

Biosimilar Market Report

2nd Edition, Q3 2023

IFOREWORD

Dear Readers,

So far in 2023, we have seen the start of biosimilars being launched within pharmacy benefits. As of early July, eight brands have entered the adalimumab market alone on various pharmacy benefit formularies. This is the start of new beginning for biosimilars in the United States.

In this exciting time in the biosimilar industry, the Samsung Bioepis Biosimilar Market Report will provide an up-to-date perspective on the US biosimilar landscape for you each quarter.

In this second edition of the report, we have updated the most recent price trends of all molecules for biosimilar(s) that have launched.

Moving forward each Market Report will consist of comprehensive updates on pricing and market penetration for all marketed biosimilars in the US.





Thomas Newcomer
Vice President
Head of Market Access, Samsung Bioepis US

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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US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
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Pharmacy Benefit

Immunology & Endocrinology

Biosimilar Market Dynamics

Correlation between biosimilar price & market adoption

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Reference

- Endocrinology
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FDA Approval and Launch Status of US Biosimilars

- * As of July 2023, the FDA has approved a total of 41 biosimilars across 11 unique biological molecules. Of the 41 approvals, 37 biosimilars have been launched in the US market.
 - Seven of Humira biosimilars launched in early July, joining Amjevita that was already in market since January.
 - In Q2, one new biosimilar was approved in the US (Yuflyma for Humira) and two other previously approved products were launched. Vegzelma became the 4th biosimilar for Avastin and Fylnetra's commercial launch represented the 5th competitor to Neulasta.

Cumulative **Approvals**

Ophthalmolog

Ranibizumab

Lucentis Novartis 2006

Coherus

Figure 1. Biosimilars Approval and Launch Status in the US^{1*} (As of July 2023)

TA	Oncology				Supportive Care		Immunology			
Molecule	Trastuzumab	Bevacizumab	Rituximab	Filgrastim	Pegfilgrastim	Epoetin alfa	Infliximab	Adalimumab	Etanercept	Insulir
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	La Sa 2
	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	Se M
	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	Rez El
	Ontruzant Samsung Bioepis&Organon 2019	Alymsys Amneal 2022	Riabni Amgen 2020	Releuko Amneal&Kashiv 2022	Ziextenzo Sandoz 2019		Avsola Amgen 2019	Hyrimoz Sandoz 2018		
Biosimilar	Trazimera Pfizer 2019	Vegzelma Celltrion 2022			Nyvepria Hospira&Pfizer 2020		lxifi 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		
	■ Launched ■ Not launched □ Updated brand vs. last report									

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

US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Pharmacy Benefit

Immunology & Endocrinology

Biosimilar Market Dynamics

Correlation between biosimilar price & market adoption

Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Figure 1-1. Biosimilars Approval and Launch Status in the US^{1*} (As of July 2023, with Suffix)

				1.1				•			
TA		Oncology			Supportive Care			Immunology		Endocrinology	Ophthalmology
Molecule	Trastuzumab	Bevacizumab	Rituximab	Filgrastim	Pegfilgrastim	Epoetin alfa	Infliximab	Adalimumab	Etanercept	Insulin Glargine	Ranibizumab
Reference Product	Herceptin (trastuzumab) Roche 1998	Avastin (bevacizumab) Roche 2004	Rituxan (rituximab) Genentech&Biogen 1997	Neupogen (Filgrastim) Amgen 1991	Neulasta (pegfilgrastim) Amgen 2002	Epogen (epoetin alfa) Amgen 1898	Remicade (infliximab) Janssen 1998	Humira (adalimumab) AbbvVie 2002	Enbrel (etanercept) Amgen 2003	Lantus (insulin glargine) Sanofi 2000	Lucentis (ranibizumab) Novartis 2006
Biosimilar	Ogivri (trastuzumab-dkst) Mylan 2017	Mvasi (bevacizumab-awwb) Amgen 2017	Truxima (rituximab-abbs) Celltrion&Teva 2018	Zarxio (filgrastim-sndz) Sandoz 2015	Fulphila (pegfilgrastim-jmdb) Mylan 2018	Retacrit (epoetin alfa-epbx) Hospira&Pfizer 2018	Inflectra (infliximab-dyyb) Celltrion&Pfizer 2016	Amjevita (adalimumab-atto) Amgen 2016	Erelzi (etanercept-szzs) Sandoz 2016	Semglee (insulin glargine-yfgn) Mylan 2021	Byooviz (Ranibizumab-nuna) Samsung Bioepis 2021
	Herzuma (trastuzumab-pkrb) Celltrion&Teva 2018	Zirabev (bevacizumab-bvzr) Pfizer 2019	Ruxience (rituximab-pvvr) Pfizer 2019	Nivestym (filgrastim-aafi) Hospira&Pfizer 2018	Udenyca (pegfilgrastim-cbqv) Coherus 2018		Renflexis (infliximab-abda) Samsung Bioepis&Organon 2017	Cyltezo (adalimumab-adbm) Boehringer Ingelheim 2017	Eticovo (etanercept-ykro) Samsung Bioepis 2019	Rezvoglar (insulin glargine-aglr) Eli Lilly 2021	Cimerli (Ranibizumab-eqrn) Coherus 2022
	Ontruzant (trastuzumab-dttb) Samsung Bioepis&Organon 2019	Alymsys (bevacizumab-maly) Amneal 2022	Riabni (rituximab-arrx) Amgen 2020	Releuko (filgrstim-ayow) Amneal&Kashiv 2022	Ziextenzo (pegfilgrastim-bmez) Sandoz 2019		Avsola (infliximab-axxq) Amgen 2019	Hyrimoz (adalimumab-adaz) Sandoz 2018			
	Trazimera (trastuzumab-qyyp) Pfizer 2019	Vegzelma (Bevacizumab-adcd) Celltrion 2022			Nyvepria (pegfilgrastim-apgf) Hospira&Pfizer 2020		Ixifi (infliximab-qbtx) Pfizer 2017	Hadlima (adalimumab-bwwd) Samsung Bioepis&Organon 2019			
	Kanjinti (trastuzumab-anns) Amgen 2019				Stimufend (pegfilgrastim-fpgk) Fresenius Kabi 2022			Abrilada (adalimumab-afzb) Pfizer 2019			
					Fylnetra (pegfilgrastim-pbbk) Amneal&Kashiv 2022			Hulio (adalimumab-fkjp) Mylan 2020			
								Yusimry (adalimumab-aqvh) Coherus 2021			
								Idacio (adalimumab-aacf) Fresenius Kabi 2022			
	Launche	ed 🔳 Not la	aunched 🔲	Updated br	and vs. last re	eport		Yuflyma (adalimumab-aaty) Celltrion 2023			
Launched Not launched Updated brand vs. last report								Abrilada	ı		

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

US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Pharmacy Benefit

· Immunology & Endocrinology

Biosimilar Market Dynamics

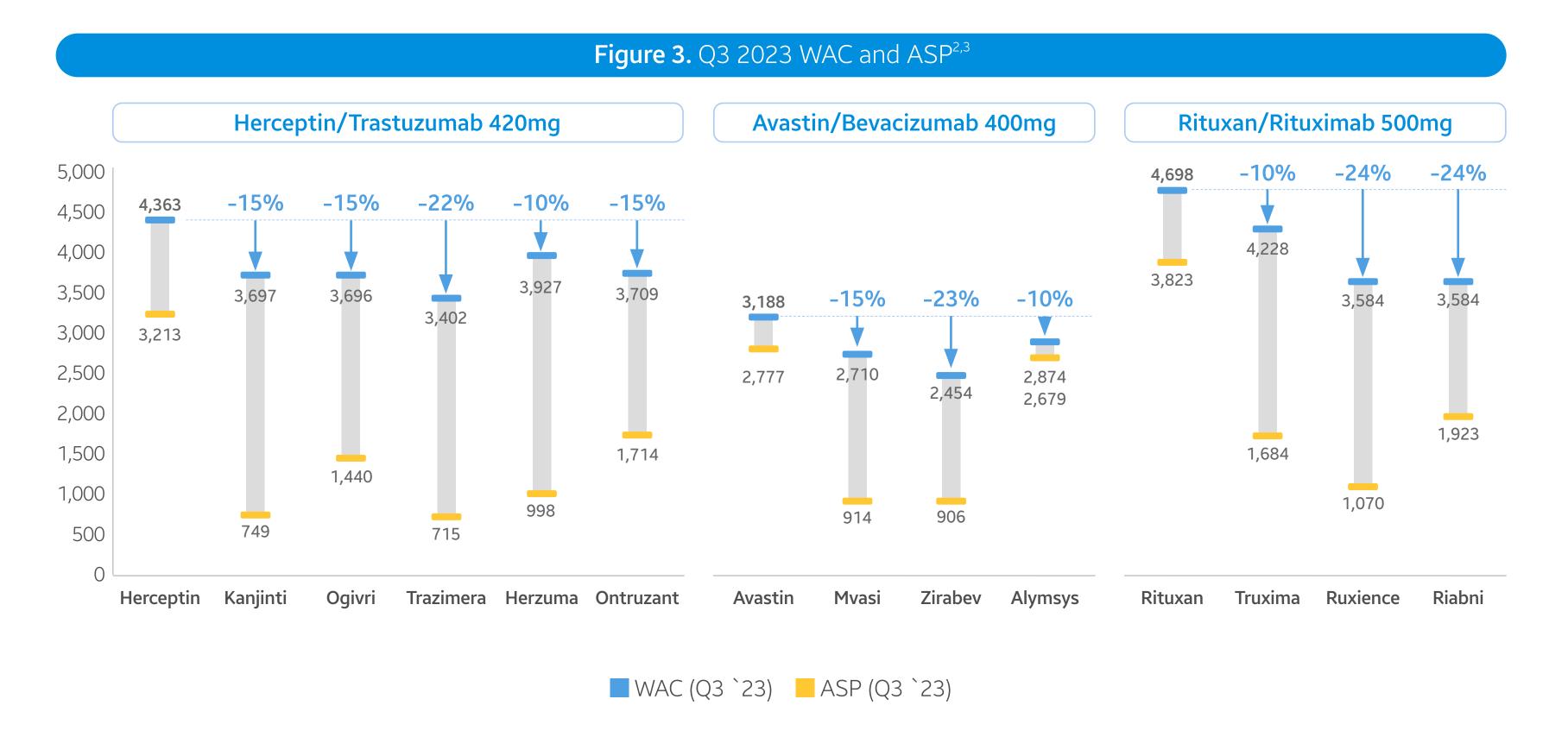
Correlation between biosimilar price & market adoption

Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Oncology WAC and ASP - Q3 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.



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

US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Pharmacy Benefit

· Immunology & Endocrinology

Biosimilar Market Dynamics

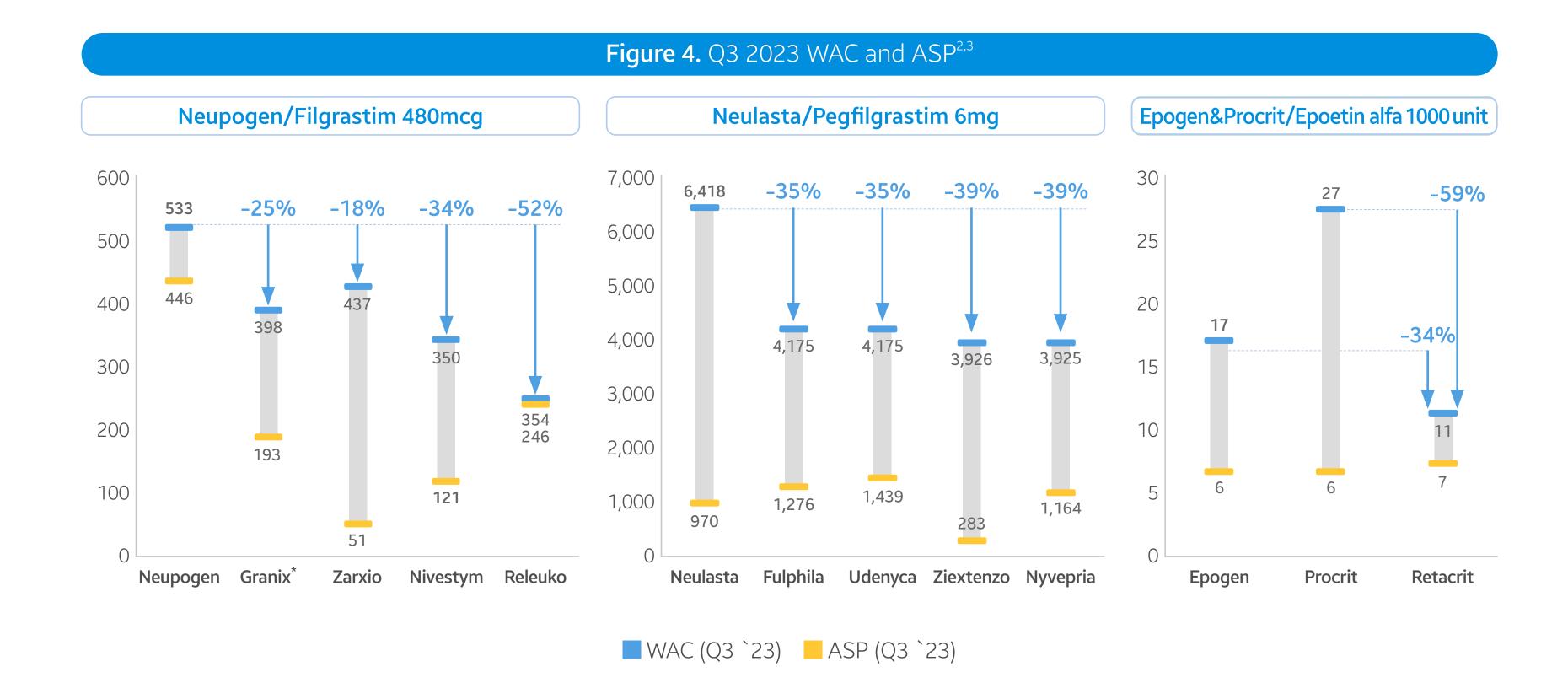
Correlation between biosimilar price & market adoption

Market Share & Price Trends

- Oncology
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- Immunology
- Endocrinology
- Ophthalmology

Supportive Care WAC and ASP - Q3 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.



*Granix is not a biosimilar. It's approved under FDA, a new drug application pathway

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

US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Immunology & Ophthalmology

Biosimilar Market Dynamics

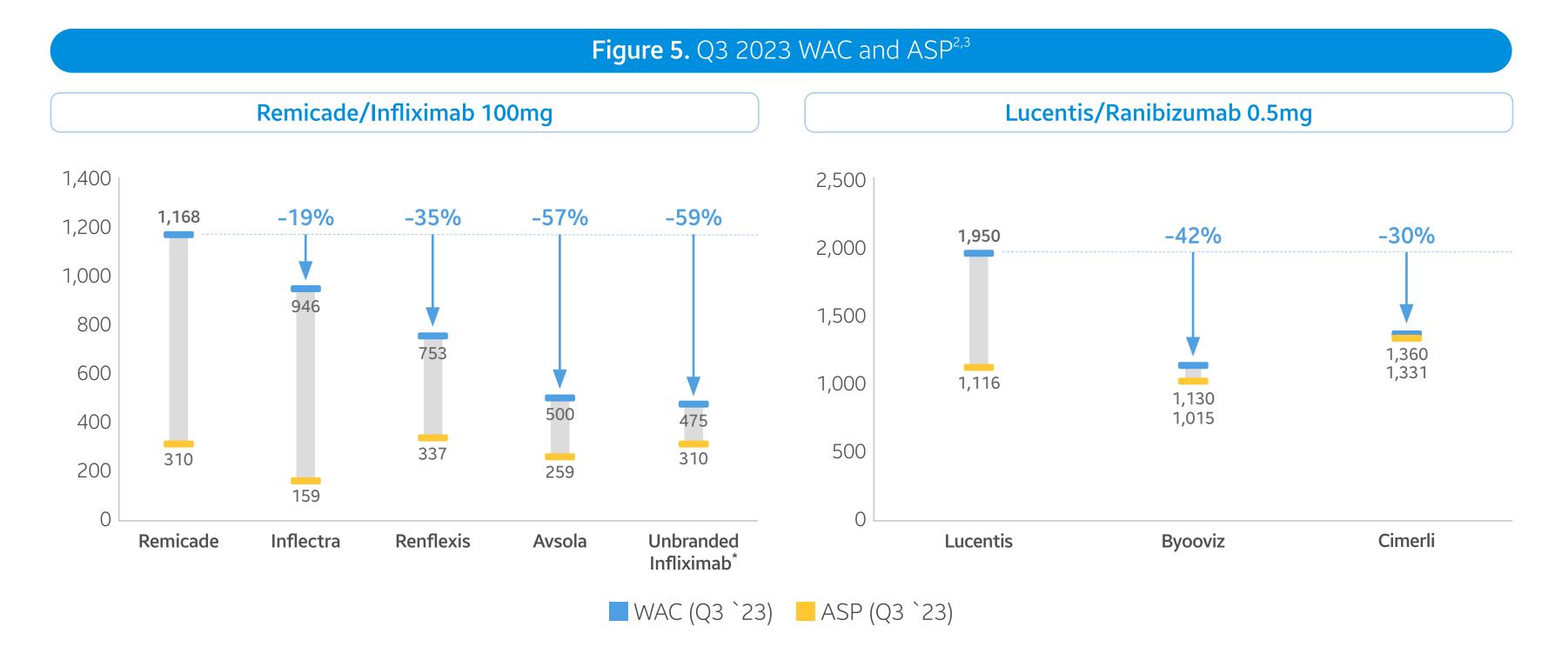
Correlation between biosimilar price & market adoption

Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Immunology & Ophthalmology **WAC and ASP - Q3 2023**

- * Infliximab 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 infliximab had discounted WAC by over 50%.
- * Recent ranibizumab biosimilar launches have already led to lower costs.



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

US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Pharmacy Benefit

· Immunology & Endocrinology

Biosimilar Market Dynamics

Correlation between biosimilar price & market adoption

Market Share & Price Trends

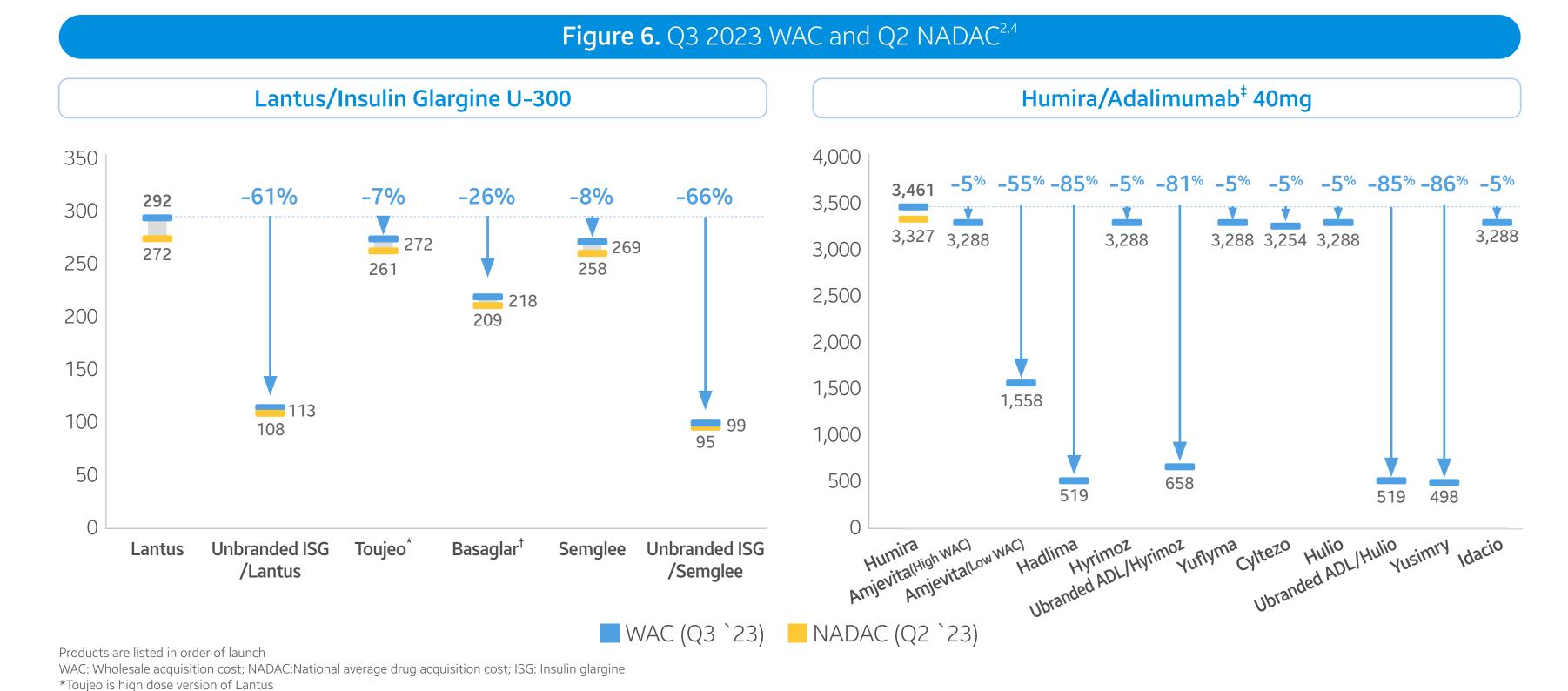
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Immunology & Endocrinology WAC and NADAC - Q2&3 2023

†Basaglar is not a biosimilar because it's approved under FDA, a new drug application pathway

‡Adalimumab biosimilars' NADAC price is not published yet

- * 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.



US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- · Immunology & Ophthalmology

Pharmacy Benefit

Immunology & Endocrinology

Biosimilar Market Dynamics

Correlation between biosimilar price & market adoption

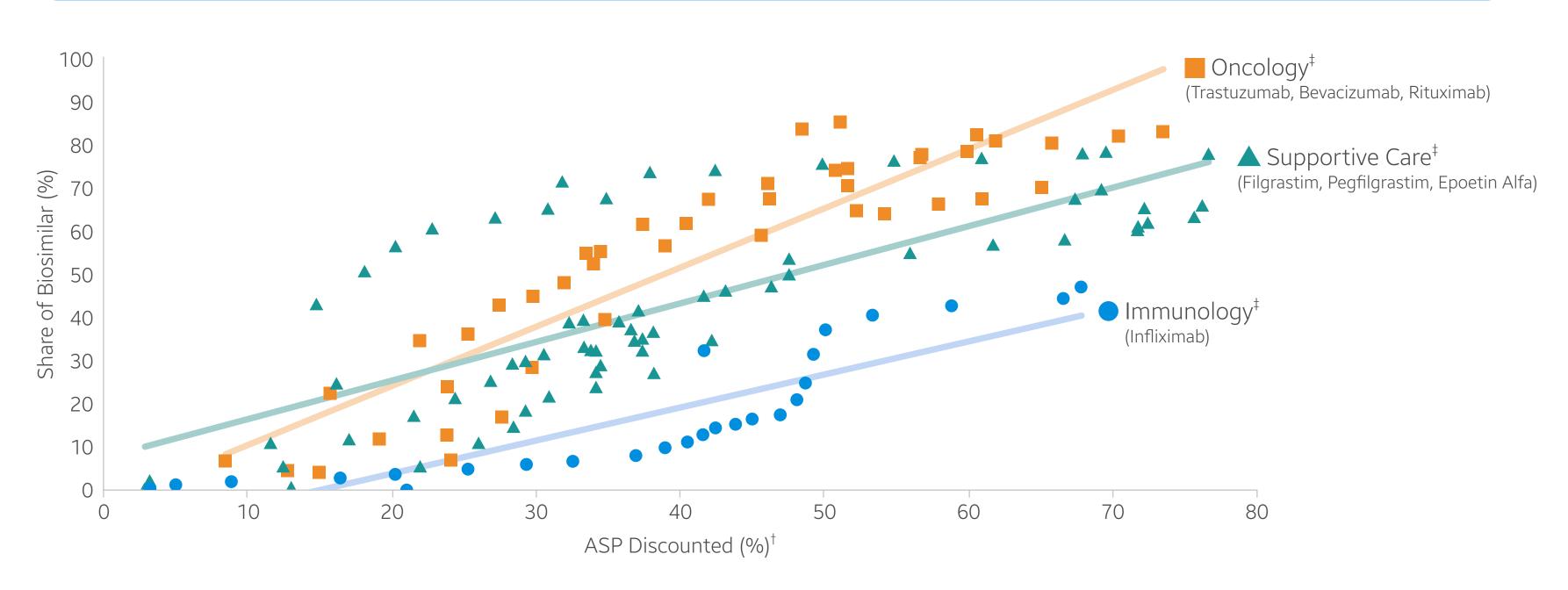
Market Share & Price Trends

- Oncology
- · Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

Increased Biosimilar Usage Shows Correlation to Lower Costs

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





^{*}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

US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Pharmacy Benefit

Immunology & Endocrinology

Biosimilar Market Dynamics

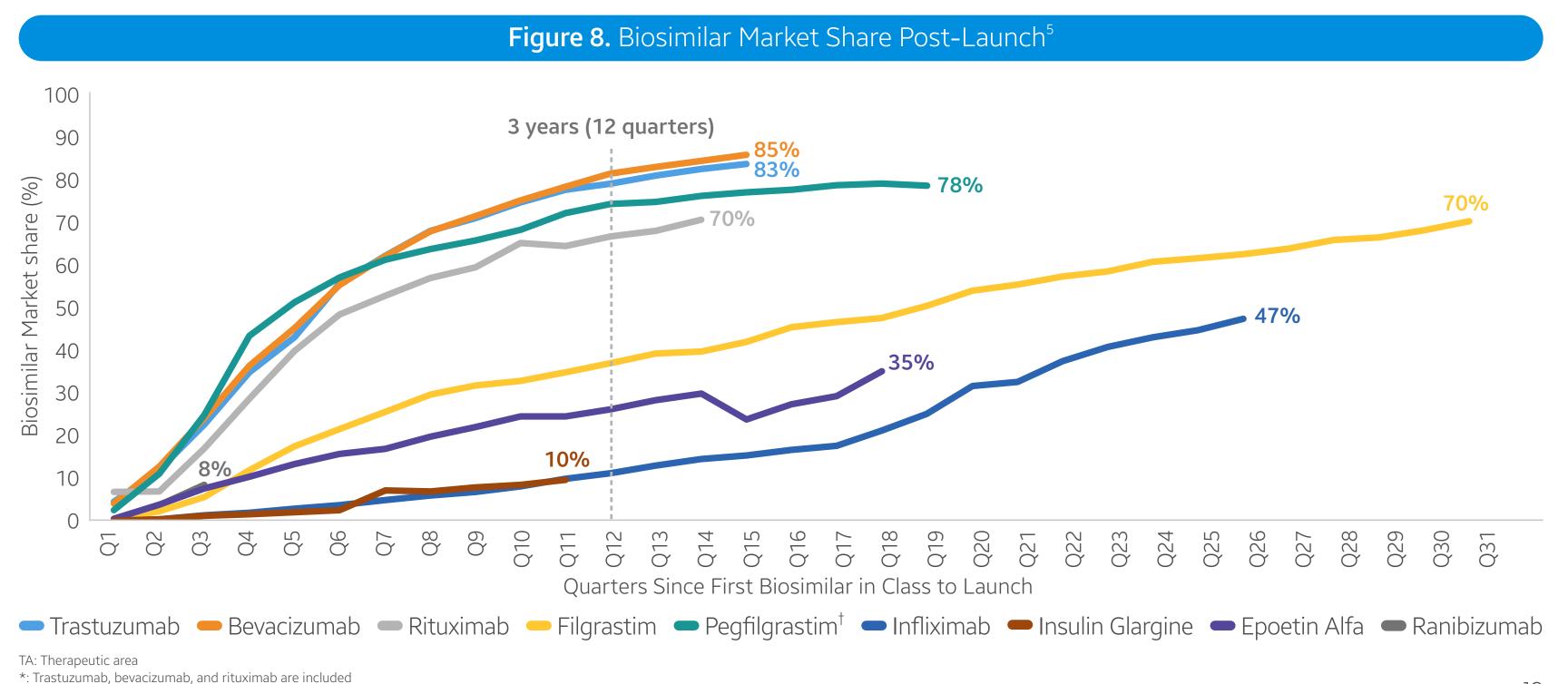
Correlation between biosimilar price & market adoption

Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

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

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



Reference

US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Pharmacy Benefit

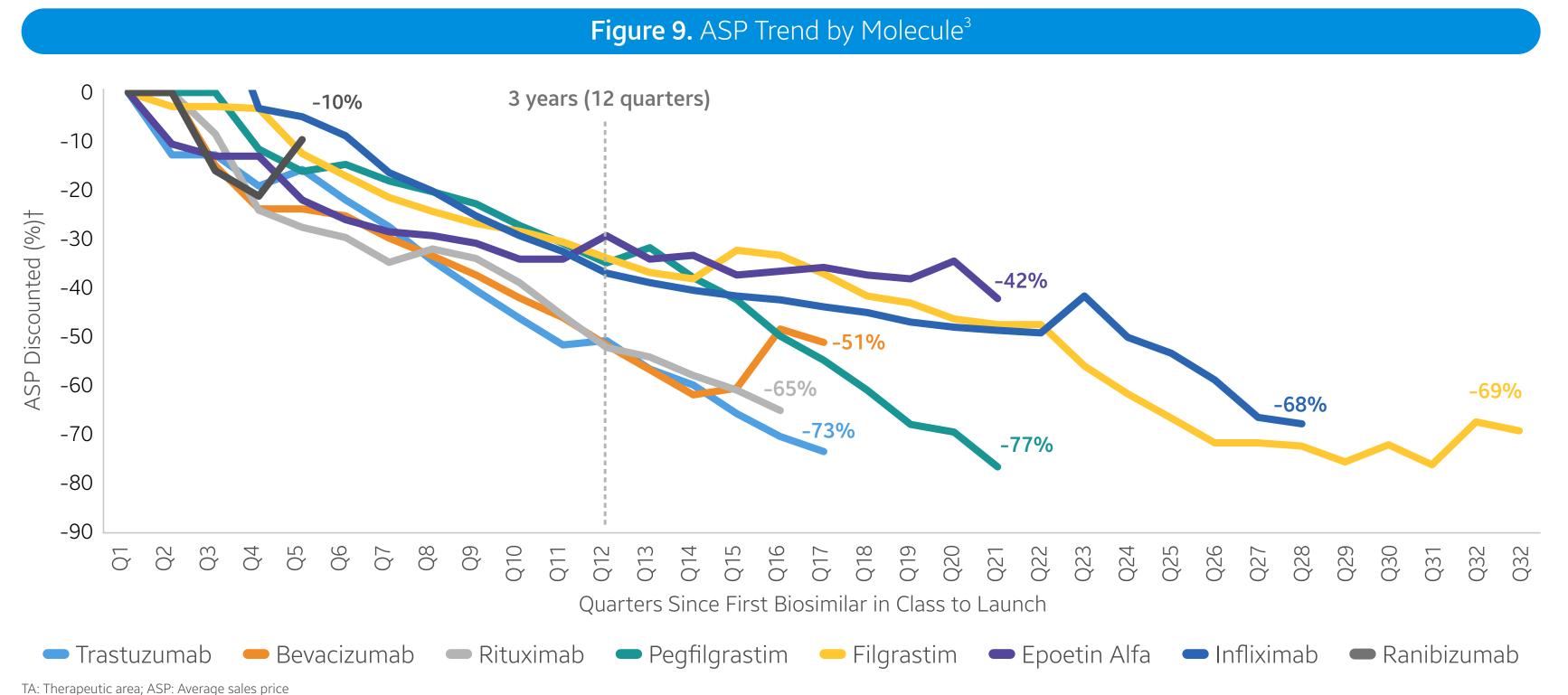
Immunology & Endocrinology

Biosimilar Market Dynamics

Correlation between biosimilar price & market adoption

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.



Reference

^{*:} Trastuzumab, bevacizumab, and rituximab are included

US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
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Pharmacy Benefit

Immunology & Endocrinology

Biosimilar Market Dynamics

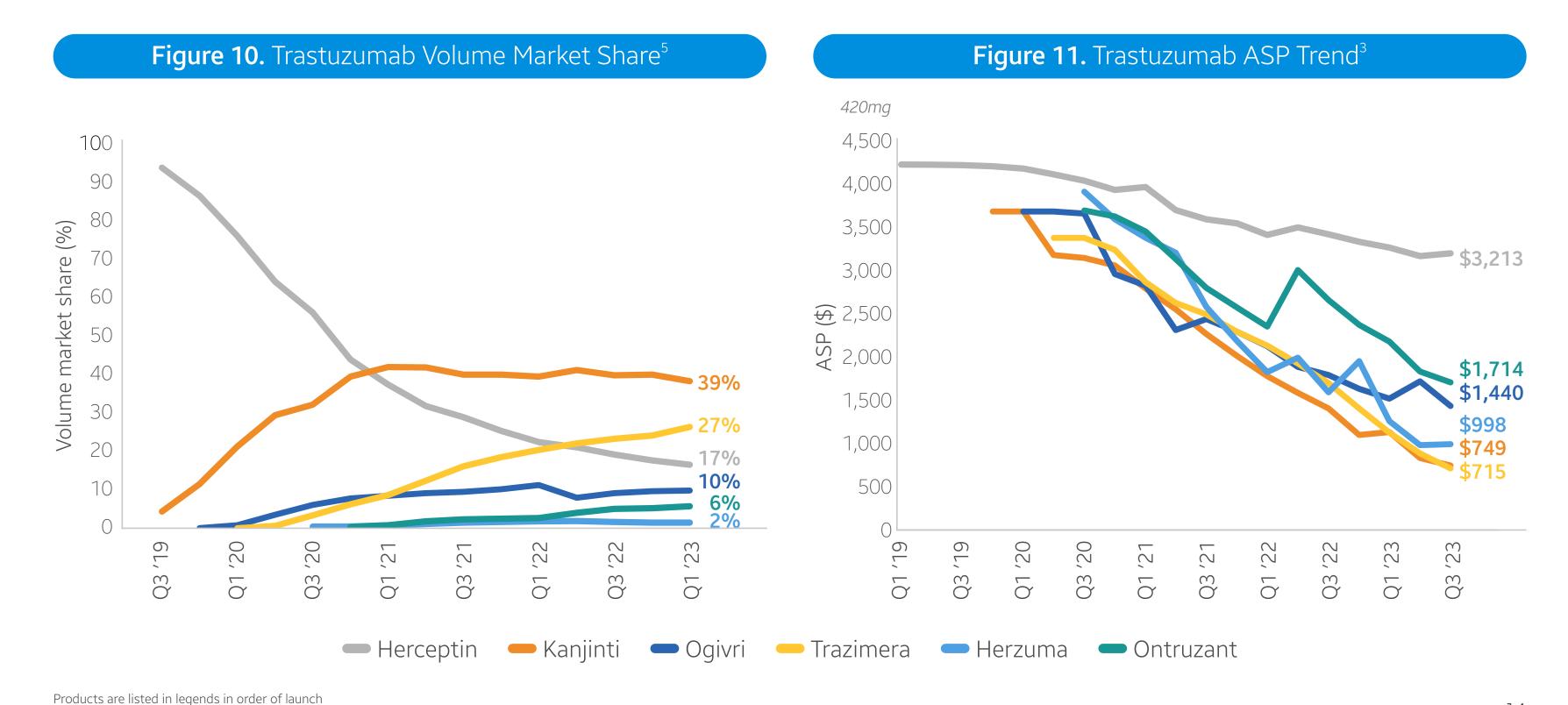
Correlation between biosimilar price & market adoption

Market Share & Price Trends

- Oncology
- · Supportive Care
- Immunology
- Endocrinolog
- Ophthalmology

Market Share and ASP Trends - Herceptin (Trastuzumab)

- *As of Q1 2023, the biosimilar share of the trastuzumab market has reached 83%.
 - The first biosimilar of trastuzumab has been the market leader since Q4 2020.
- *As of Q3 2023, the average ASP of all products is \$1,471 (-65%) and the average for biosimilars alone is \$1,123 (-73%) vs. the reference product's ASP at the time of the first biosimilar launch.



Reference

ASP: Average sales price

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US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- · Immunology & Ophthalmology

Pharmacy Benefit

· Immunology & Endocrinology

Biosimilar Market Dynamics

Correlation betweer biosimilar price & market adoption

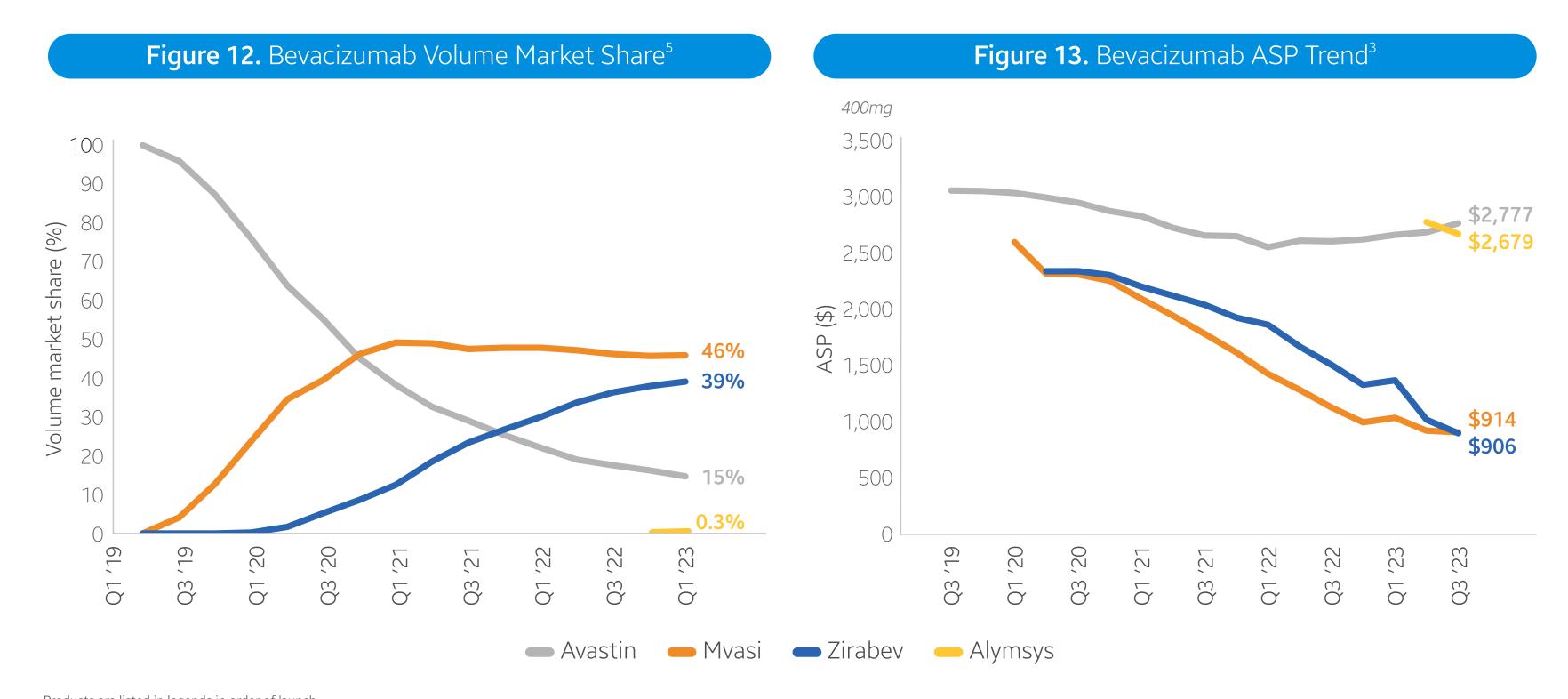
Market Share & Price Trends

- Oncology
- · Supportive Care
- Immunolog
- Endocrinology
- Ophthalmology

Market Share and ASP Trends

- Avastin (Bevacizumab)

- *As of Q1 2023, the biosimilar share of the bevacizumab market was 85%.
 - Both biosimilars have surpassed the bevacizumab reference product in market share.
- *As of Q3 2023, the average ASP of all products is \$1,819 (-41%) and the average for biosimilars alone is \$1,499 (-51%) vs the reference product's ASP at the time of the first biosimilar launch.



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



US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
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Pharmacy Benefit

· Immunology & Endocrinology

Biosimilar Market Dynamics

Correlation between biosimilar price & market adoption

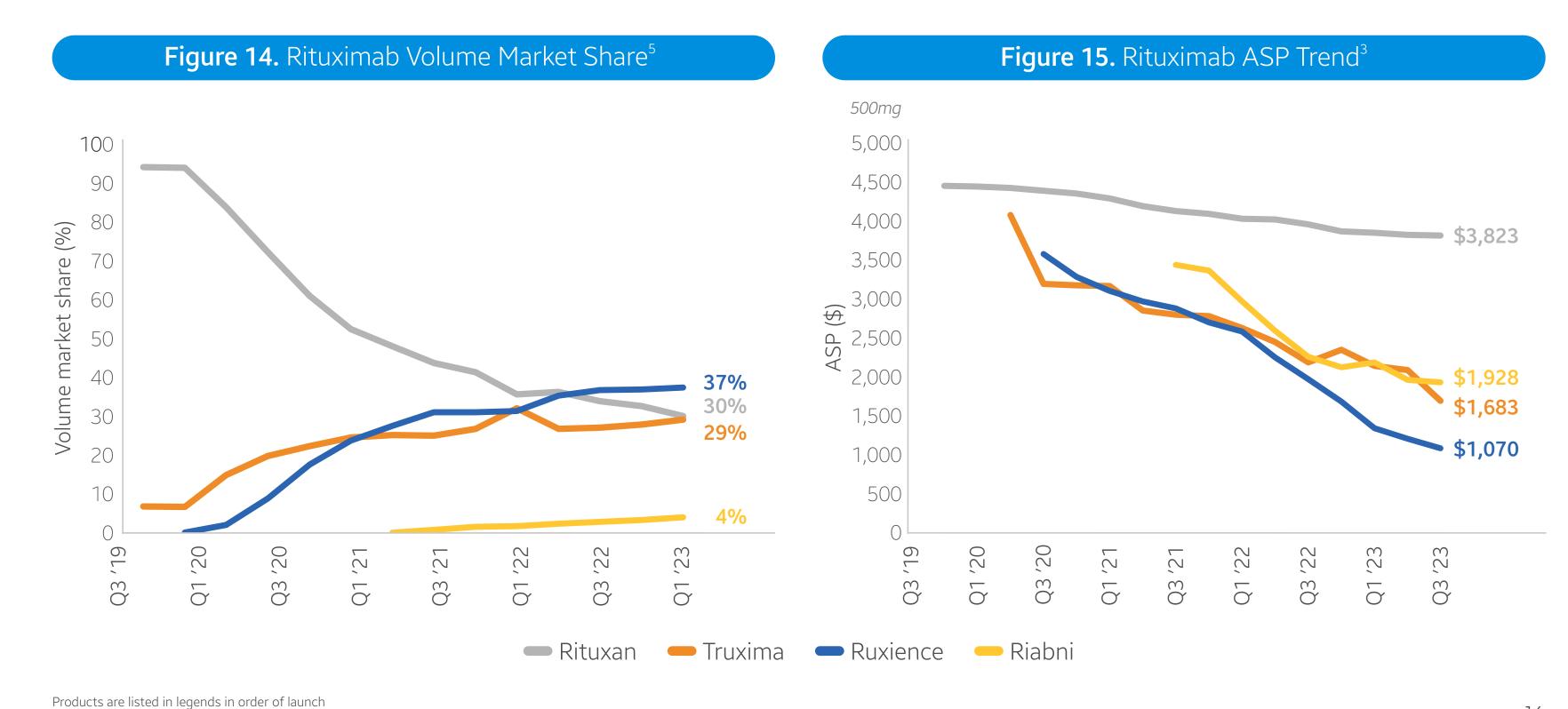
Market Share & Price Trends

- Oncology
- Supportive Care
- · Immunolog
- Endocrinolog
- Ophthalmology

Market Share and ASP Trends - Rituxan (Rituximab)

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- *As of Q1 2023, the biosimilar share of the rituximab market was 70%.
 - A rituximab biosimilar has been the market leader since Q3 of 2022.
- *As of Q3 2023, the average ASP of all products is \$2,125 (-52%) and the average for biosimilars alone is \$1,559 (-65%) vs. the reference product's ASP at the time of the first biosimilar launch.



Reference

ASP: Average sales price

US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Pharmacy Benefit

Immunology & Endocrinology

Biosimilar Market Dynamics

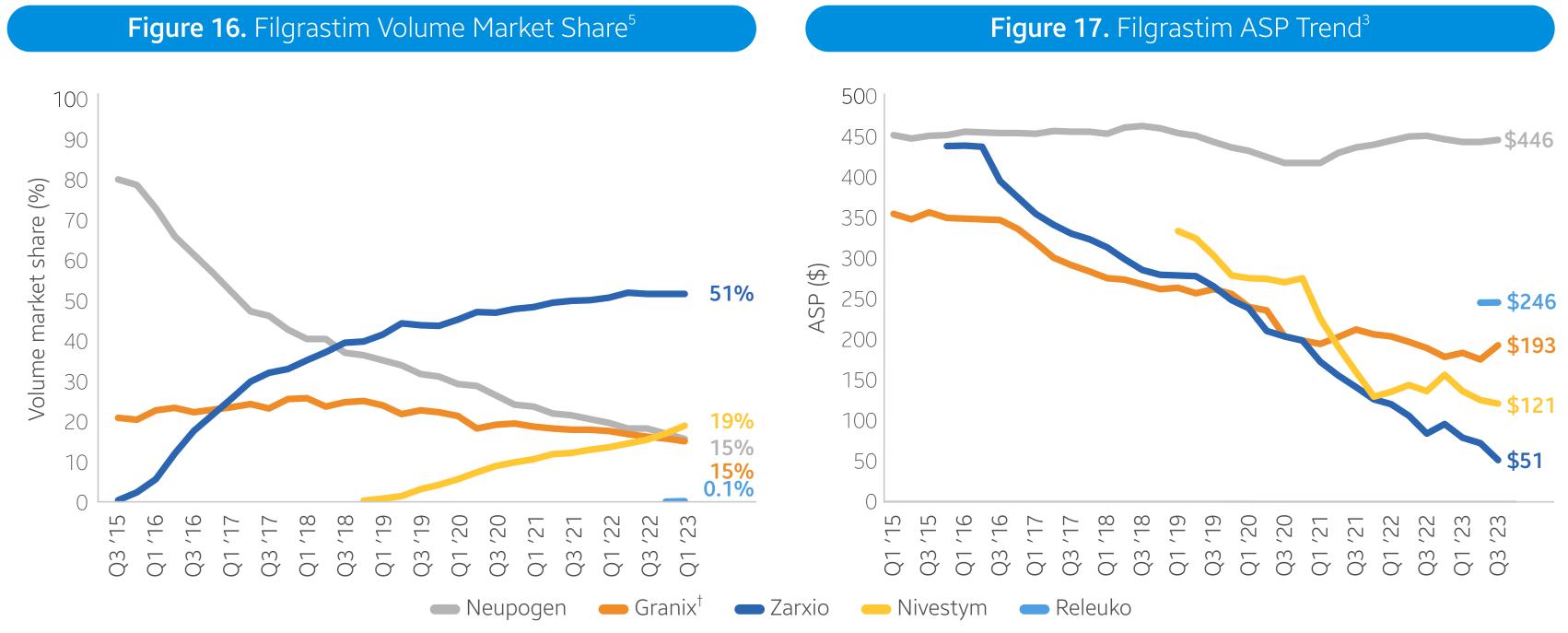
Correlation between biosimilar price & market adoption

Market Share & Price Trends

- Oncology
- Supportive Care
- Immunolog
- Endocrinology
- Ophthalmology

Market Share and ASP Trends - Neupogen (Filgrastim)

- *As of Q1 2023, the biosimilar share of the filgrastim market has reached 70%.
 - The first filgrastim biosimilar to launch has been the US market leader since Q3 2018.
- *As of Q3 2023, the average ASP of all products is \$211 (-53%) and the average for biosimilars alone is \$139 (-69%) vs the reference product's ASP at the time of the first biosimilar launch.



Products are listed in legends in order of launch

ASP: Average sales price

[†] Granix is not abiosimilar; It's approved under FDA, a new drug application pathway

US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Pharmacy Benefit

Immunology & Endocrinology

Biosimilar Market Dynamics

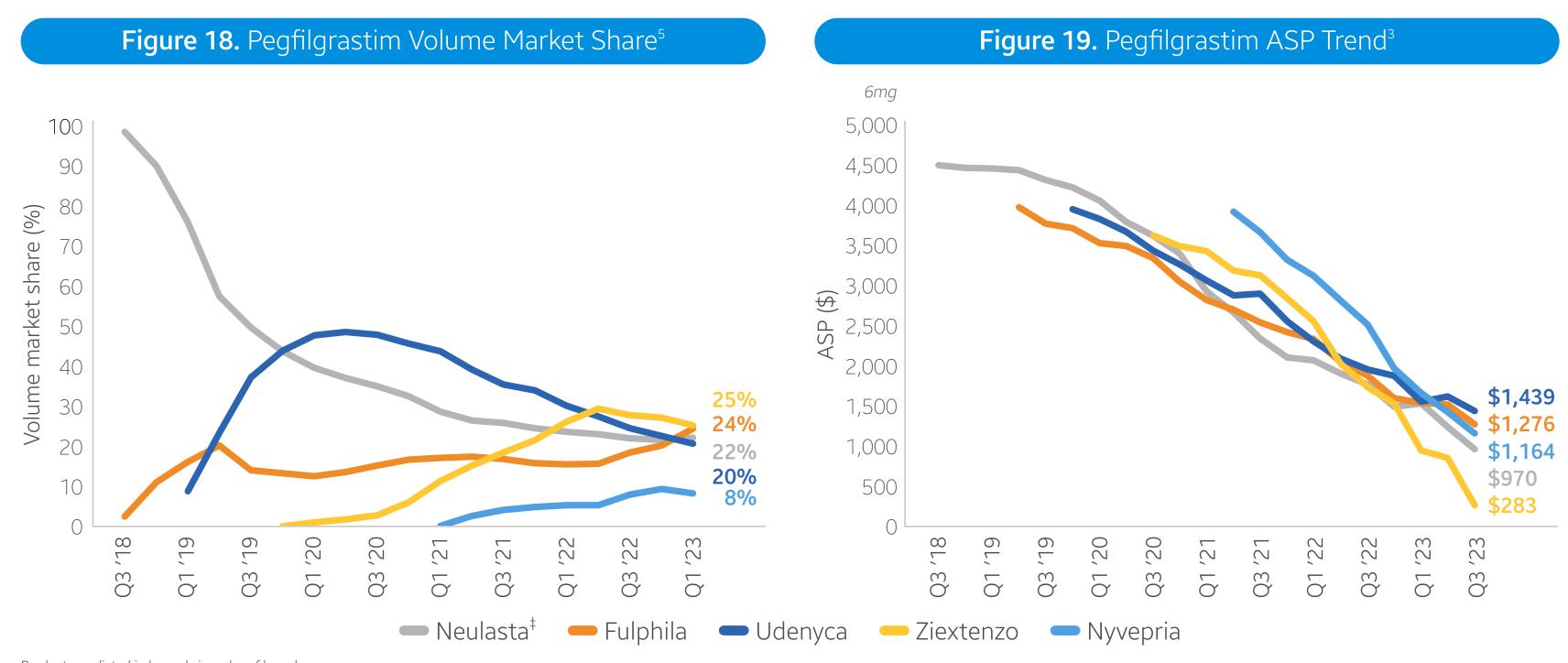
Correlation between biosimilar price & market adoption

Market Share & Price Trends

- Oncology
- Supportive Care
- Immunolog
- Endocrinolog
- Ophthalmology

Market Share and ASP Trends - Neulasta (Pegfilgrastim)

- *As of Q1 2023, the biosimilar share of the pegfilgrastim market was 78%.
 - Note that, Stimufend, the 5th Pegfilgrastim biosimilar has now launched, but is not yet captured in the market share or ASP data.
- *As of Q3 2023, the average ASP of all products is \$1,026 (-77%) and the average for biosimilars alone is \$1,041 (-77%) vs. the reference product's ASP at the time of the first biosimilar launch.



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

US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
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Pharmacy Benefit

Immunology & Endocrinology

Biosimilar Market Dynamics

Correlation between biosimilar price & market adoption

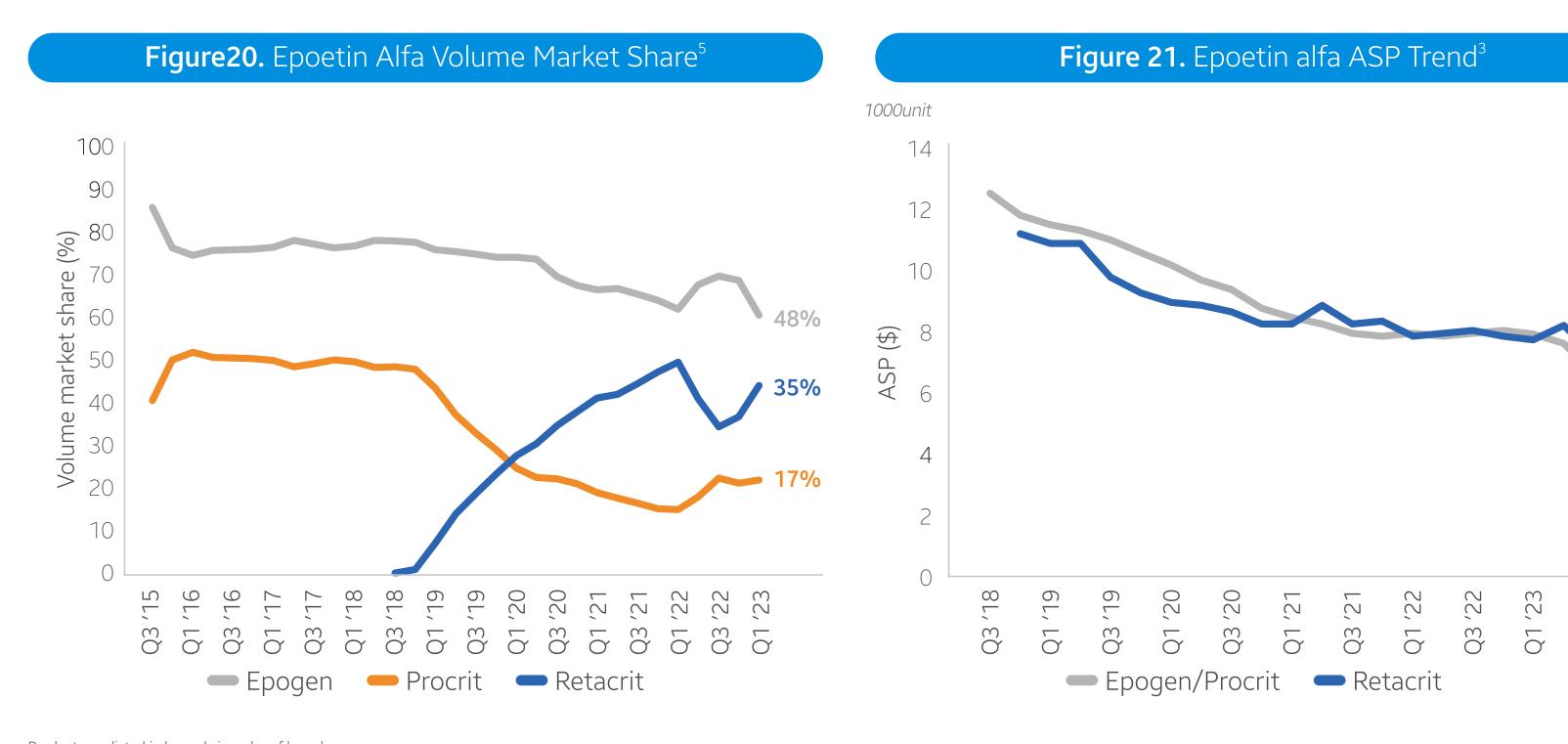
Market Share & Price Trends

- Oncology
- Supportive Care
- Immunolog
- Endocrinolog
- Ophthalmology

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



- * Retracrit is only biosimilar of Epoetin alfa, which has resulted in less of a decline in ASP compared to markets with multiple biosimilars, however the Epoetin alfa ASP fell about 13% in the latest quarter and is now about half of what it was prior to the Retracrit launch.
- * By matching ASP, the two reference products have maintained a combined 65% share, but that share fell by 7% in the latest quarter.



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

US Biosimilars Approval & Launch Status

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Biosimilar Market Dynamics

Correlation between biosimilar price & market adoption

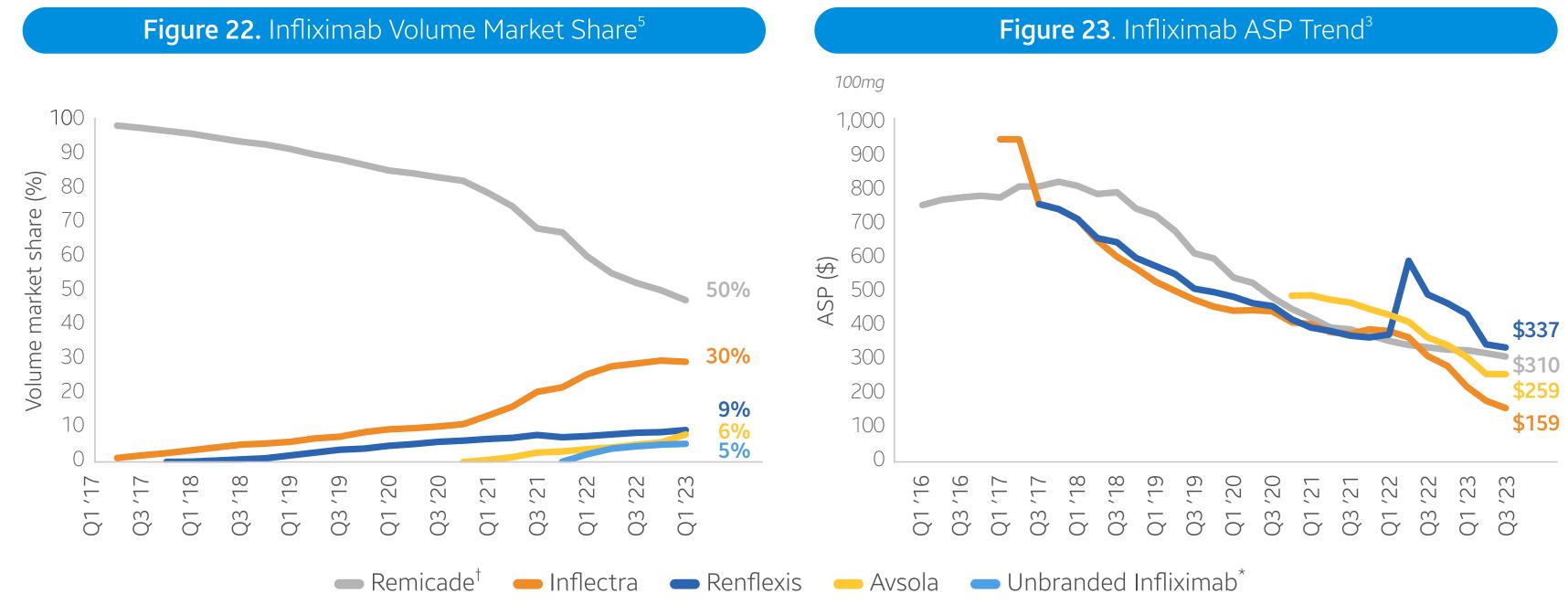
Market Share & Price Trends

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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 Q4 2022, Infliximab biosimilar market share has reached 50%.
- * Janssen launched an unbranded biosimilar of Remicade in Q4 2022, re-accelerating the price erosion that had slowed in 2020/21.
- *As of Q3 2023, the average ASP of all products products is \$266 (-66%) and the average for biosimilars alone is \$252 (-68%) vs. the reference product's ASP at the time of the first biosimilar launch.



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

Reference

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^{*}Unbranded Infliximab is Remicade without the brand name †Remicade and Unbranded Infliximab share their J code

US Biosimilars Approval & Launch Status

Biosimilar Price

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Pharmacy Benefit

Immunology & Endocrinology

Biosimilar Market Dynamics

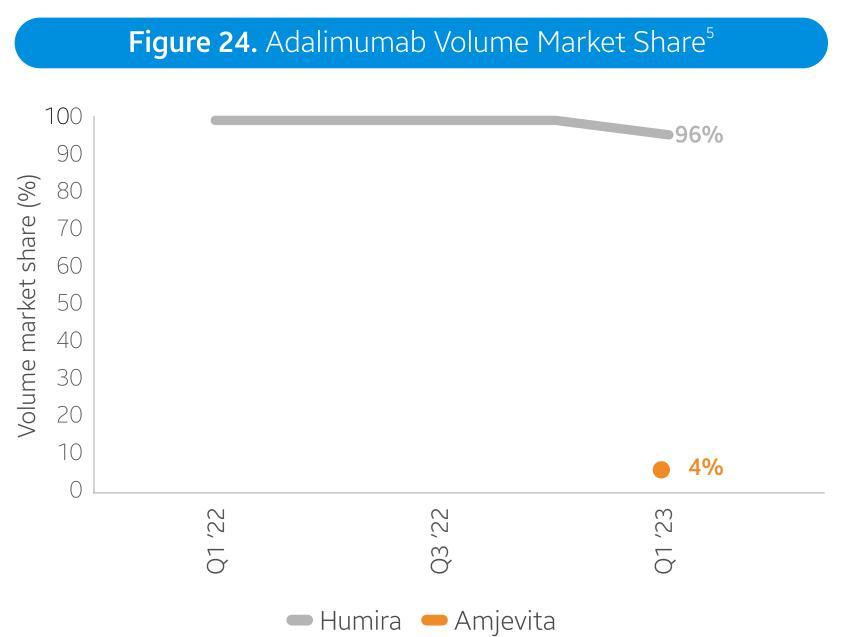
Correlation between biosimilar price & market adoption

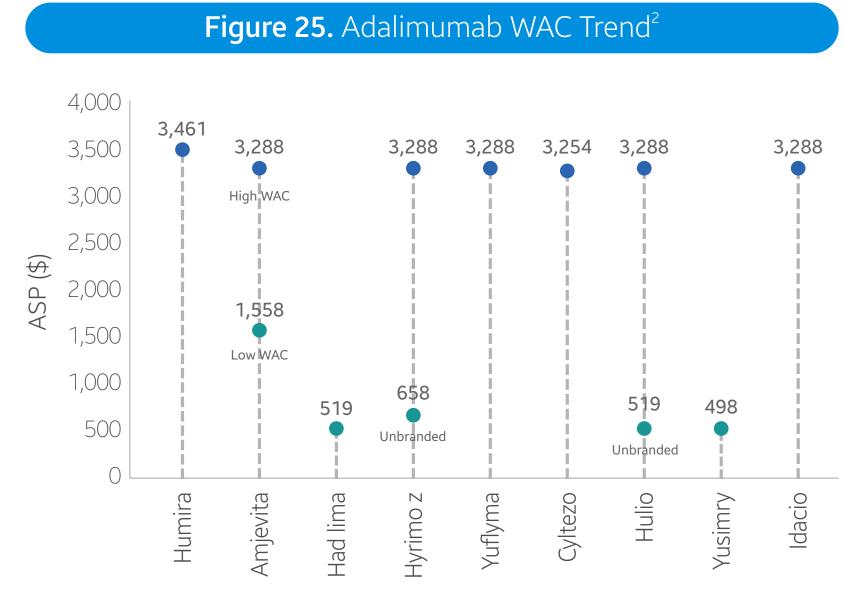
Market Share & Price Trends

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- 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, Cyltezo, and Idacio are o ffering a high WAC just -5~7% below Humira
 - 3. Amjevita, Hyrimoz, and Hulio are offering two pricing options including both a low and a high WAC





Reference

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Pharmacy Benefit

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Biosimilar Market Dynamics

Correlation between biosimilar price & market adoption

Market Share & Price Trends

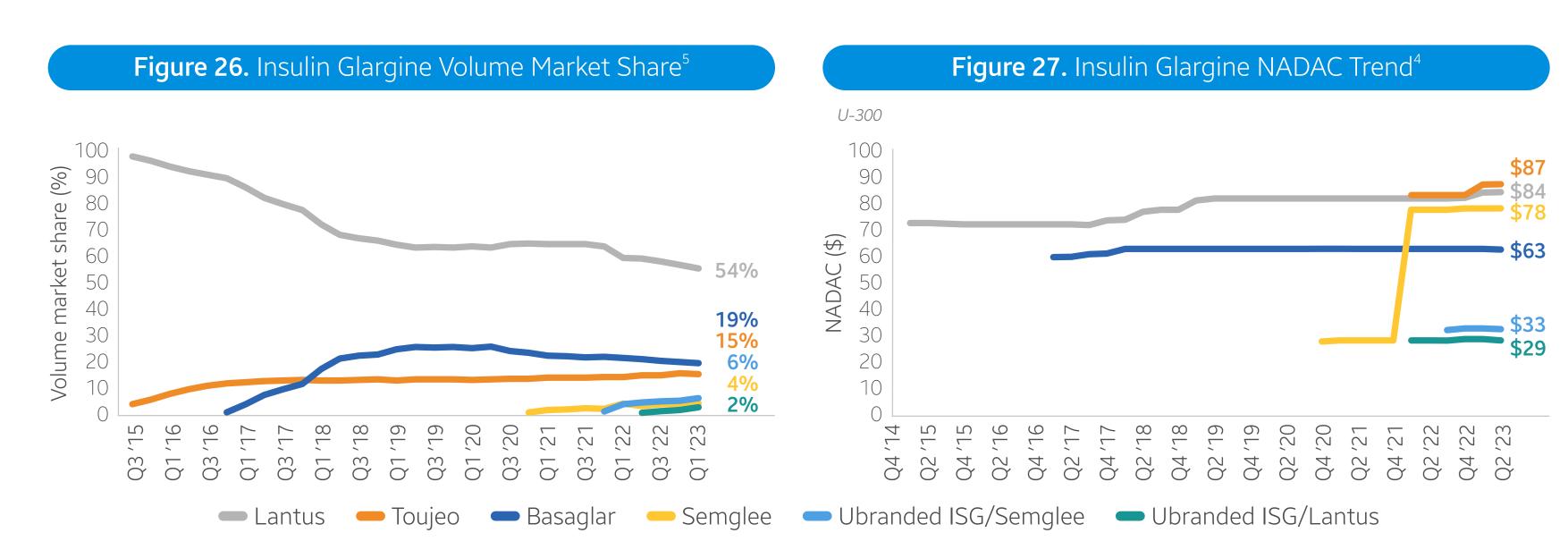
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Reference

- Endocrinology
- Ophthalmology

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.



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

US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- Immunology & Ophthalmology

Pharmacy Benefit

· Immunology & Endocrinology

Biosimilar Market Dynamics

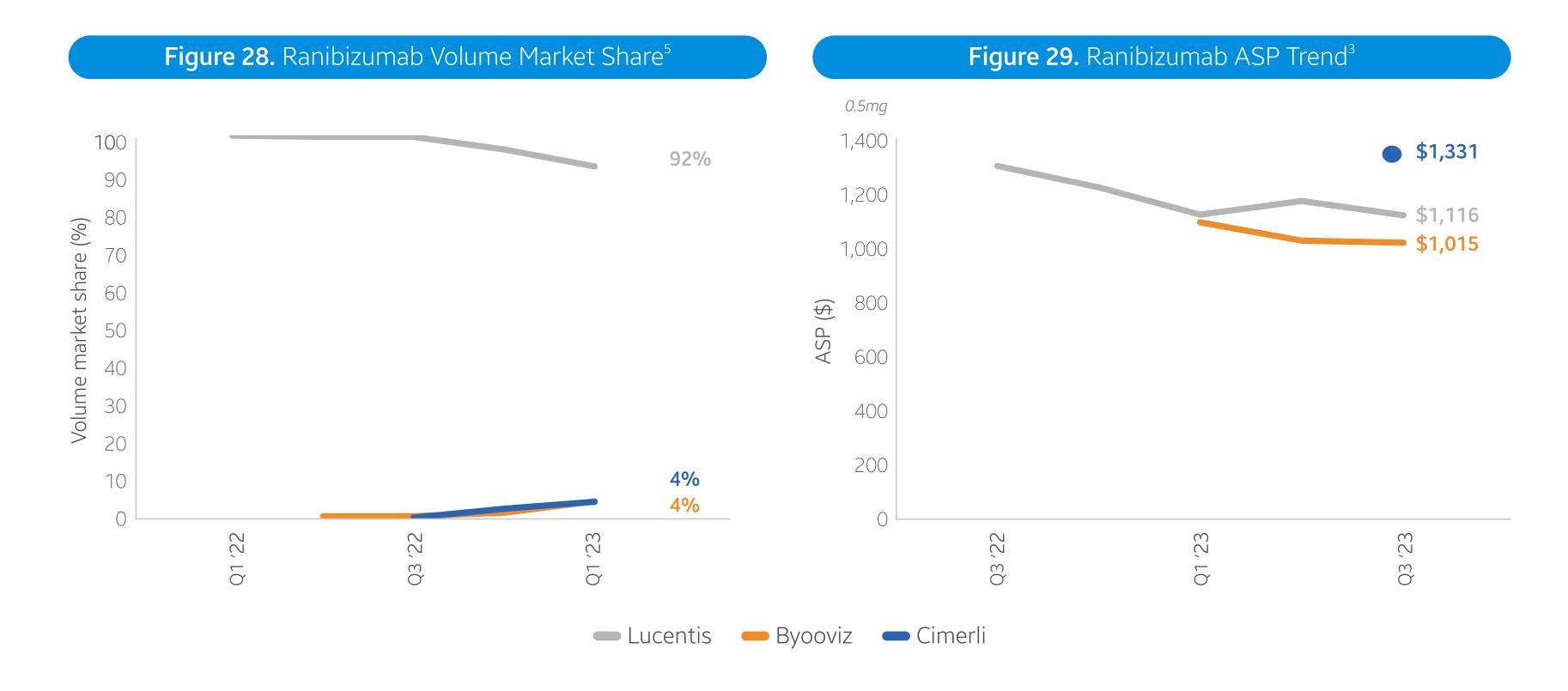
Market Share & Price Trends

- Ophthalmology

Market Share and ASP Trends

- Lucentis (Ranibizumab)

- * As of Q1 2023, two biosimilars have launched and their market share is 8%.
- * As of Q3 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.



Products are listed in legends in order of launch Reference 23 ASP: Average sales price



US Biosimilars Approval & Launch Status

Biosimilar Price

Medical Benefit

- Oncology
- Supportive Care
- · Immunology & Ophthalmology

Pharmacy Benefit

Immunology & Endocrinology

Biosimilar Market Dynamics

Correlation between biosimilar price & market adoption

Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology

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Based on internal analysis by SAMSUNG BIOEPIS CO., LTD. using data from the following source: IQVIA MIDAS® in Standard Units for the period Jan 2017 – Mar 2023 reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved.

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