

Launch Landscape Monthly Launch Tracker

April 2024 Edition

Launches through April 2024

Weekly NBRx data through week ending May 3rd, 2024

Monthly Sales data through April 2024

Issued by Launch COE on June 10th, 2024

The IQVIA Launch Center of Excellence (LCoE)



Our mission:

The U.S. Launch Center of Excellence at IQVIA aims to partner with our clients through the entire launch process to achieve sustainable commercial success. Through in-depth research in all facets of Launch, the LCoE provides a best-in-industry perspective on the evolving launch environment.



Brian Lasky
U.S. Lead, LCoE

Brian's career spans 25+ years in pharmaceutical sales, consulting and analytics. He has expertise in commercialization, launch dynamics, and deep therapy area expertise in markets like HIV, diabetes/obesity and MASH



Ester Oben Etah, PhD
Senior Principal, LCoE

Dr. Oben Etah has extensive experience in quantitative market analytics, forecasting, patient-level data, and industry analysis in Europe and the U.S.



Nadine Vangelov
Senior Principal, LCoE

With over 22 years of industry experience in the U.S. and Canada, Nadine specializes in advising companies on launch strategies and tactics based on market archetypes



Nora Hannigan
Associate Director, Brand Performance & Launch Solutions

With over 20 years at IQVIA, Nora has a deep knowledge of the IQVIA data assets, offering development, and thought leadership. She is an expert in launch performance assessment framework



Michael MacArthur
Engagement Manager, LCoE

With over 18 years of experience in pharmaceutical finance and human data science, Michael specializes in competitive analysis, forecasting, and leveraging big data to inform strategic decision-making



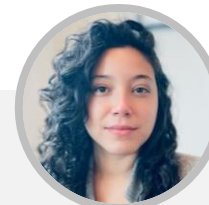
Robert Unger
Engagement Manager, LCoE

Rob has a background in mechanical engineering, and over 20 years of experience in the pharmaceutical industry. He specializes in custom APLD and forecasting studies



Peter Zavitsanos
Senior Consultant, LCoE

Peter has over a decade of experience working in public health and healthcare data, and is responsible for publishing the Launch Landscape report each month



Elyse Muñoz, PhD
Director, U.S. Research & Insights

Elyse leads a team of researchers focused on developing evidence-based perspectives on emerging healthcare trends and the strategies needed to improve outcomes for stakeholders across the system

Launch Landscape as of April 2024

There have been 14 new launches through April 2024;
Infectious disease is the top therapy area in 2024, accounting for 21% of new product launches

14 new launches through April 2024

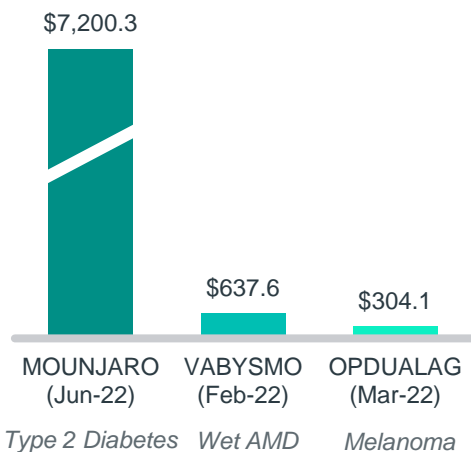


16 FDA Approved New Molecular Entities (NMEs) in 2024
*There were **54** NMEs in 2023 and **36** NMEs in 2022*

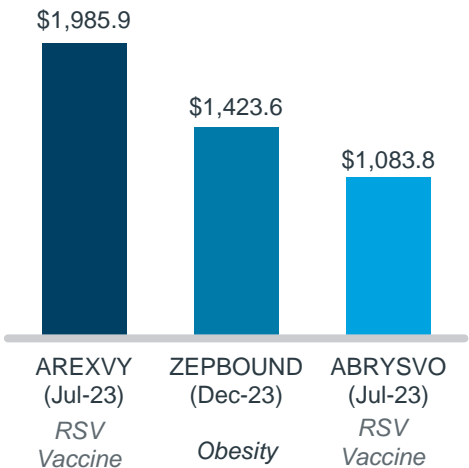
Top therapy areas (share of launches)

2024 n=14	Anti-Infectives 21%	Digestive 21%	CNS 14%
2023 n=85	Immunology 28%	Oncology 13%	Anti-Infectives 9%
2022 n=57	Oncology 19%	CNS 17%	Anti-Infectives 15%

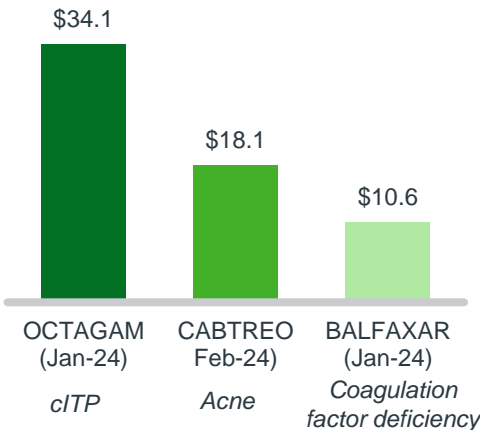
Top 2022 launches by sales (USD millions)



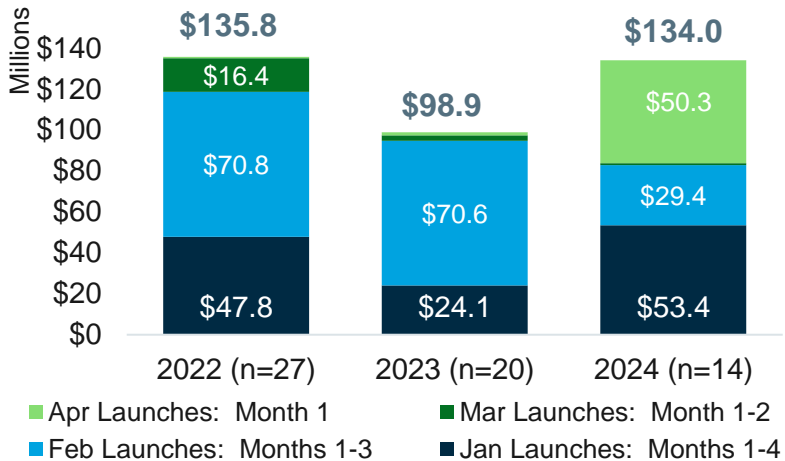
Top 2023* launches by sales (USD millions)



Top 2024* launches by sales (USD millions)



Monthly Sales (through April)

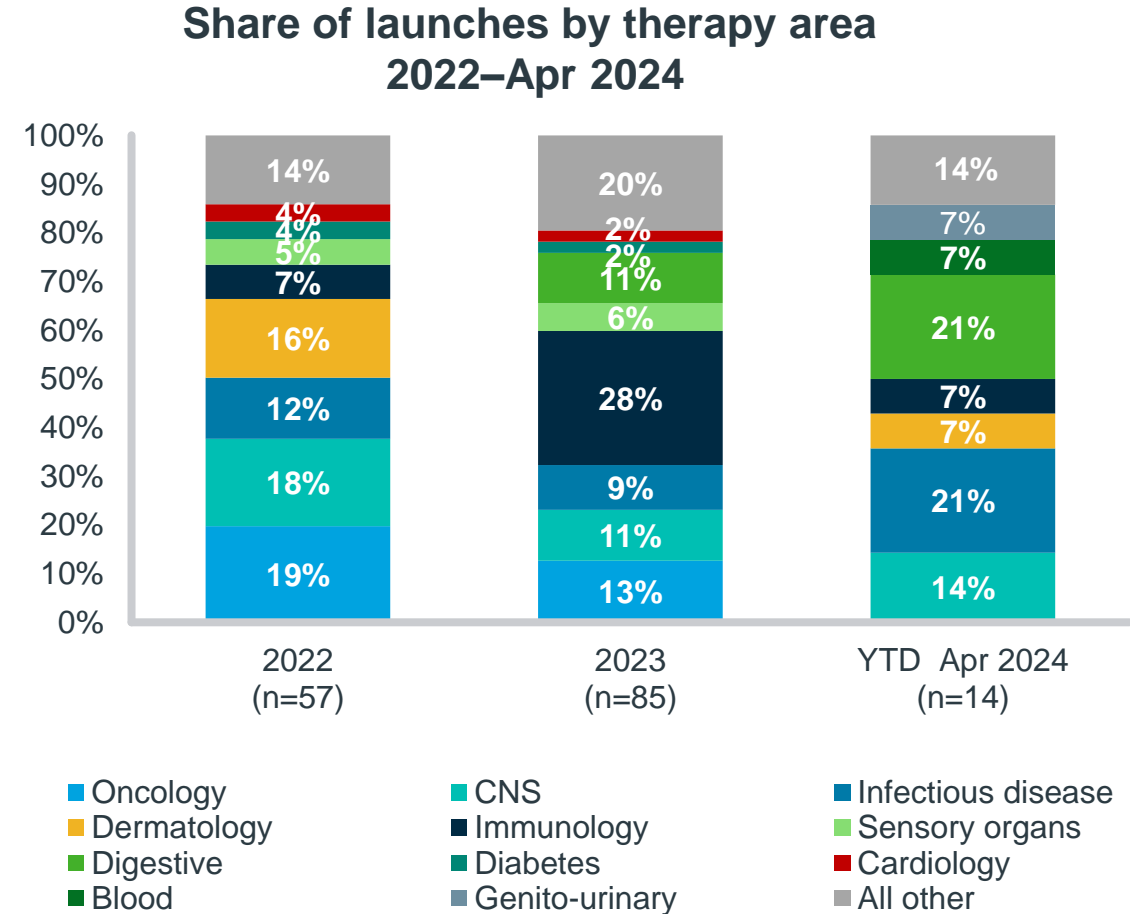
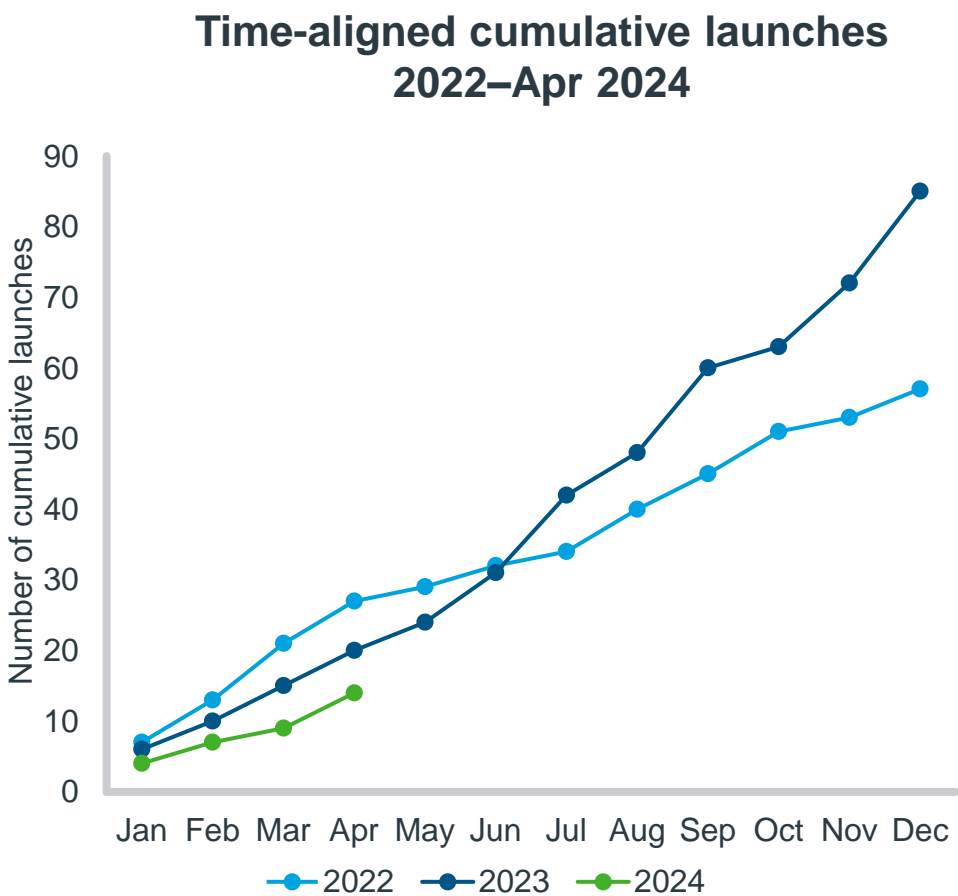


*First year sales from launch month through April 2024

Notes: All sales values are USD. AMD = age-related macular degeneration; cITP = Chronic immune thrombocytopenic purpura; CNS = Central nervous system; NME = new molecular entity
IQVIA U.S. Launch Landscape Tracker, April 2024

There have been 14 new launches through April 2024, which is down from prior years

2023 closed with 85 total launches, surpassing the 57 launches in 2022

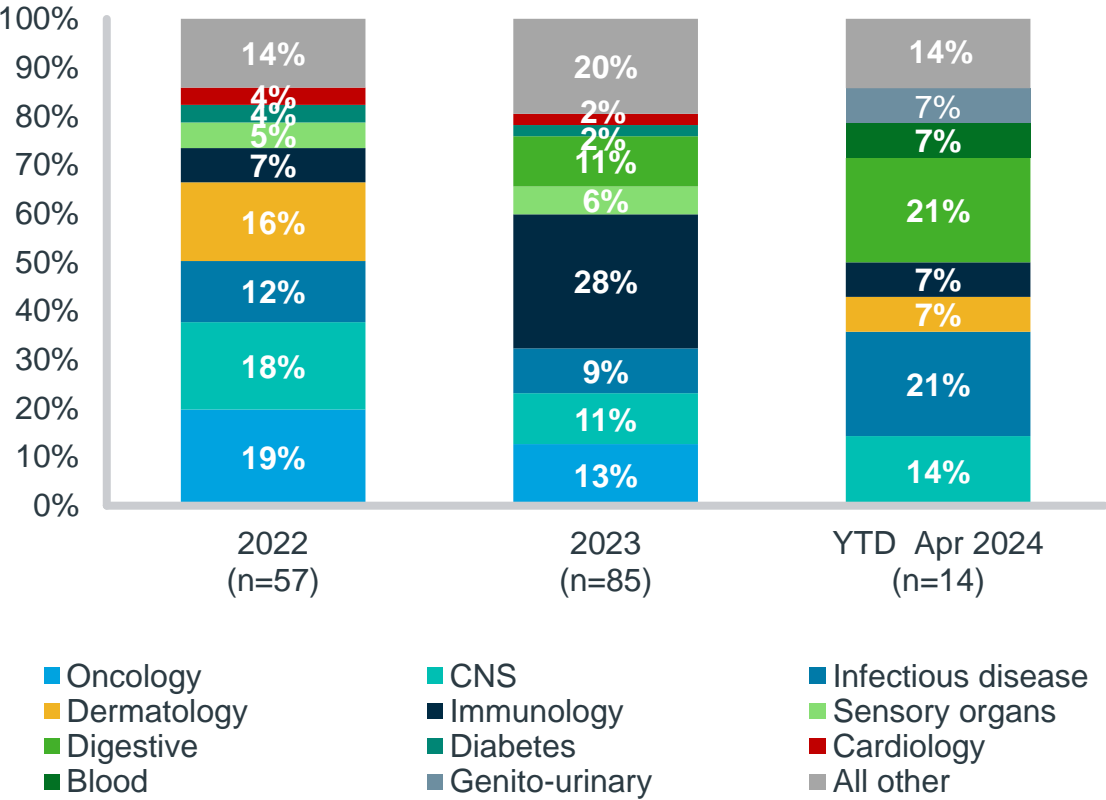


Source: National Sales Perspective; Launch Center of Excellence, IQVIA; publicly available information from the FDA
Notes: CNS = Central nervous system

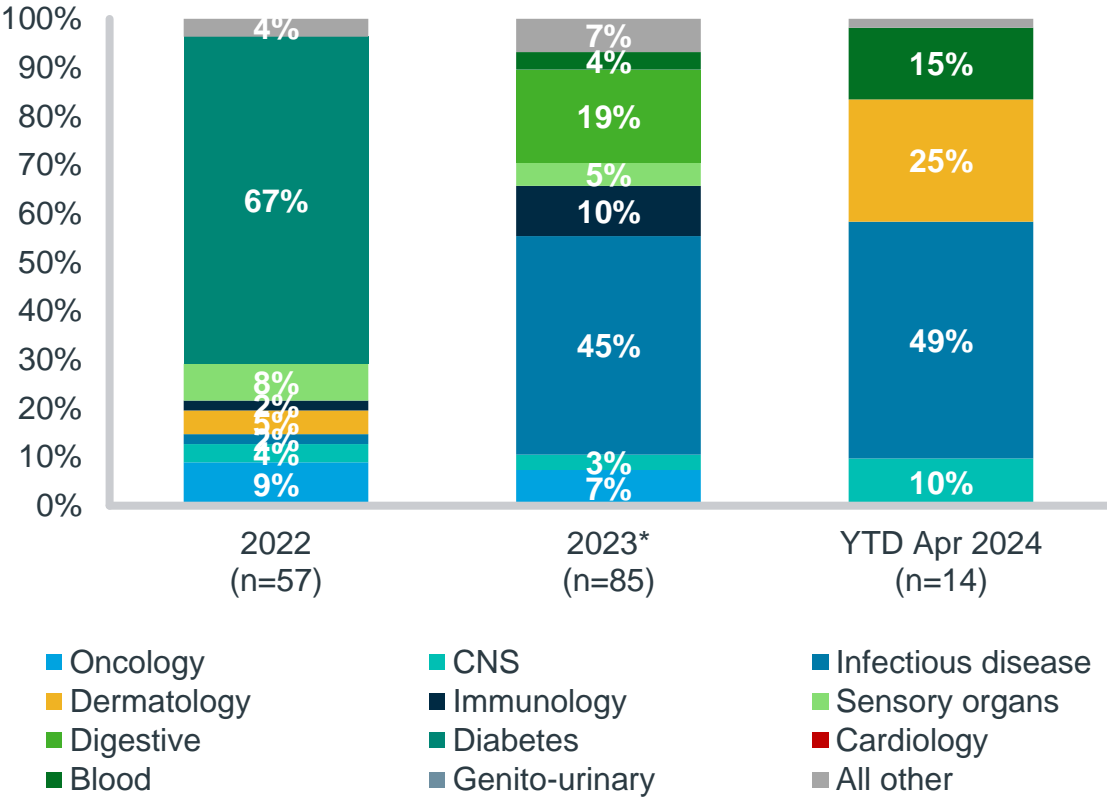
Therapy area mix remains similar, but sales shares are driven by transformative therapies like Mounjaro in 2022 and Arexvy in 2023

Thus far, nearly half of 2024 sales are attributed to infectious disease launches

Share of launches by therapy area
2022–Apr 2024



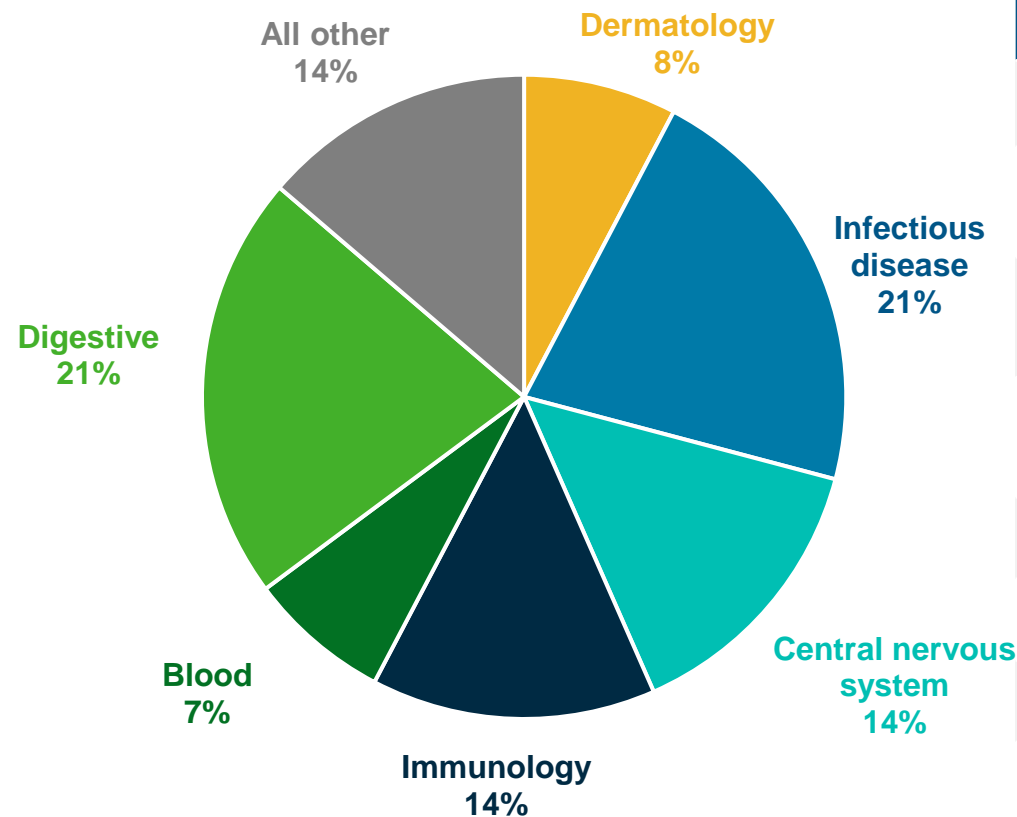
Share of sales by therapy area
2022–Apr 2024



Source: National Sales Perspective; Launch Center of Excellence, IQVIA; publicly available information from the FDA
Notes: CNS = Central nervous system; RSV = Respiratory Syncytial Virus
IQVIA U.S. Launch Landscape Tracker, April 2024

2024 launches are led by Pfizer’s Octagam, for chronic immune thrombocytopenic purpura (cITP)

2024 – 14 Launches



Source: National Sales Perspective; Launch Center of Excellence, IQVIA
Notes: All sales values are USD.
cITP = chronic immune thrombocytopenic purpura;
hATTR-PN = hereditary transthyretin amyloidosis

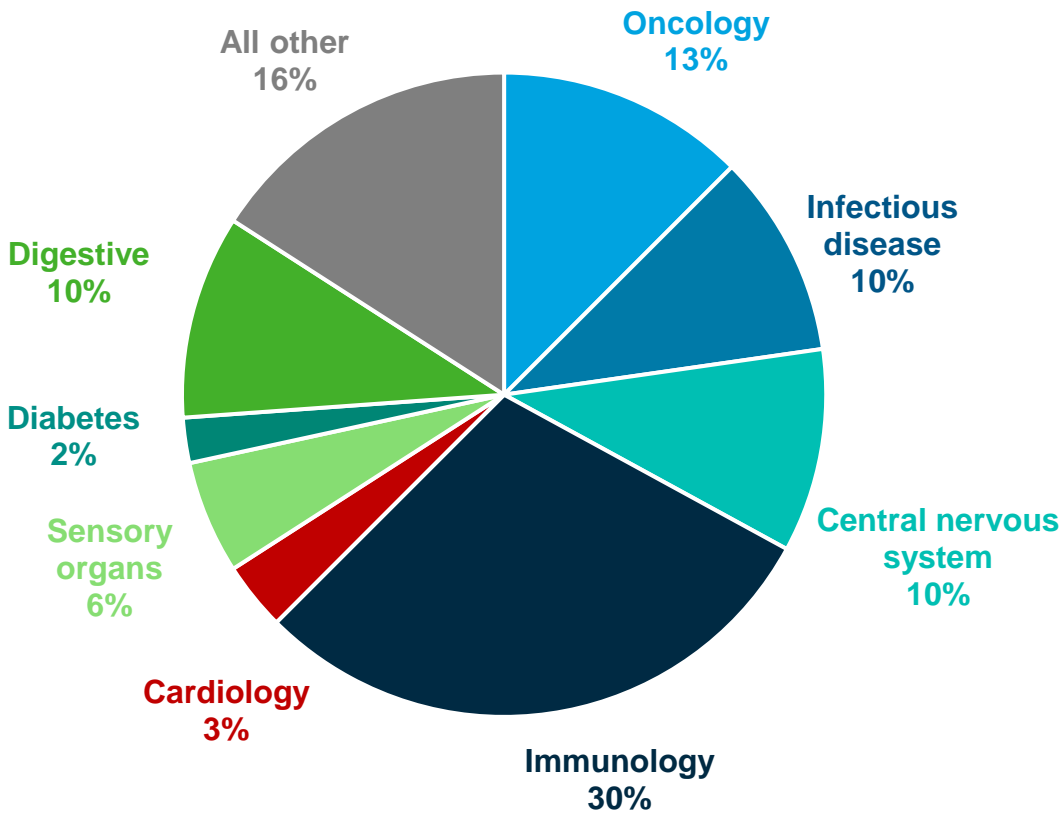
2024 – Top 10 Performers

Product	Company	Indication	Launch date	First year gross sales (as of Apr-24)
Octagam <i>Immune globulin intravenous (human)</i>	Pfizer	Chronic immune thrombocytopenic purpura (cITP)	Jan-24	\$34.1M
Cabtreo <i>clindamycin phosphate, adapalene & benzoyl peroxide</i>	Bausch Health	Acne	Feb-24	\$18.1M
Balfaxar <i>prothrombin complex concentrate, human-lans</i>	Octapharma	Urgent reversal of warfarin-induced acquired blood coagulation factor deficiency	Jan-24	\$10.6M
Wainua <i>eplontersen</i>	AstraZeneca	Polyneuropathy caused by hereditary transthyretin amyloidosis (hATTR-PN)	Jan-24	\$6.9M
Ixchiq <i>Chikungunya disease vaccine</i>	Valneva	Chikungunya disease	Feb-24	\$915K
Elfabrio <i>pegunigalsidase alfa-iwxj</i>	Chiesi	Fabry disease	Mar-24	\$629K
Rezdiffra <i>resmetirom tablets</i>	Madrigal	Nonalcoholic steatohepatitis (NASH)	Apr-24	\$326K
Zymfentra <i>antihemophilic factor recombinant</i>	Celltrion	Maintenance treatment of UC following IV infliximab	Mar-24	\$296K
Penbraya <i>meningococcal meningitis vaccine</i>	Sanofi	Meningococcal meningitis	Jan-24	\$121K
Rivfloza <i>nedosiran injection</i>	Novo Nordisk	Primary hyperoxaluria type 1 (PH1)	Apr-24	\$81K

2023 sales have been led by GSK's RSV vaccine, Arexvy

Lilly's Zepbound for obesity is on its way to surpass \$2B in sales

2023 – 84 Launches



2023 – Top 10 Performers

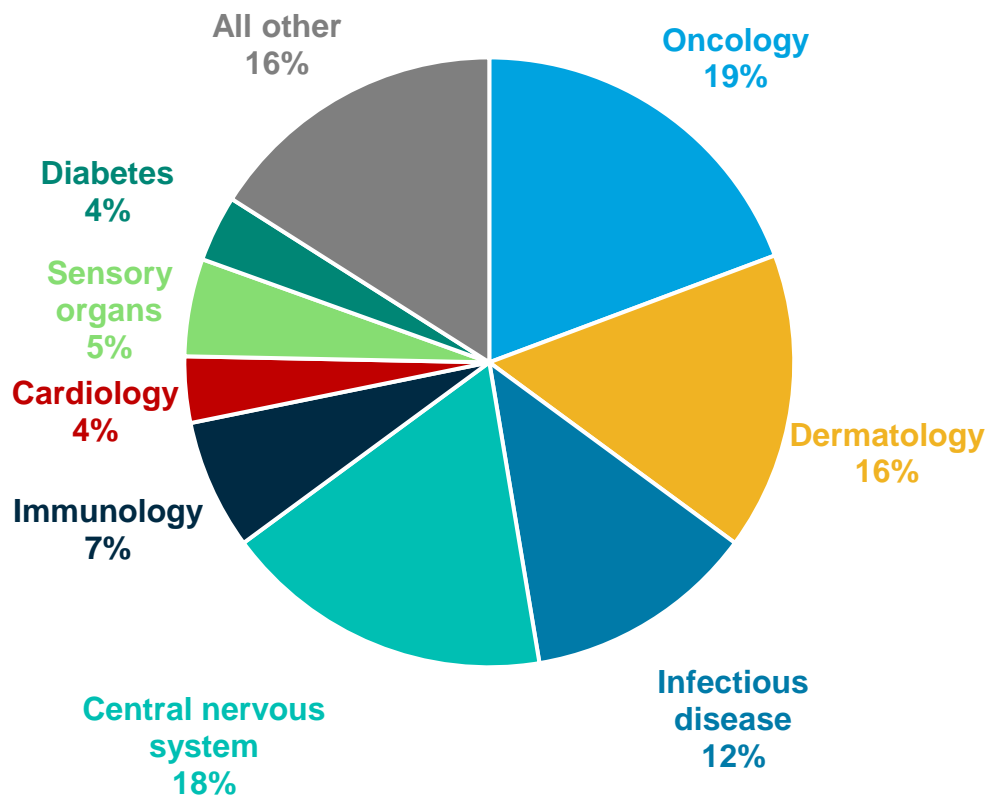
Product	Company	Indication	Launch date	First year gross sales (as of Apr-24)
Arexvy <i>RSV vaccine</i>	GSK	Prevention of LRTD caused by RSV (60+ y/o)	Jul-23	\$1.99B
Zepbound <i>tirzepatide</i>	Lilly	Obesity	Dec-23	\$1.42B
Abrysvo <i>RSV vaccine</i>	Pfizer	RSV vaccine (gest. age 32-36wks, 60+ y/o)	Jul-23	\$1.08B
Altuviiio <i>Antihemophilic factor recombinant</i>	Sanofi	Hemophilia A	Apr-23	\$264.5M
Beyfortus <i>nirsevimab</i>	Sanofi	RSV vaccine Pediatrics 0-24m	Sep-23	\$248.0M
Miebo <i>perfluorohexyloctane ophthalmic solution</i>	Bausch + Lomb	Dry eye disease	Sep-23	\$162.6M
Elahere <i>mirvetuximab soravtansine</i>	Immunogen	Ovarian, fallopian tube and peritoneal cancer	Mar-23	\$160.9M
Orserdu <i>elacestrant</i>	Stemline	ER+ / HER2- breast cancer	Feb-23	\$158.4M
Amjevita <i>adalimumab</i>	Amgen	CD, PsA, PsO, RA, UC	Feb-23	\$118.4M
Jaypirca <i>pirtobrutinib</i>	Eli Lilly	Mantle cell lymphoma	Feb-23	\$82.5M

Source: National Sales Perspective; Launch Center of Excellence, IQVIA

Notes: All sales values are USD. CD = Crohn's disease; LRTD = lower respiratory tract disease; PsA = psoriatic arthritis; PsO = plaque psoriasis; RA = rheumatoid arthritis; UC = ulcerative colitis; y/o = years old

Lilly's Mounjaro is the best-selling launch product of 2022, followed by Genentech's Vabysmo for wet macular degeneration

2022 – 57 Launches



Source: National Sales Perspective; Launch Center of Excellence, IQVIA
Notes: All sales values are USD.

2022 – Top 10 Performers

Product	Company	Indication	Launch date	First year gross sales
Mounjaro <i>tirzepatide</i>	Eli Lilly	Type 2 diabetes	Jun-22	\$7.2B
Vabysmo <i>faricimab</i>	Genentech	Wet macular degeneration	Feb-22	\$632.4M
Opdualag <i>nivolumab/relatlimab</i>	BMS	Metastatic melanoma	Mar-22	\$304.1M
Radicava <i>edaravone</i>	Mitsubishi Tanabe	Amyotrophic lateral sclerosis	Jun-22	\$165.9M
Bebtelovimab <i>monoclonal antibody</i>	Eli Lilly	COVID-19	Aug-22	\$156.9M
Tezspire <i>tezepelumab</i>	Amgen	Severe asthma	Jan-22	\$156.2M
Vyvgart <i>efgartigimod alfa</i>	Argenx	Generalized myasthenia gravis	Jan-22	\$151.6M
Adbry <i>tralokinumab</i>	Leo Pharma	Atopic dermatitis	Feb-22	\$145.3M
Kimmtrak <i>tebentafusp</i>	Immunocore	Uveal melanoma	Feb-22	\$101.3M
Leqvio <i>inclisiran</i>	Novartis	Atherosclerosis	Jan-22	\$59.1M

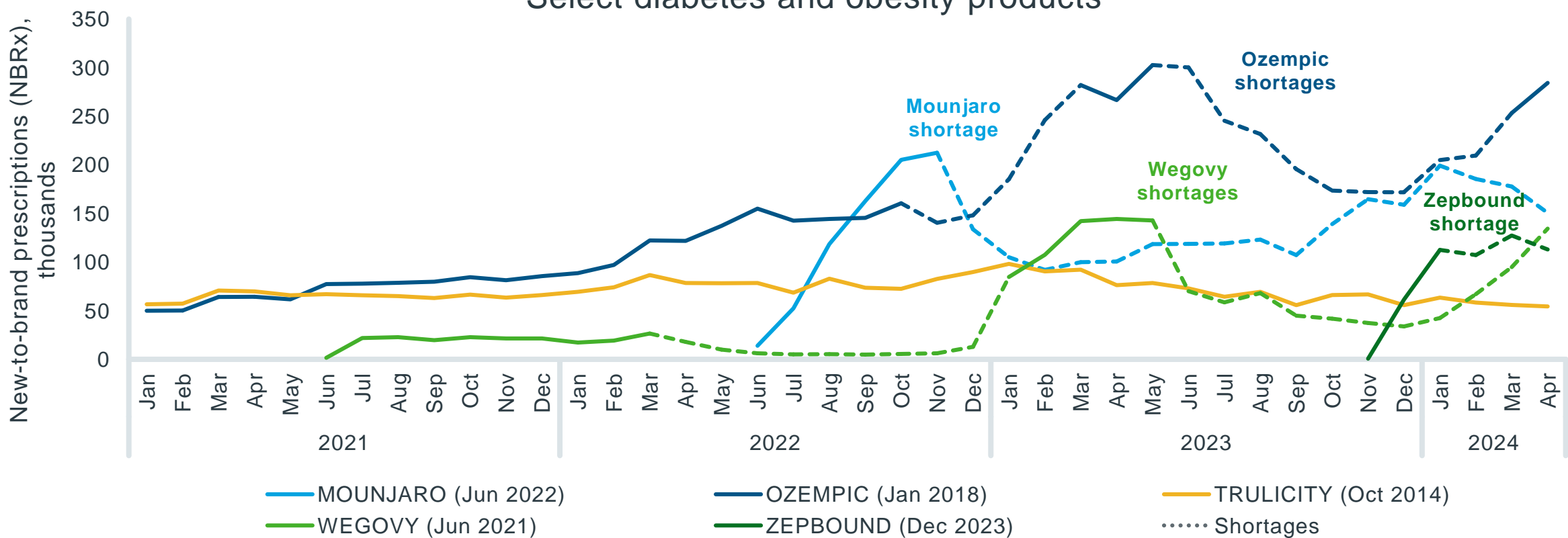
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Market Spotlight: Obesity and Diabetes

Despite ongoing shortages, the GLP-1 market continues to grow at an unprecedented rate

Manufacturers prepare as favorable trial results emerge for GLP-1 use in sleep apnea, metabolic dysfunction-associated steatohepatitis (MASH), kidney disease and cardiovascular mortality

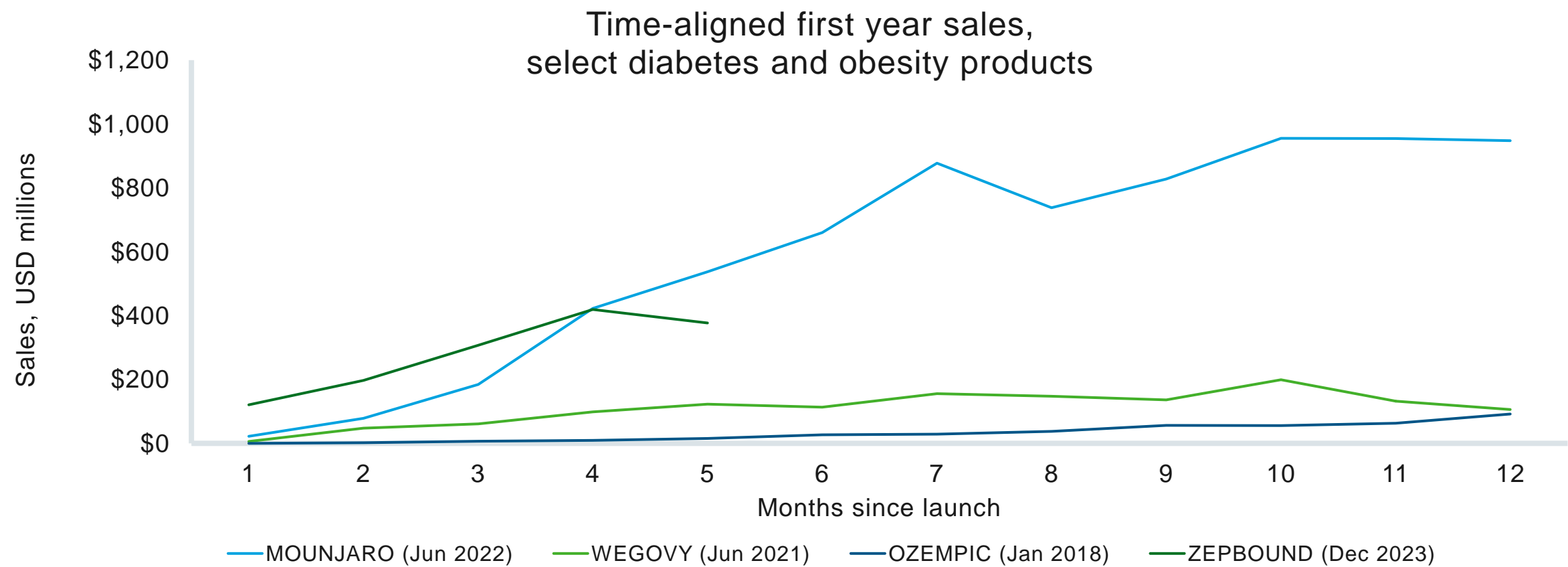
Monthly new-to-brand (NBRx) volumes,
Select diabetes and obesity products



Source: National Sales Perspective, National Prescription Audit, Patient Insights; Launch Center of Excellence, IQVIA

From a sales perspective, Lilly's Zepbound has been outperforming previous GLP-1 launches throughout its first year

Despite shortages, Mounjaro and Zepbound sales exceed Ozempic and Wegovy during the same launch timeframe



Source: IQVIA SMART, Launch Edition, National Sales Perspective; Launch Center of Excellence, IQVIA

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Market Spotlight: Humira Biosimilars

Humira Biosimilar Approvals

Product	Company	Approval Year	Launch Year	Approval to Launch	Y1 Sales (Apr 2024)	Y1 Promo (Apr 2024)
Amjevita (adalimumab-atto)	Amgen	Sep-16	Jan-23 Launched with 2 pricing options: Low WAC: (\$3,115) 55% discount High WAC: (\$6,576) 5% discount Interchangeability designation P3 study is ongoing	6y 4mo	\$ 118.4M	\$ 39.5M
Cyltezo (adalimumab-adbm)	Boehringer Ingelheim	Aug-17 (original approval); Oct 2021 (interchangeable)	Jul-23 Launched at 5% discount Now generic form available at low WAC (will be priced at 81% discount)	6 years	\$ 15.8M	\$ 112.7M
Hyrimoz (adalimumab-adaz)	Sandoz	Oct-18	Jul-23 Launched at (WAC: \$6,576) 5% discount	4y 9mo	\$42.1M	\$ 11.8M
Hadlima (adalimumab-bwwd)	Samsung Bioepis and Organon	Jul-19; FDA accepted sBLA for interchangeability designation	Jul-23 launched at 85% discount; top-line results announced in Aug 2023 from P4 from Interchangeability Study	4 years	\$ 24.7M	\$ 3.9M
Abrilada (adalimumab-afzb)	Pfizer	Nov-19 (original approval) Oct-23 (interchangeable approval)	Late Oct-23 , it will be available at WAC of 5% discount of Humira list price. Later in 2023, it will be available at a second list price 60% below Humira	4 years	\$ 40.3k	\$ 219k
Hulio (adalimumab-fkjp)	Mylan/Fujifilm Kyowa Kirin Biologics	Jul-20	Jul-23 Launched at (WAC: \$6,576) 5% discount	3 years	\$ 474k	\$ 534k
Yusimry (adalimumab-aqvh)	Coherus Biosciences	Dec-21	Jul-23 Launched at (WAC: \$995) 86% discount	1y 7mo	\$ 6.4M	\$ 170k
Idacio (adalimumab-aacf)	Fresenius Kabi USA	Dec-22	Jul-23 Launched at (WAC: \$6,576) 5% discount	7 months	\$ 6.4M	\$ 1.4M
Yuflyma (adalimumab-aaty)	Celltrion	May-23; Filed IND for global P3 trial to demonstrate interchangeability with Humira	Jul-23 Launched at (WAC: \$6,576) 5% discount	2 months	\$ 4.1M	\$ 4.9M
Simlandi (adalimumab-ryvk)	Teva/Alvotech	Feb-24 (approved as interchangeable)	Launch anticipated in Q2 2024 . First high-concentration, citrate-free biosimilar to Humira	N/A	N/A	N/A

*Interchangeable Approval

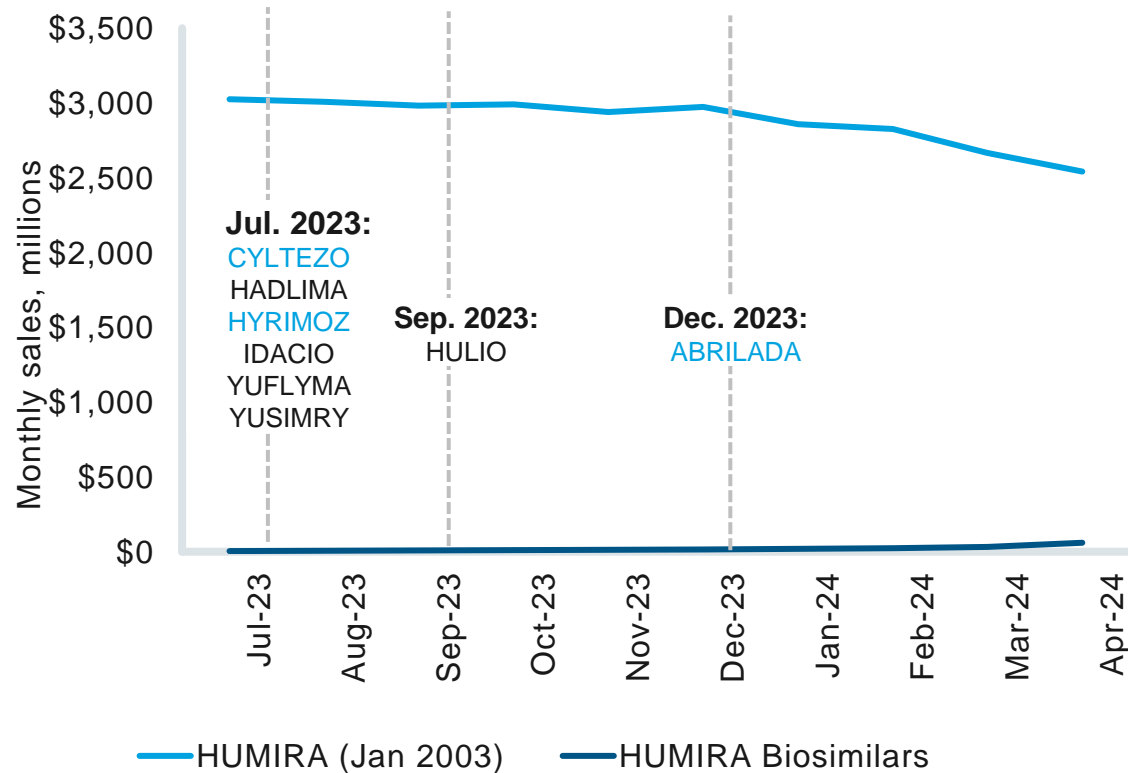
Source: National Sales Perspective; Launch Center of Excellence, IQVIA

Notes: All sales values are USD. WAC = wholesale acquisition cost

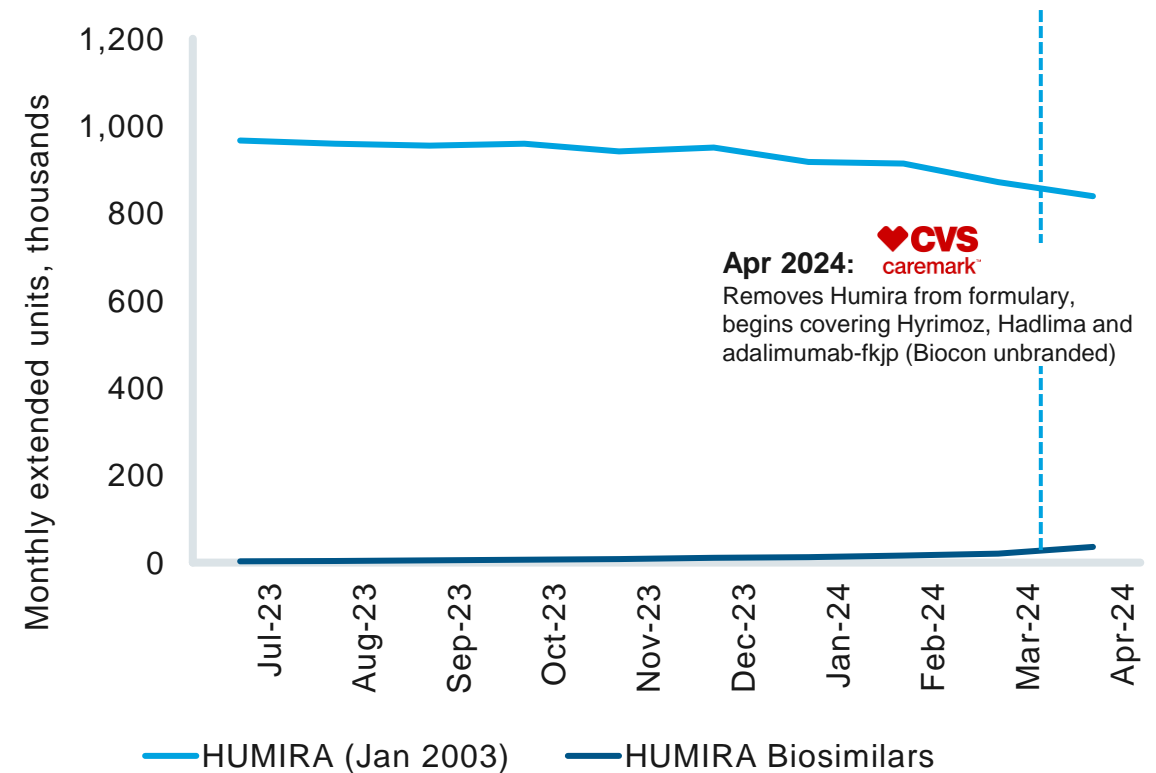
The recent PBM reprioritization of Humira biosimilars has started to make an impact on the reference product

As of April 1st, 2024, CVS Caremark removed Humira from its major national commercial template formularies, and is now covering biosimilars

Monthly sales, Humira and Humira biosimilars
Jul 2023 – Apr 2024



Monthly Ext. units, Humira and Humira biosimilars
Jul 2023 – Apr 2024



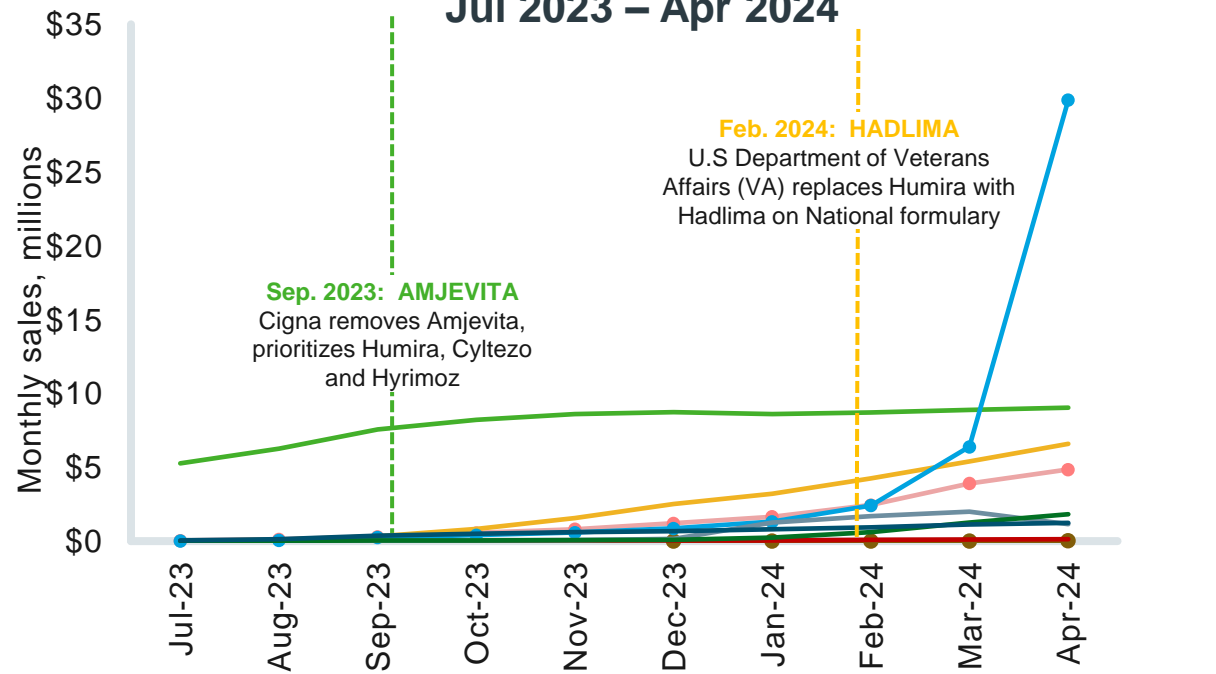
***Interchangeable Approval**

Source: National Sales Perspective; Launch Center of Excellence, IQVIA

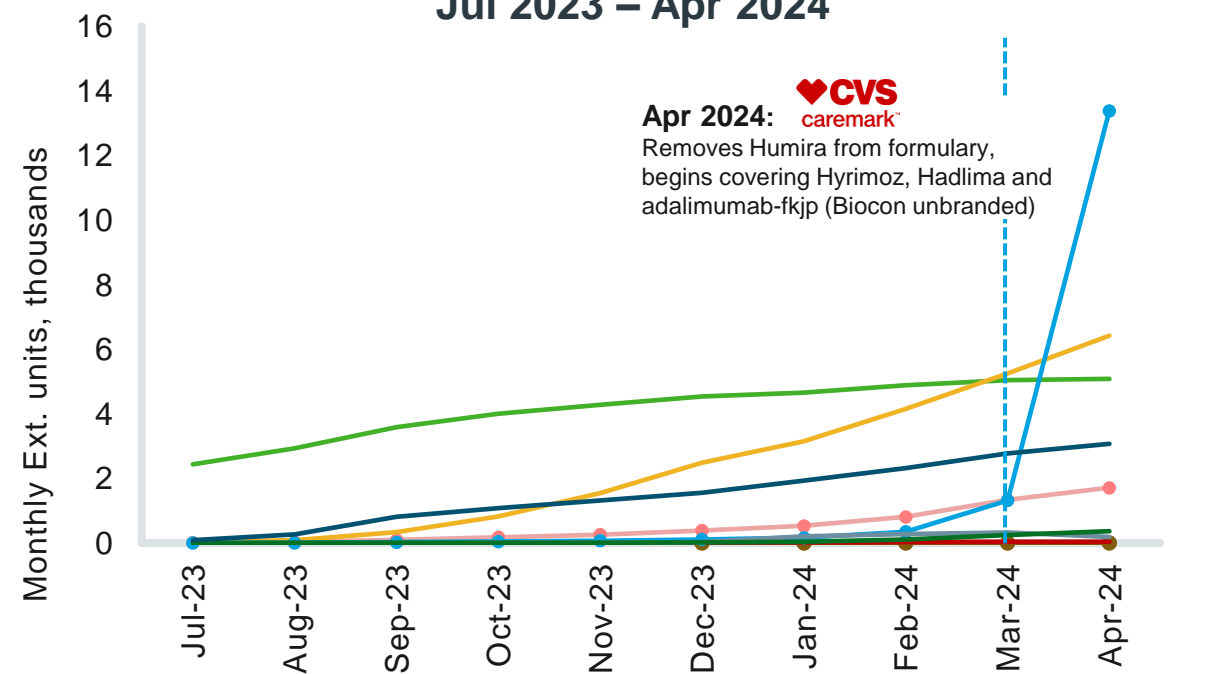
Notes: All sales values are USD. EU = extended units; PBM = pharmacy benefit manager

The April 2024 removal of Humira from CVS Caremark was pivotal for Sandoz's interchangeable biosimilar, Hyrimoz

Monthly sales, Humira biosimilars
Jul 2023 – Apr 2024



Monthly Ext. units, Humira biosimilars
Jul 2023 – Apr 2024



ABRILADA (Dec 2023) AMJEVITA (Feb 2023) CYLTEZO (Jul 2023)
HADLIMA (Jul 2023) HULIO (Sep 2023) HYRIMOZ (Jul 2023)
IDACIO (Jul 2023) YUFLYMA (Jul 2023) YUSIMRY (Jul 2023)
Interchangeable

ABRILADA (Dec 2023) AMJEVITA (Feb 2023) CYLTEZO (Jul 2023)
HADLIMA (Jul 2023) HULIO (Sep 2023) HYRIMOZ (Jul 2023)
IDACIO (Jul 2023) YUFLYMA (Jul 2023) YUSIMRY (Jul 2023)
Interchangeable

Source: National Sales Perspective; Launch Center of Excellence, IQVIA
Notes: All sales values are USD. BI = Boehringer Ingelheim; VA = Veterans affairs