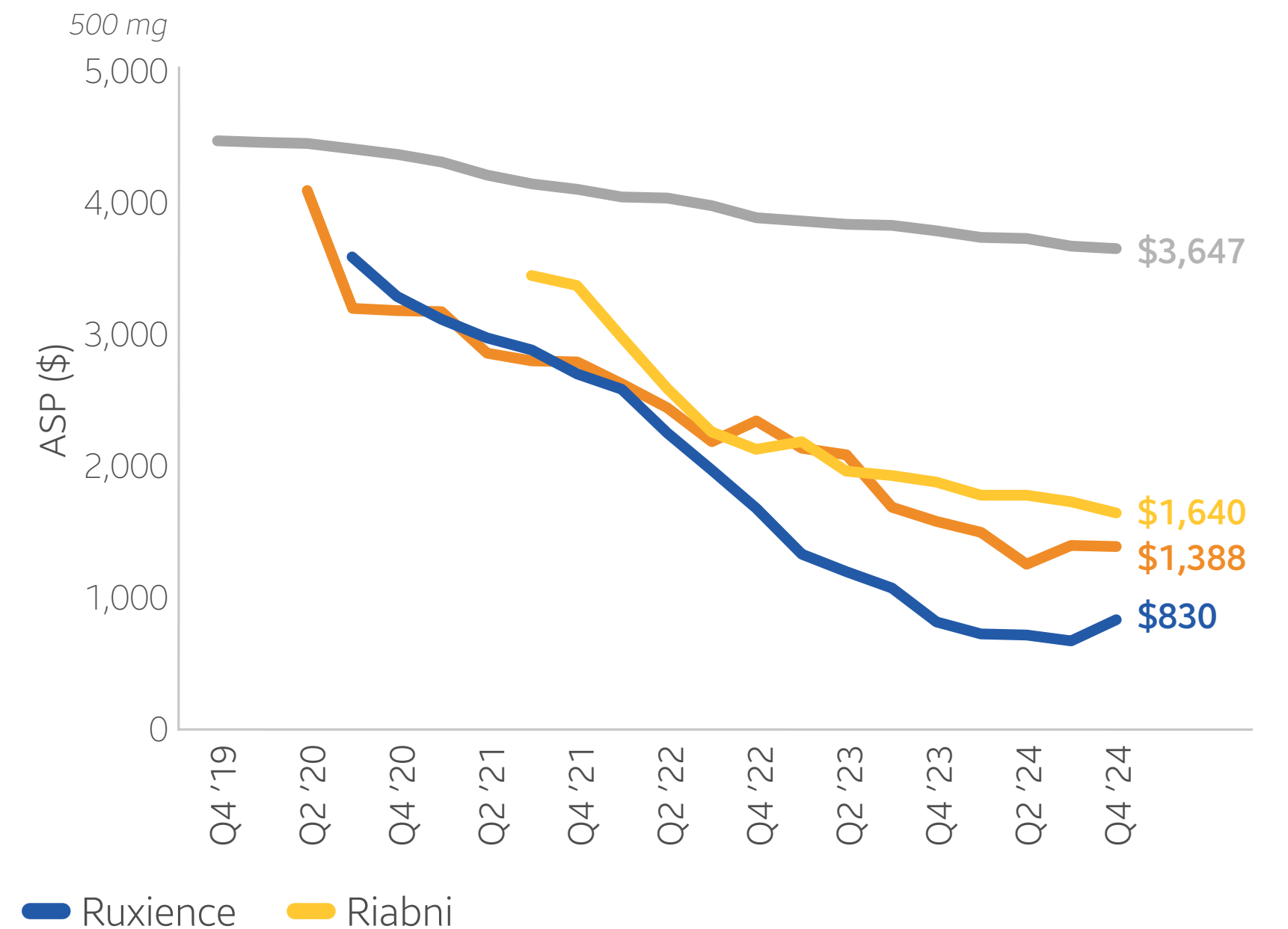


Figure 14. Rituximab ASP Trend³



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

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
- Supportive Care
- Immunology
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- Ophthalmology

Market Share and ASP Trends - Neupogen (Filgrastim)

- ✦ As of Q2 2024, the biosimilar share of the filgrastim market has reached 87% (+2% vs. last quarter).
- ✦ As of Q4 2024, the average ASP of all biosimilar products is \$141 (+24% vs. last quarter).
- ✦ In the filgrastim market, lower priced biosimilars are dominating the market.

Figure 15. Filgrastim Volume Market Share⁴

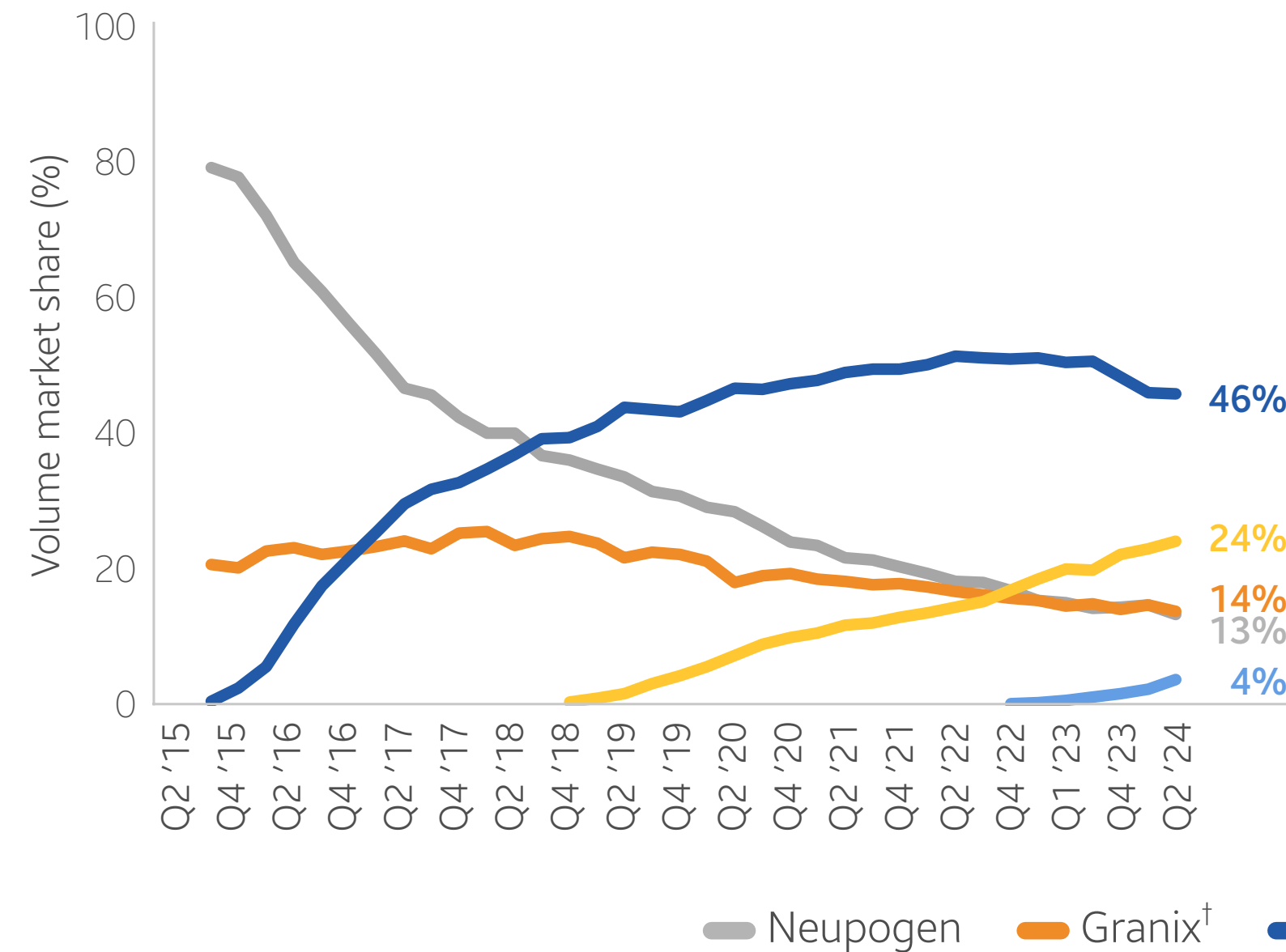
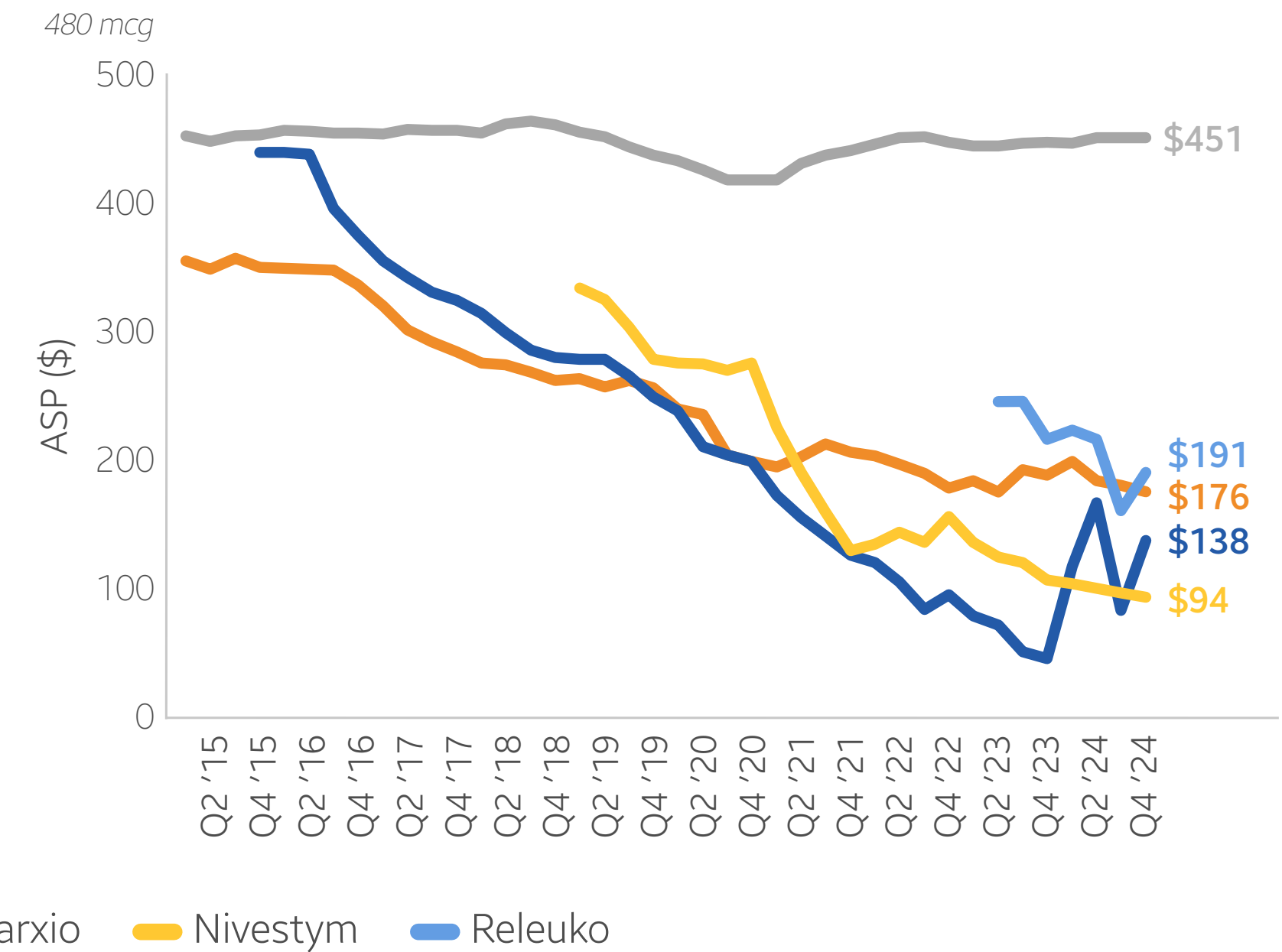


Figure 16. Filgrastim ASP Trend³



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

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Market Share and ASP Trends - Neulasta (Pegfilgrastim)

- ✦ As of Q2 2024, the biosimilar share of the pegfilgrastim market was 85% (+1% vs. last quarter).
- ✦ As of Q4 2024, the average ASP of all biosimilar products is \$2,059 (-5% vs. last quarter).
- ✦ The pegfilgrastim biosimilar market is quite competitive with narrow differences in market share and two more recent entrants. (i.e. Flynetra and Stimufend)

Figure 17. Pegfilgrastim Volume Market Share⁴

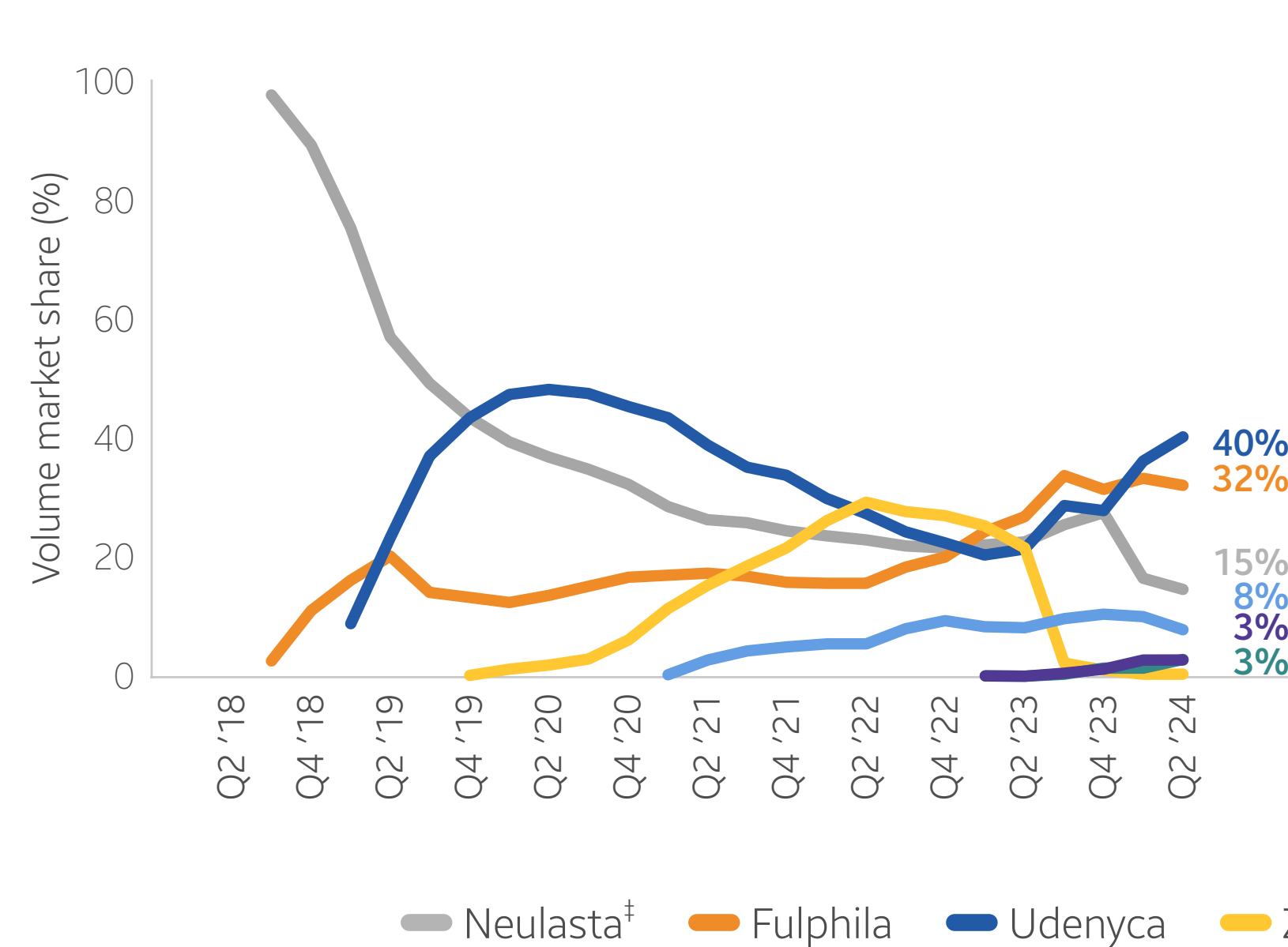
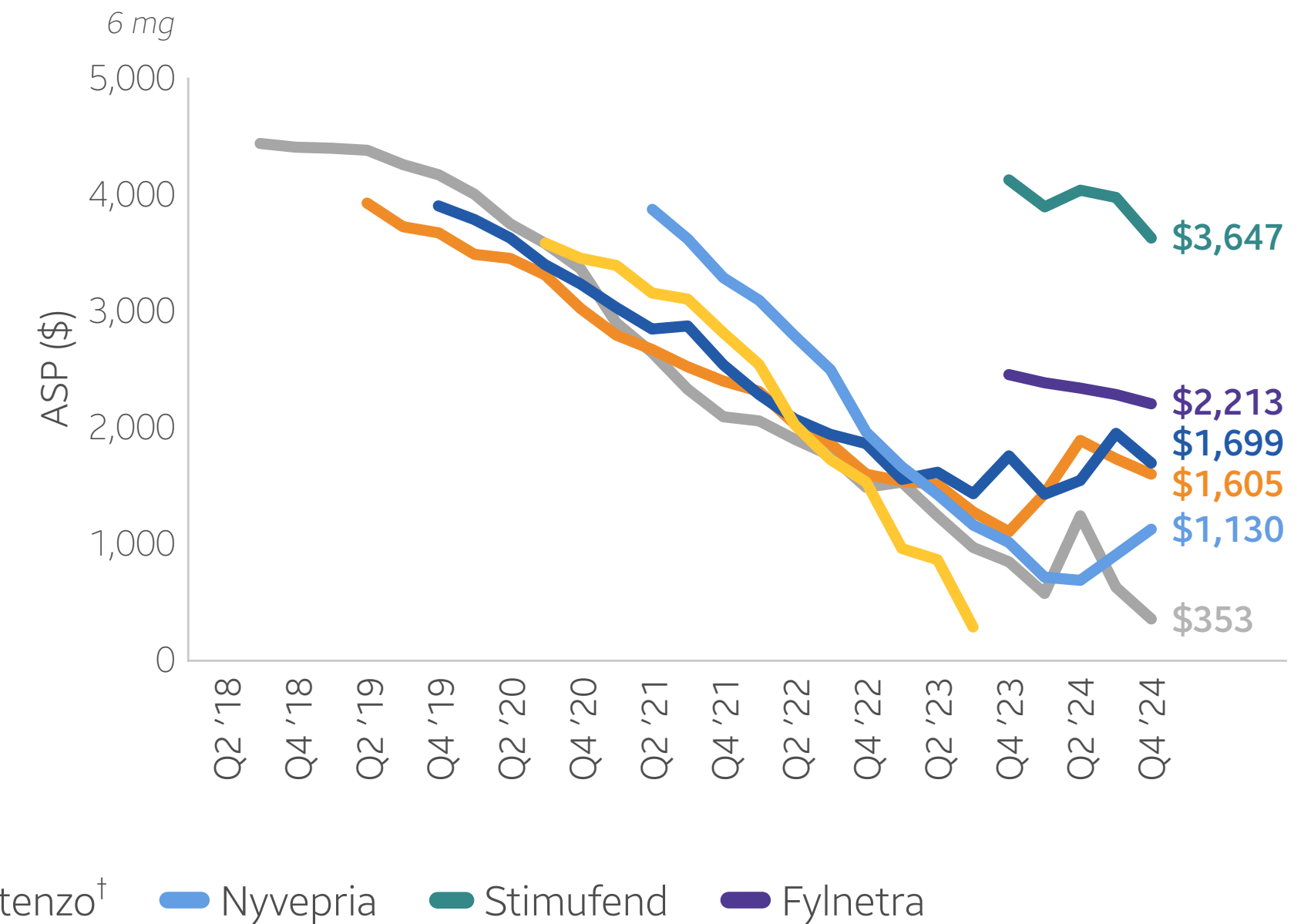


Figure 18. Pegfilgrastim ASP Trend³



Legends are listed in order of launch ASP: Average Sales Price
[†]Ziextenzo ASP has unpublished since Q4 2023 [†]Onpro is not included

Biosimilar Price - Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Biosimilar Price - 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

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

- ✦ Retracrit, the only biosimilar of epoetin alfa, maintains about a third of the epoetin alfa market share.
- ✦ By matching ASP, the two reference products have maintained a combined share of approximately 60-70%.

Figure 19. Epoetin Alfa Volume Market Share⁴

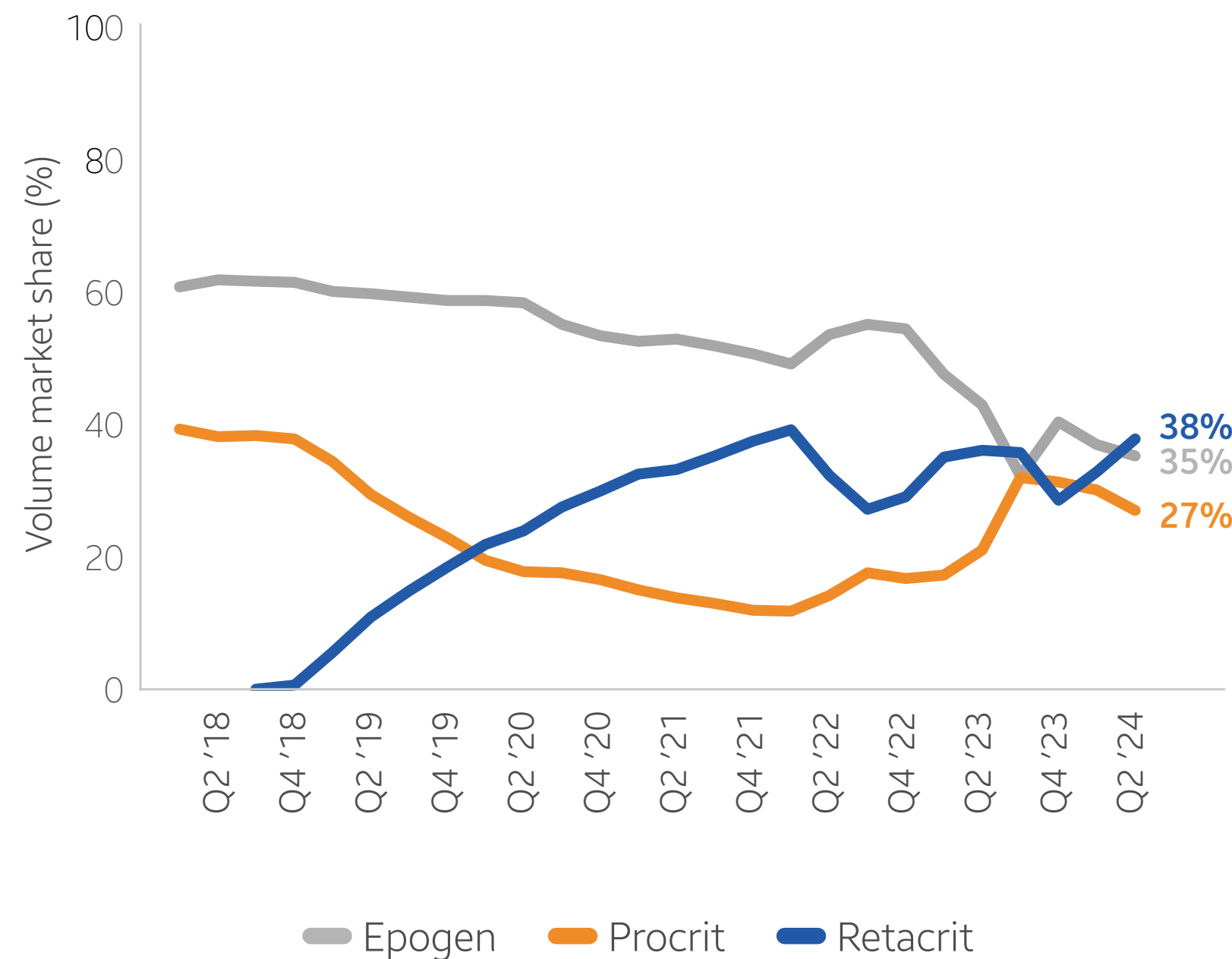
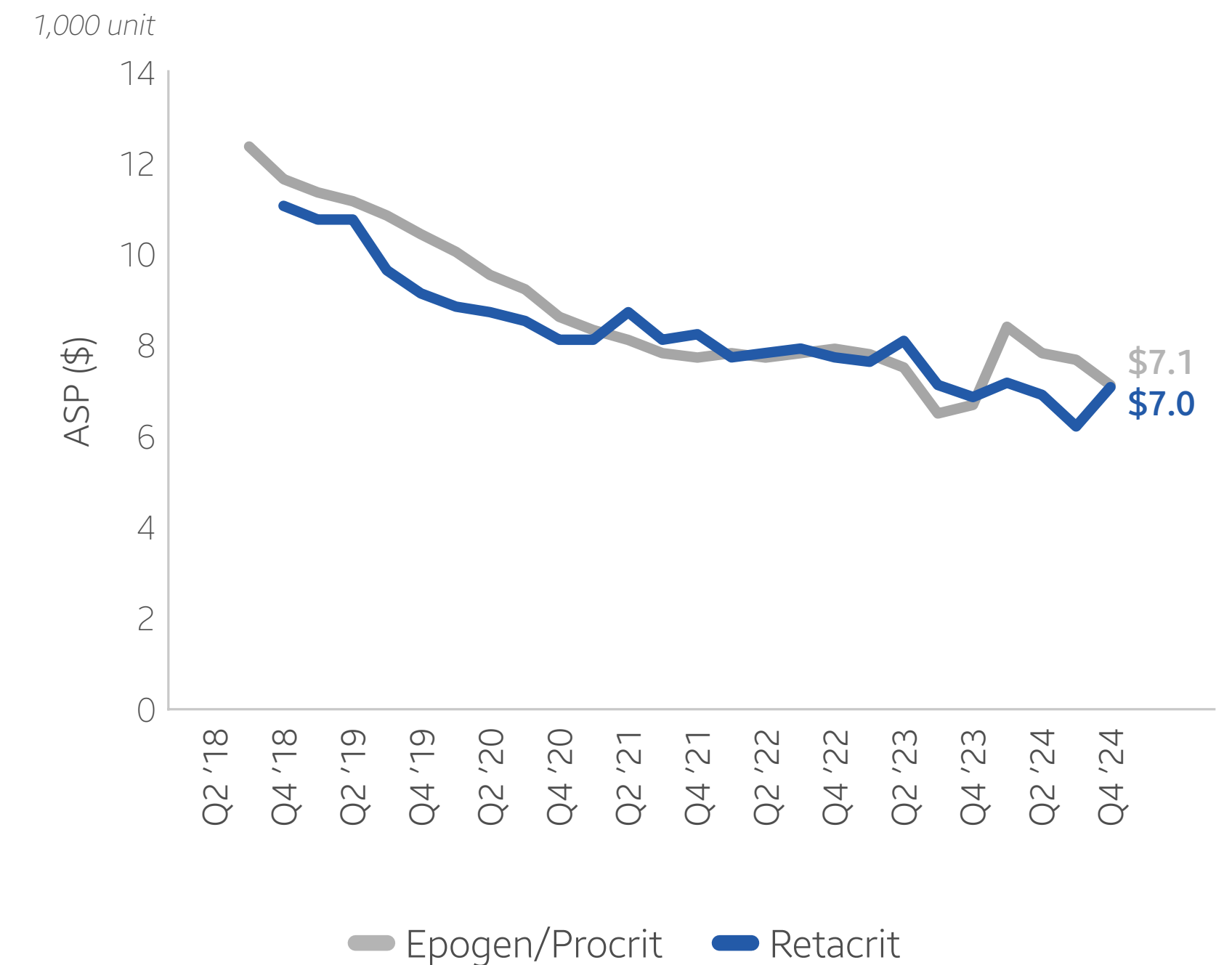


Figure 20. Epoetin alfa ASP Trend³



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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- Immunology
- Endocrinology
- Ophthalmology

Market Share and ASP Trends - Remicade (Infliximab)

- ✦ As of Q2 2024, Infliximab biosimilar market share has reached 47% (-2% vs. last quarter).
- ✦ As of Q4 2024, the average ASP of all biosimilar products is \$183 (-1% vs. last quarter).
- ✦ Janssen's competitive ASP pricing and launch of an unbranded infliximab of Remicade in Q4 2021 has allowed the reference product to hold onto the market leading position.

Figure 21. Infliximab Volume Market Share⁴

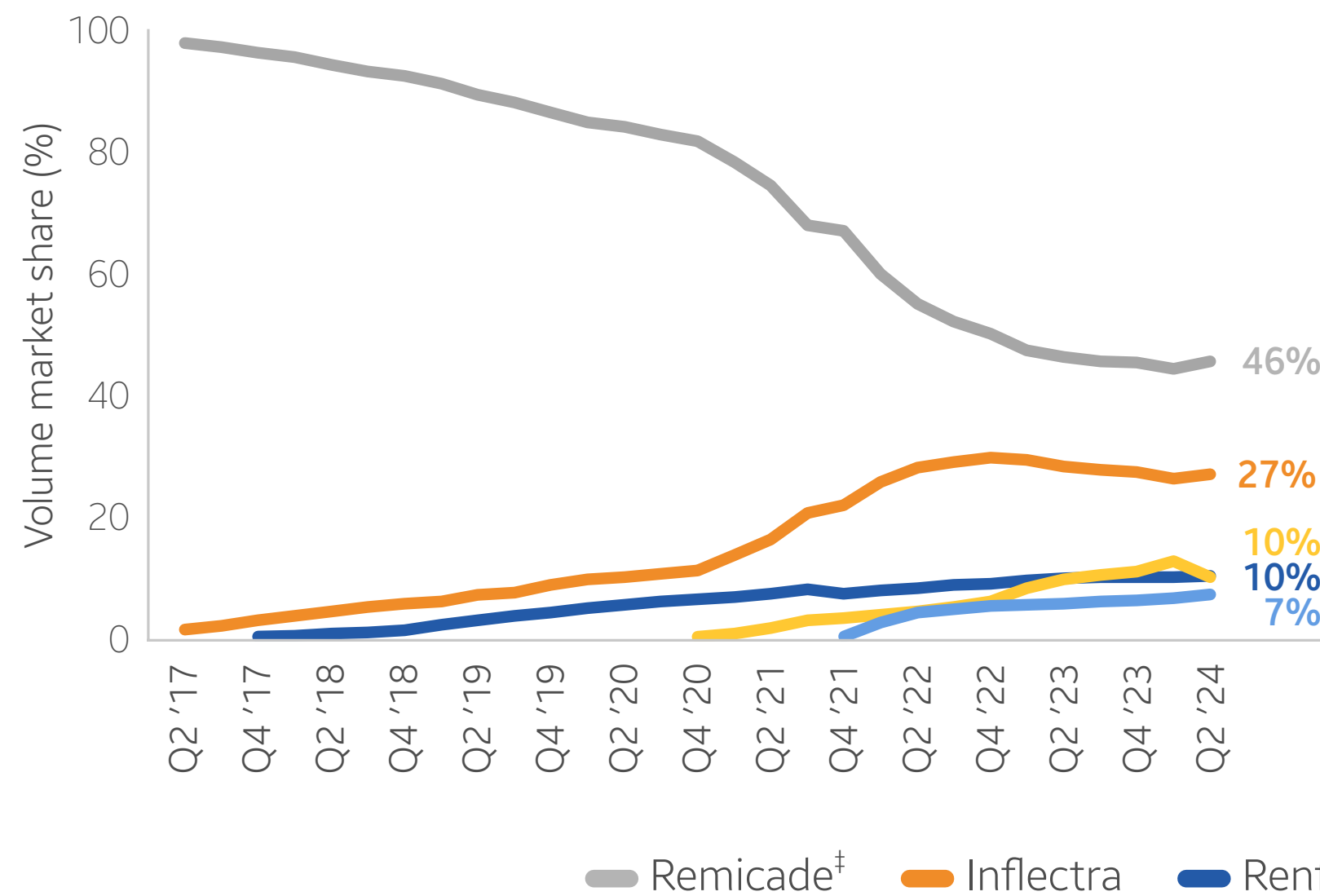
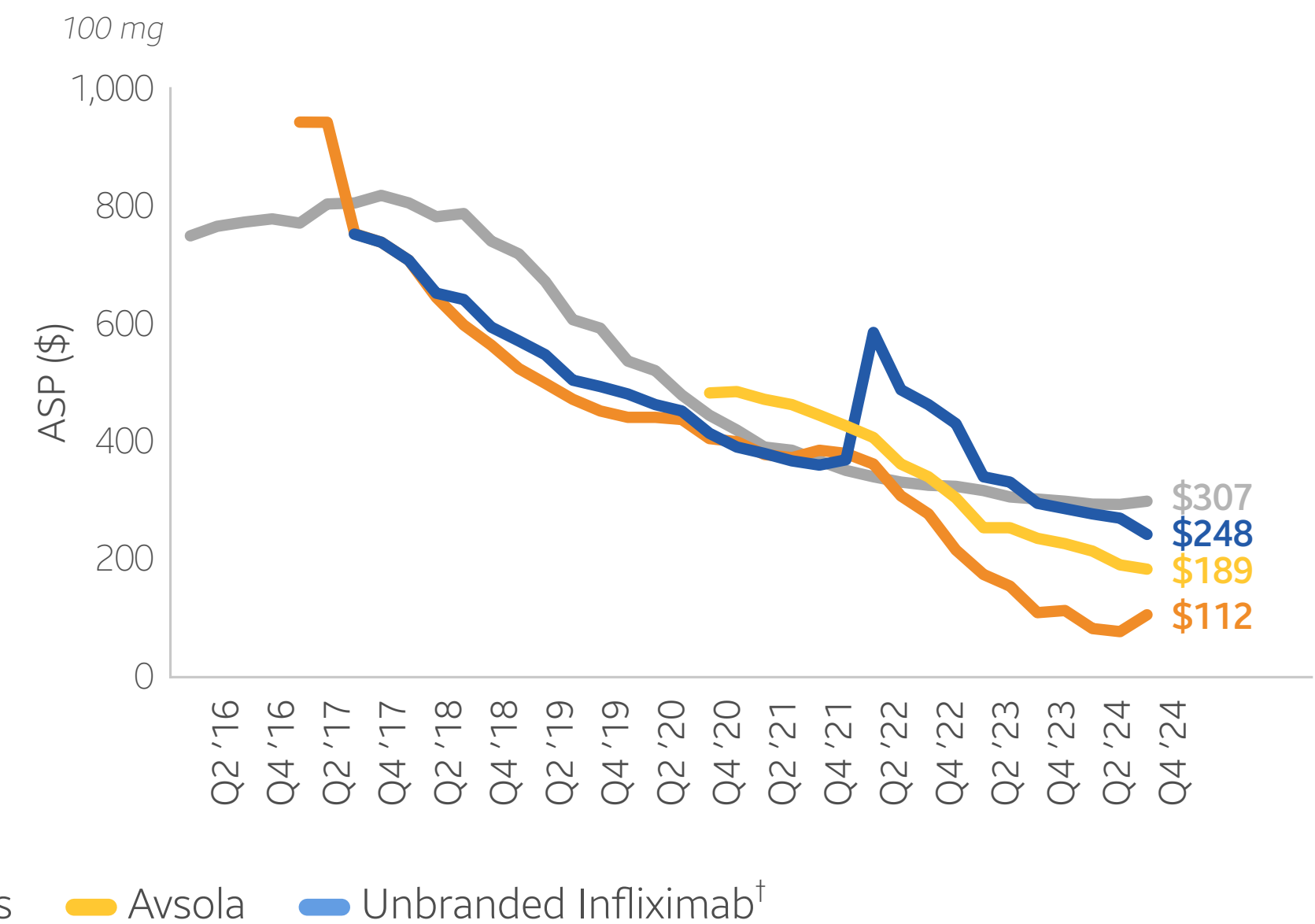


Figure 22. Infliximab ASP Trend³



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

- Oncology
- Supportive Care
- Immunology & Ophthalmology

- Immunology & Endocrinology

- Biosimilar Market Adoption & Price Erosion

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Market Share and WAC Trends - Humira (Adalimumab)

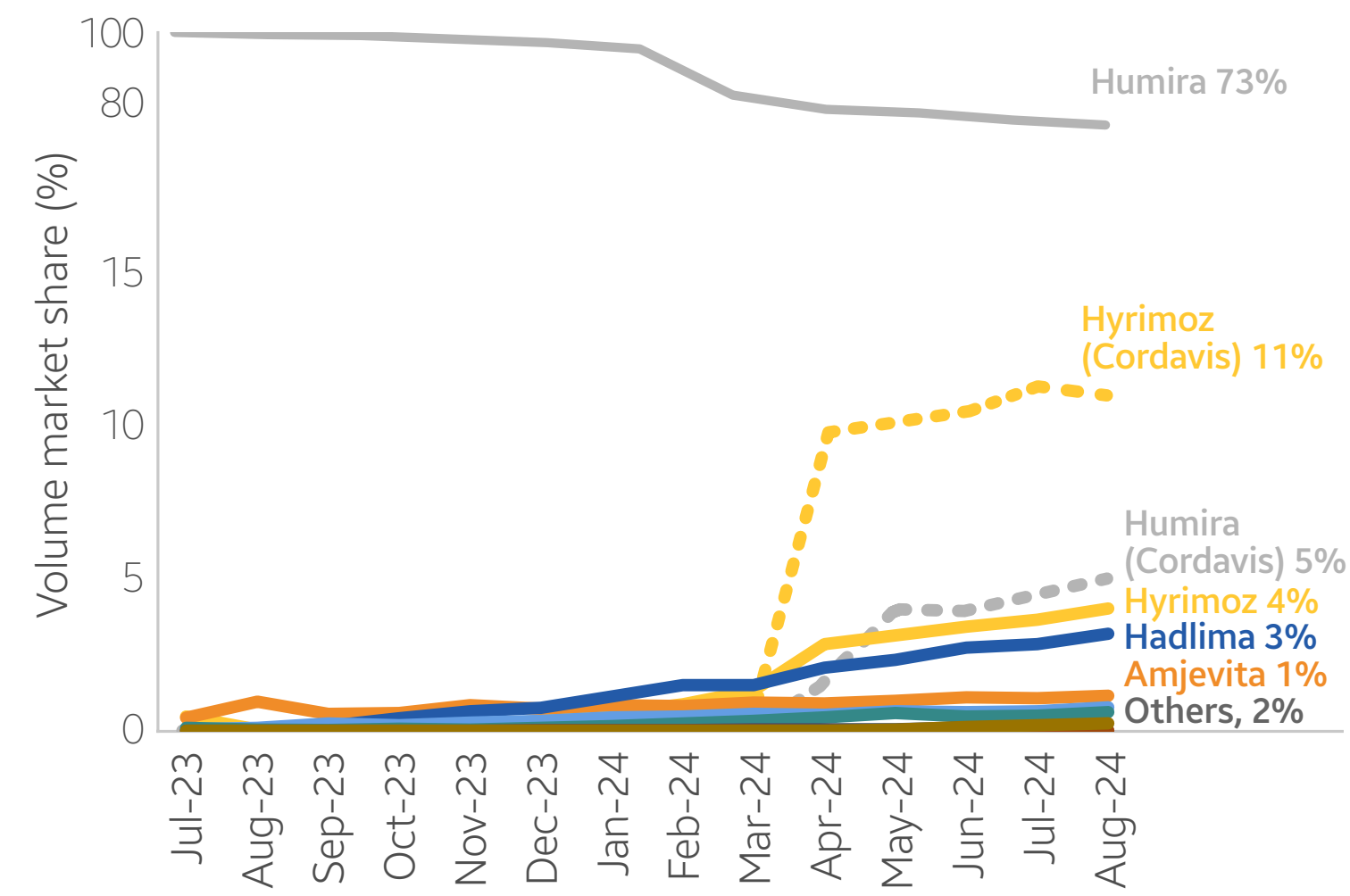
✦ As of Aug 2024, adalimumab biosimilar market share has reached 22% (+4% vs. May 24).

- Most biosimilar gains have come from Hyrimoz and Hadlima.

✦ Biosimilar brands have provided the market with diverse WAC pricing options.

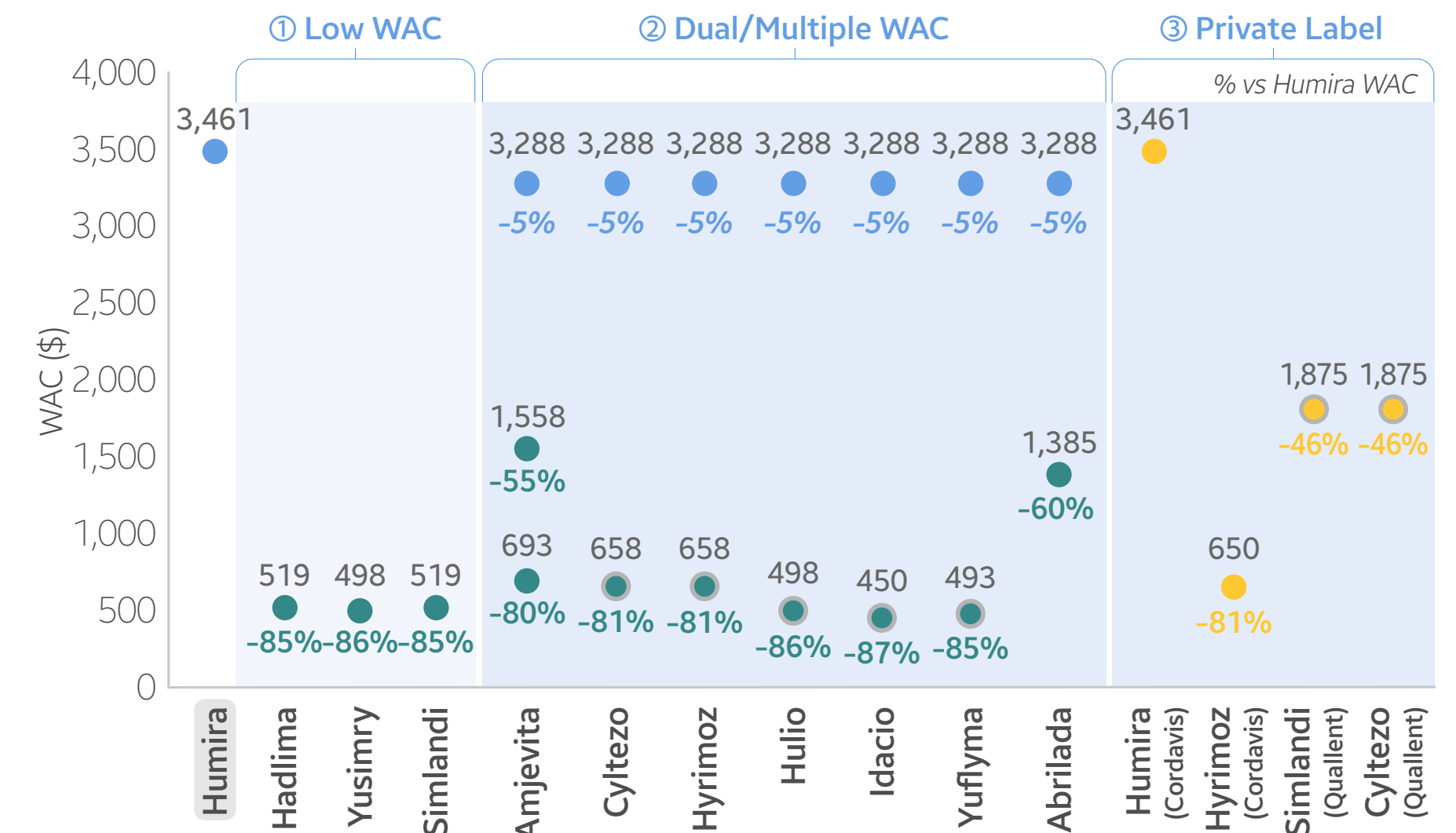
- 1) Hadlima, Yusimry and Simlandi offer a low WAC: ~85-86% less than Humira.
- 2) Amjevita, Cyltezo, Hyrimoz, Hulio, Idacio, Yuflyma, and Abrilada offer dual/multiple pricing options (i.e. high and low WAC).
- 3) Private Label brands offer alternative WAC prices.

Figure 23. Adalimumab Volume Market Share⁵



- AbbVie, Humira
- Organon/Samsung Bioepis, Hadlima
- Sandoz, Hyrimoz (Cordavis)
- Biocon, Hulio
- Pfizer, Abrilada
- AbbVie, Humira (Cordavis)
- Coherus, Yusimry
- Fresenius Kabi, Idacio
- Teva/Alvotect, Simlandi
- Amgen, Amjevita
- Sandoz, Hyrimoz
- Boehringer Ingelheim, Cyltezo
- Celltrion, Yuflyma

Figure 24. Adalimumab WAC Trend²



- High WAC (Q4 `24)
- Low WAC (Q4 `24)
- Private Label
- Unbranded

WAC: Wholesale acquisition cost

[†] Amjevita only launched in low WAC for high concentration

[§] Cordavis price of Hyrimoz

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Market Share and WAC Trends - Actemra (Tocilizumab)

- ✦ As of Q2 2024, the Actemra, the reference biologic for tocilizumab still holds most of the market as the biosimilars just launched in Q2.
- ✦ Actemra has marketed two formulations at different WAC prices, a \$2,656 vial and \$1,175 pre-filled syringe/auto-injector.
- ✦ Two biosimilars have entered the tocilizumab market (vial formulation only), one at a WAC discount of -16% (\$2,220) and the other with a WAC discount of -26% (\$1,960) as compared to the reference biologic (\$2,656).

Figure 25. Tocilizumab Volume Market Share⁴

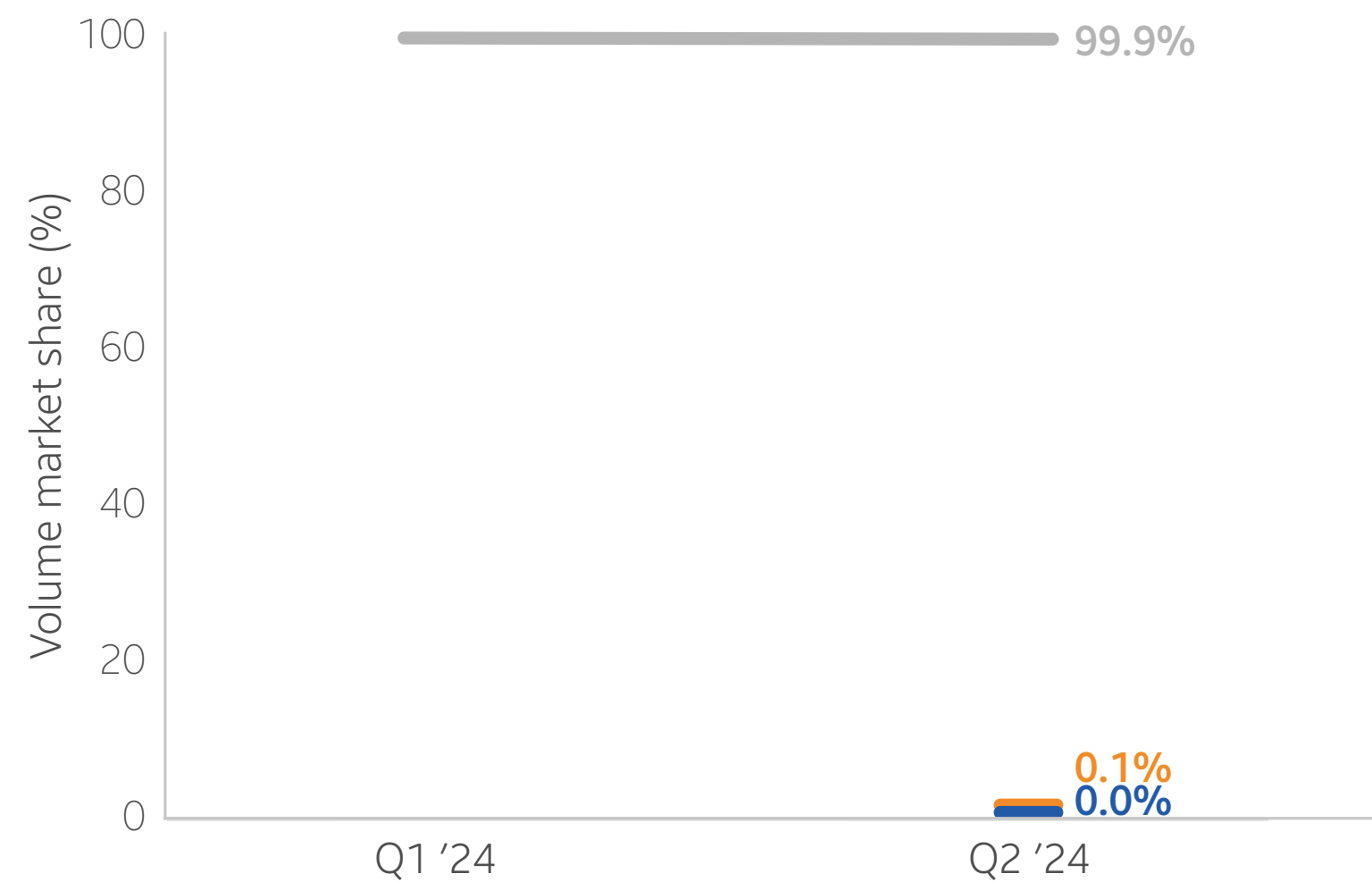
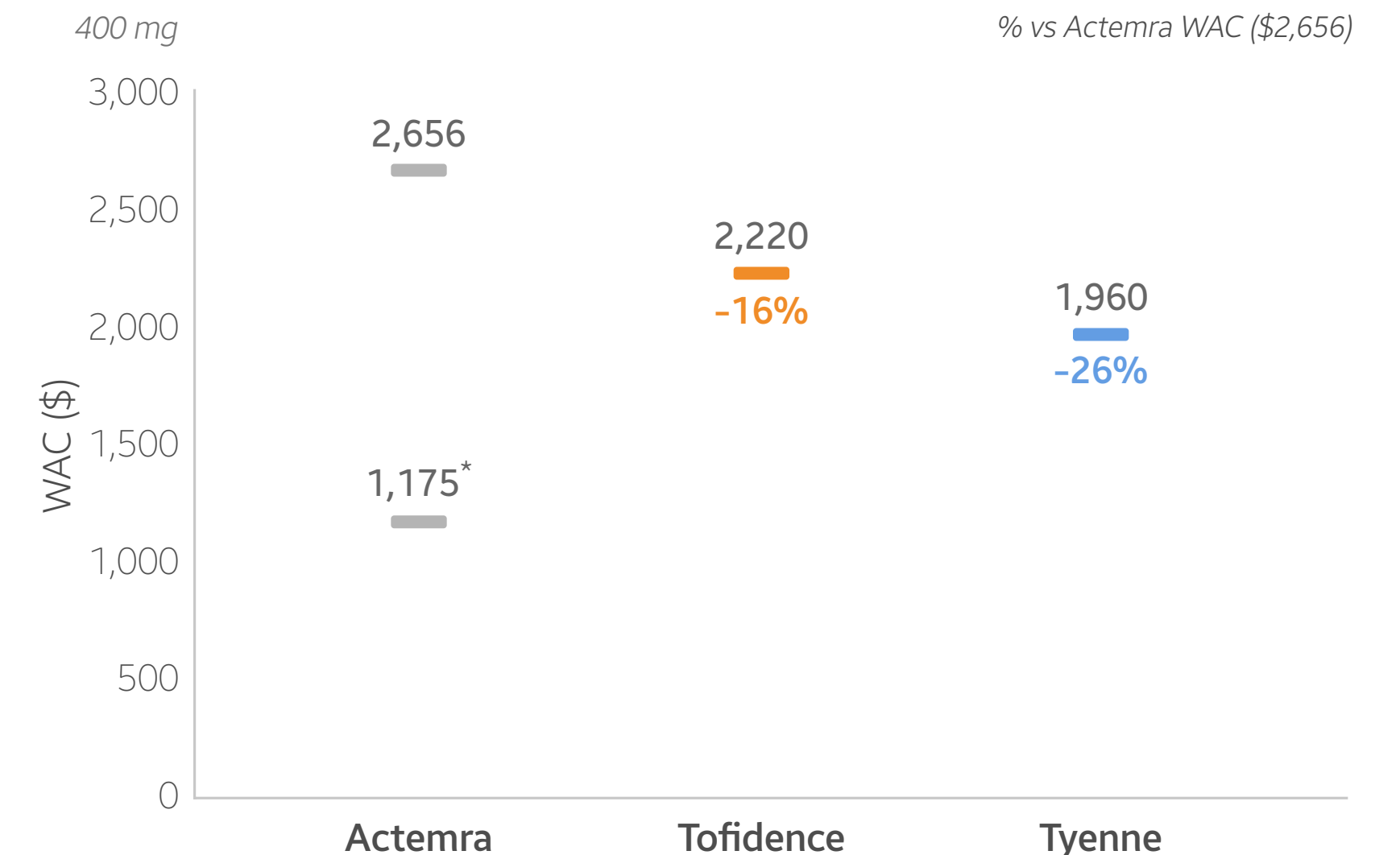


Figure 26. Tocilizumab WAC Trend²



Actemra Tofidence Tyenne

WAC: Wholesale acquisition cost

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

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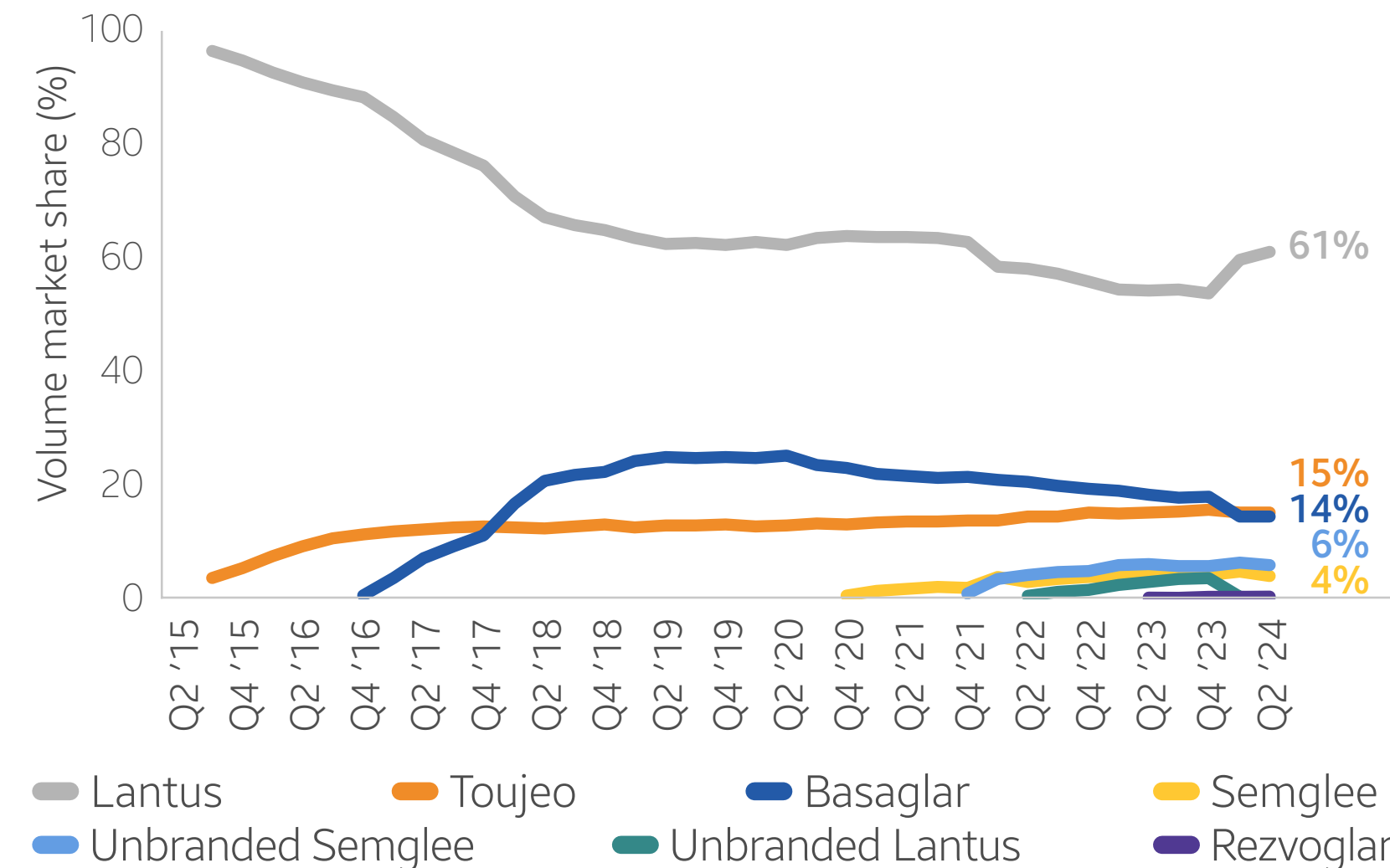
Market Share and WAC Trends - Lantus (Insulin glargine)

- ✦ As of Q2 2024, insulin glargine biosimilar market share is 24% (-1% vs. last quarter).
- ✦ Sanofi's dual pricing strategy and competitive rates have helped to maintain Lantus' position as the market leader

✦ Insulin Glargine Market Background

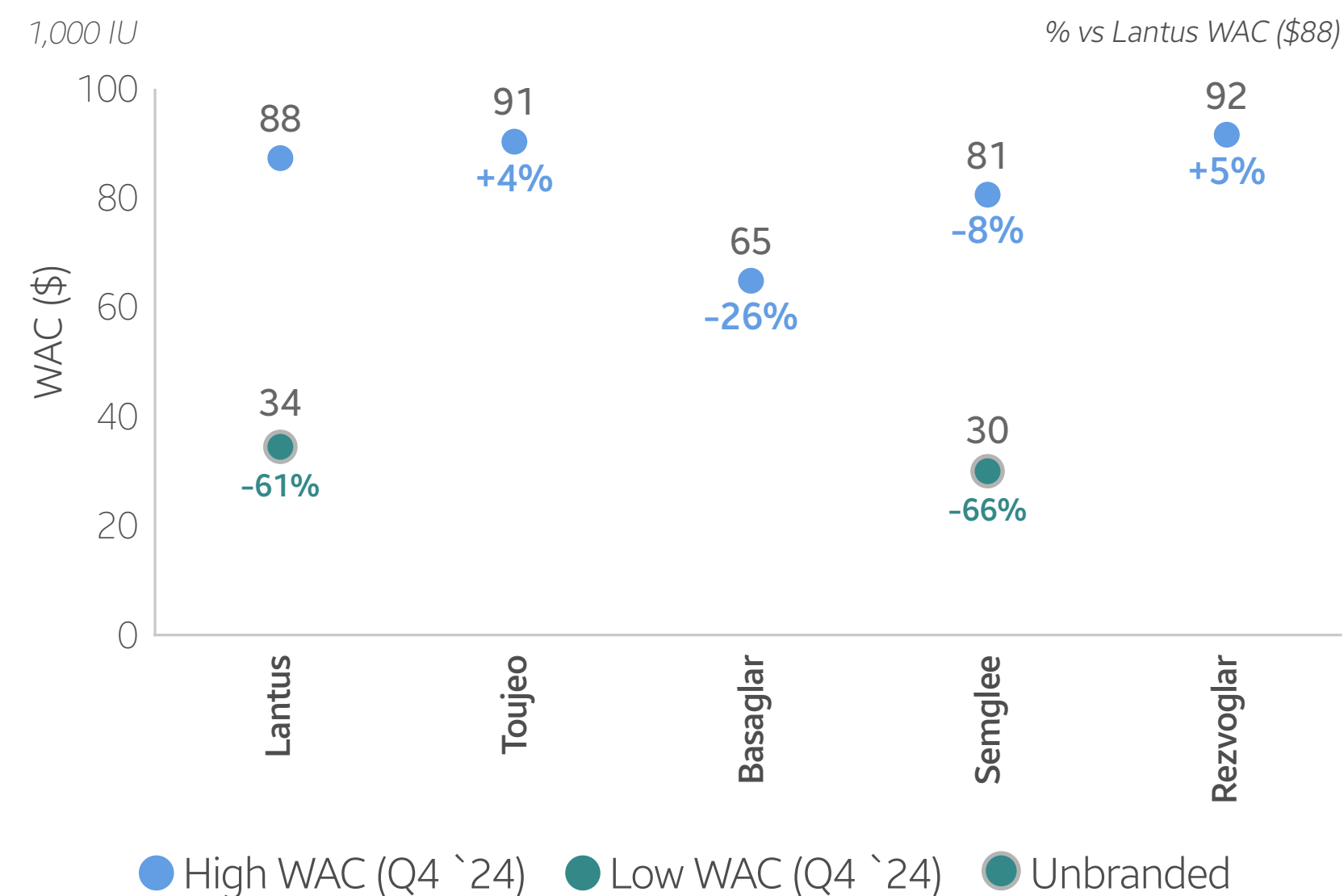
- Lantus (Sanofi): reference product, available unbranded
- Toujeo (Sanofi): higher dose insulin glargine product
- Rezvoglar (Eli Lilly): Lantus biosimilar, interchangeable
- Semglee (Biocon): Lantus biosimilar, available unbranded
- Basaglar (Eli Lilly): ISG product approved via New Drug Application pathway

Figure 27. Insulin Glargine Volume Market Share⁴



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

Figure 28. Insulin Glargine WAC Trend²



● High WAC (Q4 '24) ● Low WAC (Q4 '24) ● Unbranded

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Market Share and ASP Trends - Lucentis (Ranibizumab)

- ✦ As of Q2 2024, ranibizumab biosimilar market share has reached 56% (+5% vs. last quarter).
- ✦ As of Q4 2024, the average ASP of all biosimilar products is \$891 (+3% vs. last quarter).

Figure 29. Ranibizumab Volume Market Share⁴

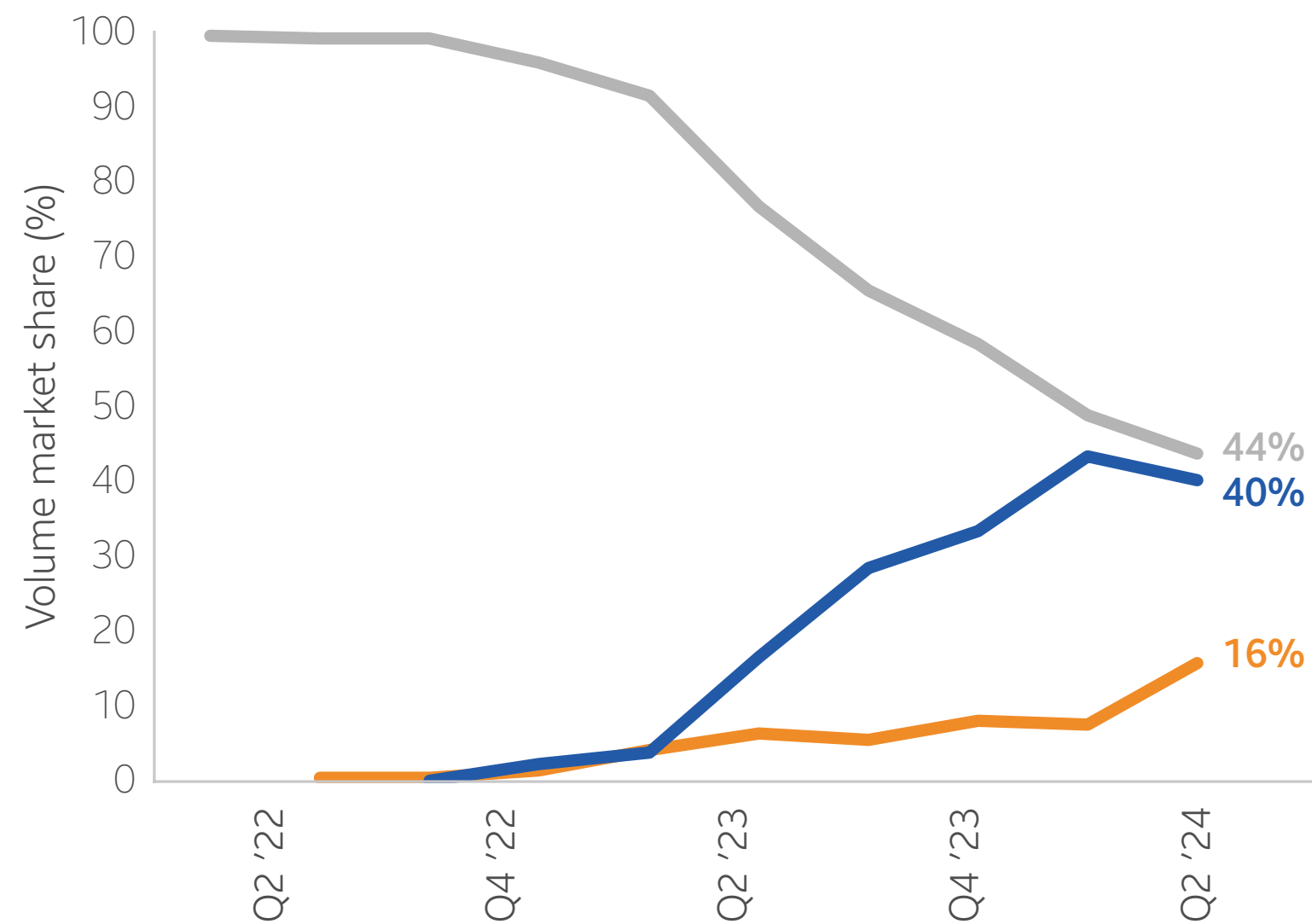
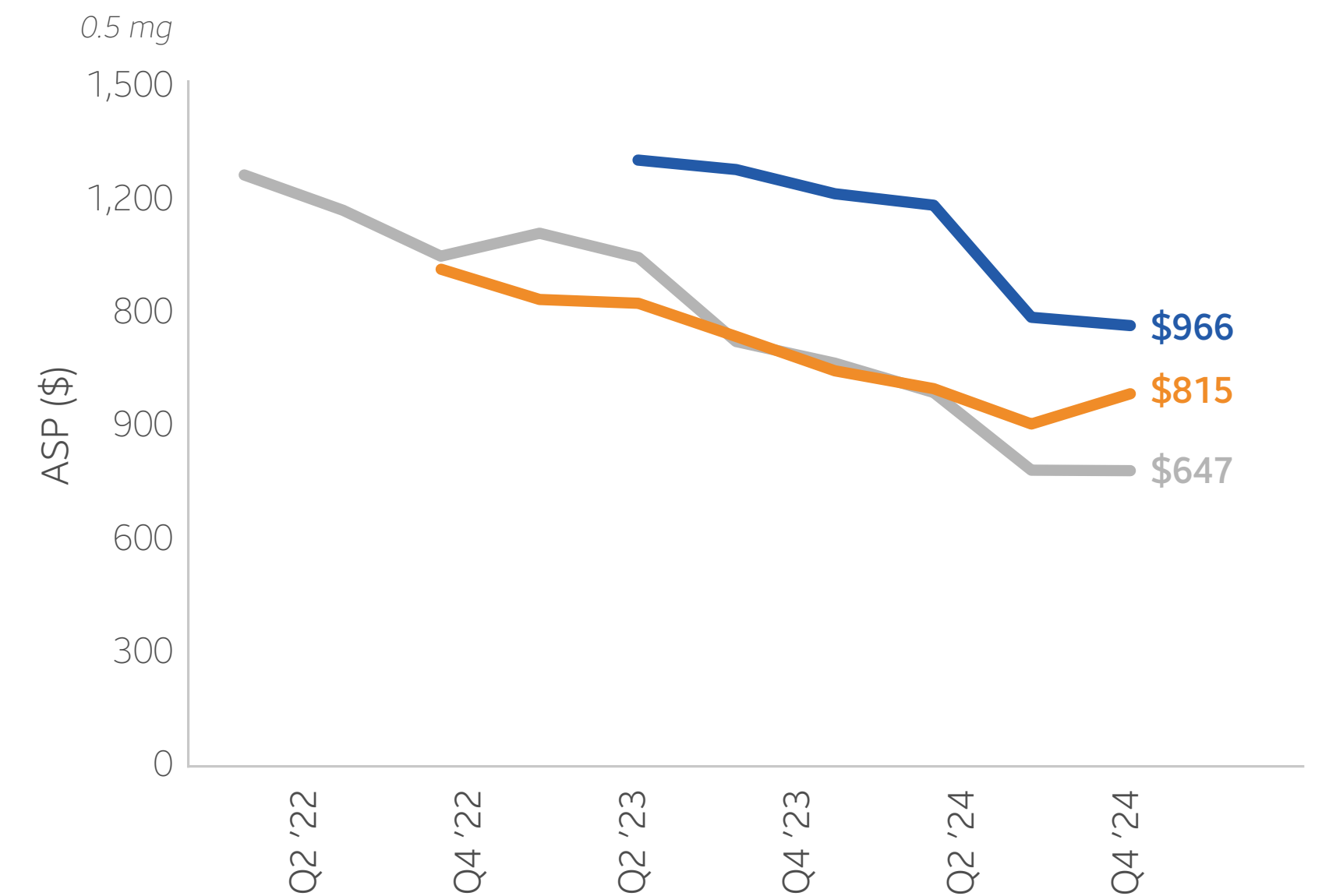


Figure 30. Ranibizumab ASP Trend³



— Lucentis — Byooviz — Cimerli

Legends are listed in order of launch
³Percentages reflect the change from the reference product's ASP at the time of the first biosimilar launch.



IV. Biosimilar Deep Dive



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- Biosimilar Market Adoption & Price Erosion

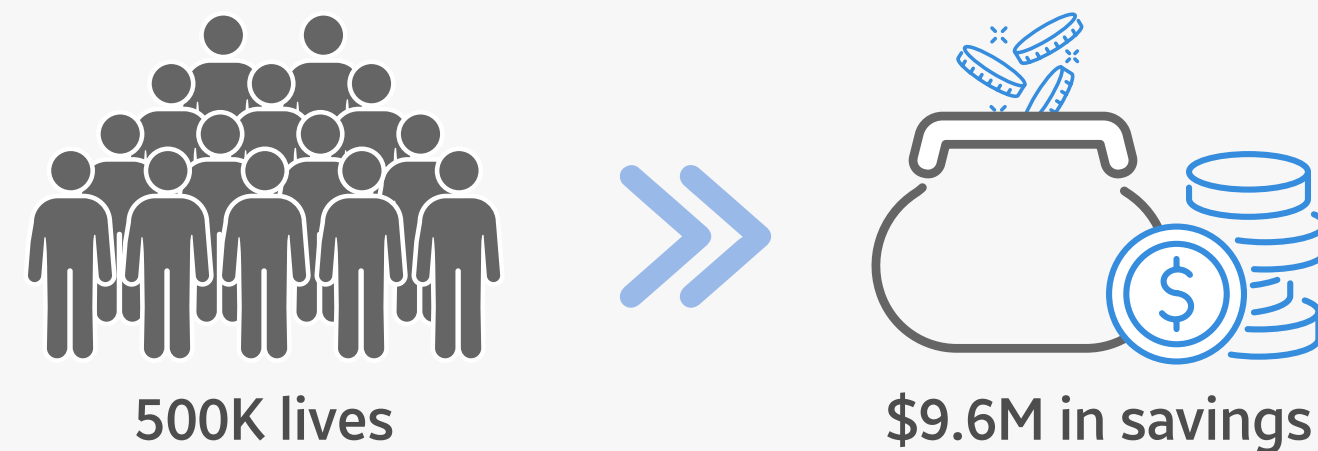
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Biosimilars will Remain Critical to Healthcare Affordability, Allowing Resources to be Redirected Toward Innovative Medicines

US Biosimilar Cost Savings

- From 2015-2023, total US biosimilar savings have been calculated at \$36B with a third of those savings occurring in 2023⁶
- Payers have recognized an average of \$1.6 PMPM savings to date with some payers reporting savings as high as \$6 PMPM⁷

A hypothetical Health Plan covering 500k lives can save **\$9.6M** annually



How can savings be leveraged?

US payer primary market research identifies that biosimilar savings are predominantly reinvested to offset drug trends and reduce premium growth⁷

By providing cost relief in expensive biologic markets, healthcare dollars can be freed up to pay for new therapies and the drug trends associated with innovation

As costs for certain biologic markets come down, payer utilization management restrictions can in some instances be reduced, allowing for wider patient access to biologic therapies and improved patient outcomes

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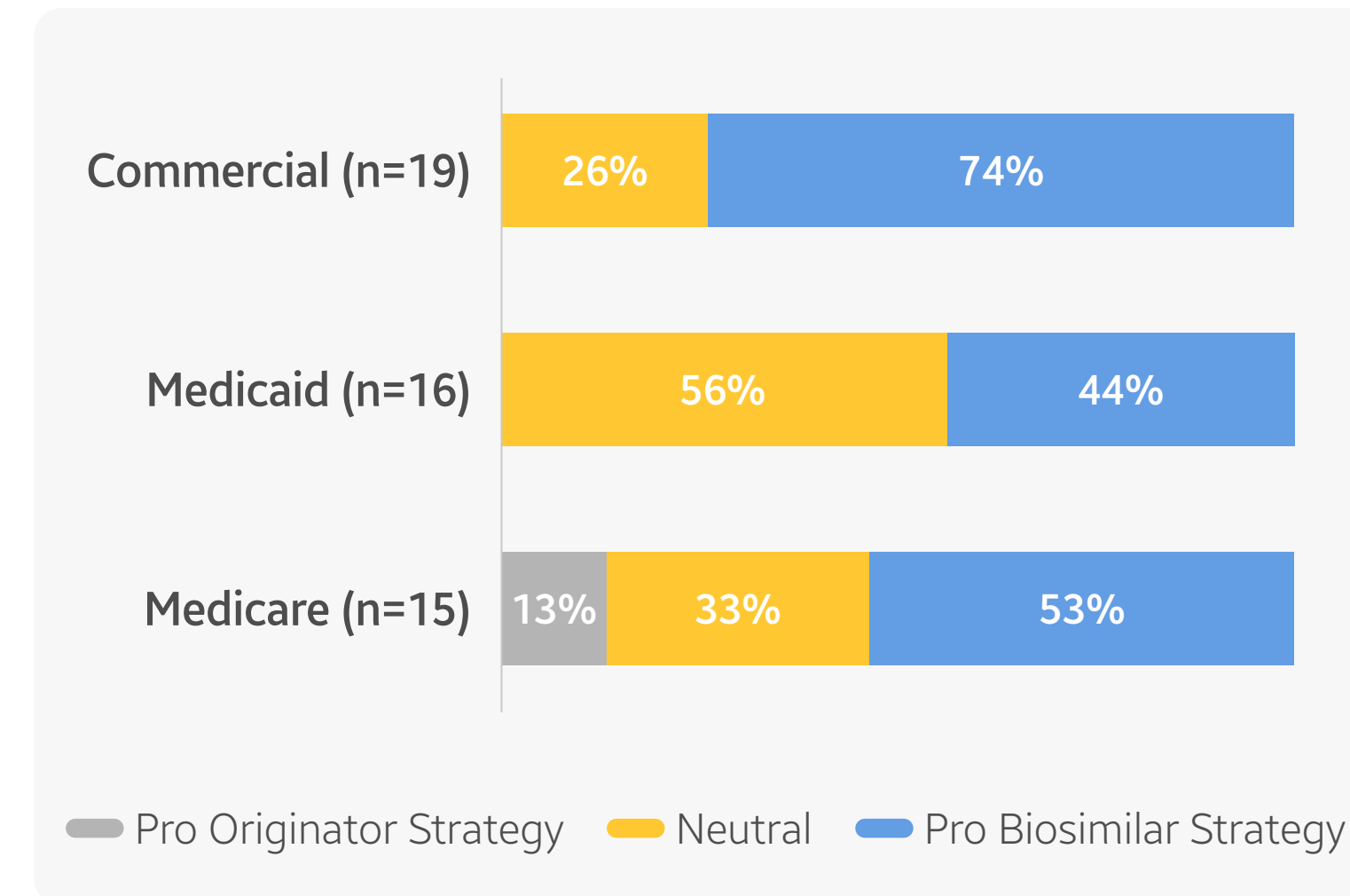
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US Biosimilar Adoption and Associated Savings, while Growing, can be Optimized in Each Line of Business

Although biosimilar adoption rates are higher amongst medical benefit molecules such as oncology, ophthalmology, and pegfilgrastim, biosimilar share remains low in pharmacy benefit markets including adalimumab and insulin.

Pro biosimilar strategies favoring biosimilars over reference biologics have started to emerge in Commercial, yet still lag in Medicare and state-managed Medicaid formularies.⁷

How does your biosimilar strategy philosophically differ, if at all, by line of business (LOB)?⁷



Why biosimilar adoption may lag in each LOB⁷

Commercial

- Loss of rebates on reference biologics poses challenges with employers, plans, and PBMs.

Medicaid

- State Medicaid agencies typically have contracts in place that make the reference biologics more affordable and patient disruption less attractive.

Medicare

- Medicare reimbursement for the reference biologics is typically higher, the additional percentage payment is also higher, creating a financial disincentive for providers to switch to lower-cost biosimilars.
- Medicare also has a lot of strict rules on continuation of care (grandfathering) and concerns about members filing grievances and satisfaction, which make health plans hesitant to switch them to biosimilars.

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Payers Weigh in on How Biosimilar Adoption can be Optimized in the US⁷

*Payers cite the role of **state and national policy** in accelerating biosimilar adoption*



- Encouraging patient and provider adoption by requiring or incentivizing government programs (Medicaid and Medicare) to **prefer biosimilars over reference products**
- **Remove grandfathering requirements** that hinder conversions
- Addressing **administrative burden** on pharmacies and providers by viewing all biosimilars as interchangeable
- **Encourage more competition** by incentivizing and simplifying biosimilar regulatory approval pathways

*Payer discussions highlight **strategies for payers** to optimize the benefits of biosimilars*



- **Improved speed of conversions to biosimilars** is critical to realizing cost reductions, noting that any initial negative cost impact should be offset by long-term savings
- Improving the **robustness of step therapy** such as applying step therapy to patients established on the reference biologic or promoting a switch to another biosimilar rather than reverting to the brand-name drug upon biosimilar failure
- To align plan and member incentives, payers may consider creation of **novel benefit designs** (e.g. a biosimilar tier)

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
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Biosimilar Deep Dive

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SAMSUNG BIOEPIS

76, Songdogyoyuk-ro, Yeonsu-gu, Incheon, Republic of Korea

E-mail: bioepisinfo@samsung.com

For more information, please visit: www.samsungbioepis.com

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