

# Eli Lilly and Company

## Q4 2023 Earnings Call

February 6, 2024

# Safe Harbor Provision

**This presentation contains forward-looking statements that are based on management's current expectations, but actual results may differ materially due to various factors. The company's results may be affected by factors including, but not limited to, the risks and uncertainties in pharmaceutical research and development; competitive developments; regulatory actions; litigation and investigations; business development transactions; economic conditions; and changes in laws and regulations, including health care reform.**

**For additional information about the factors that affect the company's business, please see the company's latest Form 10-K and subsequent Forms 10-Q and 8-K filed with the Securities and Exchange Commission. Certain financial information in this presentation is presented on a non-GAAP basis. Investors should refer to the reconciliations included in this presentation and should consider the company's non-GAAP measures in addition to, not as a substitute for or superior to, measures prepared in accordance with GAAP.**

**These materials are not intended to promote the products referenced herein or otherwise influence healthcare prescribing decisions**

**The company undertakes no duty to update forward-looking statements  
except as required by applicable law**

# Agenda



## Introduction and Key Events

Dave Ricks, Chair and Chief Executive Officer

---

## Q4 2023 Financial Results & 2024 Financial Guidance

Anat Ashkenazi, Chief Financial Officer

---

## R&D Update

Dan Skovronsky, M.D., Ph.D., Chief Scientific Officer

---

## Closing Remarks

Dave Ricks, Chair and Chief Executive Officer

---

## Question & Answer Session

# Strategic Deliverables

PROGRESS SINCE THE LAST EARNINGS CALL

## Invest in Current Portfolio

- **Gross Margin:** Non-GAAP gross margin of 82.3% in Q4
- **SG&A:** 17% increase in Q4 primarily driven by launches of new products and indications as well as higher incentive compensation costs

## Invest in Future Innovation

- **R&D:** 28% increase in Q4 driven by portfolio progression
- **Business Development:** Completed the acquisitions of POINT Biopharma and Mablink Bioscience
- **Capex:** Progressed manufacturing expansion agenda and announced plans to add a new parenteral manufacturing site in Germany

## Deliver Revenue Growth

- Revenue grew 28% in Q4 driven by Mounjaro<sup>®</sup>, Verzenio<sup>®</sup>, Jardiance<sup>®1</sup> and Zepbound<sup>®</sup>
- New Products<sup>2</sup> grew by \$2.19 billion to \$2.49 billion in Q4
- Growth Products<sup>2</sup> increased 9% to \$5.27 billion in Q4

## Speed Life-Changing Medicines

- FDA approval of **Zepbound** for the treatment of adults with obesity or overweight with weight-related comorbidities
- FDA approval of **Jaypirca**<sup>®</sup> under the Accelerated Approval Program for the treatment of adults with CLL or SLL who have received a BTK inhibitor and a BCL-2 inhibitor

## Return Capital to Shareholders via:

- **Dividend:** Distributed over \$1 billion in Q4

- **Share Repurchase:** \$750 million in 2023

<sup>1</sup> Jardiance is part of the Boehringer Ingelheim and Lilly Alliance, and Boehringer Ingelheim holds the marketing authorization for Jardiance

<sup>2</sup> Refer to slide 9 for a list of New Products and Growth Products

# Key Events Since Last Earnings Call

## Regulatory

- Announced the U.S. Food and Drug Administration (FDA) approved:
  - **Zepbound** for the treatment of obesity or overweight with weight-related comorbidities; and
  - **Jaypirca** under the Accelerated Approval Program for the treatment of patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor.
- Announced **Ebglyss**<sup>®</sup> was approved in the European Union<sup>1</sup> and Japan for the treatment of moderate-to-severe atopic dermatitis.

## Clinical

- Presented **Verzenio** data at the San Antonio Breast Cancer Symposium showing final overall survival analysis from the Phase 3 MONARCH 3 study in HR+ HER2-, metastatic breast cancer;
- Announced **Verzenio** added to abiraterone did not meet the primary endpoint of improved radiographic progression-free survival in men with metastatic castration-resistant prostate cancer in the Phase 3 CYCLONE-2 study;
- Announced positive topline results from the Phase 2 SYNERGY-NASH study, showing up to 74% of participants taking **tirzepatide** achieved an absence of MASH with no worsening of fibrosis at 52 weeks, compared to nearly 13% of participants on placebo; and

## Clinical (Cont)

- Published **Zepbound** data in The Journal of the American Medical Association (JAMA) showing results from the Phase 3 SURMOUNT-4 study in adults with obesity or overweight with weight-related comorbidities, excluding type 2 diabetes.

## Other

- Expanded **LillyDirect**<sup>™</sup>, a digital healthcare experience for patients in the U.S. living with obesity, migraine and diabetes that offers disease management resources, including options to find independent healthcare providers and direct home delivery of select Lilly prescription medicines through third-party pharmacy dispensing services;
- Announced plans to construct a new \$2.5 billion high-tech **manufacturing** site in Alzey, Rhineland-Palatinate, Germany to further expand the company's global parenteral (injectable) product and device manufacturing network;
- Completed the acquisitions of **POINT Biopharma Global, Inc.** and **Mablink Bioscience**;
- Announced the retirement of **Johna Norton**, executive vice president of Global Quality, effective July 31, 2024; and
- Announced a 15% **dividend** increase for 2024.

<sup>1</sup>Lilly's partner, Almirall S.A., has licensed the rights to develop and commercialize Ebglyss in Europe

# Reconciliation of GAAP Reported to Non-GAAP Adjusted Information; Certain Line Items (Unaudited)

Dollars in millions; except per share data

Q4 2023

	GAAP Reported	Adjustments	Non-GAAP Adjusted	YoY Non-GAAP Adjusted Change
TOTAL REVENUE	<b>\$9,353</b>	\$ –	<b>\$9,353</b>	28%
GROSS MARGIN	<b>80.9%</b>	1.4pp	<b>82.3%</b>	1.8pp
TOTAL OPERATING EXPENSE	<b>5,178</b>	(68)	<b>5,110</b>	32%
OPERATING INCOME	<b>2,388</b>	197	<b>2,585</b>	29%
OPERATING MARGIN	<b>25.5%</b>	2.1pp	<b>27.6%</b>	0.2pp
OTHER INCOME (EXPENSE)	<b>121</b>	(117)	<b>4</b>	(91)%
EFFECTIVE TAX RATE	<b>12.7%</b>	0.4pp	<b>13.1%</b>	5.8pp
NET INCOME	<b>\$2,190</b>	\$59	<b>\$2,249</b>	19%
EPS	<b>\$2.42</b>	\$0.07	<b>\$2.49</b>	19%
Acquired IPR&D Charges per share*	<b>\$0.62</b>	\$ –	<b>\$0.62</b>	NM

\*Acquired IPR&D (in process research and development) of \$623 million (pre-tax)

Numbers may not add due to rounding; see slide 25 for a complete list of adjustments; NM = not meaningful

# Reconciliation of GAAP Reported to Non-GAAP Adjusted Information; Certain Line Items (Unaudited)

Dollars in millions; except per share data

FY 2023

	GAAP Reported	Adjustments	Non-GAAP Adjusted	YoY Non-GAAP Adjusted Change
TOTAL REVENUE	<b>\$34,124</b>	\$ –	<b>\$34,124</b>	20%
GROSS MARGIN	<b>79.2%</b>	1.5pp	<b>80.7%</b>	1.9pp
TOTAL OPERATING EXPENSE	<b>20,584</b>	(68)	<b>20,516</b>	41%
OPERATING INCOME	<b>6,458</b>	574	<b>7,032</b>	(12)%
OPERATING MARGIN	<b>18.9%</b>	1.7pp	<b>20.6%</b>	(7.2)pp
OTHER INCOME (EXPENSE)	<b>97</b>	25	<b>121</b>	87%
EFFECTIVE TAX RATE	<b>20.1%</b>	–	<b>20.1%</b>	9.8pp
NET INCOME	<b>\$5,240</b>	\$473	<b>\$5,712</b>	(21)%
EPS	<b>\$5.80</b>	\$0.52	<b>\$6.32</b>	(20)%
Acquired IPR&D Charges per share*	<b>\$4.10</b>	\$ –	<b>\$4.10</b>	NM

\*Acquired IPR&D of \$3.80 billion (pre-tax)

Numbers may not add due to rounding; see slide 25 for a complete list of adjustments; NM = not meaningful

# Price/Rate/Volume Effect on Revenue

Dollars in millions

Q4 2023

	Amount	Price	FX Rate	Volume	Total	CER
U.S.	\$6,455	27%	–	12%	39%	39%
EUROPE	1,338	(5)%	8%	22%	24%	17%
JAPAN	439	(2)%	(4)%	17%	11%	15%
CHINA	377	(3)%	0%	10%	7%	7%
REST OF WORLD	744	(1)%	1%	(9)%	(10)%	(10)%
TOTAL REVENUE	\$9,353	16%	1%	11%	28%	27%

FY 2023

	Amount	Price	FX Rate	Volume	Total	CER
U.S.	\$21,791	9%	–	11%	20%	20%
EUROPE	6,175	(7)%	2%	48%	44%	41%
JAPAN	1,673	(1)%	(7)%	4%	(4)%	2%
CHINA	1,540	(8)%	(5)%	19%	6%	11%
REST OF WORLD	2,946	(1)%	(1)%	5%	3%	4%
TOTAL REVENUE	\$34,124	4%	(0)%	16%	20%	20%

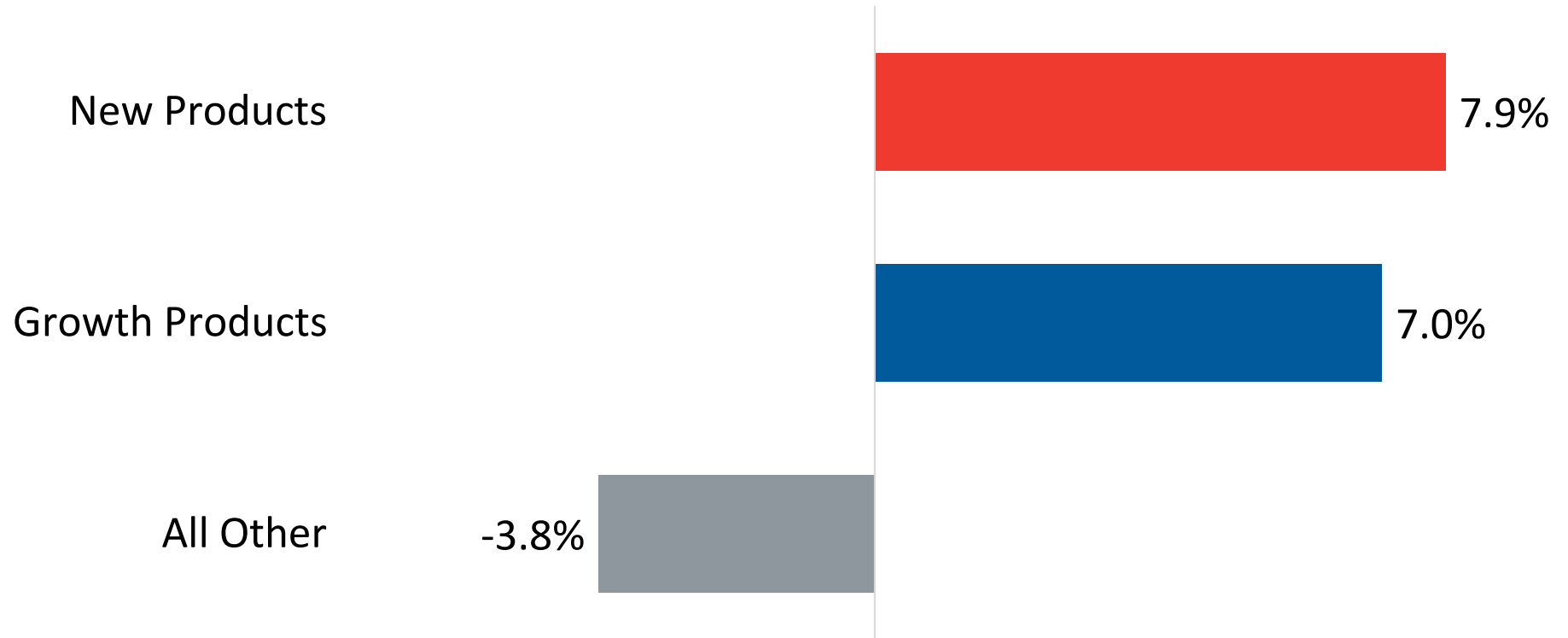
Numbers may not add due to rounding

CER = price change + volume change



# Products Driving WW Volume Growth

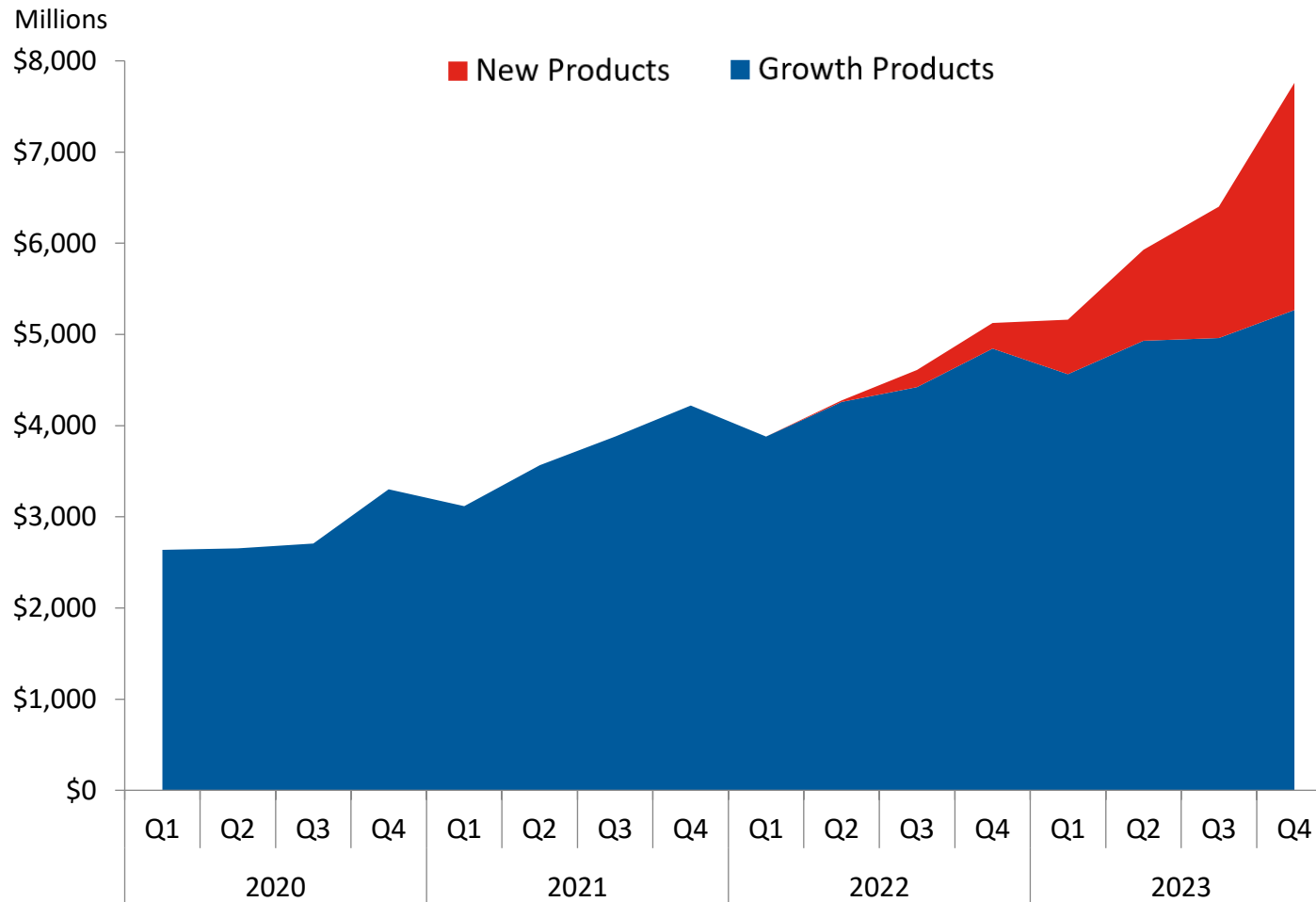
Contribution to 11% Q4 WW Volume Increase



**New Products:** Ebglyss, Jaypirca, Mounjaro, Omvoh™, and Zepbound

**Growth Products:** Cyramza®, Emgality®, Jardiance, Olumiant®, Retevmo®, Taltz®, Trulicity®, Tyvyt®, and Verzenio

# Q4 2023 Update on Select Products



**New Products:** Ebglyss, Jaypirca, Mounjaro, Omvoh, and Zepbound

**Growth Products:** Cyramza, Emgality, Jardiance, Olumiant, Retevmo, Taltz, Trulicity, Tyvyt, and Verzenio

## NEW PRODUCTS

### MOUNJARO

- U.S. T2D injectable incretins TRx SOM over 27% and NBRx SOM over 38% at end of Q4 2023

### ZEPBOUND

- U.S. approval and launch in Q4 2023

### JAYPIRCA

- U.S. MCL approval in Q1 2023 and U.S. CLL/SLL approval in Q4 2023

### OMVOH

- Japan and EU approval in H1 2023; U.S. approval in Q4 2023

## GROWTH PRODUCTS

### JARDIANCE<sup>1</sup>

- SGLT2 market leader in several key countries with U.S. TRx SOM of 63% at the end of Q4
- U.S. TRx grew 26% vs. Q4 2022

### TALTZ

- U.S. immunology TRx SOM of nearly 6% at the end of Q4
- U.S. TRx grew 14% vs. Q4 2022

### TRULICITY

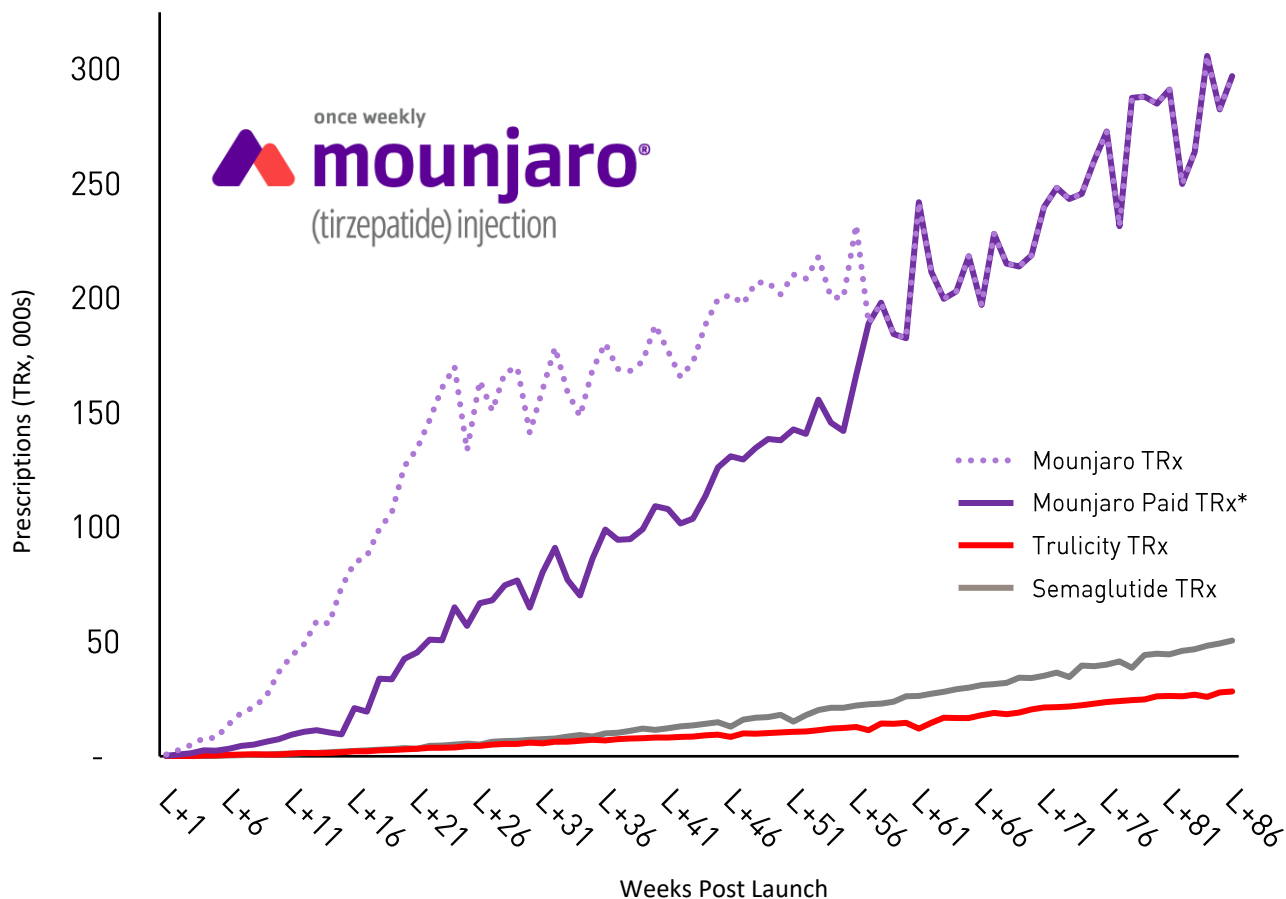
- U.S. T2D injectable incretins TRx SOM of nearly 22% at the end of Q4

### VERZENIO

- U.S. TRx grew over 41% vs. Q4 2022
- Strong uptake in adjuvant breast cancer indication

<sup>1</sup> Jardiance is part of the company's alliance with Boehringer Ingelheim. Lilly reports as revenue royalties received on net sales of Jardiance.

# Mounjaro U.S. Launch Progress



Mounjaro volume has significantly outpaced prior launches in the type 2 diabetes injectable incretin class

- Robust growth in prescriptions for type 2 diabetes patients
- Q4 U.S. revenue of \$2.11 billion
  - Continued expansion of access and decreased utilization of savings cards
  - One-time favorable change in estimates for rebates and discounts in Q4 2023; adjusting for this change, net sales would have grown ~30% vs Q3 2023
- Access on February 1<sup>st</sup> was 90% for patients with type 2 diabetes across commercial and Part D lives, consisting of 92% commercial and 82% of Part D

\*Internal estimate of weekly paid TRx  
IQVIA weekly data for week ending Jan 26, 2024 (type 2 diabetes injectable incretin class)

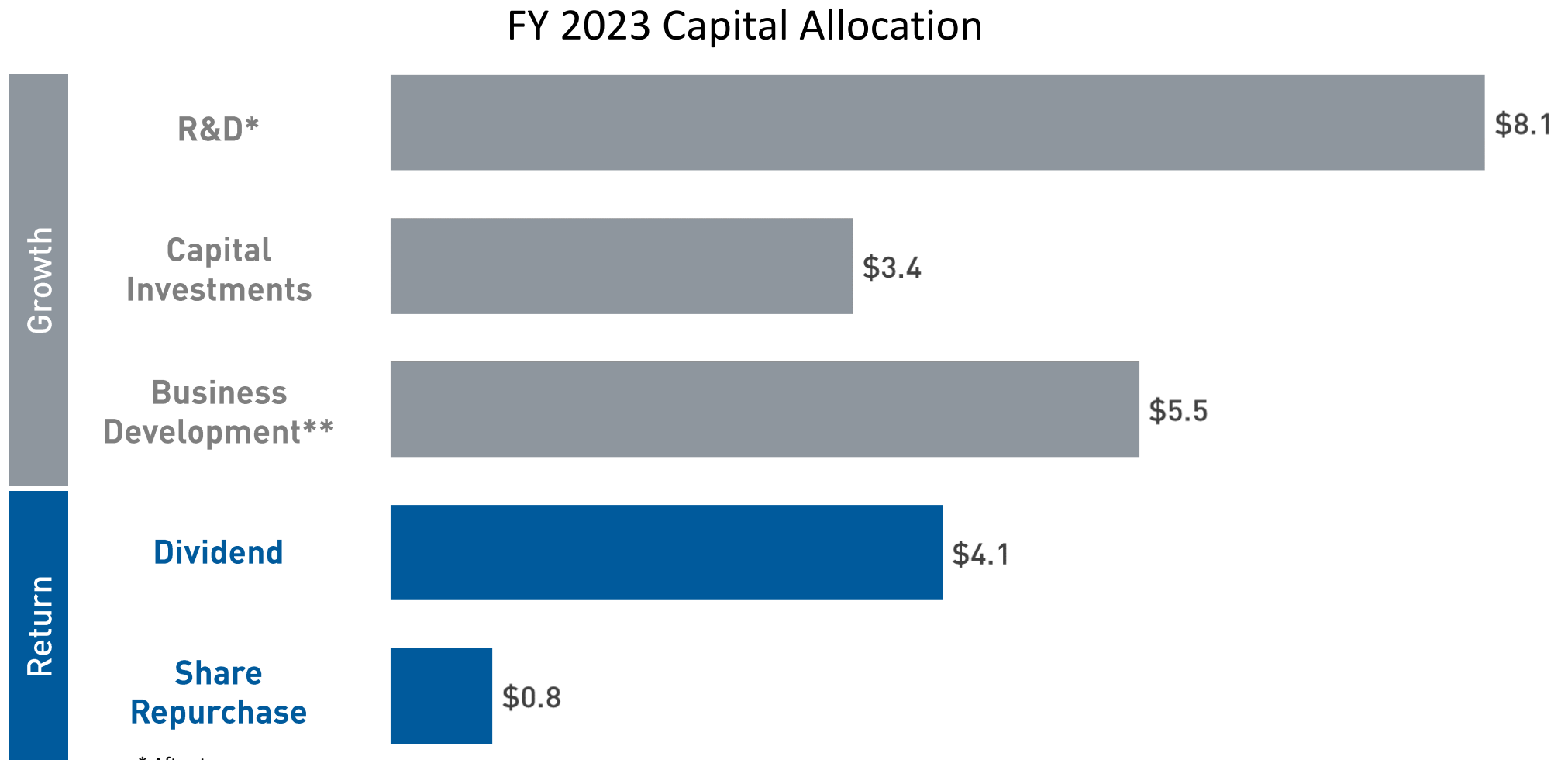
# Zepbound U.S. Launch Progress

once weekly  
**zepbound**<sup>TM</sup>  
(tirzepatide) injection

- **FDA approval** on November 8, 2023 and pharmacy availability announced December 5, 2023
- **Exceptional prescription uptake** since launch
- Strong **early formulary access** of approximately 1/3 of commercial lives covered as of February 1<sup>st</sup>; focused on expanding payer access and employer opt-in
- **Commercial savings card program** in place to provide access to people who may benefit from Zepbound
- Zepbound available via **LillyDirect**, allowing patients to find independent healthcare providers and direct home delivery through third-party pharmacy dispensing services

# Capital Allocation

Billions



\* After tax

\*\* Includes development milestones, closed acquisitions and cash outflows associated with equity investments; does not include cash inflows from divestitures

# Strategic Deliverables

## OUTLOOK

### Invest in Current Portfolio

- **Gross Margin:** Maintain at ~80% with productivity gains and volume growth offsetting price pressures and increased manufacturing costs
- **SG&A:** Invest for launch success; drive margin expansion over time

### Invest in Future Innovation

- **R&D:** Invest to fuel future growth
- **Business Development:** Pursue external innovation
- **Capex:** Bolster manufacturing capacity and supply chain resilience

### Deliver Revenue Growth

- Deliver top-tier revenue growth driven by volume from innovative medicines
- Growth catalysts include recent launches of Mounjaro, Jaypirca, Omvoh and Zepbound and potential launches of donanemab and lebrilizumab

### Speed Life-Changing Medicines

- Achieve breakthroughs for patients in the most burdensome diseases, including neurodegeneration, obesity, diabetes, cancer and autoimmune disorders
- Expand and enhance our world-class team and capabilities
- Potential growth catalysts toward the end of the decade include orforglipron, retatrutide, insulin efsitora alfa, remteterug and imlunestrant

Return Capital to Shareholders via: • **Dividend:** Increase in-line with earnings growth over time • **Share Repurchase:** Return excess capital

# Dynamics Affecting 2024 Revenue Outlook

- Momentum from recently launched products, including Mounjaro, Zepbound, Jaypirca and Omvoh
- Continued strong revenue contribution from Verzenio, Taltz and Jardiance<sup>1</sup>
- Acceleration of revenue growth in all major geographies
- Timing and ramp of injectable incretin production, with more significant expansion expected in the second half of 2024
- Continued erosion of Trulicity volume amid supply limitations and broader injectable incretin growth
- Net price decline in the high single-digits excluding divestitures

<sup>1</sup> Jardiance is part of the company's alliance with Boehringer Ingelheim. Lilly reports as revenue royalties received on net sales of Jardiance.

# Initial 2024 Guidance

	2023 Actuals	2024 Guidance	2024 Comments
<b>REVENUE</b>	\$34.1 billion	\$40.4 – \$41.6 billion	Midpoint represents ~20% total growth and ~29% growth excluding impact of divestiture transactions
<b><u>GROSS MARGIN – OPEX</u><sup>1</sup></b> <b>REVENUE</b>			Gross margin as a percent of revenue consistent with outlook
(GAAP)	30.3%	30% – 32%	Research and development expense increase driven by ongoing and new late-phase programs
(NON-GAAP)	31.7%	31% – 33%	Marketing, selling & administrative expense increase driven by recently launched and upcoming product launches
<b>OTHER INCOME/(EXPENSE)</b>			
(GAAP)	\$97 million	\$(500) – \$(400) million	Driven by higher interest expense
(NON-GAAP)	\$121 million	\$(500) – \$(400) million	
<b>TAX RATE</b>	20.1%	Approx. 14%	Does not assume deferral or repeal of the 2017 Tax Act
<b>EARNINGS PER SHARE</b> <sup>2</sup>			
(GAAP)	\$5.80	\$11.80 – \$12.30	Acquired IPR&D included in 2023 actuals, while 2024 guidance does not include potential or pending acquired IPR&D
(NON-GAAP)	\$6.32	\$12.20 – \$12.70	

<sup>1</sup> OPEX is defined as the sum of research and development expenses and marketing, selling and administrative expenses

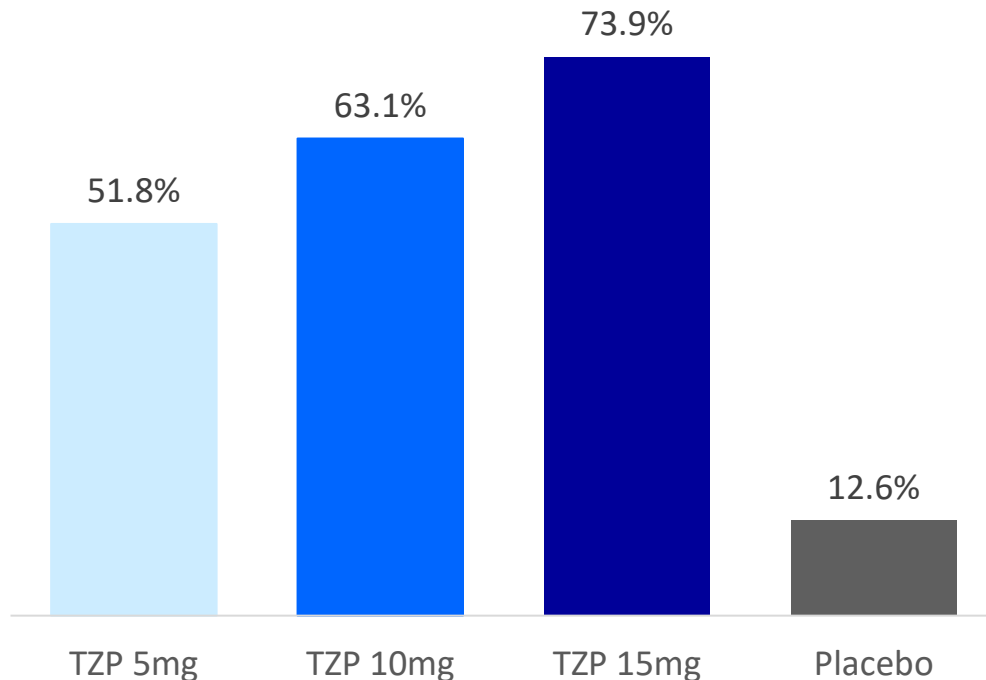
<sup>2</sup> 2024 assumes shares outstanding of approximately 903 million. Earnings per share (non-GAAP) reflects \$0.40 adjustment for amortization of intangible assets

FX assumptions of 1.09 (Euro), 145 (Yen) and 7.20 (Renminbi)



# Tirzepatide SYNERGY-NASH Phase 2 Study

Proportion of participants with absence of MASH and no worsening of fibrosis on liver histology at 52 weeks



- Phase 2 study in adults with biopsy-proven MASH with stage 2 or 3 fibrosis
- All doses met primary endpoint of absence of MASH with no worsening of liver histology
- Secondary endpoint of decrease in fibrosis by at least one stage with no worsening of MASH on liver histology was clinically meaningful across doses
- Adverse events were consistent with other tirzepatide studies in people living with obesity or type 2 diabetes

TZP = tirzepatide; MASH = metabolic dysfunction-associated steatohepatitis

# Lilly Select NME and NILEX Pipeline

FEBRUARY 5, 2024

LA-ANP Heart Failure	NOT DISCLOSED Immunology	
SCAP siRNA NASH	GS INSULIN RECEPTOR AGONIST Diabetes	ITACONATE MIMETIC Immunology
PI3K SELECTIVE Cancer	PNPLA3 siRNA NASH	SARM1 INHIBITOR Neurodegeneration
NOT DISCLOSED Neurodegeneration	NOT DISCLOSED Pain	NRG4 AGONIST Heart Failure
G1TR ANTAGONIST Immunology	NISOTIROSTIDE Diabetes	NOT DISCLOSED Diabetes
FGFR3 SELECTIVE Cancer	G1PR AGONIST LA Diabetes	G1PR AGONIST LA II Diabetes
CD19 ANTIBODY Immunology	DACRA QW II Obesity	DC-853 Immunology
AMYLIN AGONIST LA Obesity	APOC3 siRNA CVD	AT2R ANTAGONIST Pain

PHASE 1

RET INHIBITOR II  
Cancer

TIRZEPATIDE NASH	
RETATRUTIDE Diabetes	TIRZEPATIDE Higher Doses
GBA1 GENE THERAPY Gaucher Disease Type 1	GBA1 GENE THERAPY Gaucher Disease Type 2
OLOMORASIB (KRAS G12C II) KRAS G12C-mutant NSCLC	OTOF GENE THERAPY Hearing Loss
KV1.3 ANTAGONIST Psoriasis	MAZDUTIDE Obesity
UCENPRUBART Atopic Dermatitis	VOLENRELAXIN Heart Failure
SOLBINSIRAN CVD	SSTR4 AGONIST Pain
P2X7 INHIBITOR Pain	PERESOLIMAB Rheumatoid Arthritis
OCADUSERTIB (RIPK1 INHIBITOR) Rheumatoid Arthritis	O-GLCNACASE INH Alzheimer's Disease
MEVIDALEN Symptomatic LBD	MUVALAPLIN CVD
GRN GENE THERAPY Frontotemporal Dementia	LEPODISIRAN CVD
ELTREKIBART Hidradenitis Suppurativa	GBA1 GENE THERAPY Parkinson's Disease
BIMAGRUMAB Obesity	DC-806 Psoriasis

PHASE 2

TIRZEPATIDE Obstructive Sleep Apnea	
TIRZEPATIDE Heart Failure pEF	TIRZEPATIDE MMO
SELPERCATINIB Adjuvant RET+ NSCLC	TIRZEPATIDE CV Outcomes
PIRTOBRUTINIB R/R CLL Monotherapy	PIRTOBRUTINIB R/R MCL Monotherapy
PIRTOBRUTINIB 1L CLL Monotherapy	PIRTOBRUTINIB R/R CLL Combination
MIRIKIZUMAB Crohn's Disease	ORFORGLIPRON Diabetes
EMPAGLIFLOZIN* Post MI	IMLUNESTRANT Adjuvant Breast Cancer
ABEMACICLIB MBC Sequencing	DONANEMAB Preclinical Alzheimer's Disease
RETATRUTIDE Obesity, OA, OSA	ABEMACICLIB Hormone Sensitive Prostate Cancer
ORFORGLIPRON Obesity	REMTERNETUG Alzheimer's Disease
IMLUNESTRANT ER+ HER2- mBC	INSULIN EFSITORA ALFA Diabetes

PHASE 3

ABEMACICLIB  
Castrate Resistant  
Prostate Cancer

**LEGEND**

● NME  
○ NILEX  
\* Commercial Collaboration

**MOVEMENT SINCE October 30, 2023**

▲ ADDITION or MILESTONE ACHIEVED  
▼ REMOVAL

◆ Phase 3 in China with Innovent for T2DM and Obesity

† Approval in Japan where Lilly has full rights to develop and commercialize Lebrikizumab and in EU by Lilly's partner Almirall which will provide Lilly royalties for sales in Europe.

DONANEMAB  
Alzheimer's Disease

REG REVIEW

TIRZEPATIDE  
Obesity

PIRTOBRUTINIB  
CLL Accelerated Approval

† LEBRIKIZUMAB  
Atopic Dermatitis

APPROVED

# Key Events 2023

New since last update

## Phase 3 Initiations

- ✓+ Basal Insulin-Fc for type 2 diabetes [QWINT-1]
- ✓+ Tirzepatide H2H study vs. semaglutide [SURMOUNT-5] <sup>1</sup>
- ✓+ Retatrutide for chronic weight management
- ✓+ Orforglipron for chronic weight management
- ✓+ Orforglipron for type 2 diabetes

## Phase 3 Data Disclosures

- ✓+ Donanemab for early Alzheimer's disease
- ✓+ Tirzepatide for chronic weight management [SURMOUNT-2]
- ✓+ Tirzepatide for chronic weight management [SURMOUNT-3]
- ✓+ Tirzepatide for chronic weight management [SURMOUNT-4]
- ✓+ Mirikizumab for Crohn's disease
- ✓+ Pirtobrutinib for CLL prior BTKi [BRUIN CLL-321]

## Regulatory Submissions

- ✓+ Tirzepatide for chronic weight management [US ✓+ /EU ✓+]
- ✓+ Lebrikizumab for atopic dermatitis [J]
- ✓+ Empagliflozin<sup>2</sup> for chronic kidney disease [US ✓+ /EU ✓+ /J ✓+]
- ✓+ Donanemab for early Alzheimer's disease<sup>3</sup> [US ✓+ /EU ✓+ /J ✓+]
- ✓+ Pirtobrutinib for MCL prior BTKi [J]
- ✓+ Pirtobrutinib for CLL prior BTKi and BCL2i<sup>4</sup> [US]

## Regulatory Actions

- ✓ Donanemab for early Alzheimer's disease<sup>4</sup> [US]
- Lebrikizumab for atopic dermatitis [US ✓- /EU ✓+]
- ✓+ Mirikizumab for ulcerative colitis [US ✓+ /EU ✓+ /J ✓+]
- ✓+ Pirtobrutinib for MCL prior BTKi [US<sup>4</sup> ✓+ /EU ✓+]
- ✓+ Empagliflozin<sup>2</sup> for chronic kidney disease [US ✓+ /EU ✓+]
- ✓+ Tirzepatide for chronic weight management [US ✓+ /EU ✓+]
- ✓+ Pirtobrutinib for CLL prior BTKi and BCL2i<sup>4</sup> [US]

<sup>1</sup> Classified as a Phase 3B/4 study

<sup>2</sup> Jardiance is part of the company's alliance with Boehringer Ingelheim. Lilly reports as revenue royalties received on net sales of Jardiance.

<sup>3</sup> Under the traditional approval pathway

<sup>4</sup> Under the FDA Accelerated Approval Program

# Potential Key Events 2024

## Phase 3 Initiations

- Retatrutide for type 2 diabetes
- Retatrutide for cardiovascular outcomes in chronic weight management
- Lepodisiran [Lp(a) siRNA] for cardiovascular disease
- Olomorasib [KRAS G12C] for first-line non-small cell lung cancer
- Remternetug for early Alzheimer's disease [efficacy trials]

## Phase 3 Data Disclosures

- Tirzepatide for obstructive sleep apnea [SURMOUNT-OSA]
- Tirzepatide for HFpEF [SUMMIT]
- Tirzepatide H2H study vs. semaglutide [SURMOUNT-5] <sup>1</sup>
- Insulin efsitora alfa for diabetes [QWINT-1 / 2 / 3 / 4 / 5]
- ✓ Abemaciclib for metastatic CRPC<sup>2</sup> [CYCLONE-2]
- Imlunestrant for metastatic breast cancer [EMBER-3]

## Regulatory Submissions

- Mirikizumab for Crohn's disease [US/EU/J]
- Tirzepatide for obstructive sleep apnea [US]
- Tirzepatide for HFpEF [US]
- Imlunestrant for metastatic breast cancer [US/EU/J]
- Pirtobrutinib for CLL prior BTKi + BCL2 [EU/J]

## Regulatory Actions

- Lebrikizumab for atopic dermatitis [US/J] ✓<sup>4</sup>
- Donanemab for early Alzheimer's disease<sup>3</sup> [US/EU/J]
- Empagliflozin<sup>4</sup> for chronic kidney disease [J]
- Pirtobrutinib for MCL prior BTKi [J]

<sup>1</sup> Classified as a Phase 3B/4 study

<sup>2</sup> CRPC = castrate-resistant prostate cancer

<sup>3</sup> Under the traditional approval pathway

<sup>4</sup> Jardiance is part of the company's alliance with Boehringer Ingelheim. Lilly reports as revenue royalties received on net sales of Jardiance.

# Q4 2023 Summary

- **Revenue grew 28%** driven by Mounjaro, Verzenio, Jardiance<sup>1</sup> and Zepbound
- Continued to **speed life-changing medicines** to patients with:
  - FDA approval of Zepbound for the treatment of adults with obesity or overweight with weight-related comorbidities
  - FDA approval of Jaypirca under the Accelerated Approval Program for the treatment of adults with CLL or SLL who have received a BTK inhibitor and a BCL-2 inhibitor
  - Announced topline results from the Phase 2 SYNERGY-NASH study evaluating tirzepatide for treatment of MASH and the Phase 3 CYCLONE-2 study evaluating Verzenio for the treatment of metastatic castrate-resistant prostate cancer
- Q4 **investment growth** largely driven by investments in new products and indications and late-stage pipeline
- Completed notable **acquisitions** and announced a new **manufacturing site** in Germany while deploying over \$1 billion to shareholders via the **dividend**



<sup>1</sup> Jardiance is part of the company's alliance with Boehringer Ingelheim. Lilly reports as revenue royalties received on net sales of Jardiance.

# Supplemental Slides



# 2023 Income Statement – Reported

Millions; except per share data

	Q4 2023	Change	FY 2023	Change
TOTAL REVENUE	\$9,353	28%	\$34,124	20%
GROSS MARGIN	80.9%	2.1pp	79.2%	2.4pp
TOTAL OPERATING EXPENSE*	5,178	32%	20,584	39%
OPERATING INCOME	2,388	30%	6,458	(9)%
OPERATING MARGIN	25.5%	0.4pp	18.9%	(6.1)pp
OTHER INCOME (EXPENSE)	121	(53)%	97	NM
EFFECTIVE TAX RATE	12.7%	5.1pp	20.1%	11.8pp
NET INCOME	\$2,190	13%	\$5,240	(16)%
EARNINGS PER SHARE	\$2.42	13%	\$5.80	(16)%

\* Includes research and development expense; marketing, selling and administrative expense; acquired in-process research and development charges; and asset impairment, restructuring and other special charges  
 NM = not meaningful

# Effect of FX on 2023 Results

Year-on-Year Change

REPORTED	Q4 2023		FY 2023	
	With FX	w/o FX	With FX	w/o FX
TOTAL REVENUE	28%	27%	20%	20%
COST OF SALES	15%	17%	7%	8%
GROSS MARGIN	31%	30%	23%	24%
OPERATING EXPENSE	32%	31%	39%	39%
OPERATING INCOME	30%	27%	(9)%	(9)%
EARNINGS PER SHARE	13%	11%	(16)%	(16)%
<b>NON-GAAP</b>				
	With FX	w/o FX	With FX	w/o FX
TOTAL REVENUE	28%	27%	20%	20%
COST OF SALES	17%	18%	9%	10%
GROSS MARGIN	31%	29%	23%	23%
OPERATING EXPENSE	32%	31%	41%	41%
OPERATING INCOME	29%	27%	(12)%	(12)%
EARNINGS PER SHARE	19%	17%	(20)%	(21)%

Presentation includes GAAP and non-GAAP figures excluding impact of foreign exchange rates. Current period figures recalculated by keeping constant the exchange rates from the base period.



# EPS Reconciliation

	<u>Q4 2023</u>	<u>Q4 2022</u>	<u>% Change</u>	<u>FY 2023</u>	<u>FY 2022</u>	<u>% Change</u>
EARNINGS PER SHARE (REPORTED)	\$2.42	\$2.14	13%	\$5.80	\$6.90	(16)%
AMORTIZATION OF INTANGIBLE ASSETS	0.11	0.11	–	0.45	0.50	(10)%
NET LOSSES (GAINS) ON INVESTMENTS IN EQUITY SECURITIES	(0.11)	(0.19)	(42)%	0.02	0.33	(94)%
ASSET IMPAIRMENT, RESTRUCTURING AND OTHER SPECIAL CHARGES	0.06	0.03	100%	0.06	0.21	(71)%
EARNINGS PER SHARE (NON-GAAP)	\$2.49	\$2.09	19%	\$6.32	\$7.94	(20)%
Acquired IPR&D	\$0.62	\$0.23	NM	\$4.10	\$0.90	NM

Numbers may not add due to rounding; see slides 26 & 27 for more details on these adjustments; NM = not meaningful

# Q4 2023 Income Statement Notes

## Q4 2023 NON-GAAP INFORMATION HAS BEEN ADJUSTED TO EXCLUDE:

- amortization of intangibles (cost of sales) primarily associated with costs of marketed products acquired or licensed from third parties totaling \$129.0 million (pretax), or \$0.11 per share (after-tax);
- net gains on investments in equity securities totaling \$117.0 million (pretax), or (\$0.11) per share (after-tax); and
- asset impairment, restructuring and other special charges totaling \$67.7 million (pretax), or \$0.06 per share (after-tax).

## Q4 2022 NON-GAAP INFORMATION HAS BEEN ADJUSTED TO EXCLUDE:

- net gains on investments in equity securities totaling \$216.5 million (pretax), or (\$0.19) per share (after-tax);
- amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties totaling \$124.1 million (pretax), or \$0.11 per share (after-tax); and
- asset impairment, restructuring and other special charges totaling \$38.1 million (pretax), or \$0.03 per share (after-tax).

# FY 2023 Income Statement Notes

## FY 2023 NON-GAAP INFORMATION HAS BEEN ADJUSTED TO EXCLUDE:

- amortization of intangibles (cost of sales) primarily associated with costs of marketed products acquired or licensed from third parties totaling \$506.2 million (pretax), or \$0.45 per share (after-tax);
- asset impairment, restructuring and other special charges totaling \$67.7 million (pretax), or \$0.06 per share (after-tax); and
- net losses on investments in equity securities totaling \$24.8 million (pretax), or \$0.02 per share (after-tax).

## FY 2022 NON-GAAP INFORMATION HAS BEEN ADJUSTED TO EXCLUDE:

- amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties totaling \$574.1 million (pretax), or \$0.50 per share (after-tax); and
- net losses on investments in equity securities totaling \$385.9 million (pretax), or \$0.33 per share (after-tax); and
- asset impairment, restructuring and other special charges primarily related to an intangible asset impairment charge for GBA1 Gene Therapy (PR001) due to changes in estimated product launch timing, totaling \$244.6 million (pretax), or \$0.21 per share (after-tax).

# Comparative EPS Summary 2022/2023

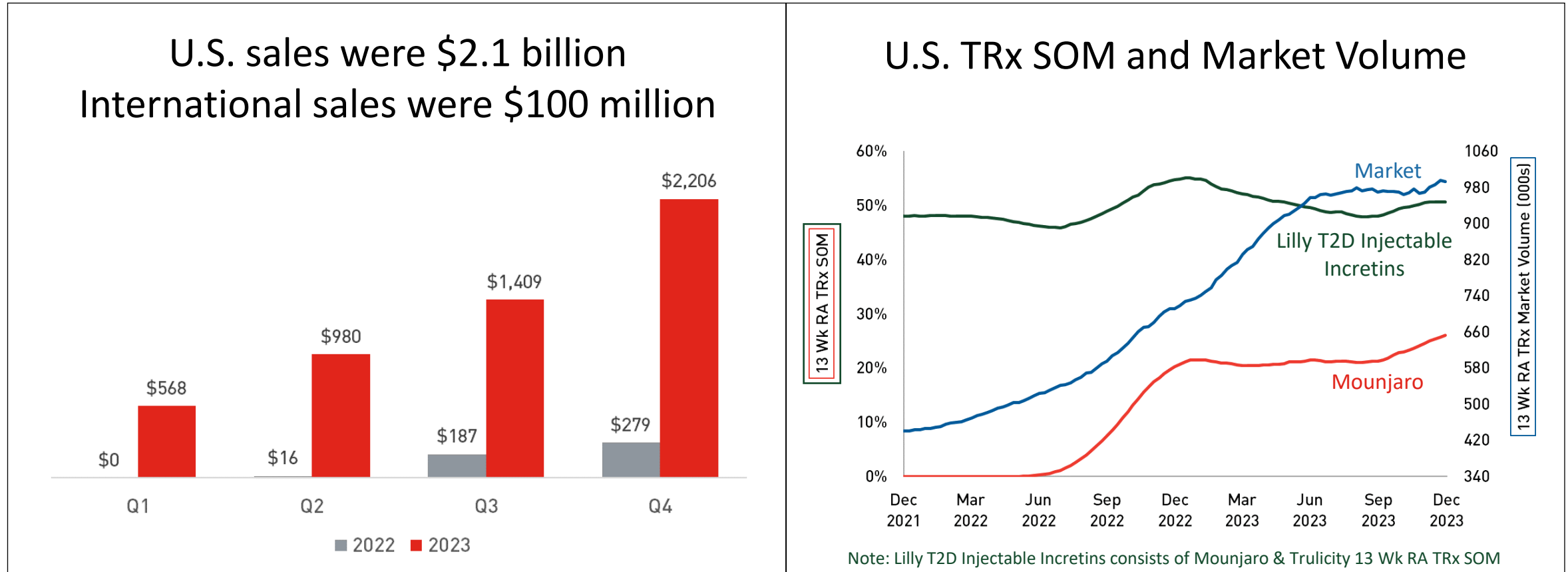
	1Q22	2Q22	3Q22	4Q22	2022	1Q23	2Q23	3Q23	4Q23	2023
Reported	2.10	1.05	1.61	2.14	6.90	1.49	1.95	(0.06)	2.42	5.80
Non-GAAP	2.62	1.25	1.98	2.09	7.94	1.62	2.11	0.10	2.49	6.32

Numbers may not add due to rounding

For a complete reconciliation to reported earnings, see slide 25 and our earnings press release dated February 6, 2024

# Q4 2023 Mounjaro Sales Increased \$1.9B

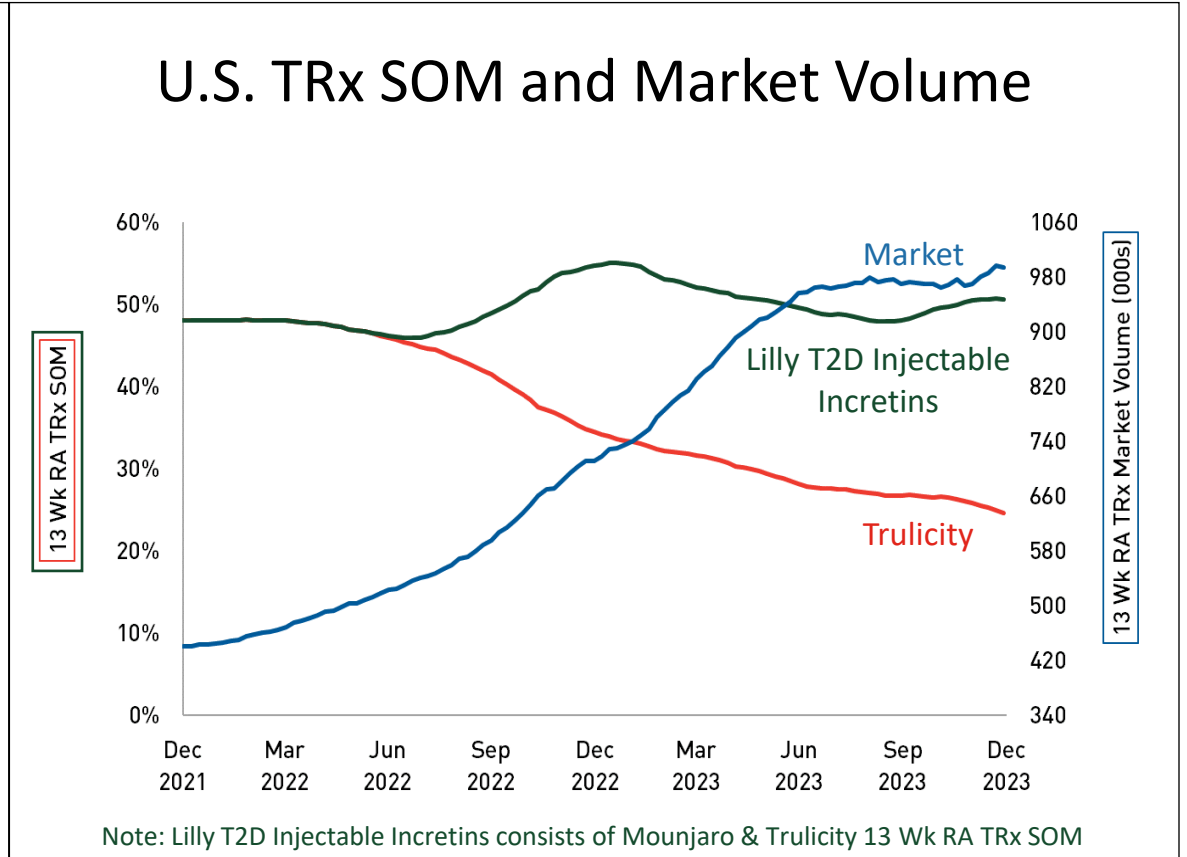
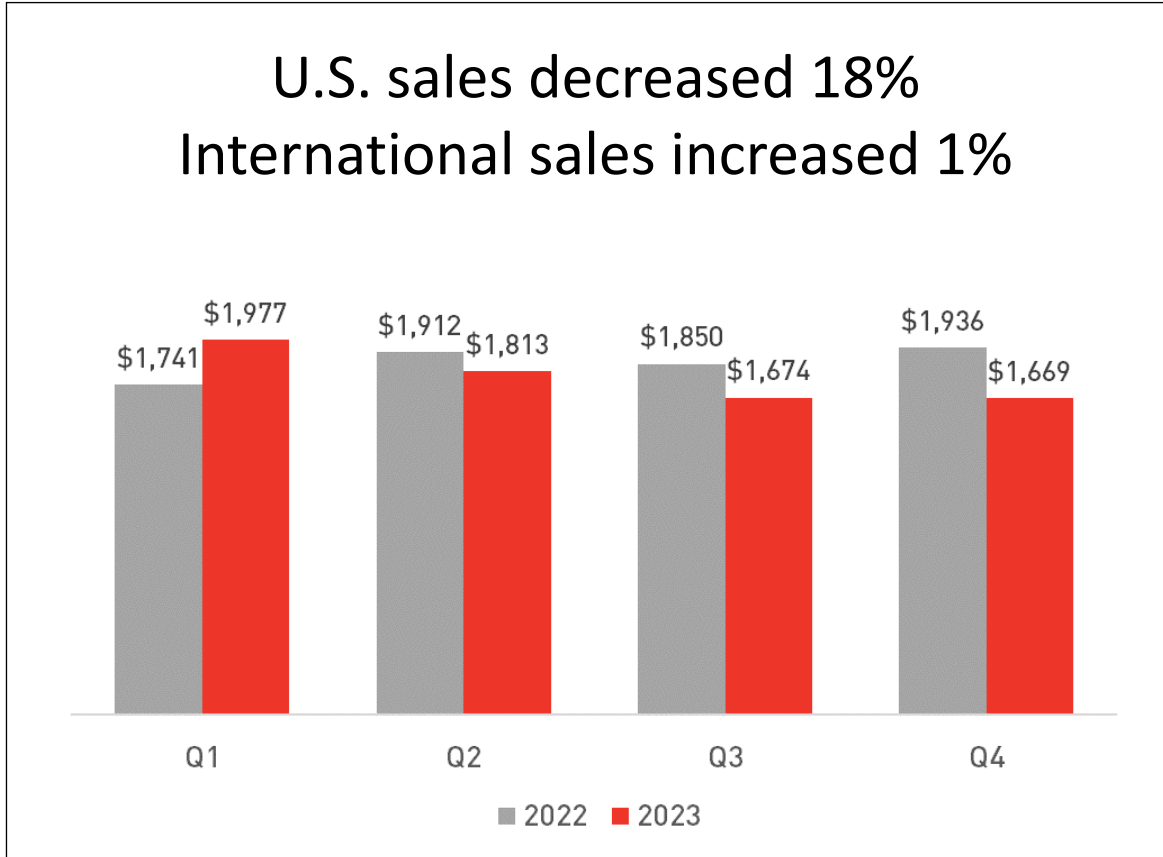
Millions



Source: IQVIA NPA TRx 3MMA, weekly data December 29, 2023; RA = rolling average  
TRx data is representative of the injectable incretin market

# Q4 2023 Trulicity Sales Decreased 14%

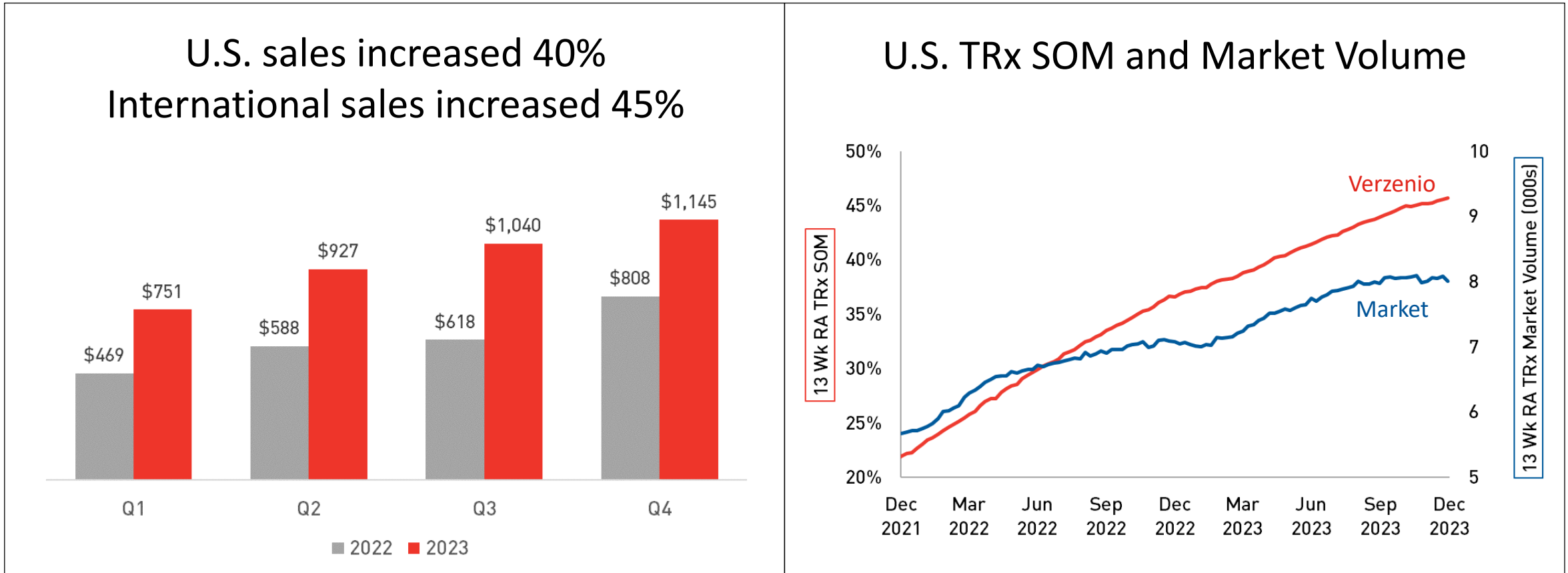
Millions



Source: IQVIA NPA TRx 3MMA, weekly data December 29, 2023; RA = rolling average  
TRx data is representative of the injectable incretin market

# Q4 2023 Verzenio Sales Increased 42%

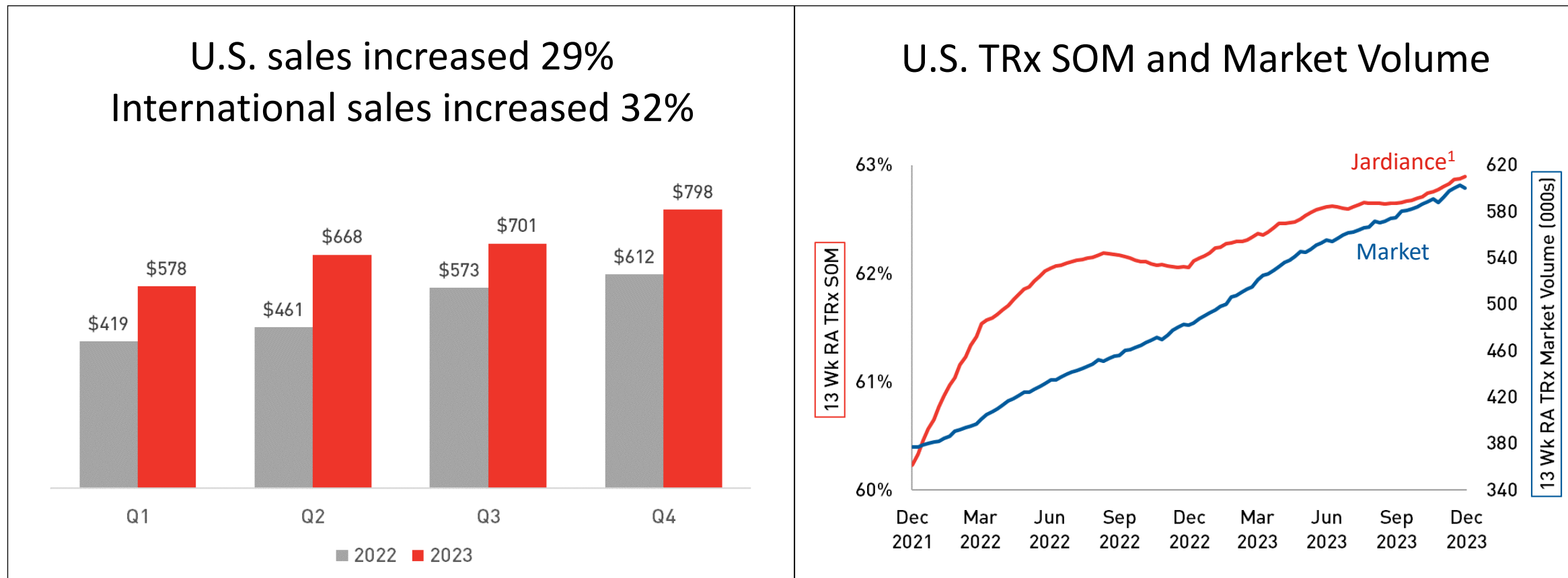
Millions



Source: IQVIA NPA TRx 3MMA, weekly data December 29, 2023; RA = rolling average

# Q4 2023 Jardiance Sales Increased 30%

Millions

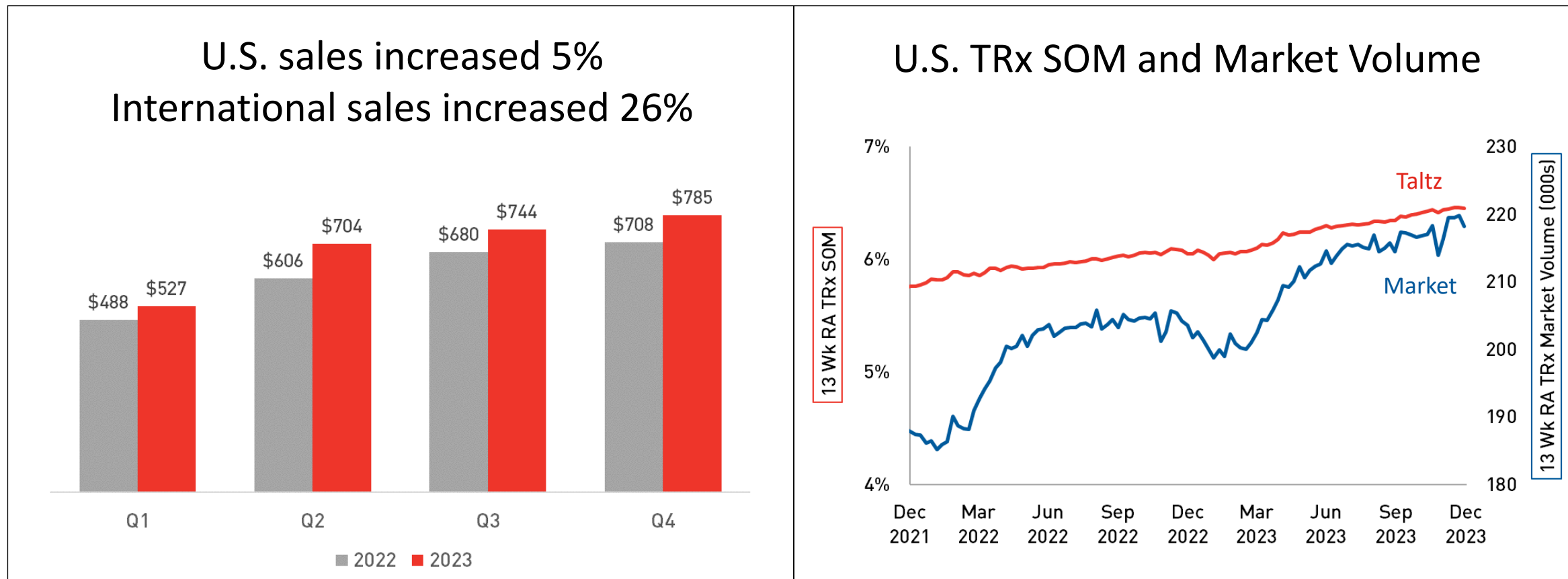


Source: IQVIA NPA TRx 3MMA, weekly data December 29, 2023; RA = rolling average  
<sup>1</sup>Jardiance includes Glyxambi and Synjardy. Jardiance is part of the company's alliance with Boehringer Ingelheim. Lilly reports as revenue royalties received on net sales of Jardiance.



# Q4 2023 Taltz Sales Increased 11%

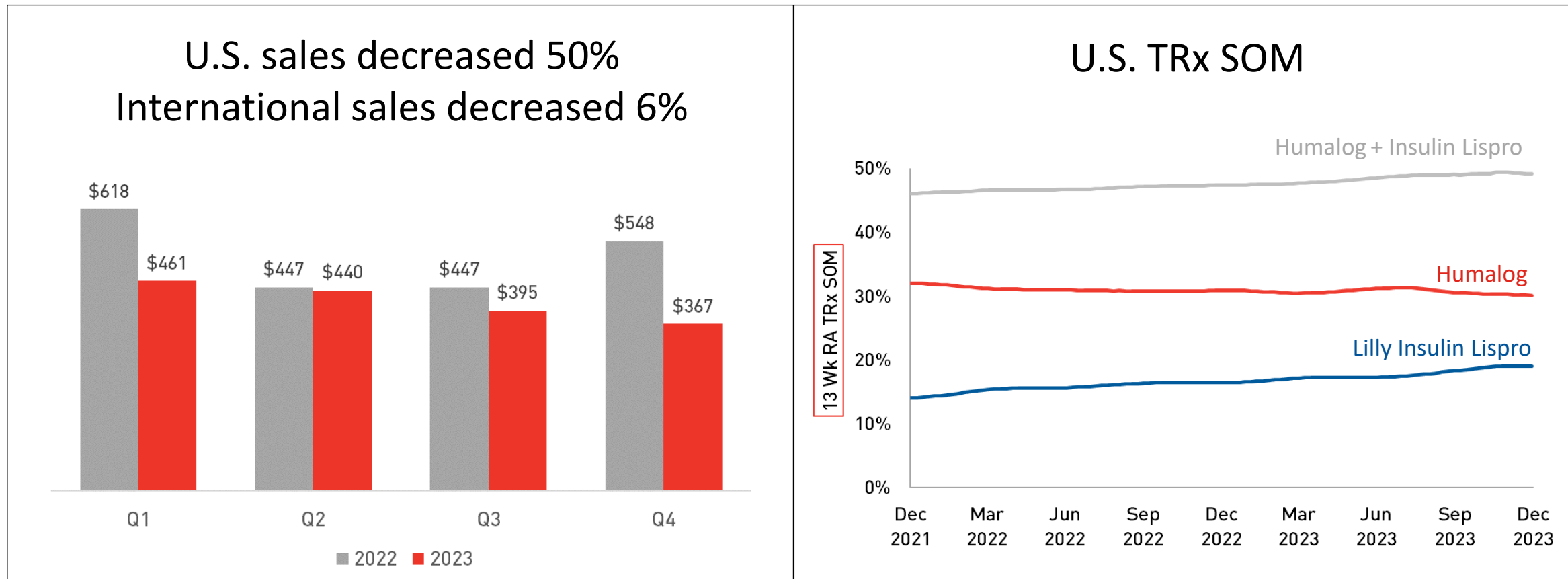
Millions



Source: IQVIA NPA TRx 3MMA, weekly data December 29, 2023; RA = rolling average  
TRx data is representative of the full molecule market

# Q4 2023 Humalog Sales Decreased 33%

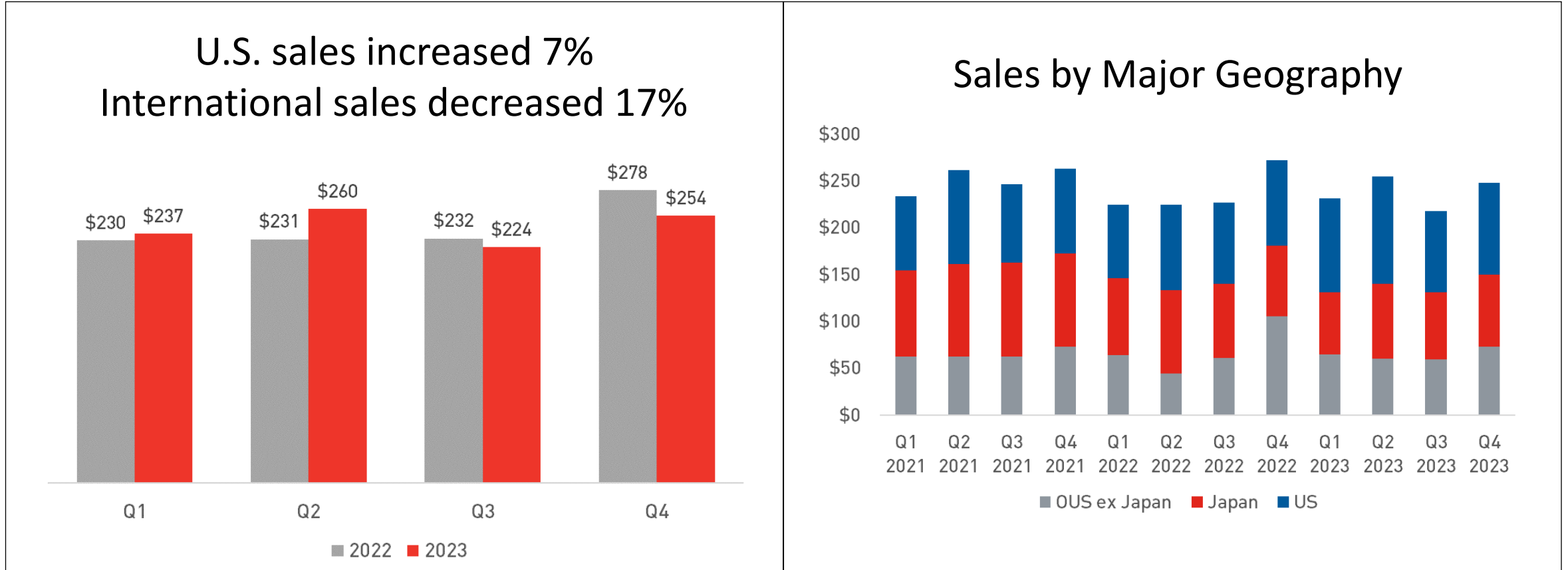
Millions



Source: IQVIA NPA TRx 3MMA, weekly data December 29, 2023; RA = rolling average

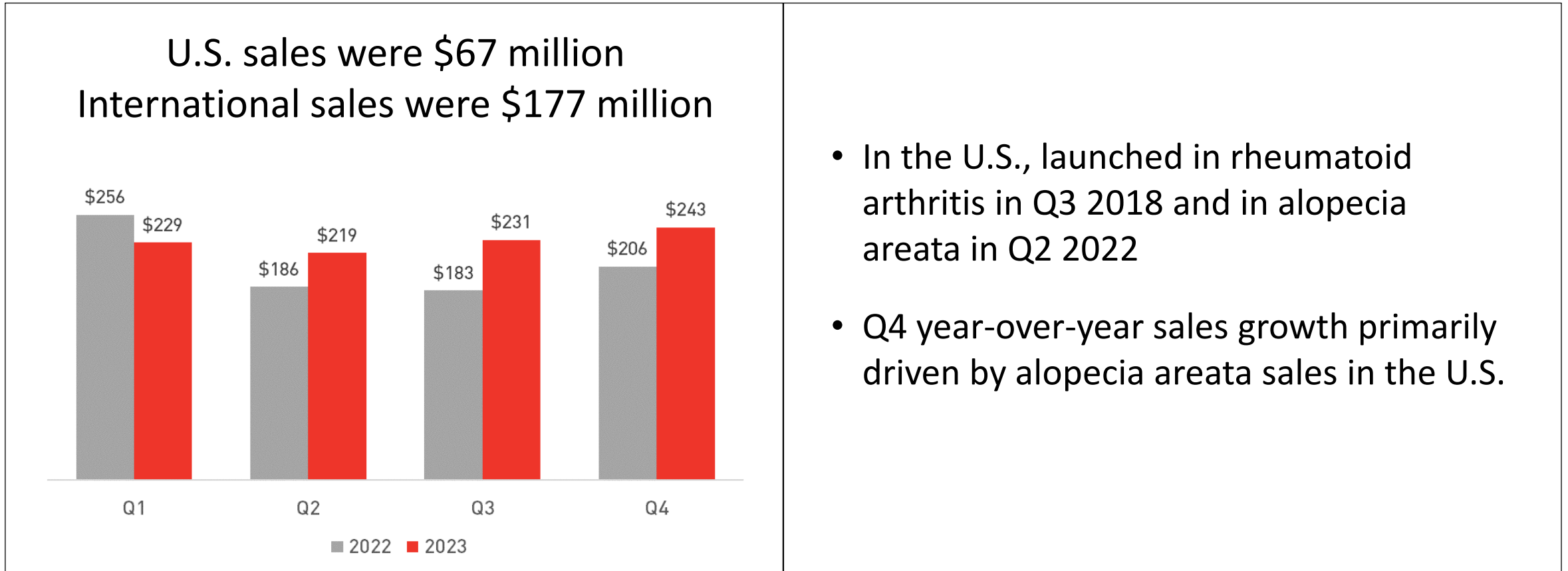
# Q4 2023 Cyramza Sales Decreased 9%

Millions



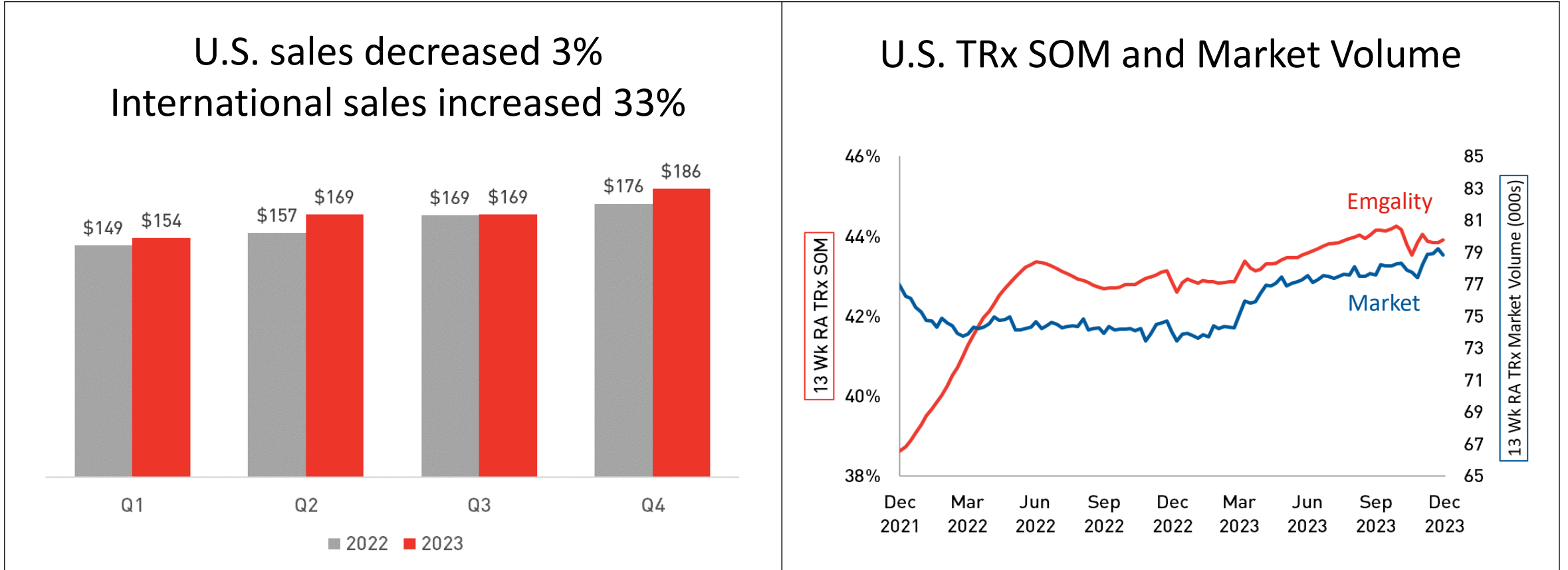
# Q4 2023 Olumiant Sales Increased 18%

Millions



# Q4 2023 Emgality Sales Increased 6%

Millions



Source: IQVIA NPA TRx 3MMA, weekly data December 29, 2023; RA = rolling average  
TRx data is representative of the injectable CGRP market

# Select Trials – Insulin Efsitora Alfa

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT05462756	Type 2 Diabetes	A Study of Insulin Efsitora Alfa (LY3209590) as a Weekly Basal Insulin Compared to Insulin Glargine in Adult Participants With Type 2 Diabetes on Multiple Daily Injections (QWINT-4)	3	730	Change from Baseline in Hemoglobin A1c (HbA1c)	Mar 2024	Mar 2024
NCT05362058	Diabetes	A Study of Insulin Efsitora Alfa (LY3209590) Compared to Degludec in Adults With Type 2 Diabetes Who Are Starting Basal Insulin for the First Time (QWINT-2)	3	912	Change from Baseline in Hemoglobin A1c (HbA1c)	Apr 2024	Apr 2024
NCT05275400	Type 2 Diabetes	A Study of Insulin Efsitora Alfa (LY3209590) Compared With Insulin Degludec in Participants With Type 2 Diabetes Currently Treated With Basal Insulin (QWINT-3)	3	986	Change from Baseline in Hemoglobin A1c (HbA1c)	May 2024	May 2024
NCT05662332	Type 2 Diabetes	A Study of Insulin Efsitora Alfa (LY3209590) Compared to Glargine in Adult Participants With Type 2 Diabetes Who Are Starting Basal Insulin for the First Time (QWINT-1)	3	796	Change from Baseline in Hemoglobin A1c (HbA1c)	Jul 2024	Jul 2024
NCT05463744	Type 1 Diabetes	A Study of Insulin Efsitora Alfa (LY3209590) Compared With Insulin Degludec in Participants With Type 1 Diabetes Treated With Multiple Daily Injection Therapy (QWINT-5)	3	692	Change from Baseline in Hemoglobin A1c (HbA1c)	May 2024	May 2024

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 22, 2024

# Select Trials – Donanemab

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04437511	Alzheimer Disease	A Study of Donanemab (LY3002813) in Participants With Early Alzheimer's Disease (TRAILBLAZER-ALZ 2)	3	1800	Change from Baseline on the integrated Alzheimer's Disease Rating Scale (iADRS)	Apr 2023	Aug 2025
NCT04640077	Alzheimer Disease	A Follow-On Study of Donanemab (LY3002813) With Video Assessments in Participants With Alzheimer's Disease (TRAILBLAZER-EXT)	2	90	Part A: Correlation between VTC and on-site assessment for PAIR 1 for Alzheimer's Disease Assessment Scale - Cognitive Subscale (ADAS-Cog13)	Mar 2024	Mar 2024
NCT05738486	Alzheimer Disease	A Study of Different Donanemab (LY3002813) Dosing Regimens in Adults With Early Alzheimer's Disease (TRAILBLAZER-ALZ 6)	3	800	Percentage of Participants with Any Occurrence of Amyloid-Related Imaging Abnormality-Edema/Effusion (ARIA-E)	Mar 2024	May 2025
NCT05508789	Alzheimer Disease	A Study of Donanemab (LY3002813) in Participants With Early Symptomatic Alzheimer's Disease (TRAILBLAZER-ALZ 5)	3	1500	Change from Baseline on the Integrated Alzheimer's Disease Rating Scale (iADRS)	Apr 2027	Apr 2027
NCT05026866	Alzheimer Disease	A Donanemab (LY3002813) Prevention Study in Participants With Alzheimer's Disease (TRAILBLAZER-ALZ 3)	3	2600	Time to clinical progression as measured by Clinical Dementia Rating - Global Score (CDR-GS)	Nov 2027	Nov 2027

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 18, 2024

# Select Trials – Imlunestrant

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04975308	Breast Neoplasms	A Study of Imlunestrant, Investigator's Choice of Endocrine Therapy, and Imlunestrant Plus Abemaciclib in Participants With ER+, HER2- Advanced Breast Cancer (EMBER-3)	3	860	Progression Free Survival (PFS) in the Intent-to-Treat (IIT) Population	Apr 2024	Aug 2027
NCT05514054	Breast Neoplasms	A Study of Imlunestrant Versus Standard Endocrine Therapy in Participants With Early Breast Cancer (EMBER-4)	3	6000	Invasive Disease-Free Survival (IDFS)	Oct 2027	Mar 2032

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 5, 2024



# Select Trials – Lebrikizumab

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT05369403	Atopic Dermatitis	A Study of Lebrikizumab (LY3650150) in Adult and Adolescent Participants With Moderate-to-Severe Atopic Dermatitis Previously Treated With Dupilumab (ADapt)	3	120	Percentage of Participants Achieving Eczema Area and Severity Index-75 (EASI-75) >75% Reduction in EASI Score	Jan 2024	Dec 2024
NCT05372419	Atopic Dermatitis	A Study of (LY3650150) Lebrikizumab to Assess the Safety and Efficacy of Adult and Adolescent Participants With Moderate-to-Severe Atopic Dermatitis and Skin of Color (ADmirable)	3	80	Percentage of Participants Achieving Eczema Area and Severity Index-75 (EASI-75) (≥75% reduction from baseline in EASI)	Mar 2024	Dec 2024
NCT05559359	Atopic Dermatitis	A Study of Lebrikizumab (LY3650150) in Participants 6 Months to <18 Years of Age With Moderate-to-Severe Atopic Dermatitis (ADorable-1)	3	300	Percentage of Participants Achieving Eczema Area and Severity Index-75 (EASI-75) ≥75% Reduction from Baseline in EASI Score	Jul 2024	Jun 2025
NCT04392154	Atopic Dermatitis	Long-term Safety and Efficacy Study of Lebrikizumab (LY3650150) in Participants With Moderate-to-Severe Atopic Dermatitis (ADjoin)	3	1000	Percentage of Participants Discontinued from Study Treatment due to Adverse Events through the Last Treatment Visit	Sep 2024	Sep 2024
NCT05735483	Atopic Dermatitis	A Study to Assess the Long-Term Safety and Efficacy of Lebrikizumab (LY3650150) in Participants 6 Months to <18 Years of Age With Moderate-to-Severe Atopic Dermatitis (ADorable-2)	3	250	Percentage of Participants Discontinued From Study Treatment due to Adverse Events (AEs)	Jun 2026	Jun 2026

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 18, 2024

# Select Trials – Mirikizumab

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04232553	Crohn's Disease	A Long-term Extension Study of Mirikizumab (LY3074828) in Participants With Crohn's Disease (VIVID-2)	3	778	Percentage of Participants Achieving Endoscopic Response	Jan 2025	Dec 2026
NCT03518086	Ulcerative Colitis	An Induction Study of Mirikizumab in Participants With Moderately to Severely Active Ulcerative Colitis (LUCENT-1)	3	1281	Percentage of Participants With Clinical Remission at Week 12	Jan 2021	Mar 2024
NCT03524092	Ulcerative Colitis	A Maintenance Study of Mirikizumab in Participants With Moderately to Severely Active Ulcerative Colitis (LUCENT-2)	3	1177	Percentage of Participants in Clinical Remission at Week 40	Nov 2021	Dec 2024
NCT03519945	Ulcerative Colitis	A Study to Evaluate the Long-Term Efficacy and Safety of Mirikizumab in Participants With Moderately to Severely Active Ulcerative Colitis (LUCENT-3)	3	1063	Percentage of Participants in Clinical Remission	Jul 2026	Dec 2027

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 22, 2024

# Select Trials – Orforglipron

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT05971940	Type 2 Diabetes	A Study of Orforglipron (LY3502970) in Adult Participants With Type 2 Diabetes and Inadequate Glycemic Control With Diet and Exercise (ACHIEVE-1)	3	520	Change from Baseline in Hemoglobin A1c (HbA1c)	Apr 2025	Apr 2025
NCT05803421	Type 2 Diabetes	A Study of Daily Oral Orforglipron (LY3502970) Compared With Insulin Glargine in Participants With Type 2 Diabetes and Obesity or Overweight at Increased Cardiovascular Risk (ACHIEVE-4)	3	2620	Time to First Occurrence of Any Major Adverse Cardiovascular Event (MACE-4) [Myocardial Infarction (MI), Stroke, Hospitalization for Unstable Angina, or Cardiovascular (CV) Death]	Apr 2025	Dec 2025
NCT06109311	Type 2 Diabetes	A Study of Orforglipron (LY3502970) in Participants With Type 2 Diabetes and Inadequate Glycemic Control With Insulin Glargine, With or Without Metformin and/or SGLT-2 Inhibitor (ACHIEVE-5)	3	520	Change from Baseline in Hemoglobin A1c (HbA1c) Compared to Placebo	Jun 2025	Jun 2025
NCT06010004	Type 2 Diabetes	A Long-term Safety Study of Orforglipron (LY3502970) in Participants With Type 2 Diabetes (ACHIEVE-J)	3	399	Number of Participants with Treatment Emergent Adverse Events (TEAEs)	Jun 2025	Jun 2025
NCT06045221	Type 2 Diabetes	A Study of Orforglipron (LY3502970) Compared With Semaglutide in Participants With Type 2 Diabetes Inadequately Controlled With Metformin (ACHIEVE-3)	3	1576	Change from Baseline in Hemoglobin A1c (HbA1c)	Jul 2025	Jul 2025
NCT06192108	Type 2 Diabetes	A Study of Orforglipron (LY3502970) Compared With Dapagliflozin in Adult Participants With Type 2 Diabetes and Inadequate Glycemic Control With Metformin (ACHIEVE-2)	3	888	Change from Baseline in Hemoglobin A1c (HbA1c)	Oct 2025	Oct 2025

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 23, 2024

# Select Trials – Orforglipron (Cont.)

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT05872620	Obesity	A Study of Orforglipron in Adult Participants With Obesity or Overweight and Type 2 Diabetes (ATTAIN-2)	3	1500	Mean Percent Change from Baseline in Body Weight	Jun 2025	Jun 2025
NCT05931380	Obesity	A Study of Once-Daily Oral Orforglipron (LY3502970) in Japanese Adult Participants With Obesity Disease (ATTAIN-J)	3	236	Mean Percent Change in Body Weight	Jun 2025	Jul 2025
NCT05869903	Obesity	A Study of Orforglipron (LY3502970) in Adult Participants With Obesity or Overweight With Weight-Related Comorbidities (ATTAIN-1)	3	3000	Mean Percent Change from Baseline in Body Weight	Sep 2025	Sep 2027

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 23, 2024

# Select Trials – Pirtobrutinib

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04666038	Chronic Lymphocytic Leukemia	Study of LOXO-305 Versus Investigator's Choice (IdelaR or BR) in Patients With Previously Treated Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) (BRUIN CLL-321)	3	250	To evaluate progression-free survival (PFS) of LOXO-305 monotherapy (Arm A) compared to investigator's choice of idelalisib plus rituximab (IdelaR) or bendamustine plus rituximab (BR) (Arm B)	Nov 2023	May 2027
NCT05023980	Chronic Lymphocytic Leukemia	A Study of Pirtobrutinib (LOXO-305) Versus Bendamustine Plus Rituximab (BR) in Untreated Patients With Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) (BRUIN CLL-313)	3	250	To evaluate progression-free survival (PFS) of pirtobrutinib (Arm A) compared to bendamustine and rituximab (Arm B)	Nov 2024	Jul 2026
NCT04965493	Chronic Lymphocytic Leukemia	A Trial of Pirtobrutinib (LOXO-305) Plus Venetoclax and Rituximab (PVR) Versus Venetoclax and Rituximab (VR) in Previously Treated Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) (BRUIN CLL-322)	3	600	To evaluate progression-free survival (PFS) of pirtobrutinib plus venetoclax and rituximab (Arm A) compared to venetoclax and rituximab (Arm B)	Oct 2025	Jan 2027
NCT05254743	Chronic Lymphocytic Leukemia	A Study of Pirtobrutinib (LOXO-305) Versus Ibrutinib in Participants With Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL) (BRUIN CLL-314)	3	650	Percentage of Participants Achieving Complete Response (CR) or Partial Response (PR): Overall Response Rate (ORR)	Mar 2028	Mar 2029
NCT04662255	Lymphoma, Mantle-Cell	Study of BTK Inhibitor LOXO-305 Versus Approved BTK Inhibitor Drugs in Patients With Mantle Cell Lymphoma (MCL) (BRUIN MCL-321)	3	500	To compare progression-free survival (PFS) of pirtobrutinib as monotherapy (Arm A) to investigator choice of covalent BTK inhibitor monotherapy (Arm B) in patients with previously treated mantle cell lymphoma (MCL)	Apr 2025	Apr 2025

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 25, 2024

# Select Trials – Remternetug

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT05463731	Alzheimer Disease	A Study of Remternetug (LY3372993) in Participants With Alzheimer's Disease (TRAILRUNNER-ALZ 1)	3	600	Percentage of Participants Who Reach Amyloid Plaque Clearance on Amyloid PET Scan for Remternetug versus Placebo	Oct 2025	Oct 2026

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 16, 2024

# Select Trials – Retatrutide

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT05936151	Chronic Kidney Disease	A Study of Retatrutide (LY3437943) on Renal Function in Participants With Overweight or Obesity and Chronic Kidney Disease With or Without Type 2 Diabetes	2	120	Change from Baseline in Glomerular Filtration Rate (GFR)	Nov 2025	Nov 2025
NCT05882045	Obesity	A Study of Retatrutide (LY3437943) in Participants With Obesity and Cardiovascular Disease (TRIUMPH-3)	3	1800	Percent Change from Baseline in Body Weight	Jan 2026	Feb 2026
NCT05931367	Obesity	A Study of Retatrutide (LY3437943) Once Weekly in Participants Who Have Obesity or Overweight and Osteoarthritis of the Knee (TRIUMPH-4)	3	405	Percent Change from Baseline in Body Weight and Change from Baseline in the Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) Pain Subscale Score	Feb 2026	Mar 2026
NCT05929066	Obesity	A Study of Retatrutide (LY3437943) in Participants Who Have Obesity or Overweight (TRIUMPH-1)	3	2100	Percent Change From Baseline in Body Weight	Apr 2026	May 2026
NCT05929079	Obesity	A Study of Retatrutide (LY3437943) in Participants With Type 2 Diabetes Mellitus Who Have Obesity or Overweight (TRIUMPH-2)	3	1000	Percent Change from Baseline in Body Weight	May 2026	May 2026

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 19, 2024

# Select Trials – Retevmo

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04211337	Medullary Thyroid Cancer	A Study of Selpercatinib (LY3527723) in Participants With RET-Mutant Medullary Thyroid Cancer (LIBRETTO-531)	3	291	Progression Free Survival (PFS) by Blinded Independent Central Review (BICR)	May 2023	Feb 2026
NCT04194944	Non-Small Cell Lung Cancer	A Study of Selpercatinib (LY3527723) in Participants With Advanced or Metastatic RET Fusion-Positive Non-Small Cell Lung Cancer (LIBRETTO-431)	3	261	Progression Free Survival (PFS) by Blinded Independent Central Review (BICR) (with Pembrolizumab)	May 2023	Jun 2026
NCT03157128	Non-Small Cell Lung Cancer	A Study of Selpercatinib (LOXO-292) in Participants With Advanced Solid Tumors, RET Fusion-Positive Solid Tumors, and Medullary Thyroid Cancer (LIBRETTO-001)	1 2	875	Phase 1: MTD; Phase 2: ORR	Feb 2025	Feb 2026
NCT04819100	Carcinoma, Non-Small-Cell Lung	A Study of Selpercatinib After Surgery or Radiation in Participants With Non-Small Cell Lung Cancer (NSCLC) (LIBRETTO-432)	3	170	Event-Free Survival (EFS)	May 2027	Aug 2032

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 18, 2024



# Select Trials – Tirzepatide

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04184622	Obesity	A Study of Tirzepatide (LY3298176) in Participants With Obesity or Overweight (SURMOUNT-1)	3	2539	Percent Change from Baseline in Body Weight	Apr 2022	Jul 2024
NCT05822830	Obesity	A Study of Tirzepatide (LY3298176) in Participants With Obesity or Overweight With Weight Related Comorbidities (SURMOUNT-5)	3	700	Percent Change from Baseline in Body Weight	Nov 2024	Nov 2024
NCT06047548	Obesity	A Study of LY3298176 (Tirzepatide) For the Maintenance of Body Weight Reduction in Participants Who Have Obesity or Overweight With Weight-Related Comorbidities (SURMOUNT-MAINTAIN)	3	400	Percent Maintenance of Body Weight (BW) Reduction Achieved during the 60-Week Weight Loss Period	May 2026	May 2026
NCT06075667	Obesity	A Study of Tirzepatide (LY3298176) Once Weekly in Adolescent Participants Who Have Obesity or Overweight With Weight-Related Comorbidities (SURMOUNT-ADOLESCENTS)	3	150	Percent Change from Baseline in Body Mass Index (BMI)	Oct 2026	Oct 2026
NCT05556512	Obesity	A Study of Tirzepatide (LY3298176) on the Reduction on Morbidity and Mortality in Adults With Obesity (SURMOUNT-MMO)	3	15000	Time to First Occurrence of Any Component Event of Composite (All-Cause Death, Nonfatal Myocardial Infarction (MI), Nonfatal Stroke, Coronary Revascularization, or Heart Failure Events)	Oct 2027	Oct 2027

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 25, 2024

# Select Trials – Tirzepatide (Cont.)

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04255433	Type 2 Diabetes	A Study of Tirzepatide (LY3298176) Compared With Dulaglutide on Major Cardiovascular Events in Participants With Type 2 Diabetes (SURPASS-CVOT)	3	13299	Time to First Occurrence of Death from Cardiovascular (CV) Causes, Myocardial Infarction (MI), or Stroke (MACE-3)	Oct 2024	Oct 2024
NCT05260021	Type 2 Diabetes	A Study to Evaluate Tirzepatide (LY3298176) in Pediatric and Adolescent Participants With Type 2 Diabetes Mellitus Inadequately Controlled With Metformin or Basal Insulin or Both (SURPASS-PEDS)	3	90	Change From Baseline in Hemoglobin A1c (HbA1c)	Nov 2024	Dec 2024
NCT06037252	Type 2 Diabetes	A Study of Investigational Tirzepatide (LY3298176) Doses in Participants With Type 2 Diabetes and Obesity	2	350	Percent Change From Baseline in Body Weight	Jan 2025	Oct 2025

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 25, 2024

# Select Trials – Tirzepatide (Cont.)

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04166773	Nonalcoholic Steatohepatitis	A Study of Tirzepatide (LY3298176) in Participants With Nonalcoholic Steatohepatitis (SYNERGY-NASH)	2	196	Percentage of Participants with Absence of NASH with no Worsening of Fibrosis on Liver Histology	Jan 2024	Feb 2024
NCT05412004	Sleep Apnea	Obstructive Sleep Apnea Master Protocol GPIF: A Study of Tirzepatide (LY3298176) in Participants With Obstructive Sleep Apnea (SURMOUNT-OSA)	3	469	Change from Baseline in Apnea-Hypopnea Index (AHI)	Mar 2024	Mar 2024
NCT04847557	HFpEF	A Study of Tirzepatide (LY3298176) in Participants With Heart Failure With Preserved Ejection Fraction and Obesity (SUMMIT)	3	700	A Hierarchical Composite of All-Cause Mortality, Heart Failure Events, 6-minute Walk Test Distance (6MWD) and Kansas City Cardiomyopathy Questionnaire (KCCQ) Clinical Summary Score (CSS) Category	Jun 2024	Jul 2024
NCT05536804	CKD	A Study of Tirzepatide (LY3298176) in Participants With Overweight or Obesity and Chronic Kidney Disease With or Without Type 2 Diabetes (TREASURE-CKD)	2	140	Change from Baseline in Kidney Oxygenation in Participants With or Without T2D [ Time Frame: Baseline, Week 52 ]; Blood oxygenation-level dependent magnetic resonance imaging (BOLD MRI)	Jan 2026	Feb 2026

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 25, 2024

# Select Trials – Verzenio

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03155997 <sup>1</sup>	Breast Cancer	Endocrine Therapy With or Without Abemaciclib (LY2835219) Following Surgery in Participants With Breast Cancer (monarchE)	3	5637	Invasive Disease-Free Survival (IDFS)	Mar 2020	May 2029
NCT05169567	Breast Neoplasm	Abemaciclib (LY2835219) Plus Fulvestrant Compared to Placebo Plus Fulvestrant in Previously Treated Breast Cancer (postMonarch)	3	350	Progression-Free Survival (PFS)	Feb 2024	Feb 2026
NCT03706365	Prostate Cancer	A Study of Abiraterone Acetate Plus Prednisone With or Without Abemaciclib (LY2835219) in Participants With Prostate Cancer (CYCLONE 2)	2 3	350	Radiographic Progression-Free Survival (rPFS)	Jan 2024	Jun 2026
NCT05288166	Prostatic Neoplasms	A Study of Abemaciclib (LY2835219) With Abiraterone in Men With Prostate Cancer That Has Spread to Other Parts of the Body and is Expected to Respond to Hormonal Treatment (Metastatic Hormone-Sensitive Prostate Cancer) (CYCLONE 3)	3	900	Radiographic Progression-Free Survival (rPFS) Assessed by Investigator	Oct 2025	Oct 2027

<sup>1</sup> Also lists NSABP Foundation Inc

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, December 12, 2023

# Select Trials – Early Phase Diabetes and Obesity

Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
Lepodisiran	NCT05565742	Lipoprotein Disorder	A Study of LY3819469 in Participants With Elevated Lipoprotein(a) [Lp(a)] (ALPACA)	2	254	Percent Change from Baseline in Time Averaged Lipoprotein(a) [Lp(a)]	Oct 2023	Oct 2024
Muvalaplin	NCT05563246	Lipoprotein Disorder	A Study of LY3473329 in Adult Participants With Elevated Lipoprotein(a) at High Risk for Cardiovascular Events (KRAKEN)	2	233	Percent Change from Baseline in Lipoprotein (a) Lp(a)	Mar 2024	Mar 2024
Solbinsiran	NCT05256654	Dyslipidemias	A Study of LY3561774 in Participants With Mixed Dyslipidemia (PROLONG-ANG3)	2	175	Percent Change from Baseline for Apolipoprotein B (ApoB)	Mar 2024	Jun 2024
Bimagrumab	NCT05616013	Obesity	Safety and Efficacy of Bimagrumab and Semaglutide in Adults who are Overweight or Obese	2	507	Change from baseline in body weight at 48 weeks	May 2024	Jun 2025
Volenrelaxin	NCT05592275	Heart Failure	A Study of LY3540378 in Participants With Worsening Chronic Heart Failure With Preserved Ejection Fraction (HFpEF)	2	432	Change from Baseline in Left Atrial Reservoir Strain (LARS)	Nov 2024	Jan 2025
Mazdutide	NCT06124807	Obesity	A Study of LY3305677 Compared With Placebo in Adult Participants With Obesity or Overweight	2	165	Percent Change from Baseline in Body Weight	Nov 2024	May 2025

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 30, 2024

# Select Trials – Early Phase Diabetes and Obesity (Cont.)

Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
GIPR Agonist LA II	NCT05407961	Diabetes Mellitus, Type 2	A Study of LY3532226 in Participants With Type 2 Diabetes Mellitus	1	92	Part A: Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Jan 2024	Jan 2024
Amylin Agonist LA	NCT05295940	Obesity	A Study of LY3841136 in Healthy and Overweight Participants	1	160	Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Jan 2024	Jan 2024
DACRA QW II	NCT05380323	Obesity	A Study of LY3541105 in Healthy and Overweight Participants	1	160	Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Aug 2024	Aug 2024
GS Insulin Receptor Agonist	NCT06132126	Healthy	A Study to Investigate the Safety and Tolerability of LY3938577 in Healthy Participants and Participants With Type 2 Diabetes Mellitus	1	88	Part A: Number of participants with one or more Adverse Event (s) (AEs), and Serious Adverse Event(s) (SAEs) considered by the investigator to be related to study drug administration	Aug 2024	Aug 2024
LA-ANP	NCT06148272	Healthy	A Study of LY3971297 in Healthy Participants and Participants With Obesity and Hypertension	1	188	Part A: Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Oct 2024	Oct 2024

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 30, 2024

# Select Trials – Early Phase Diabetes and Obesity (Cont.)

Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
APOC3 siRNA	NCT05609825	Hypertriglyceridemia	A Study of LY3875383 in Healthy Participants and Participants With Hypertriglyceridemia	1	120	Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Jan 2024	Jan 2024
NRG4 Agonist	NCT04840914	HFrEF	A Study of LY3461767 in Participants With Chronic Heart Failure With Reduced Ejection Fraction	1	50	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Mar 2024	Jul 2024
PNPLA3 siRNA	NCT05395481	Non-Alcoholic Fatty Liver Disease	A Single-Ascending and Repeated Dose Study of LY3849891 in Participants With Nonalcoholic Fatty Liver Disease	1	176	Part A: Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Nov 2024	Nov 2024
SCAP siRNA	NCT06007651	Dyslipidemias	A Study of LY3885125 in Participants With Dyslipidemia or Non-Alcoholic Fatty Liver Disease (NAFLD)	1	112	Part A: Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Apr 2025	Apr 2025

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 30, 2024

# Select Trials – Early Phase Immunology

Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
Peresolimab	NCT05516758	Rheumatoid Arthritis	A Study of Peresolimab (LY3462817) in Participants With Moderately-to-Severely Active Rheumatoid Arthritis (RESOLUTION-1)	2	491	Percentage of Participants Achieving American College of Rheumatology (ACR)20	Nov 2023	Jan 2025
DC-806	NCT05896527	Plaque Psoriasis	A Study to Evaluate the Efficacy and Safety of DC-806 in Participants With Moderate to Severe Plaque Psoriasis (ILLUMINATE)	2	229	Proportion of participants achieving a 75% reduction in Psoriasis Area of Severity Index score (PASI-75)	Feb 2024	Mar 2024
Ucenprubart	NCT05911841	Atopic Dermatitis	A Study of LY3454738 in the Treatment of Adult Participants With Moderate-to-Severe Atopic Dermatitis	2	260	Percentage of Participants Achieving Eczema Area and Severity Index (EASI) 75	Sep 2024	May 2025
Eltrekibart	NCT06046729	Hidradenitis Suppurativa	A Study of Eltrekibart (LY3041658) in Adult Participants With Moderate to Severe Hidradenitis Suppurativa	2	350	Percentage of Participant Achieving Hidradenitis Suppurativa Clinical Response 50 (HiSCR50)	May 2025	Mar 2026

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 24, 2024



# Select Trials – Early Phase Immunology (Cont.)

Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
Itaconate Mimetic	NCT06153355	Healthy	A First-In-Human Study of LY3839840 in Healthy Participants	1	112	Number of participants with one or more Adverse Event (s) (AEs), Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) considered by the investigator to be related to study drug administration	Jun 2024	Jun 2024
CD19	NCT05042310	Healthy	A Study of LY3541860 in Healthy Japanese and Non-Japanese Participants	1	84	Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Jun 2024	Jun 2024
KV1.3 Antagonist	NCT06176768	Plaque Psoriasis	A Study of LY3972406 in Adult Participants With Moderate-to-Severe Plaque Psoriasis	2	75	Percentage of Participants Achieving Psoriasis Area and Severity Index (PASI 75)	Apr 2025	Jul 2025
Ocadusertib (RIPK1 Inhibitor) <sup>1</sup>	NCT05848258	Rheumatoid Arthritis	An Adaptive Phase 2a/2b Study of LY3871801 in Adult Participants With Rheumatoid Arthritis	2	380	Phase 2a: Change from Baseline in Disease Activity Score - high-sensitivity C-reactive protein (DAS28-hsCRP)	Feb 2026	Jul 2026

<sup>1</sup> Also lists Rigel Pharmaceuticals

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 24, 2024

# Select Trials – Early Phase Neurodegeneration

Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
O-GlcNAcase Inh.	NCT05063539	Alzheimer Disease	A Study of LY3372689 to Assess the Safety, Tolerability, and Efficacy in Participants With Alzheimer's Disease	2	330	Change from Baseline to End Time Point in Integrated Alzheimer's Disease Rating Scale (iADRS)	Jul 2024	Aug 2024
SARM1 CNS Inhibitor	NCT05492201	Healthy	A Study of LY3873862 in Healthy Participants	1	90	Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Jan 2024	Jan 2024

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 23, 2024

# Select Trials – Early Phase Neurodegeneration (Cont.)

Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
OTOF Gene Therapy	NCT05821959	Sensorineural Hearing Loss, Bilateral	Gene Therapy Trial for Otoferlin Gene-mediated Hearing Loss	1 2	14	Frequency of Adverse Events (AEs)	Oct 2028	Oct 2028
GBA1 Gene Therapy	NCT04411654	Gaucher Disease, Type 2	Phase 1/2 Clinical Trial of PR001 in Infants With Type 2 Gaucher Disease (PROVIDE)	1 2	15	Number of Adverse Events (AEs), Serious Adverse Events (SAEs), and Adverse Events leading to discontinuation	Dec 2028	Dec 2028
GRN Gene Therapy	NCT04408625	Frontotemporal Dementia	Phase 1/2 Clinical Trial of PR006 in Patients With Frontotemporal Dementia With Progranulin Mutations (FTD-GRN) (PROCLAIM)	1 2	23	Number of Adverse Events (AEs), Serious Adverse Events (SAEs), and Adverse Events Leading to discontinuation	Aug 2029	Aug 2029
GBA1 Gene Therapy	NCT04127578	Parkinson Disease	Phase 1/2a Clinical Trial of PR001 (LY3884961) in Patients With Parkinson's Disease With at Least One GBA1 Mutation (PROPEL)	1 2	20	Cumulative number of Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)	Jun 2029	Jun 2029
GBA1 Gene Therapy	NCT05487599	Gaucher Disease	A Clinical Trial of PR001 (LY3884961) in Patients With Peripheral Manifestations of Gaucher Disease (PROCEED)	1 2	15	Incidence and severity of Treatment-emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)	Sep 2030	Sep 2030

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 23, 2024

# Select Trials – Early Phase Oncology

Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
Olomorasib (KRAS G12C II)	NCT06119581	Carcinoma, Non-Small-Cell Lung	A Study of LY3537982 Plus Immunotherapy With or Without Chemotherapy in Participants With Non-Small Cell Lung Cancer (NSCLC) With a Change in a Gene Called KRAS G12C (SUNRAY-01)	3	1016	PFS per Response Evaluation Criteria in Solid Tumors (RECIST) v1.1 by blinded independent central review (BICR)	Oct 2026	Oct 2029
Olomorasib (KRAS G12C II) <sup>1</sup>	NCT04956640	Carcinoma, Non-Small-Cell Lung	Study of LY3537982 in Cancer Patients With a Specific Genetic Mutation (KRAS G12C)	1 2	450	Phase 1a: To determine the recommended phase 2 dose (RP2D) of LY3537982 monotherapy	Sep 2025	Sep 2025
PI3K Selective	NCT05307705	Breast Cancer	A Study of LOXO-783 in Patients With Breast Cancer/Other Solid Tumors (PIKASSO-01)	1	400	Phase 1a: To determine the MTD/RP2D of LOXO-783: Number of patients with dose-limiting toxicities (DLTs)	May 2025	May 2025
FGFR3 Selective	NCT05614739	Urinary Bladder Neoplasms	A Study of LOXO-435 in Participants With Cancer With a Change in a Gene Called FGFR3	1	180	Phase 1a: To determine the recommended phase 2 dose (RP2D)/optimal dose of LOXO-435: Safety, number of participants with dose-limiting toxicities (DLTs)	Jun 2025	Jun 2025

<sup>1</sup> Also lists Merck Sharp & Dohme LLC

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, January 25, 2024

# Select Trials – Early Phase Pain

Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
SSTR4 Agonist	NCT06074562	Diabetic Peripheral Neuropathy	A Study of LY3556050 in Adult Participants With Diabetic Peripheral Neuropathic Pain	2	410	Mean Change from Baseline for Average Pain Intensity Numeric Rating Scale (API-NRS)	Jan 2025	Jan 2025

\* Molecule may have multiple indications

\*\* Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, October 23, 2023

*Lilly*