



# Q3 2023 Earnings Call

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**NOVEMBER 2, 2023**

# Agenda

## **INTRODUCTION AND RECENT KEY EVENTS**

Dave Ricks, Chair and Chief Executive Officer

## **Q3 2023 FINANCIAL RESULTS**

Anat Ashkenazi, Chief Financial Officer

## **R&D UPDATE**

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

## **CLOSING REMARKS**

Dave Ricks, Chair and Chief Executive Officer

## **QUESTION AND ANSWER SESSION**

2023 **Q3 EARNINGS**

# 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.

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

# STRATEGIC DELIVERABLES

## PROGRESS SINCE THE LAST EARNINGS CALL



### Invest in Current Portfolio



- **Gross Margin:** Non-GAAP gross margin of 81.7% in Q3
- **SG&A:** 12% increase in Q3 primarily driven by launches of new products and indications as well as compensation and benefit costs

### Invest in Future Innovation



- **R&D:** 34% increase in Q3 driven primarily by late-stage assets and early-stage research
- **Business Development:** Completed the acquisitions of DICE Therapeutics, Versanis Bio, Emergence Therapeutics and Sigilon Therapeutics; announced the potential acquisition of POINT Biopharma

### Deliver Revenue Growth



- Excluding the olanzapine portfolio and COVID-19 antibodies<sup>1</sup>, revenue grew 24% in Q3
- Together, New Products and Growth Products<sup>2</sup> contributed approximately 17 percentage points of volume growth in Q3

### Speed Life-Changing Medicines



- FDA approval of **Omvo**<sup>TM</sup> for the treatment of adults with moderately to severely active ulcerative colitis and **Jardiance**<sup>®3</sup> for the treatment of adults with chronic kidney disease at risk of progression
- Positive CHMP opinion in the EU and CRL in the U.S. for **lebrikizumab** for the treatment of moderate-to-severe atopic dermatitis
- Positive results in the Phase 3 VIVID-1 study of **mirikizumab** in moderately to severely active Crohn's disease

### Return Capital to Shareholders via:

- **Dividend:** Distributed over \$1 billion in Q3
- **Share Repurchase:** \$750 million YTD

<sup>1</sup> Sales for COVID-19 antibodies include bamlanivimab, etesevimab and bebtelovimab sold pursuant to Emergency Use Authorization or similar regulatory authorizations

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

<sup>3</sup> Jardiance is part of the Boehringer Ingelheim (BI) and Lilly Alliance, and BI holds the marketing authorization for Jardiance.

# KEY EVENTS SINCE THE LAST EARNINGS CALL



## REGULATORY

- Announced the U.S. Food and Drug Administration (FDA) approved:
  - **Omvo** for the treatment of adults with moderately to severely active ulcerative colitis; and
  - **Jardiance**<sup>1</sup> for the treatment of adults with chronic kidney disease at risk of progression.
- Announced the FDA issued a complete response letter for the application of **lebrikizumab** for the treatment of moderate-to-severe atopic dermatitis based on inspection findings at a third-party manufacturer;
- Announced updated timing of expected FDA action on **donanemab** for the treatment of early symptomatic Alzheimer's disease to Q1 2024.

## CLINICAL

- Announced positive results in the **mirikizumab** Phase 3 VIVID-1 study, which evaluated the safety and efficacy for the treatment of adults with moderately to severely active Crohn's disease;
- For **tirzepatide** Phase 3 studies in adults with obesity or overweight with weight-related comorbidities excluding type 2 diabetes:
  - Published SURMOUNT-3 results in Nature Medicine and presented at the Obesity Week conference; and
  - Presented SURMOUNT-4 data at the European Association for the Study of Diabetes (EASD) Annual Meeting.
- Published **muvalaplin** Phase 1 data in The Journal of the American Medical Association (JAMA) and presented at the European Society of Cardiology Congress showing dose dependent lowering of Lp(a);
- Presented **Verzenio**<sup>®</sup> data at the European Society for Medical Oncology (ESMO) Congress showing five-year results from the Phase 3 monarchE study in HR+ HER2-, node-positive early breast cancer at a high risk of recurrence;

## CLINICAL (CONT)

- Published **Retevmo**<sup>®</sup> Phase 3 data in The New England Journal of Medicine (NEJM) and presented at the ESMO Congress showing results from LIBRETTO-431 in RET fusion-positive non-small cell lung cancer and LIBRETTO-531 in advanced RET-mutant medullary thyroid cancer; and
- Presented new insights from a post hoc analysis of the **donanemab** Phase 3 TRAILBLAZER-ALZ 2 study at the Clinical Trials on Alzheimer's Disease Conference related to ARIA frequency as well as activities of daily living and independence in people with early symptomatic Alzheimer's disease.

## OTHER

- Announced an agreement to acquire **POINT Biopharma Global, Inc.**, a radiopharmaceutical company to expand oncology capabilities into next-generation radioligand therapies;
- Completed the acquisitions of **DICE Therapeutics, Inc.**, **Versanis Bio, Inc.**, **Emergence Therapeutics AG** and **Sigilon Therapeutics, Inc.**;
- Announced the following leadership changes, effective at the end of 2023:
  - **Mike Mason**, president of Lilly Diabetes and Obesity will retire;
  - **Patrik Jonsson**, currently president of Lilly Immunology, will assume leadership of Lilly Diabetes and Obesity in addition to his current responsibility as president of Lilly USA;
  - **Dan Skovronsky**, currently chief scientific and medical officer, will take on the additional role of president of Lilly Immunology; **David Hyman** will become Lilly's chief medical officer, reporting to Skovronsky; and
  - **Leigh Ann Pusey**, executive vice president of corporate affairs and communications will leave the company.

<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.

# RECONCILIATION OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION; CERTAIN LINE ITEMS (UNAUDITED)



Millions; except per share data

Q3 2023

	GAAP Reported	Adjustments	Non-GAAP Adjusted	YoY Non-GAAP Adjusted Change
TOTAL REVENUE	<b>\$9,499</b>	\$ -	<b>\$9,499</b>	37%
GROSS MARGIN	<b>80.4%</b>	1.3pp	<b>81.7%</b>	2.7pp
TOTAL OPERATING EXPENSE	<b>7,188</b>	-	<b>7,188</b>	107%
OPERATING INCOME	<b>450</b>	125	<b>575</b>	(71)%
OPERATING MARGIN	<b>4.7%</b>	1.4pp	<b>6.1%</b>	(22.9)pp
OTHER INCOME (EXPENSE)	<b>(23)</b>	65	<b>42</b>	NM
EFFECTIVE TAX RATE	<b>113.4%</b>	(28.8)pp	<b>84.6%</b>	73.9pp
NET INCOME	<b>\$(57)</b>	\$152	<b>\$95</b>	(95)%
EPS	<b>\$(0.06)</b>	\$0.16	<b>\$0.10</b>	(95)%
Acquired IPR&D Charges per share*	<b>\$3.29</b>	\$ -	<b>\$3.29</b>	NM

\*Acquired IPR&D of \$2.975 billion (pre-tax)

Numbers may not add due to rounding; see slide 21 for a complete list of adjustments; NM = not meaningful

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2023 Q3 EARNINGS

# RECONCILIATION OF GAAP REPORTED TO NON-GAAP ADJUSTED INFORMATION; CERTAIN LINE ITEMS (UNAUDITED)



Millions; except per share data

YTD 2023

	GAAP Reported	Adjustments	Non-GAAP Adjusted	YoY Non-GAAP Adjusted Change
TOTAL REVENUE	<b>\$24,771</b>	\$ -	<b>\$24,771</b>	17%
GROSS MARGIN	<b>78.6%</b>	1.5pp	<b>80.1%</b>	1.9pp
TOTAL OPERATING EXPENSE	<b>15,406</b>	-	<b>15,406</b>	45%
OPERATING INCOME	<b>4,070</b>	377	<b>4,447</b>	(25)%
OPERATING MARGIN	<b>16.4%</b>	1.6pp	<b>18.0%</b>	(10.0)pp
OTHER INCOME (EXPENSE)	<b>(24)</b>	142	<b>117</b>	NM
EFFECTIVE TAX RATE	<b>24.6%</b>	(0.5)pp	<b>24.1%</b>	12.8pp
NET INCOME	<b>\$3,051</b>	\$412	<b>\$3,463</b>	(35)%
EPS	<b>\$3.38</b>	\$0.45	<b>\$3.83</b>	(35)%
Acquired IPR&D Charges per share*	<b>\$3.48</b>	\$ -	<b>\$3.48</b>	NM

\*Acquired IPR&D of \$3.177 billion (pre-tax)

Numbers may not add due to rounding; see slide 21 for a complete list of adjustments; NM = not meaningful

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2023 Q3 EARNINGS

# PRICE/RATE/VOLUME EFFECT ON REVENUE



Millions

Q3 2023

	Amount	Price	FX Rate	Volume	Total	CER
U.S.	\$5,368	13%	-	9%	21%	21%
EUROPE	2,569	(11)%	7%	147%	143%	136%
JAPAN	391	(2)%	(4)%	(14)%	(20)%	(16)%
CHINA	391	(5)%	(6)%	25%	14%	20%
REST OF WORLD	780	(4)%	0%	28%	23%	23%
TOTAL REVENUE	\$9,499	6%	1%	31%	37%	36%

YTD 2023

	Amount	Price	FX Rate	Volume	Total	CER
U.S.	\$15,336	3%	-	10%	13%	13%
EUROPE	4,837	(7)%	1%	57%	50%	49%
JAPAN	1,234	(1)%	(8)%	(0)%	(9)%	(1)%
CHINA	1,163	(9)%	(7)%	21%	6%	12%
REST OF WORLD	2,202	(1)%	(2)%	11%	9%	10%
TOTAL REVENUE	\$24,771	0%	(1)%	17%	17%	18%

Numbers may not add due to rounding

CER = price change + volume change

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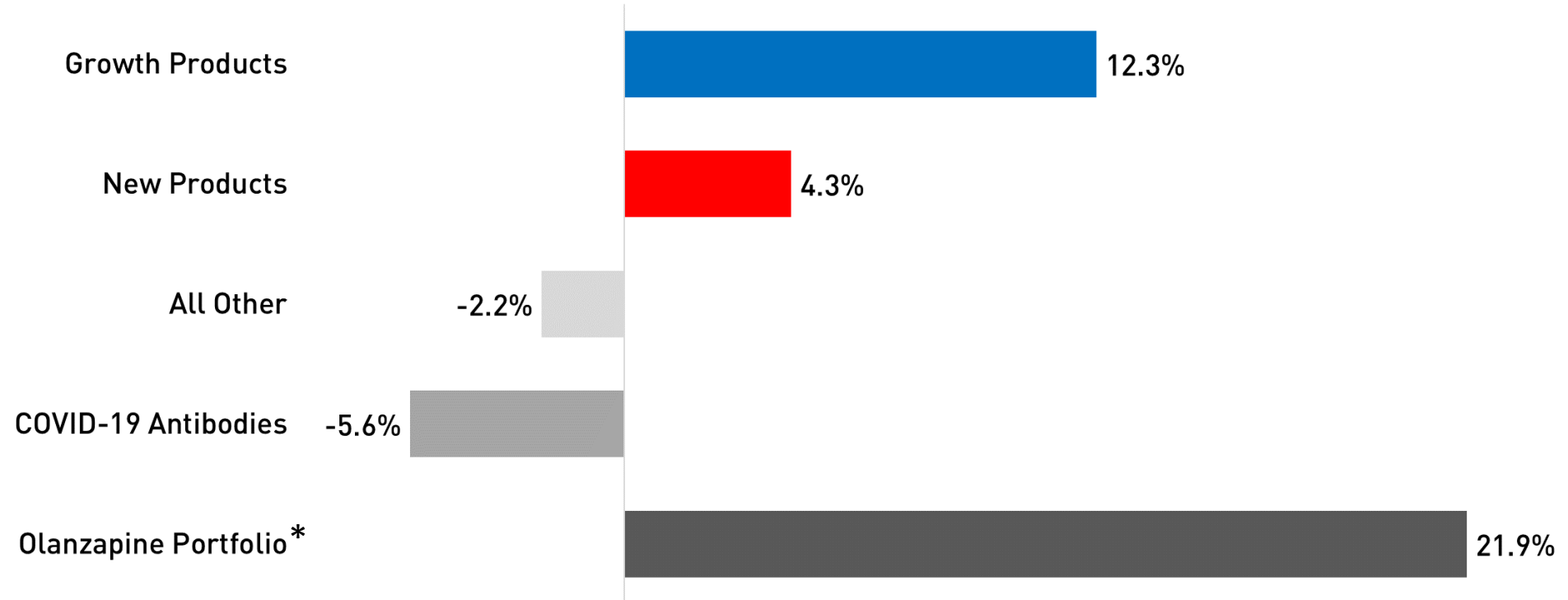
2023 Q3 EARNINGS



# PRODUCTS DRIVING WW VOLUME GROWTH



## Contribution to 31% Q3 WW Volume Increase



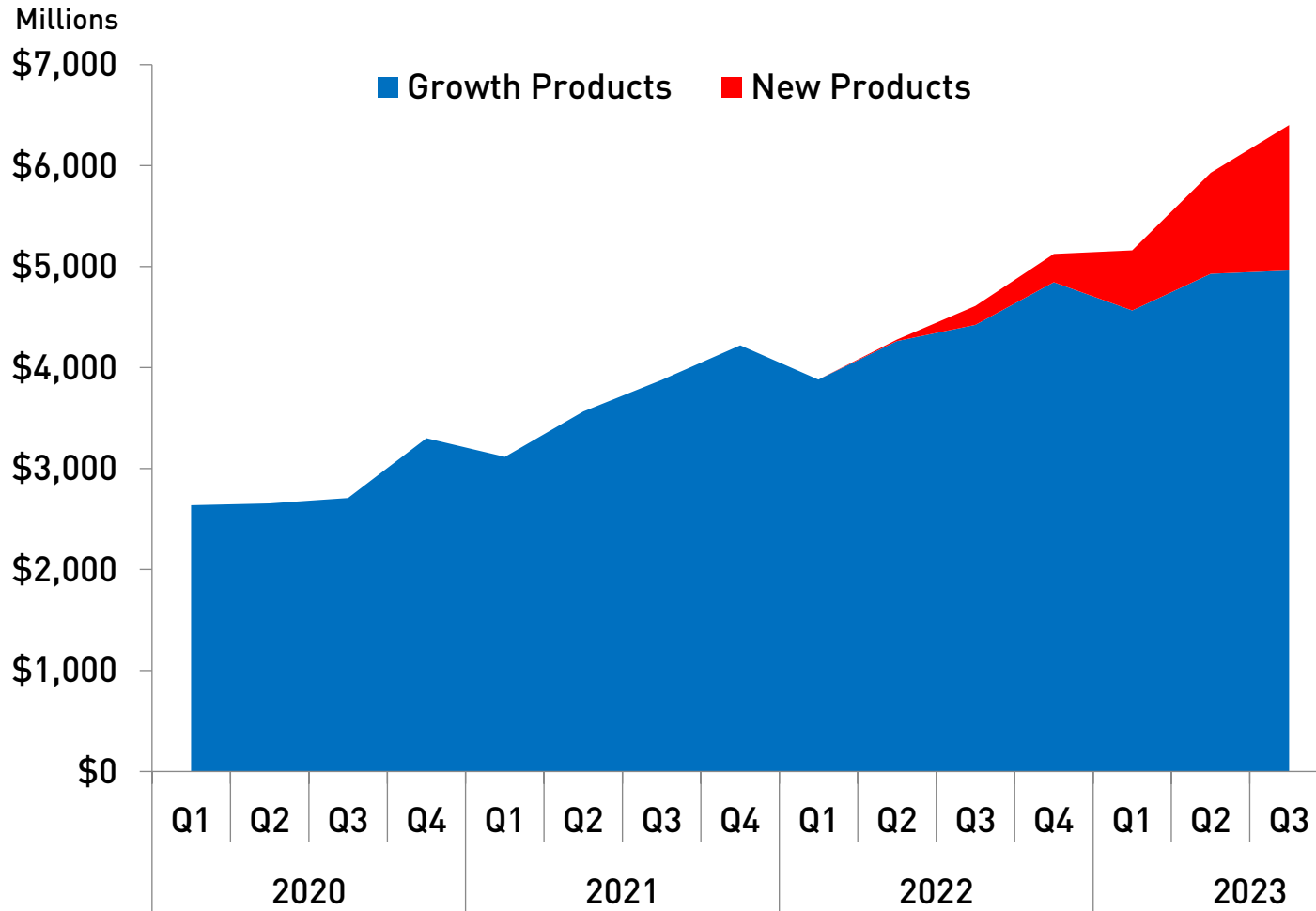
\*Includes \$1.42 billion from the sale of the worldwide rights for the olanzapine portfolio; numbers may not add due to rounding

**New Products:** Jaypirca®, Mounjaro®, and Omvoh

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

**COVID-19 Antibodies:** bamlanivimab, etesevimab and bebtelovimab for the treatment of COVID-19 sold pursuant to Emergency Use Authorization or similar regulatory authorizations

# Q3 2023 UPDATE ON SELECT PRODUCTS



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

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

## NEW PRODUCTS

### MOUNJARO

- U.S. T2D launch in Q2 2022
- U.S. T2D injectable incretins TRx SOM over 22% at end of Q3 2023

### JAYPIRCA

- U.S. MCL approval in Q1 2023

### OMVOH

- Japan approval in Q1 2023; EU approval in Q2 2023

## GROWTH PRODUCTS

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

- SGLT2 market leader in several key markets with U.S. TRx SOM over 62% at the end of Q3
- U.S. TRx grew 27% vs. Q3 2022

### TALTZ

- U.S. immunology TRx SOM at 6% at the end of Q3
- U.S. TRx grew 11% vs. Q3 2022

### TRULICITY

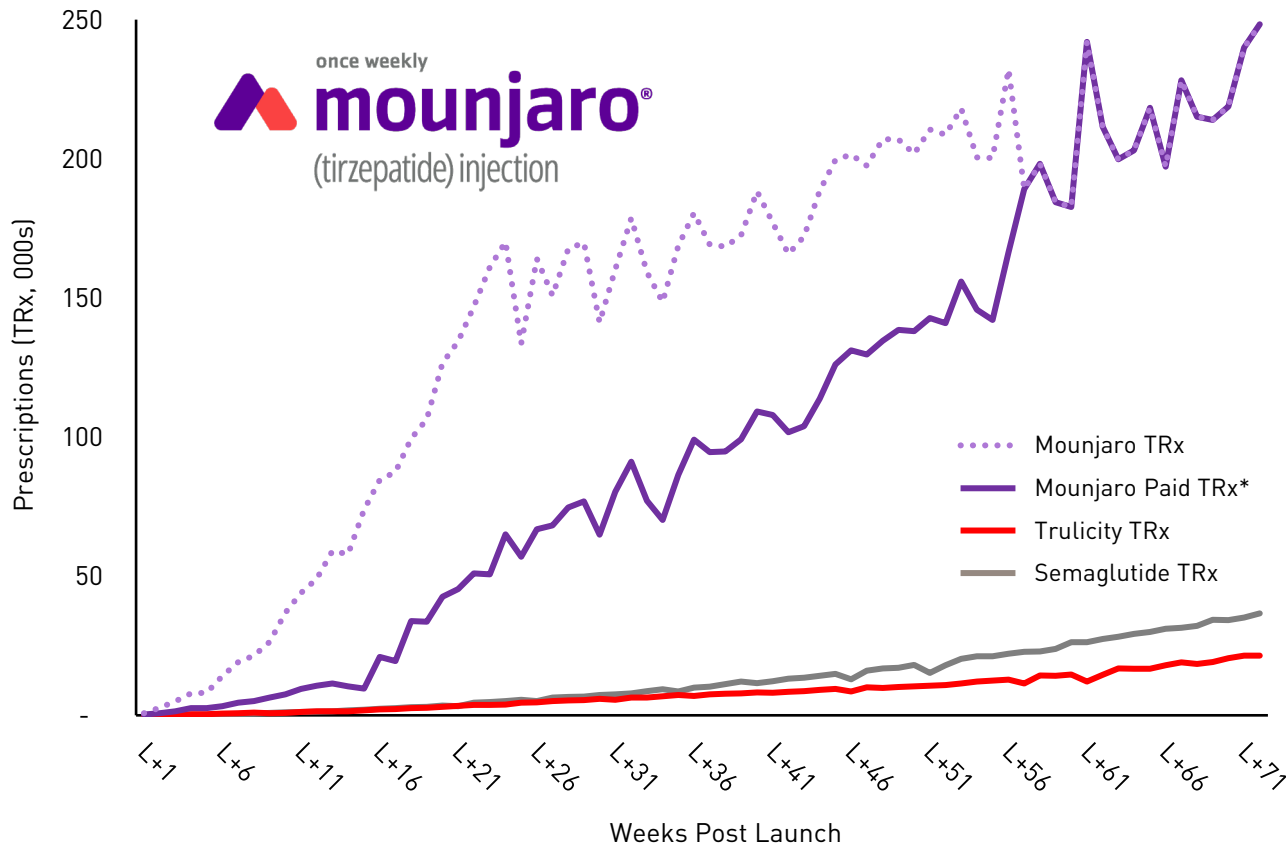
- U.S. T2D injectable incretins TRx SOM of nearly 27% at the end of Q3
- U.S. TRx grew over 5% vs. Q3 2022

### VERZENIO

- U.S. TRx grew over 51% vs. Q3 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



- Access on October 1<sup>st</sup> was 78% for patients with type 2 diabetes across commercial and Part D lives, including 85% in commercial
- Original non-covered \$25 copay card expired June 30<sup>th</sup>; all Q3 prescriptions are considered paid
- All doses are now listed as available on the FDA Drug Shortage Database
- Focused on driving new-to-brand growth with increased access and promotional efforts

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

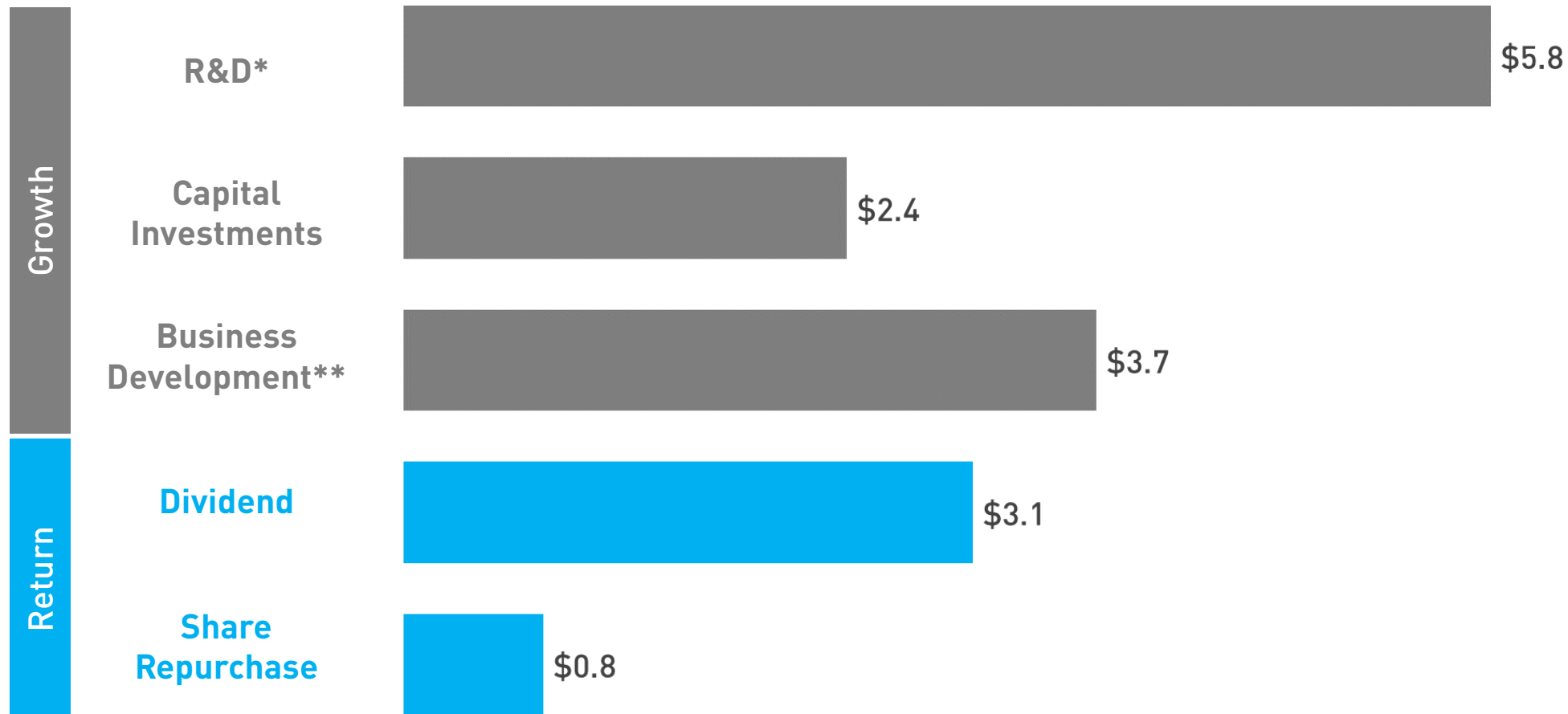
\*Internal estimate of weekly paid TRx  
IQVIA weekly data for week ending Oct 20, 2023 (type 2 diabetes injectable incretin class)

# CAPITAL ALLOCATION



Billions

## YTD 2023 Capital Allocation



\* After tax

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

# 2023 GUIDANCE



	Prior	Updated	COMMENTS
REVENUE	\$33.4 – \$33.9 billion	Unchanged	
GROSS MARGIN % OF REVENUE (GAAP) GROSS MARGIN % OF REVENUE (NON-GAAP)	Approx. 78% Approx. 80%	Unchanged	Trending toward the higher end of the estimate
MKTG, SELLING & ADMIN.	\$7.2 – \$7.4 billion	Unchanged	Trending toward the top end of the range
RESEARCH & DEVELOPMENT	\$8.9 – \$9.1 billion	Unchanged	Trending toward the top end of the range
ACQUIRED IPR&D	\$202 million	\$3.18 billion	Reflects acquired IPR&D charges incurred through Q3 2023; does not include acquired IPR&D charges associated with potential or pending business development transactions
OTHER INCOME/(EXPENSE) (GAAP) OTHER INCOME/(EXPENSE) (NON-GAAP)	\$(75) – \$25 million \$0 – \$100 million	\$(150) – \$(50) million Unchanged	GAAP change driven by net losses on investments in equity securities
TAX RATE	14% – 15%	19% – 20%	Reflects non-deductible acquired IPR&D charges incurred through Q3 2023
EARNINGS PER SHARE (GAAP) EARNINGS PER SHARE (NON-GAAP)	\$9.20 – \$9.40 \$9.70 – \$9.90	\$5.95 – \$6.15 \$6.50 – \$6.70	GAAP and non-GAAP change reflects acquired IPR&D charges incurred through Q3 2023; GAAP change includes net losses on investments in equity securities

Assumes shares outstanding of 903 million

FX assumptions: 1.05 (Euro), 149.5 (Yen) and 7.18 (Renminbi)

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2023 Q3 EARNINGS

# LILLY SELECT NME AND NILEX PIPELINE

OCTOBER 30, 2023



## LEGEND

<span style="color: blue;">●</span> NME	<b>MOVEMENT SINCE August 2, 2023</b>
<span style="color: grey;">○</span> NILEX	
* Commercial Collaboration	<span style="color: green;">■</span> ADDITION or MILESTONE ACHIEVED
◆ Phase 3 in China with Innovent for T2DM and Obesity	<span style="color: red;">▼</span> REMOVAL

NOT DISCLOSED Neurodegeneration	OTOF GENE THERAPY Hearing Loss	SCAP siRNA NASH
RET INHIBITOR II Cancer	SARM1 INHIBITOR Neurodegeneration	DC-853 Immunology
NRG4 AGONIST Heart Failure	PI3K SELECTIVE Cancer	PNPLA3 siRNA NASH
NISOTIROSTIDE Diabetes	NOT DISCLOSED Diabetes	NOT DISCLOSED Pain
KRAS G12C II Cancer	KV1.3 ANTAGONIST Immunology	MAZDUTIDE ◆ Obesity
GIPR AGONIST LA Diabetes	GIPR AGONIST LA II Diabetes	GITR ANTAGONIST Immunology
CD19 ANTIBODY Immunology	DACRA QW II Obesity	FGFR3 SELECTIVE Cancer
AMYLIN AGONIST LA Obesity	APOC3 siRNA CVD	AT2R ANTAGONIST Pain

PHASE 1

TIRZEPATIDE Higher Doses	TIRZEPATIDE NASH
RETATRUTIDE Diabetes	TIRZEPATIDE NASH
GBA1 GENE THERAPY Gaucher Disease Type 1	GBA1 GENE THERAPY Gaucher Disease Type 2
RIPK1 INHIBITOR Rheumatoid Arthritis	UCENPRUBART Atopic Dermatitis
Bimagrumab Obesity	DC-806 Psoriasis
SOLBINSIRAN CVD	SSTR4 AGONIST Pain
PERESOLIMAB Rheumatoid Arthritis	VOLENRELAXIN (RELAXIN-LA) Heart Failure
O-GLCNACASE INH Alzheimer's Disease	P2X7 INHIBITOR Pain
MEVIDALEN Symptomatic LBD	MUVALAPLIN CVD
GRN GENE THERAPY Frontotemporal Dementia	LEPODISIRAN CVD
ELTREKIBART Hidradenitis Suppurativa	GBA1 GENE THERAPY Parkinson's Disease

PHASE 2

BTLA MAB AGONIST  
Systemic Lupus Erythematosus

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

PHASE 3

PIRTOBRUTINIB CLL Accelerated Approval
TIRZEPATIDE Obesity
LEBRKIZUMAB Atopic Dermatitis
DONANEMAB Alzheimer's Disease

REG REVIEW

APPROVED

# POTENTIAL KEY EVENTS 2023

New since last update



## Phase 3 Initiations

- ✓+ Basal Insulin-Fc for type 2 diabetes (QWINT-1)
- ✓+ Tirzepatide for chronic weight management (H2H vs semaglutide 2.4 mg)
- ✓+ Retatrutide for chronic weight management
- ✓+ Orforglipron for chronic weight management
- ✓+ Orforglipron for type 2 diabetes
- Remternetug for early Alzheimer's disease (efficacy trials)

## 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
- Abemaciclib for castrate-resistant prostate cancer (CYCLONE-2)
- Pirtobrutinib for CLL prior BTKi (BRUIN CLL-321)

## Regulatory Submissions

- ✓+ Tirzepatide for chronic weight management (US ✓+ / EU ✓+)
- ✓+ Lebrikizumab for atopic dermatitis (J)
- ✓+ Empagliflozin<sup>3</sup> for chronic kidney disease (US ✓+ / EU ✓+ / J ✓+)
- ✓+ Donanemab for early Alzheimer's disease<sup>1</sup> (US ✓+ / EU ✓+ / J ✓+)
- ✓+ Pirtobrutinib for MCL prior BTKi (J)
- ✓+ Pirtobrutinib for CLL prior BTKi and BCL2i<sup>2</sup>

## Regulatory Actions

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

<sup>1</sup> Under the traditional approval pathway

<sup>2</sup> Under the FDA Accelerated Approval Program

<sup>3</sup> Jardiance is part of the company's alliance with Boehringer Ingelheim. Lilly reports as revenue royalties received on net sales of Jardiance.

# Q3 2023 SUMMARY



- Excluding the olanzapine portfolio and COVID-19 antibodies, **revenue grew 24%**
- Continued to **speed life-changing medicines** to patients with:
  - FDA approval of Omvoh for the treatment of adults with moderately to severely active ulcerative colitis and Jardiance<sup>1</sup> for the treatment of adults with chronic kidney disease at risk of progression
  - Positive CHMP opinion in the EU for lebrikizumab
  - Positive results for mirikizumab in moderately to severely active Crohn's disease
- Q3 **investment growth** largely driven by investments in new products and indications and late-stage pipeline
- Announced a new potential **acquisition** and closed several others 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

	Q3 2023	Change	YTD 2023	Change
TOTAL REVENUE	\$9,499	37%	\$24,771	17%
GROSS MARGIN	80.4%	3.2pp	78.6%	2.5pp
TOTAL OPERATING EXPENSE*	7,188	95%	15,406	42%
OPERATING INCOME	450	(73)%	4,070	(23)%
OPERATING MARGIN	4.7%	(19.4)pp	16.4%	(8.5)pp
OTHER INCOME (EXPENSE)	(23)	(79)%	(24)	(96)%
EFFECTIVE TAX RATE	113.4%	106.1pp	24.6%	16.0pp
NET INCOME (LOSS)	\$(57)	NM	\$3,051	(29)%
EARNINGS (LOSS) PER SHARE	\$(0.06)	NM	\$3.38	(29)%

\* 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

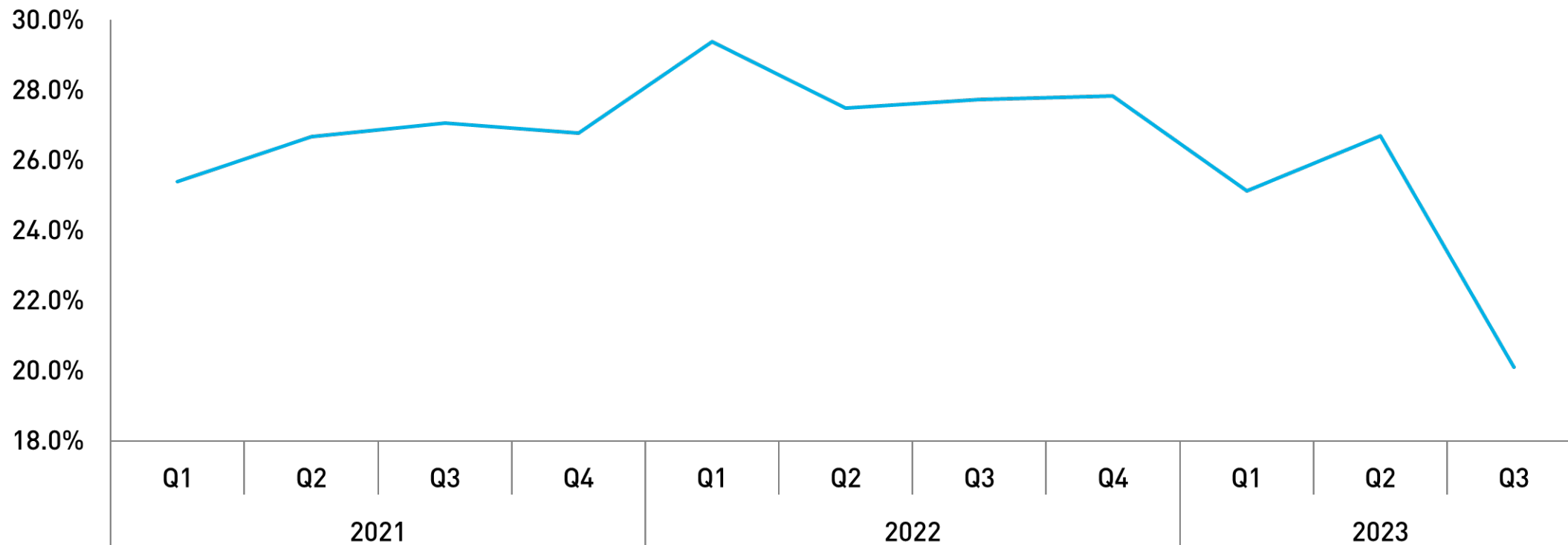
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2023 Q3 EARNINGS

# NON-GAAP OPERATING MARGIN % OF REVENUE



MOVING ANNUAL TOTAL



Individual Quarter  
Op. Margin % of Revenue:

23.1%    29.1%    27.9%    27.0%    33.4%    20.5%    28.9%    27.4%    23.3%    27.1%    6.1%

Op. Margin impact of  
Acquired IPR&D Charges

-4.6%    -0.6%    -2.6%    -5.5%    -2.1%    -6.8%    -0.9%    -3.3%    -1.5%    -1.2%    -31.3%

The line in the graph is a moving annual total (i.e. trailing 4 quarters) while the row of numbers is from specific quarters.

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2023 Q3 EARNINGS

# EFFECT OF FX ON 2023 RESULTS



Year-on-Year Change

REPORTED	Q3 2023		YTD 2023	
	With FX	w/o FX	With FX	w/o FX
TOTAL REVENUE	37%	36%	17%	18%
COST OF SALES	18%	20%	4%	6%
GROSS MARGIN	42%	41%	21%	21%
OPERATING EXPENSE	95%	95%	42%	42%
OPERATING INCOME	(73)%	(78)%	(23)%	(22)%
EARNINGS PER SHARE	(104)%	(109)%	(29)%	(28)%
<b>NON-GAAP</b>				
	With FX	w/o FX	With FX	w/o FX
TOTAL REVENUE	37%	36%	17%	18%
COST OF SALES	19%	22%	6%	8%
GROSS MARGIN	41%	40%	20%	20%
OPERATING EXPENSE	107%	106%	45%	45%
OPERATING INCOME	(71)%	(75)%	(25)%	(25)%
EARNINGS PER SHARE	(95)%	(98)%	(35)%	(34)%

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.

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**2023 Q3 EARNINGS**

# EPS RECONCILIATION



	<u>Q3 2023</u>	<u>Q3 2022</u>	<u>% Change</u>	<u>YTD 2023</u>	<u>YTD 2022</u>	<u>% Change</u>
EARNINGS (LOSS) PER SHARE (REPORTED)	\$(0.06)	\$1.61	NM	\$3.38	\$4.76	(29)%
AMORTIZATION OF INTANGIBLE ASSETS	0.11	0.11	-	0.33	0.39	(15)%
NET LOSSES (GAINS) ON INVESTMENTS IN EQUITY SECURITIES	0.06	0.09	(33)%	0.12	0.52	(77)%
ASSET IMPAIRMENT, RESTRUCTURING AND OTHER SPECIAL CHARGES	-	0.17	(100)%	-	0.17	(100)%
EARNINGS PER SHARE (NON-GAAP)	\$0.10	\$1.98	(95)%	\$3.83	\$5.85	(35)%
Acquired IPR&D	\$3.29	\$0.06	NM	\$3.48	\$0.67	NM

Numbers may not add due to rounding; see slides 22 & 23 for more details on these adjustments; NM = not meaningful

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**2023 Q3 EARNINGS**

# Q3 2023 INCOME STATEMENT NOTES



## Q3 2023 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 \$125.0 million (pretax), or \$0.11 per share (after-tax); and
- net losses on investments in equity securities totaling \$65.3 million (pretax), or \$0.06 per share (after-tax).

## Q3 2022 NON-GAAP INFORMATION HAS BEEN ADJUSTED TO EXCLUDE:

- an intangible asset impairment charge for GBA1 Gene Therapy (PR001) due to delays in the clinical development and estimated product launch totaling \$206.5 million (pretax), or \$0.17 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
- net losses on investments in equity securities totaling \$107.7 million (pretax), or \$0.09 per share (after-tax).

# YTD 2023 INCOME STATEMENT NOTES



## YTD 2023 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 \$377.2 million (pretax), or \$0.33 per share (after-tax); and
- net losses on investments in equity securities totaling \$141.8 million (pretax), or \$0.12 per share (after-tax).

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

- net losses on investments in equity securities totaling \$602.4 million (pretax), or \$0.52 per share (after-tax);
- amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties totaling \$450.0 million (pretax), or \$0.39 per share (after-tax); and
- an intangible asset impairment charge for GBA1 Gene Therapy (PR001) due to delays in the clinical development and estimated product launch totaling \$206.5 million (pretax), or \$0.17 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)		
Non-GAAP	2.62	1.25	1.98	2.09	7.94	1.62	2.11	0.10		

Numbers may not add due to rounding

For a complete reconciliation to reported earnings, see slide 21 and our earnings press release dated Nov 2, 2023

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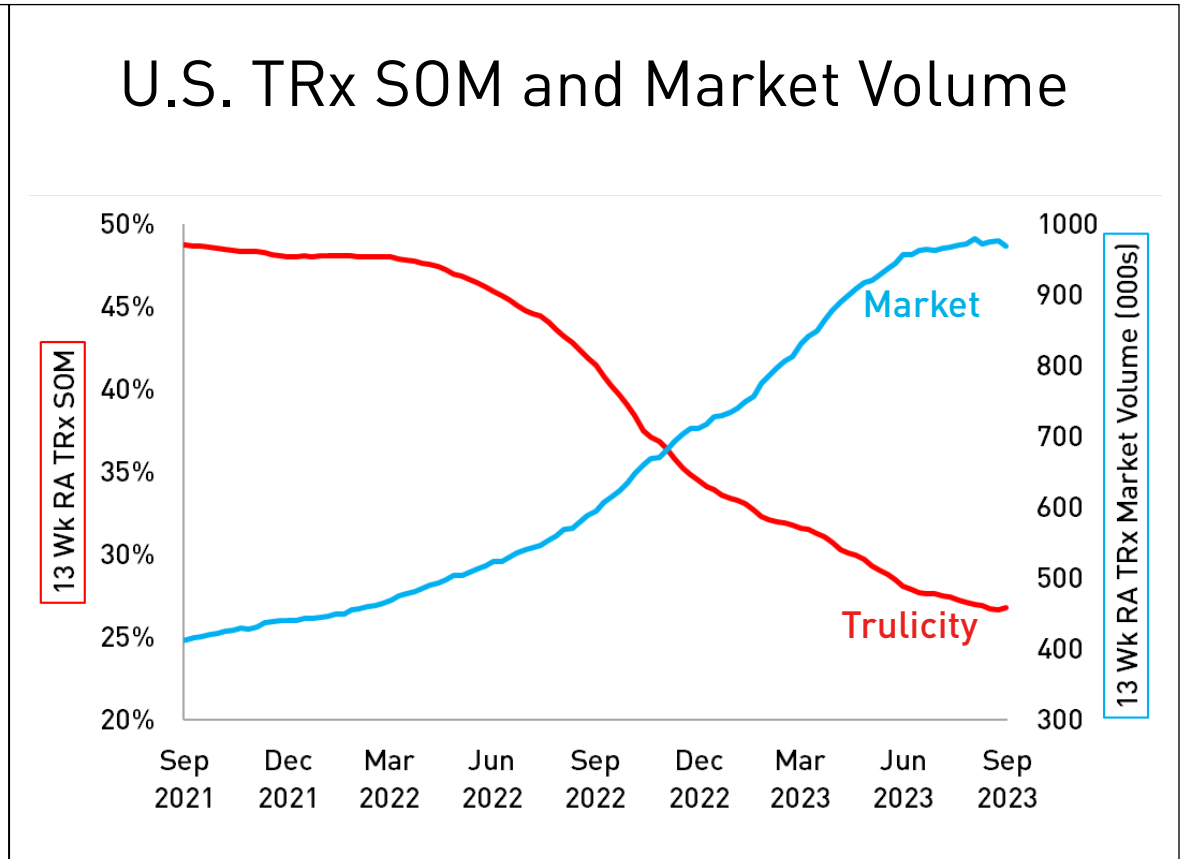
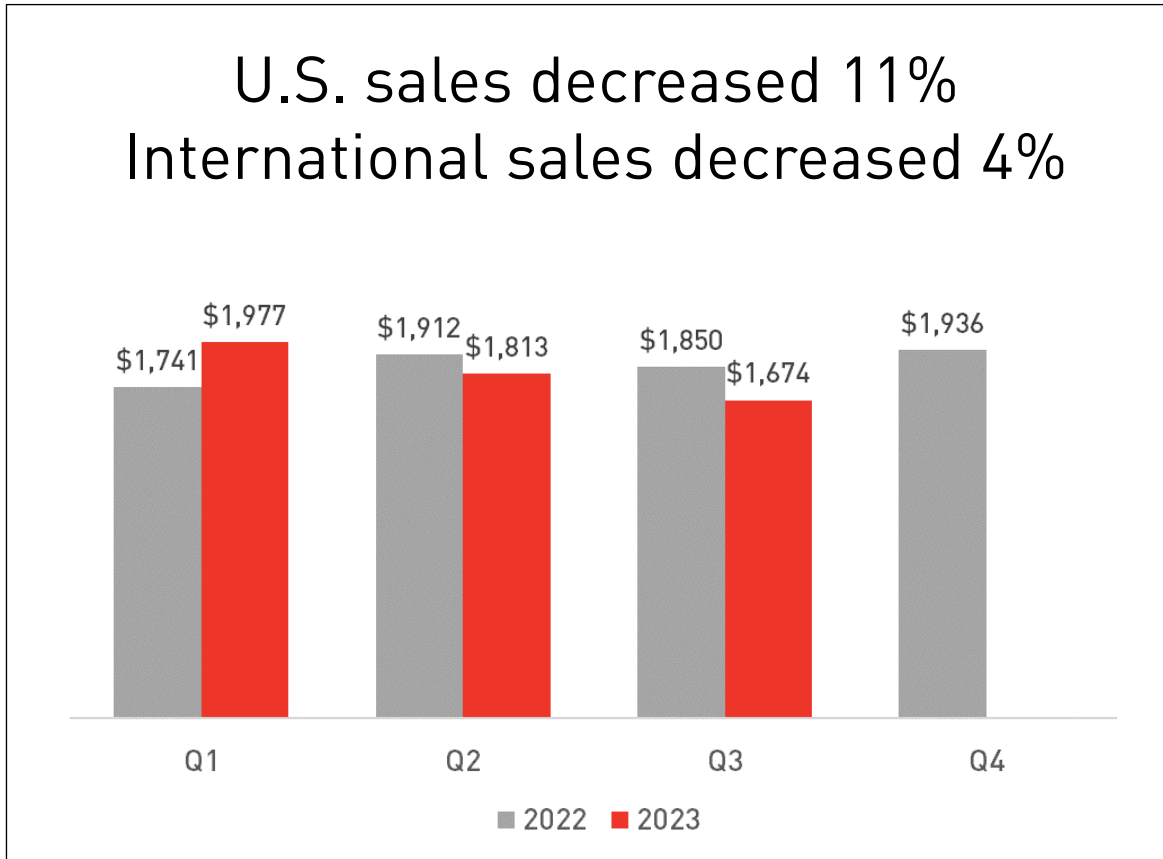
**2023 Q3 EARNINGS**



# Q3 2023 TRULICITY SALES DECREASED 10%



Millions

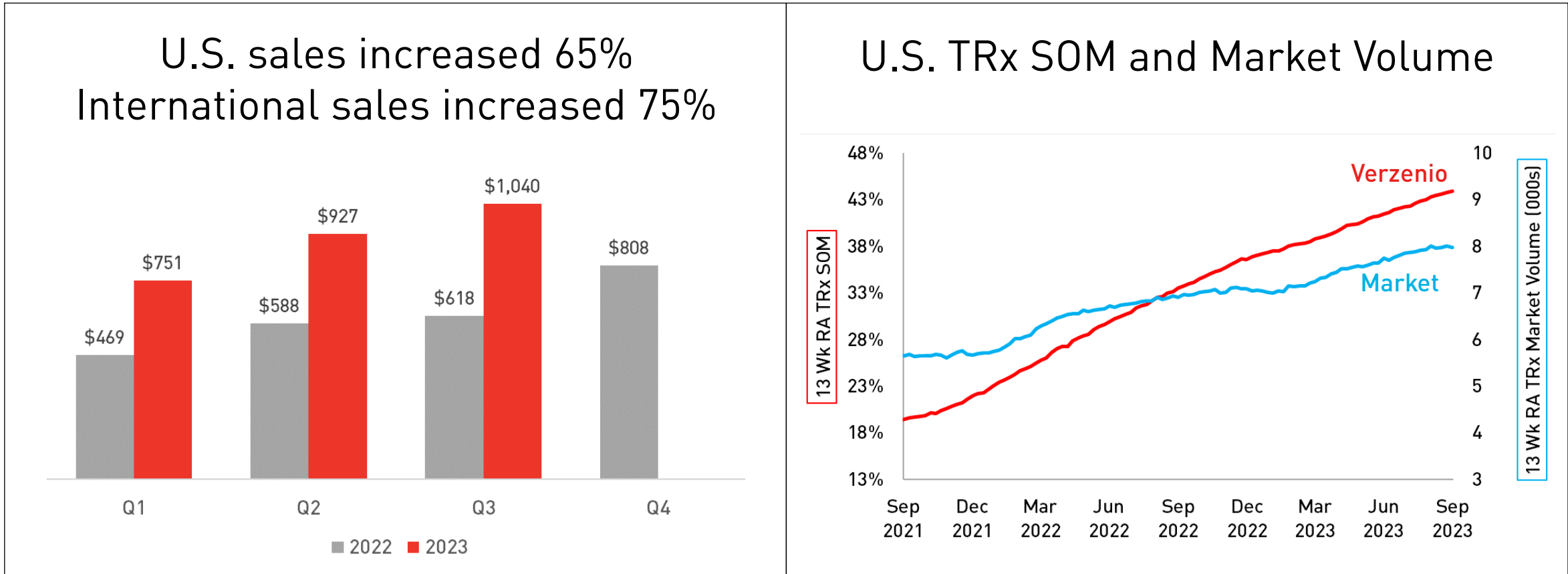


Source: IQVIA NPA TRx 3MMA, weekly data September 30, 2023; RA = rolling average TRx data is representative of the injectable incretin market

# Q3 2023 VERZENIO SALES INCREASED 68%



Millions

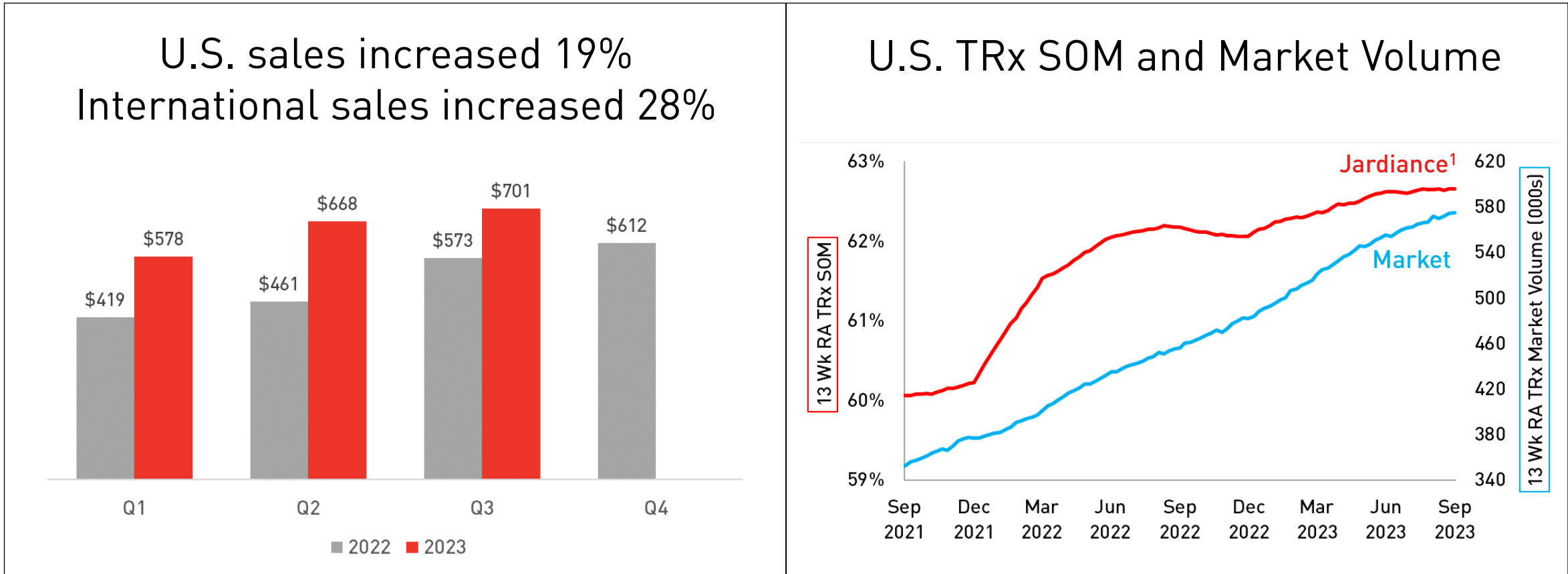


Source: IQVIA NPA TRx 3MMA, weekly data September 30, 2023; RA = rolling average

# Q3 2023 JARDIANCE SALES INCREASED 22%



Millions

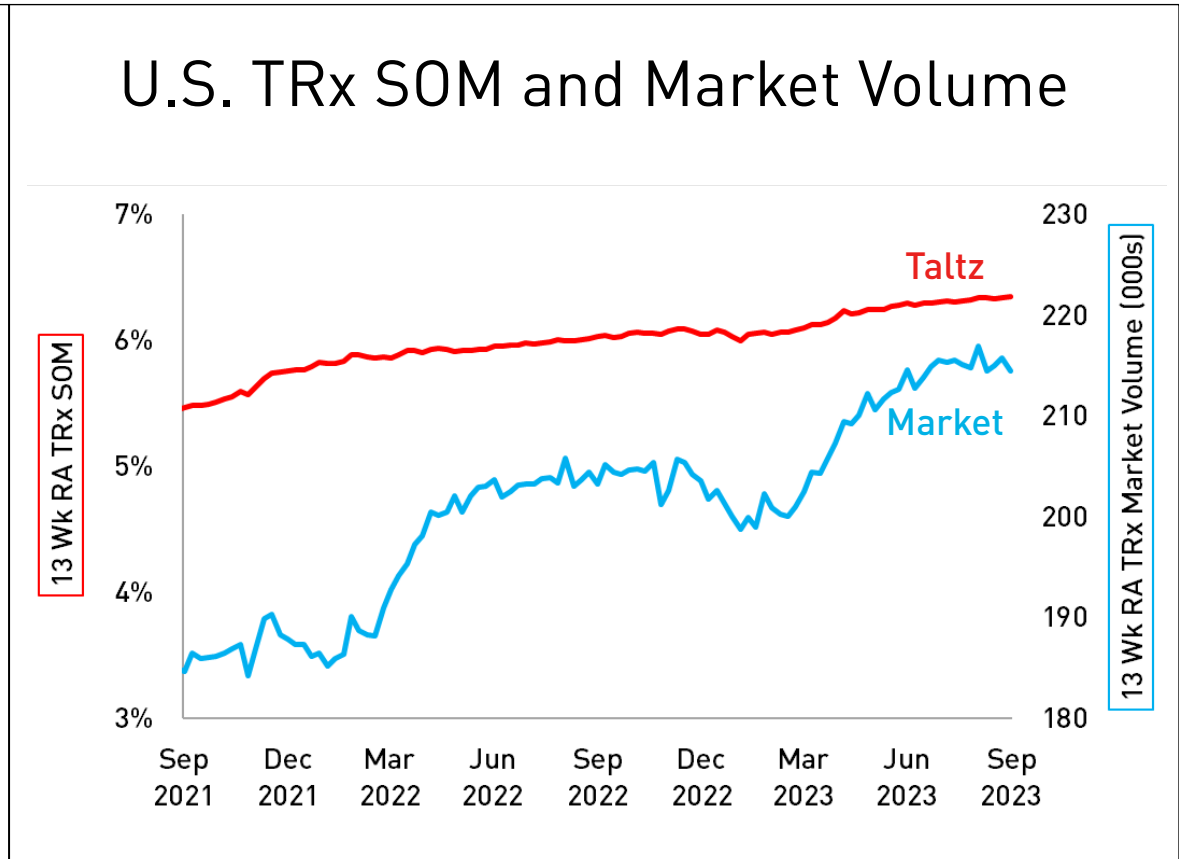
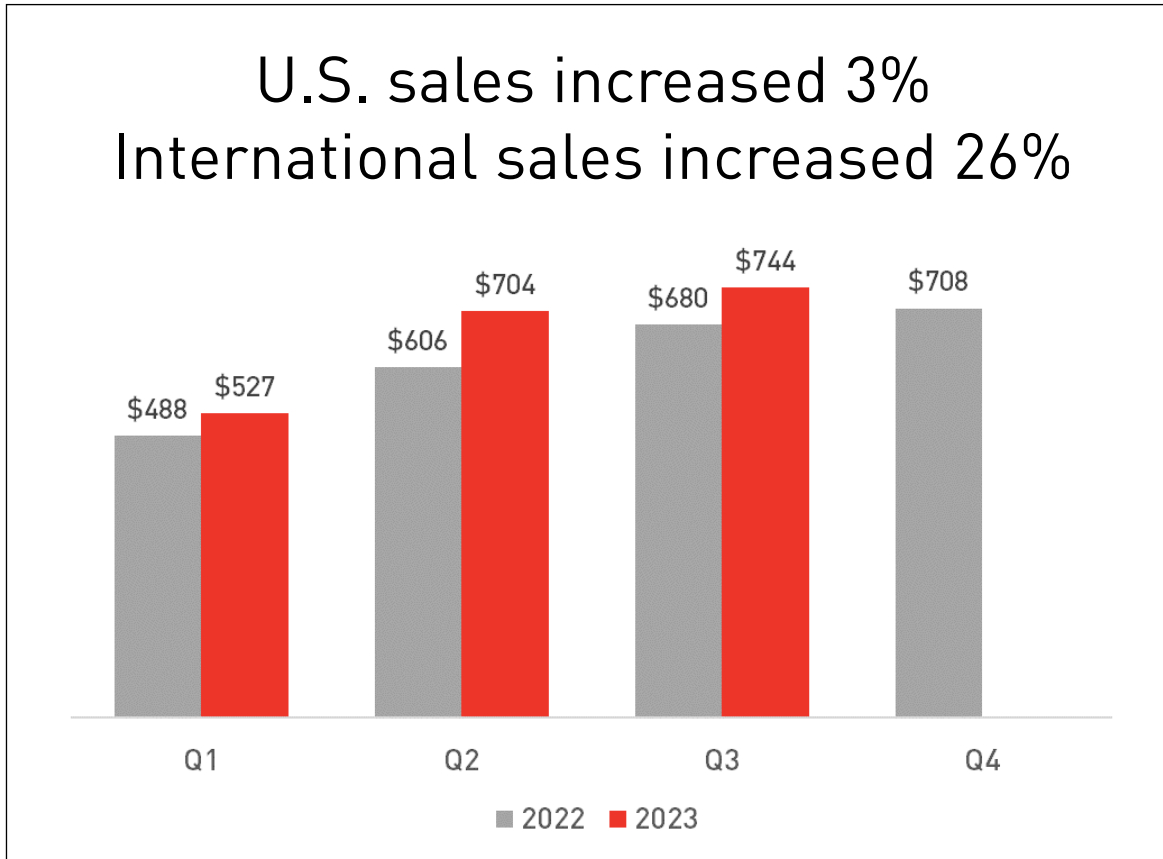


Source: IQVIA NPA TRx 3MMA, weekly data September 30, 2023; RA = rolling average  
<sup>1</sup> Jardiance includes Glyxambi and Synjardy. Jardiance is part of the company's alliance with Boehringer Ingelheim. Lilly reports as revenue royalties received on net sales of Jardiance.

# Q3 2023 TALTZ SALES INCREASED 9%



Millions

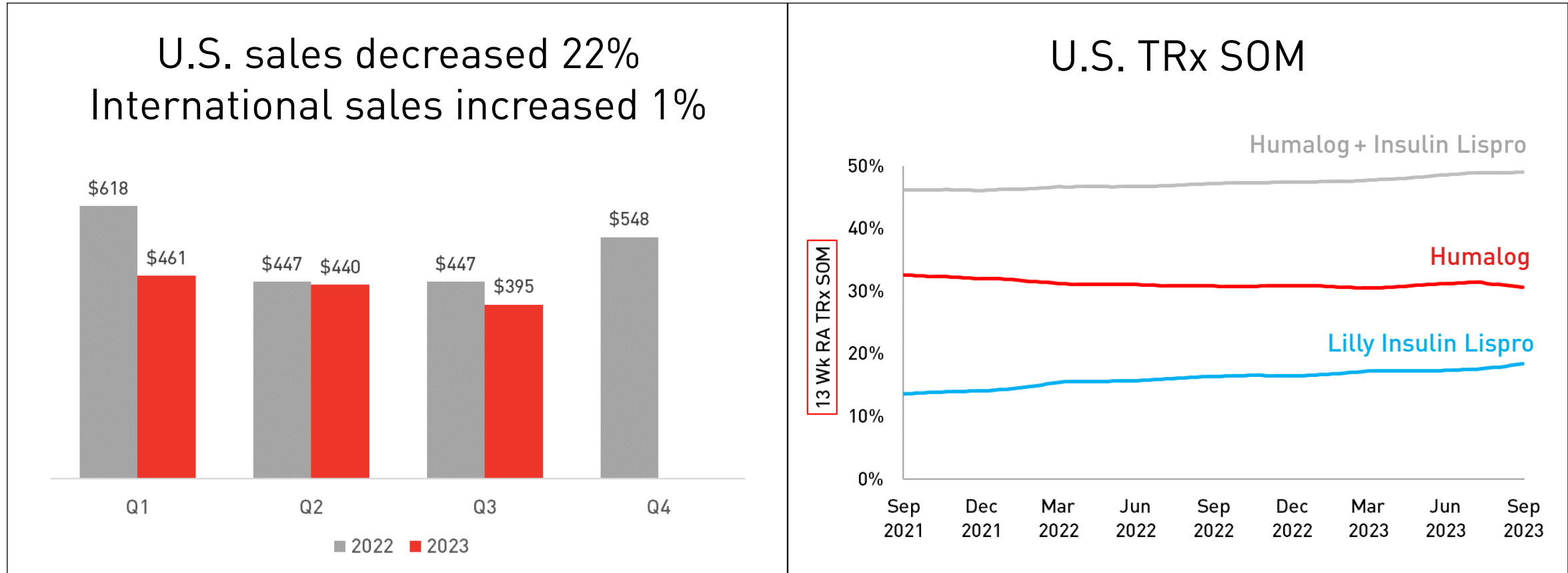


Source: IQVIA NPA TRx 3MMA, weekly data September 30, 2023; RA = rolling average  
TRx data is representative of the full molecule market

# Q3 2023 HUMALOG SALES DECREASED 12%



Millions

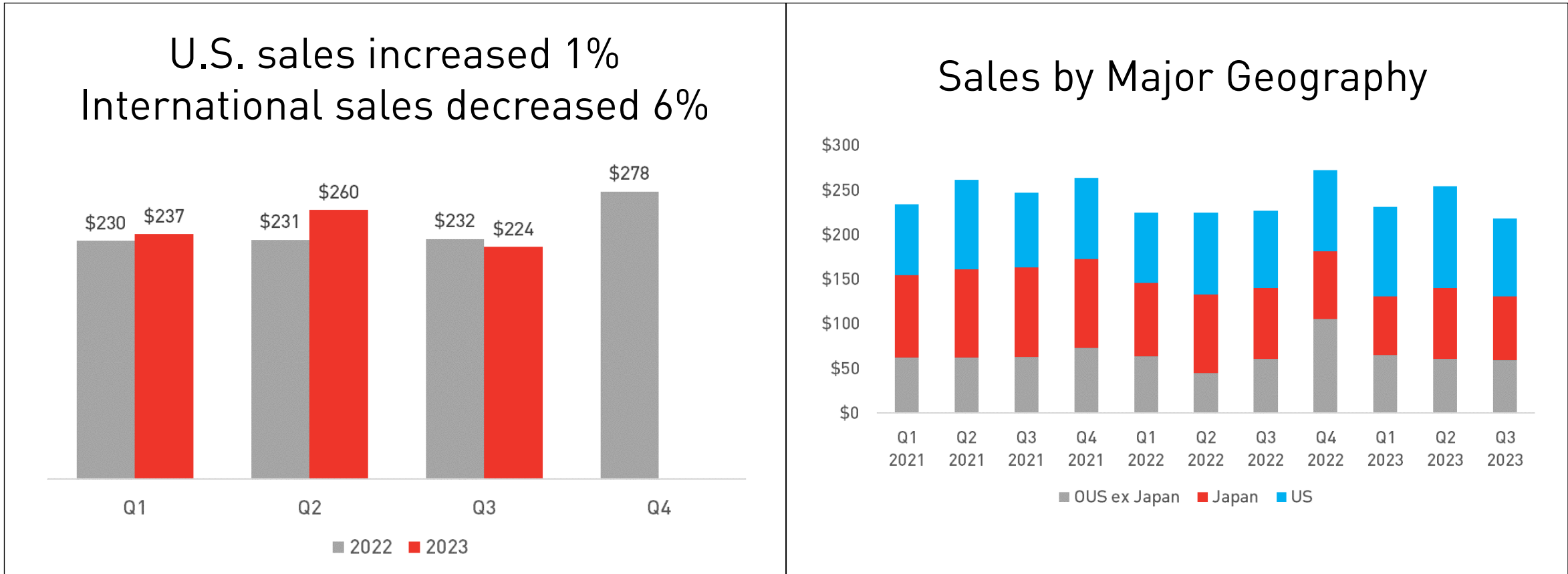


Source: IQVIA NPA TRx 3MMA, weekly data September 30, 2023; RA = rolling average

# Q3 2023 CYRAMZA SALES DECREASED 3%



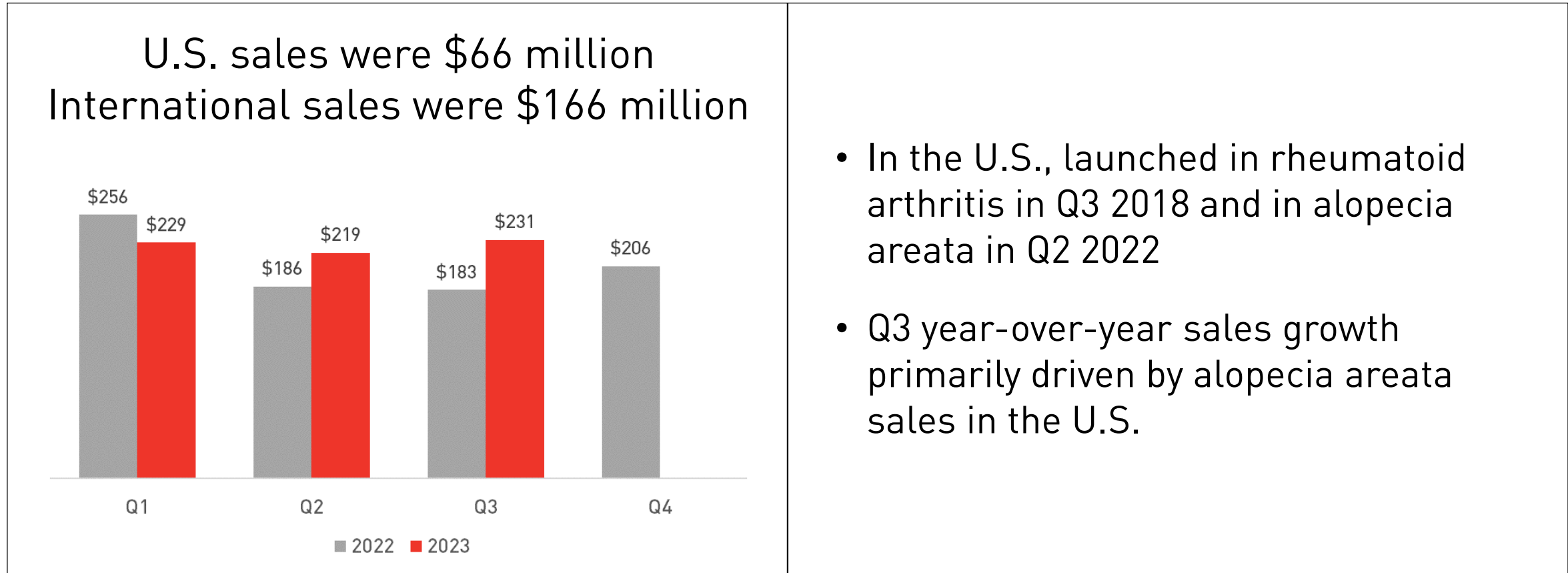
Millions



# Q3 2023 OLUMIANT SALES INCREASED 27%



Millions

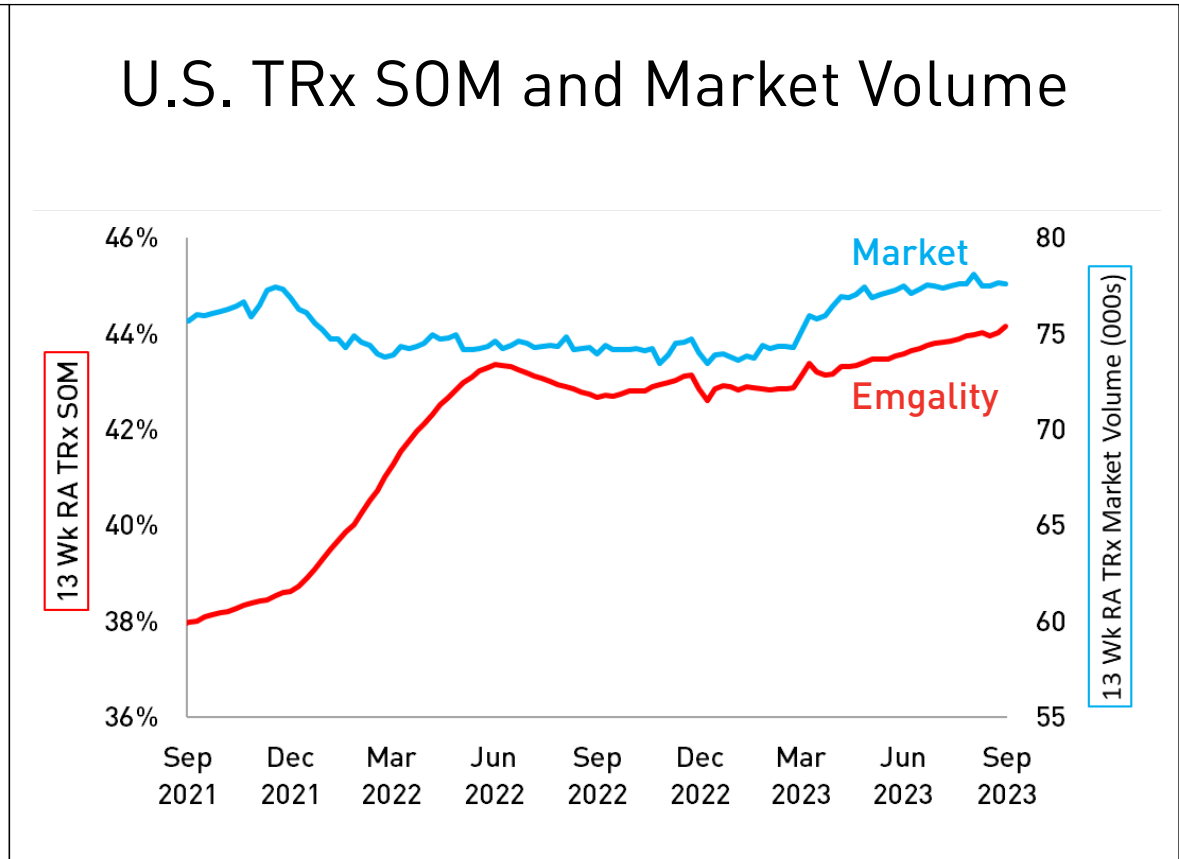
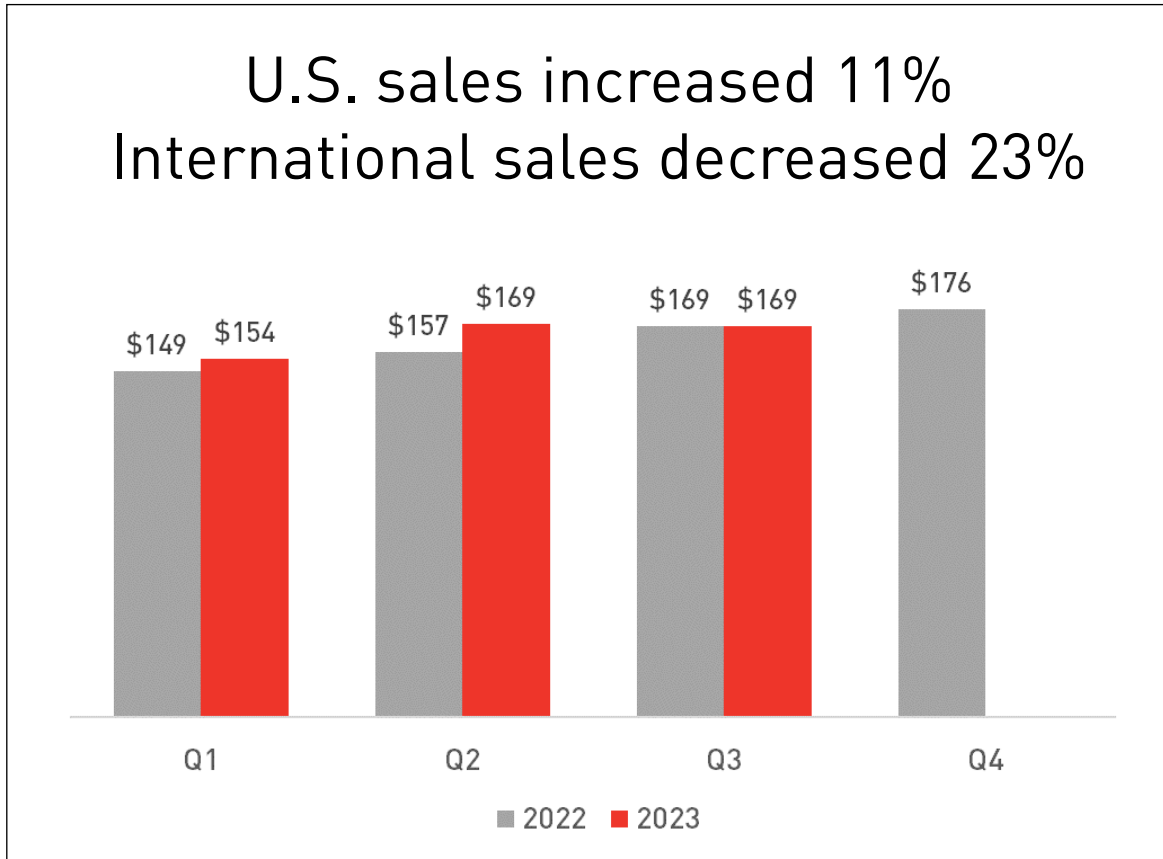


- In the U.S., launched in rheumatoid arthritis in Q3 2018 and in alopecia areata in Q2 2022
- Q3 year-over-year sales growth primarily driven by alopecia areata sales in the U.S.

# Q3 2023 EMGALITY SALES WERE FLAT



Millions



Source: IQVIA NPA TRx 3MMA, weekly data September 30, 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
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
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

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, October 23, 2023

# 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	Jun 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)	Oct 2027	Nov 2027

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, October 17, 2023

# 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 (ITT) 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, October 23, 2023

# SELECT TRIALS – JARDIANCE



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04509674	Myocardial Infarction	EMPACT-MI: A Study to Test Whether Empagliflozin <sup>1</sup> Can Lower the Risk of Heart Failure and Death in People Who Had a Heart Attack (Myocardial Infarction)	3	6522	Composite of time to first heart failure hospitalisation or all-cause mortality	Oct 2023	Oct 2023

\* Molecule may have multiple indications

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

<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

Source: clinicaltrials.gov, September 25, 2023

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2023 Q3 EARNINGS

# 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)	Nov 2025	Jun 2026

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, October 23, 2023

# 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	Apr 2027
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	Jun 2025
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	960	Percentage of Participants in Clinical Remission	Jun 2025	Apr 2029

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, October 20, 2023

# 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	Apr 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

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, October 31, 2023

# 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, October 19, 2023



# 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, October 12, 2023

# 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, October 17, 2023

# 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, October 19, 2023

# 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	400	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	250	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	Mar 2024	Sep 2024
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)	Aug 2028	Nov 2032

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, October 23, 2023

# 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
NCT06075667	Obesity	A Study of Tirzepatide (LY3298176) Once Weekly in Adolescent Participants Who Have Obesity, or Are Overweight With Weight-Related Comorbidities (SURMOUNT-ADOLESCENTS)	3	150	Percent Change from Baseline in Body Mass Index (BMI)	Feb 2026	Dec 2026
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
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, October 23, 2023

# 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	Dec 2024	Sep 2025

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, October 23, 2023

# 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	Percent 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, October 23, 2023

# 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)	Nov 2023	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)	Nov 2023	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, October 23, 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)	Jan 2024	Jan 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
Volenrelaxin (Relaxin-LA)	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
Bimagrumab	NCT05616013	Obesity	Safety and Efficacy of Bimagrumab and Semaglutide in Adults who are Overweight or Obese	2	495	Change from baseline in body weight at 48 weeks	Sept 2025	Sept 2025

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, October 23, 2023

# SELECT TRIALS – EARLY PHASE DIABETES AND OBESITY (CONT.)



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
Nisotiroside	NCT05377333	Diabetes Mellitus, Type 2	A Study of LY3457263 Alone and in Combination With Dulaglutide (LY2189265) in Participants With Type 2 Diabetes	1	86	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 2023	Nov 2023
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	Dec 2023	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	Mar 2024	Mar 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	Aug 2024	Aug 2024

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, October 23, 2023

# 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, October 23, 2023

# 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
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)	Jun 2024	Jul 2026
DC-806	NCT05896527	Plaque Psoriasis	A Study to Evaluate the Efficacy and Safety of DC-806 in Participants With Moderate to Severe Plaque Psoriasis	2	225	Proportion of participants achieving a 75% reduction in Psoriasis Area of Severity Index score (PASI-75)	Jul 2024	Aug 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)	Jul 2025	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, October 19, 2023

# SELECT TRIALS – EARLY PHASE IMMUNOLOGY (CONT.)



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
GITR Antagonist Antibody	NCT05486208	Healthy	A Study of LY3844583 in Healthy Participants and Participants With Atopic Dermatitis	1	86	Number of Participants with One or More Adverse Events (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

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, October 20, 2023

# 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
IL-34 Antibody	NCT06007638	Gaucher Disease	A Study of LY3876602 in Healthy Participants	1	42	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	Feb 2025	Feb 2025

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, October 20, 2023

# SELECT TRIALS – EARLY PHASE NEURODEGENERATION (CONT.)



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
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	Sep 2028	Sep 2028
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
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, October 20, 2023

# SELECT TRIALS – EARLY PHASE ONCOLOGY



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
KRAS G12C <sup>1</sup>	NCT04956640	Carcinoma, Non-Small-Cell Lung	Study of LY3537982 in Cancer Patients With a Specific Genetic Mutation (KRAS G12C)	1	400	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
RET Inhibitor II	NCT05241834	Carcinoma, Non-Small-Cell Lung	A Study of LOXO-260 in Cancer Patients With a Change in a Particular Gene (RET) That Has Not Responded to Treatment	1	110	Phase 1a: To determine the MTD/RP2D of LOXO-260: Dose limiting toxicity (DLT) rate	Apr 2026	Apr 2026

<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, October 13, 2023



# 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

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