



# Q2 2023 Earnings Call

---

**AUGUST 8, 2023**

# Agenda

## **INTRODUCTION AND RECENT KEY EVENTS**

**Dave Ricks**, Chair and Chief Executive Officer

## **Q2 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 **Q2 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 Forms 10-K, 10-Q, and any 8-Ks 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 79.8% in Q2
- **SG&A:** 18% increase in Q2 primarily driven by recent and upcoming product launches

### Invest in Future Innovation



- **R&D:** 32% increase in Q2 driven by late-stage assets and early-stage research
- **CAPEX:** Commercial production initiated at the RTP facility
- **Business Development:** Completed the divestitures of Baqsimi and olanzapine; announced acquisitions of DICE Therapeutics, Sigilon Therapeutics and Versanis Bio

### Deliver Revenue Growth



- Excluding Baqsimi® and sales of COVID-19 antibodies<sup>1</sup>, revenue grew 22% in Q2, driven by volume growth of 23%
- Together, New Products and Growth Products<sup>2</sup> contributed approximately 26 percentage points of volume growth in Q2

### Speed Life-Changing Medicines



- Announced positive results in the Phase 3 TRAILBLAZER-ALZ 2 study and the submission of donanemab for traditional approval to the FDA and in the EU;
- Announced the completed submission of tirzepatide in chronic weight management to the FDA and tirzepatide SURMOUNT-3 and -4 positive topline results; and
- Announced the approval of mirikizumab in the EU and re-submission in the U.S.

### Return Capital to Shareholders via:

- **Dividend:** Distributed over \$1 billion in Q2

- **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

# KEY EVENTS SINCE THE LAST EARNINGS CALL



## REGULATORY

- Announced the completed regulatory submission of **tirzepatide** for chronic weight management to the FDA;
- Announced the regulatory submission of **donanemab** for traditional approval for early Alzheimer's disease in the US and EU;
- Announced **mirikizumab** received approval in the European Union (EU) for patients with ulcerative colitis and the resubmission to the FDA;
- Announced the submission of **Jaypirca**<sup>®</sup> to the FDA for accelerated approval in CLL patients based on the Phase 1/2 BRUIN study;
- Completed the submission of **pirtobrutinib** for relapsed or refractory mantle cell lymphoma in Japan; and
- Announced the FDA approval of **Jardiance**<sup>®1</sup> to lower blood sugar along with diet and exercise in children 10 years and older with type 2 diabetes.

## CLINICAL

- Presented data at the 2023 Alzheimer's Association International Conference which showed that **donanemab** significantly slowed cognitive and functional decline in people with early symptomatic Alzheimer's disease; and
- Announced topline data from two **tirzepatide** Phase 3 trials, SURMOUNT-3 and SURMOUNT-4, in which tirzepatide demonstrated significant and superior weight loss compared to placebo in both studies.

## OTHER

- Announced an agreement to acquire **DICE Therapeutics**, a biopharmaceutical company that develops novel oral therapeutic candidates to treat chronic diseases in immunology;
- Announced an agreement to acquire **Versanis Bio**, a private clinical-stage biopharmaceutical company focused on the development of new medicines for the treatment of cardiometabolic diseases;
- Announced an agreement to acquire **Sigilon Therapeutics**, a biopharmaceutical company that seeks to develop functional cures for patients with a broad range of acute and chronic diseases; and
- Allocated an additional \$50 million to our now \$300 million **Social Impact Venture Capital Portfolio**, reflecting Lilly's commitment to going beyond the medicines it makes to have a positive impact on patients and society through for-profit investments.

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

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



Millions; except per share data

Q2 2023

	GAAP Reported	Adjustments	Non-GAAP Adjusted	YoY Non-GAAP Adjusted Change
<b>TOTAL REVENUE</b>	<b>\$8,312</b>	\$ -	<b>\$8,312</b>	28%
<b>GROSS MARGIN</b>	<b>78.3%</b>	1.5pp	<b>79.8%</b>	(0.0)pp
<b>TOTAL OPERATING EXPENSE</b>	<b>4,379</b>	-	<b>4,379</b>	14%
<b>OPERATING INCOME</b>	<b>2,126</b>	126	<b>2,252</b>	69%
<b>OPERATING MARGIN</b>	<b>25.6%</b>	1.5pp	<b>27.1%</b>	6.6pp
<b>OTHER INCOME (EXPENSE)</b>	<b>(37)</b>	54	<b>17</b>	NM
<b>EFFECTIVE TAX RATE</b>	<b>15.6%</b>	0.5pp	<b>16.1%</b>	1.9pp
<b>NET INCOME</b>	<b>\$1,763</b>	\$141	<b>\$1,904</b>	68%
<b>EPS</b>	<b>\$1.95</b>	\$0.16	<b>\$2.11</b>	69%
<b>Acquired IPR&amp;D Charges per share*</b>	<b>\$0.09</b>	\$ -	<b>\$0.09</b>	(80)%

\*Acquired IPR&D of \$97 million (pre-tax)

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

Not for promotional use

2023 Q2 EARNINGS

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



Millions; except per share data

1H 2023

	GAAP Reported	Adjustments	Non-GAAP Adjusted	YoY Non-GAAP Adjusted Change
<b>TOTAL REVENUE</b>	<b>\$15,272</b>	\$ -	<b>\$15,272</b>	7%
<b>GROSS MARGIN</b>	<b>77.5%</b>	1.7pp	<b>79.2%</b>	1.4pp
<b>TOTAL OPERATING EXPENSE</b>	<b>8,218</b>	-	<b>8,218</b>	14%
<b>OPERATING INCOME</b>	<b>3,620</b>	252	<b>3,872</b>	(2)%
<b>OPERATING MARGIN</b>	<b>23.7%</b>	1.7pp	<b>25.4%</b>	(2.2)p
<b>OTHER INCOME (EXPENSE)</b>	<b>(1)</b>	77	<b>75</b>	NM
<b>EFFECTIVE TAX RATE</b>	<b>14.1%</b>	0.6pp	<b>14.7%</b>	3.1pp
<b>NET INCOME</b>	<b>\$3,108</b>	\$260	<b>\$3,368</b>	(4)%
<b>EPS</b>	<b>\$3.44</b>	\$0.29	<b>\$3.73</b>	(4)%
<b>Acquired IPR&amp;D Charges per share*</b>	<b>\$0.19</b>	\$ -	<b>\$0.19</b>	(69)%

\*Acquired IPR&D of \$202 million (pre-tax)

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

Not for promotional use

2023 Q2 EARNINGS

# PRICE/RATE/VOLUME EFFECT ON REVENUE



Millions

## Q2 2023

	<u>Amount</u>	<u>Price</u>	<u>FX Rate</u>	<u>Volume</u>	<u>Total</u>	<u>CER</u>
<b>U.S.</b>	\$5,531	2%	-	39%	41%	41%
<b>EUROPE</b>	1,178	(6)%	1%	12%	7%	6%
<b>JAPAN</b>	456	1%	(7)%	7%	-	7%
<b>CHINA</b>	399	(1)%	(7)%	20%	13%	20%
<b>REST OF WORLD</b>	748	(1)%	(3)%	20%	16%	19%
<b>TOTAL REVENUE</b>	\$8,312	(0)%	(1)%	29%	28%	29%

## 1H 2023

	<u>Amount</u>	<u>Price</u>	<u>FX Rate</u>	<u>Volume</u>	<u>Total</u>	<u>CER</u>
<b>U.S.</b>	\$9,968	(2)%	-	11%	9%	9%
<b>EUROPE</b>	2,269	(6)%	(3)%	13%	5%	7%
<b>JAPAN</b>	843	-	(10)%	7%	(3)%	7%
<b>CHINA</b>	772	(11)%	(7)%	20%	2%	9%
<b>REST OF WORLD</b>	1,422	1%	(2)%	4%	2%	4%
<b>TOTAL REVENUE</b>	\$15,272	(3)%	(2)%	11%	7%	8%

Numbers may not add due to rounding

CER = price change + volume change

Not for promotional use

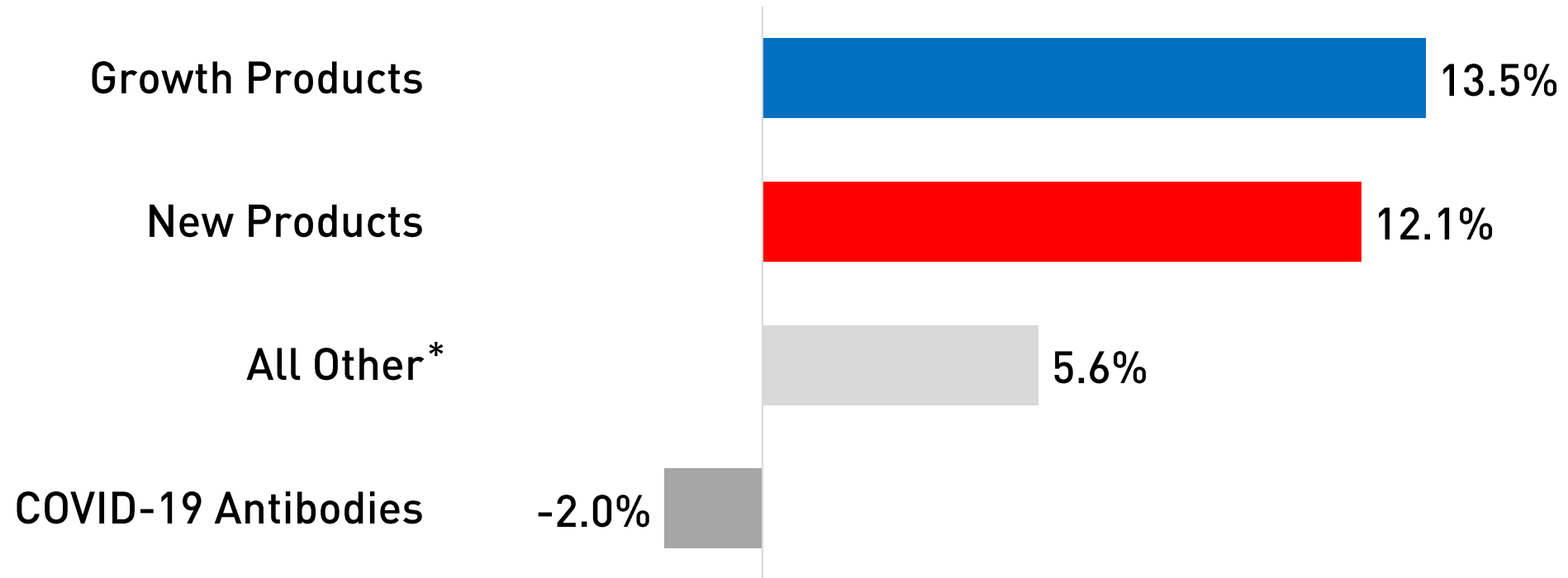
2023 Q2 EARNINGS



# PRODUCTS DRIVING WW VOLUME GROWTH



## Contribution to 29% Q2 WW Volume Increase



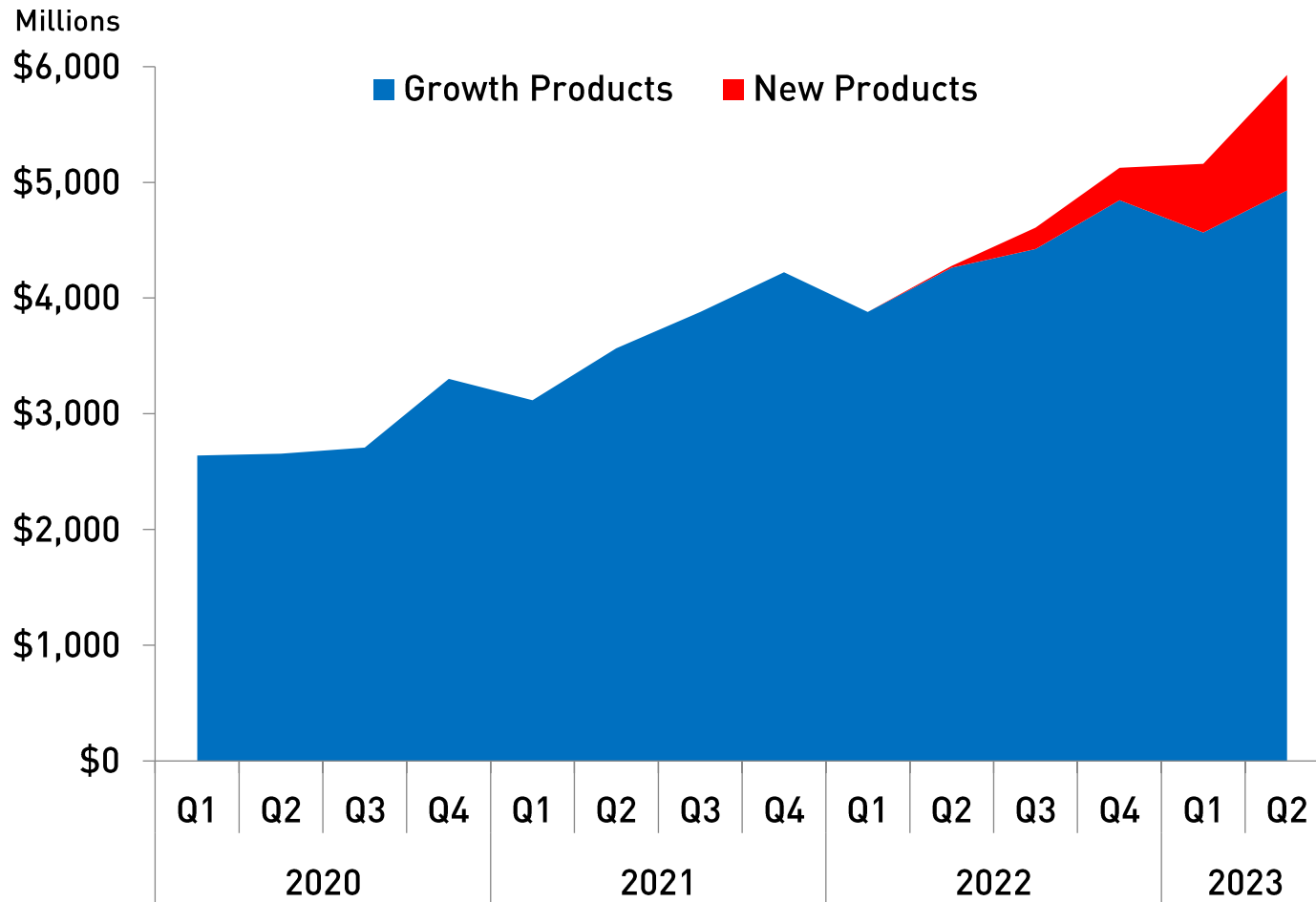
\*Includes \$579 million from the sale of the worldwide rights for Baqsimi; Numbers may not add due to rounding

**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 assumptions

# Q2 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 Q2 2023

### JAYPIRCA

- U.S. MCL approval in Q1 2023

### OMVOH

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

## GROWTH PRODUCTS

### JARDIANCE

- Market leader in U.S. with TRx SOM over 62% at the end of Q2
- U.S. TRx grew nearly 29% vs. Q2 2022, outpacing the market

### TALTZ

- U.S. TRx SOM at 6% at the end of Q2
- U.S. TRx grew over 11% vs. Q2 2022, outpacing the market

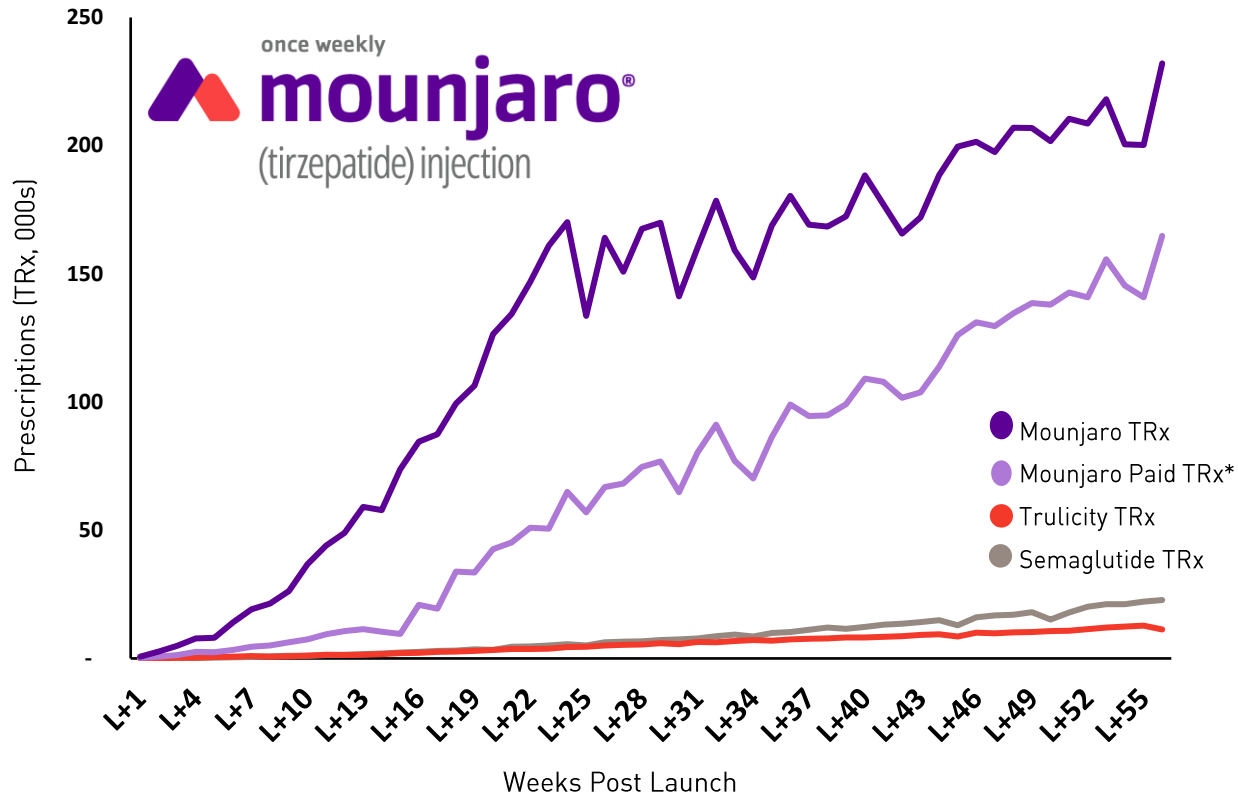
### TRULICITY

- U.S. T2D injectable incretins TRx SOM of nearly 26% at the end of Q2
- U.S. TRx grew nearly 12% vs. Q2 2022

### VERZENIO

- U.S. TRx grew nearly 60% vs. Q2 2022
- Strong uptake in adjuvant breast cancer indication

# MOUNJARO U.S. LAUNCH PROGRESS



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

- Robust U.S. uptake bolstered by strong efficacy and a positive customer experience
- Access as of July 1<sup>st</sup> at 73% for patients with type 2 diabetes across total commercial and Part D lives
- Percentage of paid prescriptions rose to 67% in Q2 due to copay program dynamics and improved access
- Original non-covered \$25 copay card ended June 30
- Focus on driving new-to-brand growth while continuing access expansion

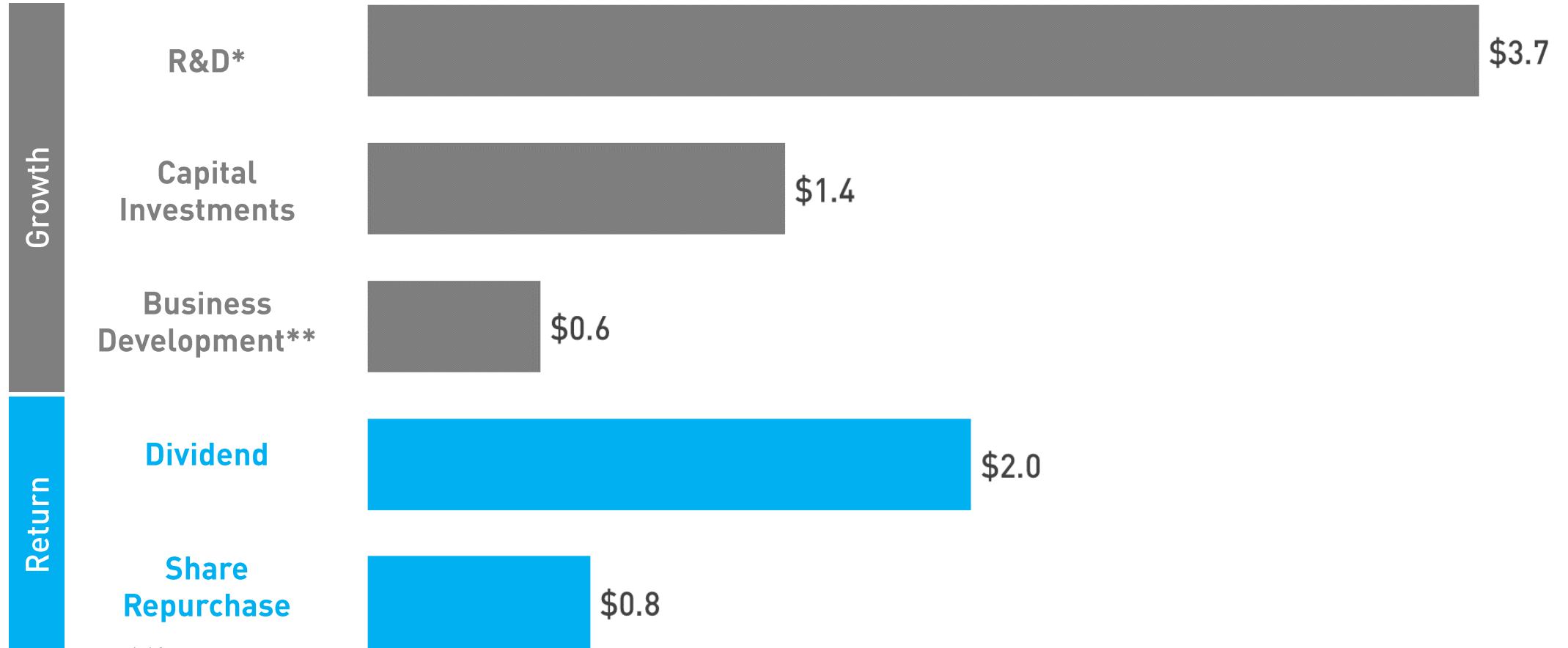
\*Internal estimate of weekly paid TRx  
IQVIA weekly data for week ending June 30, 2023 (type 2 diabetes injectable incretin class)

# CAPITAL ALLOCATION



Billions

## 1H 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
<b>REVENUE</b>	\$31.2 – \$31.7 billion	\$33.4 – \$33.9 billion	Increased range reflects revenue from the sales of rights for Baqsimi and olanzapine as well as strong performance in underlying business
<b>GROSS MARGIN % OF REVENUE (GAAP)</b> <b>GROSS MARGIN % OF REVENUE (NON-GAAP)</b>	Approx. 77% Approx. 79%	Approx. 78% Approx. 80%	Increase driven by the sales of rights for Baqsimi and our olanzapine portfolio
<b>MKTG, SELLING &amp; ADMIN.</b>	\$7.0 – \$7.2 billion	\$7.2 – \$7.4 billion	Increase reflects additional investments in recent launches and preparation for launches expected later this year
<b>RESEARCH &amp; DEVELOPMENT</b>	\$8.3 – \$8.5 billion	\$8.9 – \$9.1 billion	Increase reflects additional investments in the late-stage portfolio and early-stage research and expected incremental expense from business development activities
<b>ACQUIRED IPR&amp;D</b>	\$105 million	\$202 million	Incorporated IPR&D charges that have been incurred through Q2 2023; does not include any IPR&D charges associated with potential or pending business development transactions
<b>OTHER INCOME/(EXPENSE) (GAAP)</b> <b>OTHER INCOME/(EXPENSE) (NON-GAAP)</b>	\$(200) – \$(100) million	\$(75) – \$25 million \$0 – \$100 million	Increase driven by the interest impact of higher cash balances; reported guidance incorporates net losses on investments in equity securities
<b>TAX RATE</b>	Approx. 13%	14% – 15%	Increase reflects the impact from the sales of rights for the olanzapine portfolio and Baqsimi
<b>EARNINGS PER SHARE (GAAP)</b> <b>EARNINGS PER SHARE (NON-GAAP)</b>	\$8.18 – \$8.38 \$8.65 – \$8.85	\$9.20 – \$9.40 \$9.70 – \$9.90	

Assumes shares outstanding of 903 million

FX assumptions: 1.12 (Euro), 139 (Yen) and 7.1 (Renminbi)

# ORFORGLIPRON: PHASE 2 TRIAL IN OBESITY

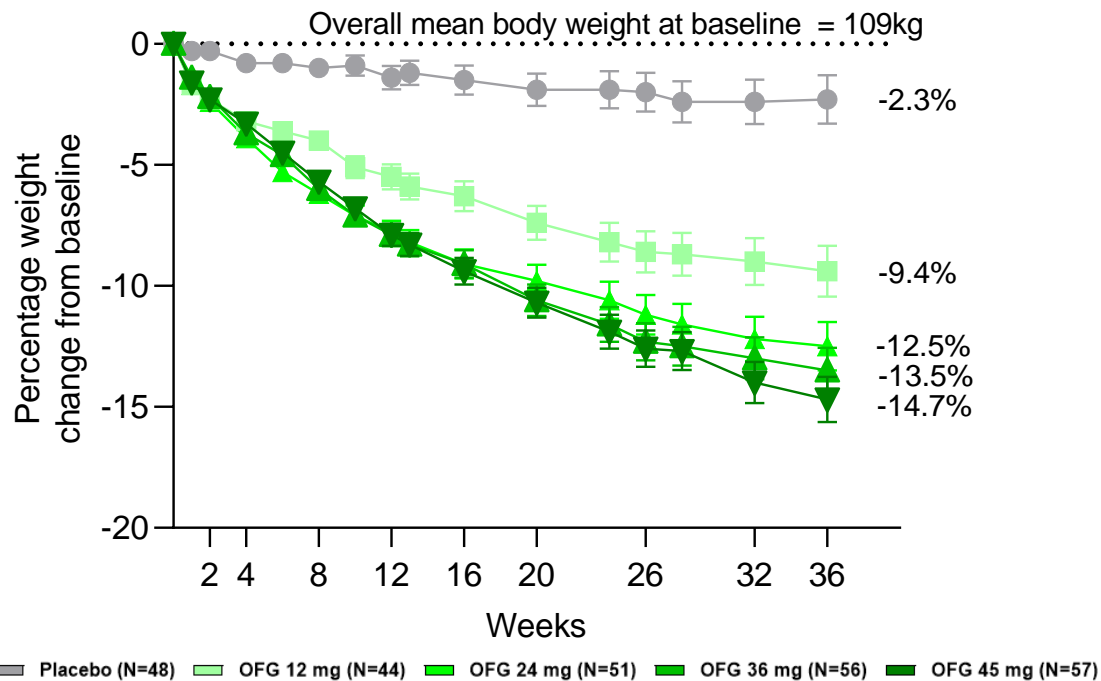
DEMONSTRATED UP TO 14.7% MEAN BODY WEIGHT REDUCTION AT 36 WEEKS



## EFFICACY RESULTS

## KEY MESSAGES

Percentage Change in Body Weight by Week (efficacy estimand)



- In the Phase 2 study of adults with obesity or overweight, 75% of participants achieved body weight reduction of 10% or more
- Safety profile was similar to other GLP-1 receptor agonists
- The ATTAIN Phase 3 program for orforglipron in chronic weight management began 1H of 2023

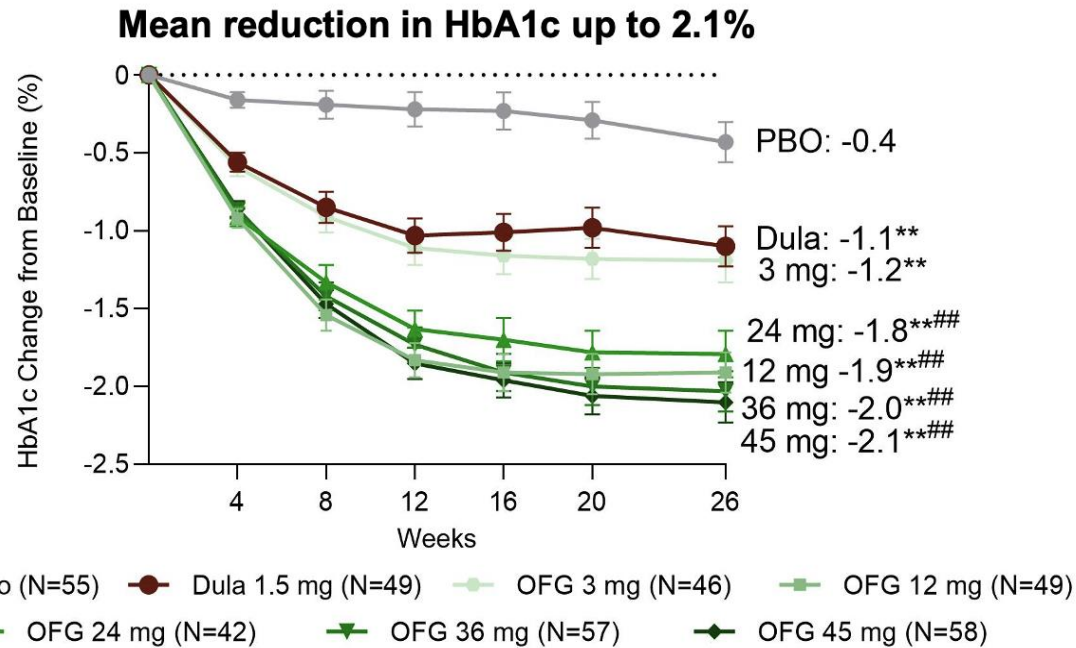
# ORFORGLIPRON: PHASE 2 TRIAL IN TYPE 2 DIABETES

DEMOSTATED MEAN REDUCTION IN HBA1C OF 2.1% IN PEOPLE WITH T2D AT 26 WEEKS



## EFFICACY RESULTS

## KEY MESSAGES



\*p<0.05 vs PBO, \*\*p<0.001 vs PBO, #p<0.05 vs dula, ##p<0.001 vs dula; Dula – dulaglutide, PBO – placebo

- Over 90% of participants on the highest three doses achieved HbA1c levels less than 7%, and 18%-34% of participants reached HbA1C less than 5.7%
- Reduction in mean body weight up to 10.1 kg
- Safety profile was similar to other incretin-based therapies
- The ACHIEVE Phase 3 program for orforglipron in type 2 diabetes is underway

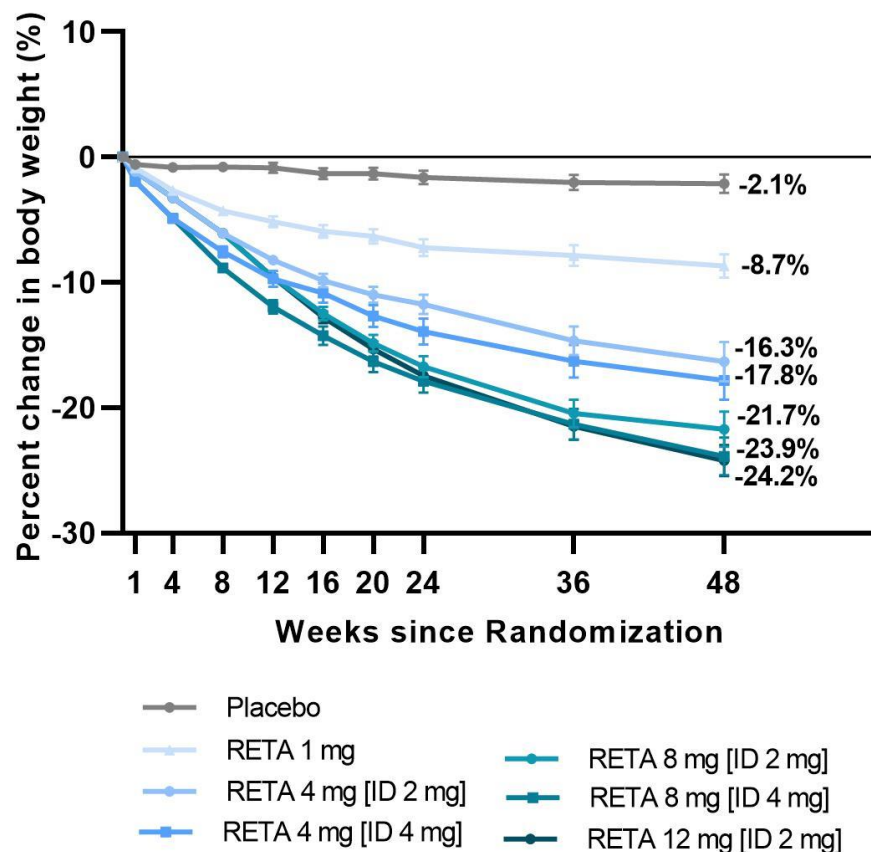
# RETATRUTIDE

DEMONSTRATED A MEAN WEIGHT REDUCTION OF UP TO 24.2% AT 48 WEEKS



## EFFICACY RESULTS

## KEY MESSAGES



- In the Phase 2 trial of adults with overweight and obesity, treatment was associated with improvements in cardiometabolic and hepatic measures at weeks 24 and 48
- Safety profile was similar to other incretin-based therapies
- Initiated the TRIUMPH Phase 3 program, which includes multiple studies that will evaluate safety and efficacy for chronic weight management, obstructive sleep apnea, and knee osteoarthritis in people with overweight and obesity
- In a Phase 2 trial in type 2 diabetes, participants achieved an HbA1c reduction of up to 2.0% on average; plan to advance retatrutide into Phase 3 for type 2 diabetes



# TIRZEPATIDE: SURMOUNT-3 & SURMOUNT-4

TRIALS DEMONSTRATED SIGNIFICANT AND SUPERIOR WEIGHT LOSS COMPARED TO PLACEBO



## SURMOUNT-3

- SURMOUNT-3 evaluated the efficacy and safety of tirzepatide compared to placebo for 72 weeks after a 12-week intensive lifestyle intervention lead-in period
- Participants, after 12 weeks of intensive lifestyle intervention, achieved an additional 21.1% mean weight loss with tirzepatide for a total mean weight loss of 26.6% over 84 weeks
- Safety profile was similar to incretin-based therapies approved for the treatment of obesity and overweight

## SURMOUNT-4

- SURMOUNT-4 evaluated the efficacy and safety of tirzepatide compared to placebo for 52 weeks after a 36-week open-label tirzepatide lead-in period
- Participants achieved 21.1% mean weight loss during a 36-week tirzepatide lead-in period and an additional 6.7% mean weight loss during a 52-week continued treatment period, for a total mean weight loss of 26.0% over 88 weeks
- Safety profile was similar to incretin-based therapies approved for the treatment of obesity and overweight

# LILLY SELECT NME AND NILEX PIPELINE

August 4, 2023



## LEGEND

<span style="color: blue;">●</span> NME	<b>MOVEMENT SINCE April 24, 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

UCENPRUBART (CD200R MAB AGONIST) Immunology		
RET INHIBITOR II Cancer	RIPK1 INHIBITOR Immunology	SARM1 INHIBITOR Neurodegeneration
NRG4 AGONIST Heart Failure	PI3K SELECTIVE Cancer	PNPLA3 siRNA NASH
NISOTIROSTIDE (PYY ANALOG) 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

IDH1/2 INHIBITOR Cancer	GIP/GLP COAGONIST PEPTIDE Diabetes
-------------------------	------------------------------------

RETATRUTIDE Diabetes	TIRZEPATIDE NASH
GBA1 GENE THERAPY Gaucher Disease Type 1	PIRTOBRUTINIB B-Cell Malignancies
SSTR4 AGONIST Pain	GBA1 GENE THERAPY Gaucher Disease Type 2
RELAXIN-LA Heart Failure	SOLBINSIRAN CVD
P2X7 INHIBITOR Pain	PERESOLIMAB Rheumatoid Arthritis
MUVALAPLIN CVD	O-GLCNACASE INH Alzheimer's Disease
LEPODISIRAN (LPA siRNA) CVD	MEVIDALEN Symptomatic LBD
GBA1 GENE THERAPY Parkinson's Disease	GRN GENE THERAPY Frontotemporal Dementia
BTLA MAB AGONIST Systemic Lupus Erythematosus	ELTREKIBART Hidradenitis Suppurativa

PHASE 2

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

PHASE 3

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

REG REVIEW

EMPAGLIFLOZIN* Chronic Kidney Disease
---------------------------------------

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** for chronic kidney disease<sup>1</sup> (US ✓+ /EU ✓+ /J ✓+)
- ✓+ **Donanemab** for early Alzheimer's disease<sup>2</sup> (US ✓+ /EU ✓+ /J)
- ✓+ **Pirtobrutinib** for MCL prior BTKi (J)
- ✓+ **Pirtobrutinib** for CLL prior BTKi and BCL2i<sup>3</sup>

## Regulatory Actions

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

<sup>1</sup> In collaboration with Boehringer Ingelheim

<sup>2</sup> Under the traditional approval pathway

<sup>3</sup> Under the FDA Accelerated Approval Program

# Q2 2023 SUMMARY



- Excluding COVID-19 antibodies and Baqsimi, **revenue grew** 22%, driven by 23% volume growth
- Continued to **speed life-changing medicines** to patients with:
  - Positive results in the Phase 3 TRAILBLAZER-ALZ 2 study and the submission of **donanemab** for traditional approval to the FDA;
  - The completed submission of **tirzepatide** in chronic weight management to the FDA and SURMOUNT-3 and SURMOUNT-4 positive topline results; and
  - The approval of **mirikizumab** in the EU and re-submission in the U.S.
- Q2 **investment growth** driven by investments in new products and indications and late-stage pipeline
- Announced several **acquisitions** and deployed over \$1 billion to shareholders via the **dividend**



**Invest in Current Portfolio**



**Invest in Future Innovation**



**Deliver Revenue Growth**



**Speed Life-Changing Medicines**

**Return Capital to Shareholders**



# SUPPLEMENTAL SLIDES

# 2023 INCOME STATEMENT – REPORTED



Millions; except per share data

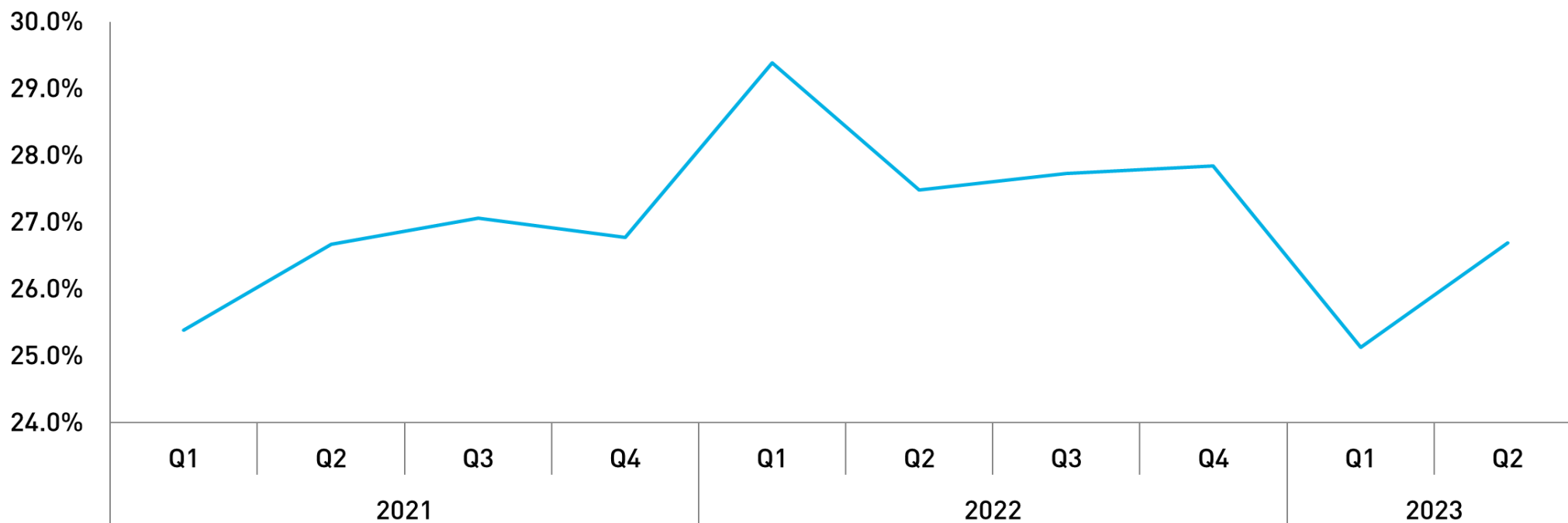
	Q2 2023	Change	1H 2023	Change
<b>TOTAL REVENUE</b>	\$8,312	28%	\$15,272	7%
<b>GROSS MARGIN</b>	78.3%	0.3pp	77.5%	2.0pp
<b>TOTAL OPERATING EXPENSE*</b>	4,379	14%	8,218	14%
<b>OPERATING INCOME</b>	2,126	76%	3,620	-
<b>OPERATING MARGIN</b>	25.6%	6.9pp	23.7%	(1.6)p
<b>OTHER INCOME (EXPENSE)</b>	(37)	(69)%	(1)	(100)%
<b>EFFECTIVE TAX RATE</b>	15.6%	2.9pp	14.1%	4.9pp
<b>NET INCOME</b>	\$1,763	85%	\$3,108	9%
<b>EARNINGS PER SHARE</b>	\$1.95	86%	\$3.44	9%

\* Includes research and development expense, marketing, selling and administrative expense, and acquired in-process research and development charges.

# 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%

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%

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

Not for promotional use

**2023 Q2 EARNINGS**

# EFFECT OF FX ON 2023 RESULTS



Year-on-Year Change

REPORTED	Q2 2023		1H 2023	
	With FX	w/o FX	With FX	w/o FX
<b>TOTAL REVENUE</b>	28%	29%	7%	8%
<b>COST OF SALES</b>	26%	27%	(2)%	(1)%
<b>GROSS MARGIN</b>	29%	30%	10%	11%
<b>OPERATING EXPENSE</b>	14%	14%	14%	15%
<b>OPERATING INCOME</b>	76%	81%	0%	3%
<b>EARNINGS PER SHARE</b>	86%	92%	9%	13%
<b>NON-GAAP</b>				
	With FX	w/o FX	With FX	w/o FX
<b>TOTAL REVENUE</b>	28%	29%	7%	8%
<b>COST OF SALES</b>	28%	29%	0%	1%
<b>GROSS MARGIN</b>	28%	29%	9%	10%
<b>OPERATING EXPENSE</b>	14%	14%	14%	15%
<b>OPERATING INCOME</b>	69%	74%	-2%	1%
<b>EARNINGS PER SHARE</b>	69%	73%	-4%	-1%

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.

Not for promotional use

**2023 Q2 EARNINGS**



# EPS RECONCILIATION



	<u>Q2 2023</u>	<u>Q2 2022</u>	<u>% Change</u>	<u>1H 2023</u>	<u>1H 2022</u>	<u>% Change</u>
<b>EPS (REPORTED)</b>	<b>\$1.95</b>	<b>\$1.05</b>	<b>86%</b>	<b>\$3.44</b>	<b>\$3.16</b>	<b>9%</b>
<b>AMORTIZATION OF INTANGIBLE ASSETS</b>	0.11	0.11	-	0.22	0.29	(24)%
<b>NET LOSSES (GAINS) ON INVESTMENTS IN EQUITY SECURITIES</b>	0.05	0.09	44%	0.07	0.43	(84)%
<b>EPS (NON-GAAP)</b>	<b>\$2.11</b>	<b>\$1.25</b>	<b>69%</b>	<b>\$3.73</b>	<b>\$3.87</b>	<b>(4)%</b>
<b>Acquired IPR&amp;D</b>	<b>\$0.09</b>	<b>\$0.46</b>	<b>(80)%</b>	<b>\$0.19</b>	<b>\$0.61</b>	<b>(69)%</b>

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

# Q2 2023 INCOME STATEMENT NOTES



## Q2 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 \$126.4 million (pretax), or \$0.11 per share (after-tax); and
- net losses on investments in equity securities totaling \$53.9 million (pretax), or \$0.05 per share (after-tax).

## Q2 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 \$121.3 million (pretax), or \$0.11 per share (after-tax); and
- net losses on investments in equity securities totaling \$106.3 million (pretax), or \$0.09 per share (after-tax).

# 1H 2023 INCOME STATEMENT NOTES



## 1H 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 \$252.2 million (pretax), or \$0.22 per share (after-tax); and
- net losses on investments in equity securities totaling \$76.5 million (pretax), or \$0.07 per share (after-tax).

## 1H 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 \$325.9 million (pretax), or \$0.29 per share (after-tax); and
- net losses on investments in equity securities totaling \$494.7 million (pretax), or \$0.43 per share (after-tax).

# COMPARATIVE EPS SUMMARY 2022/2023



	<b>1Q22</b>	<b>2Q22</b>	<b>3Q22</b>	<b>4Q22</b>	<b>2022</b>	<b>1Q23</b>	<b>2Q23</b>	<b>3Q23</b>	<b>4Q23</b>	<b>2023</b>
Reported	2.10	1.05	1.61	2.14	6.90	1.49	1.95			
Non-GAAP	2.62	1.25	1.98	2.09	7.94	1.62	2.11			

Numbers may not add due to rounding

For a complete reconciliation to reported earnings, see slide 25 and our earnings press release dated August 8<sup>th</sup>, 2023

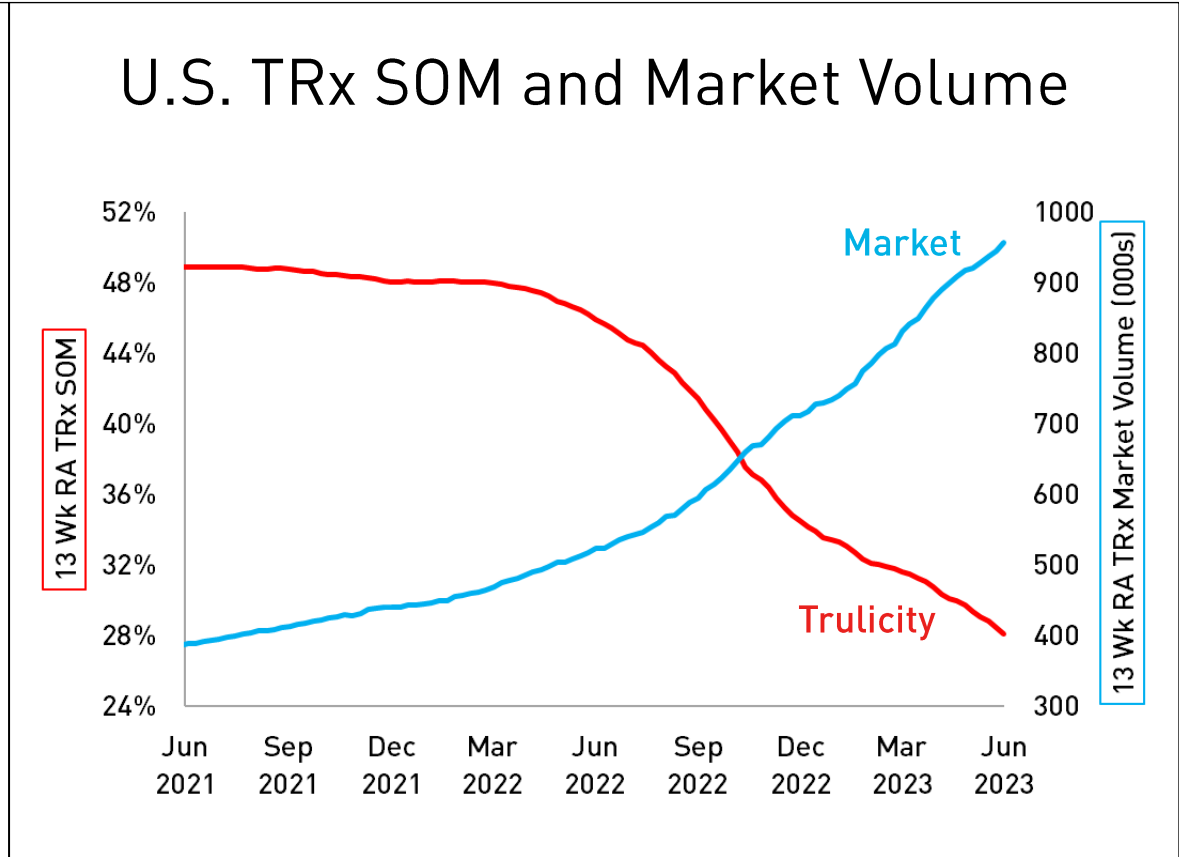
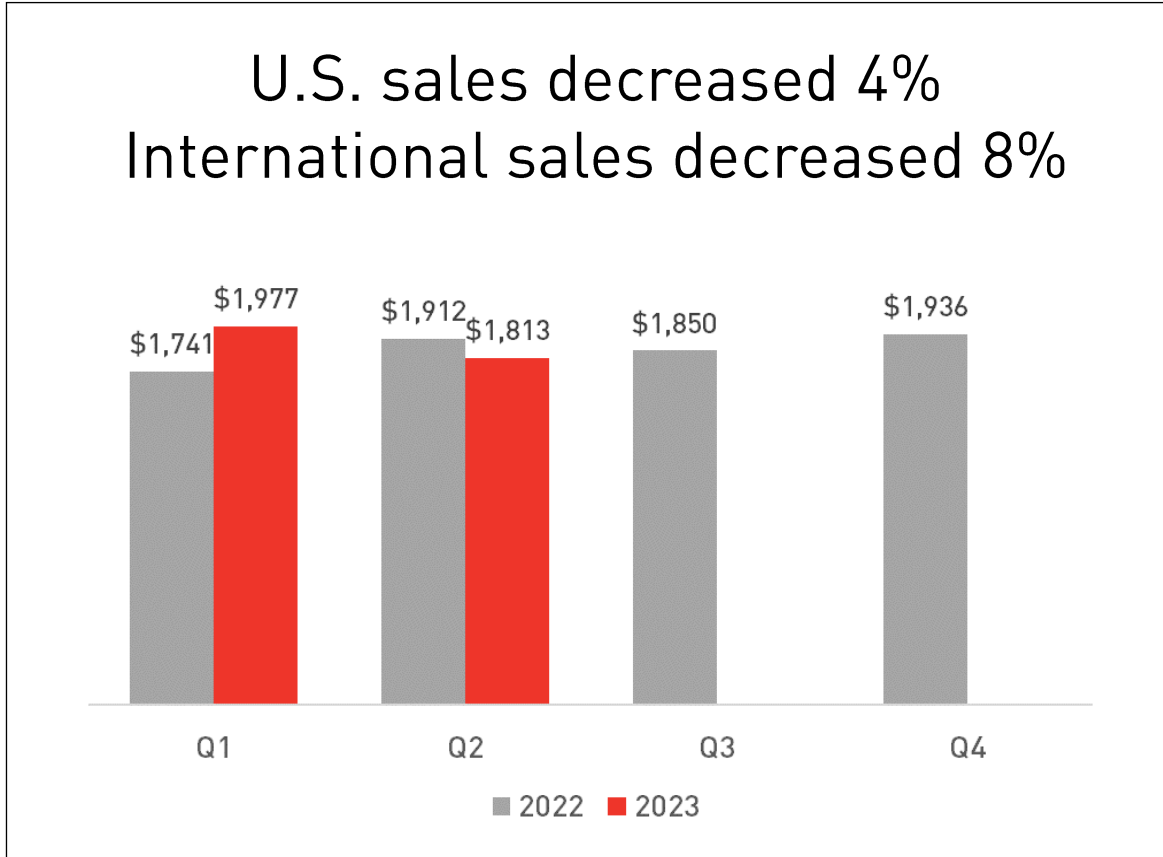
Not for promotional use

**2023 Q2 EARNINGS**

# Q2 2023 TRULICITY SALES DECREASED 5%



Millions

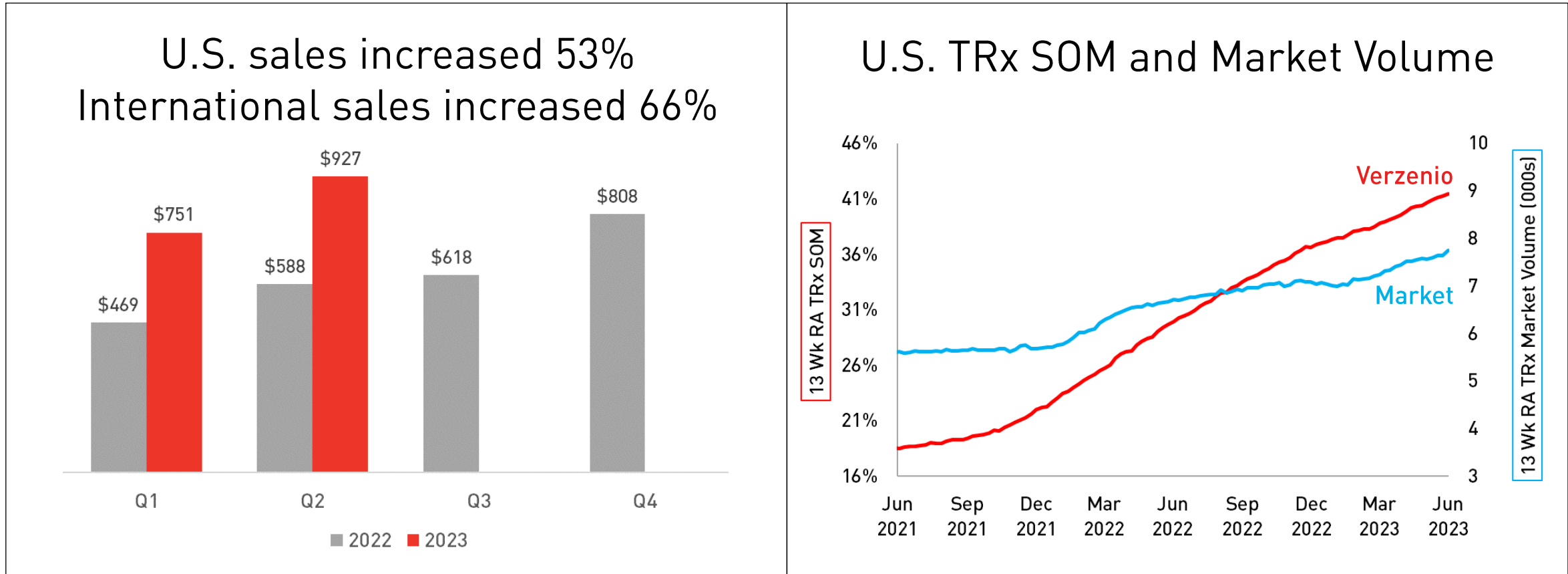


Source: IQVIA NPA TRx 3MMA, weekly data June 30, 2023; RA = rolling average TRx data is representative of the injectable incretin market

# Q2 2023 VERZENIO SALES INCREASED 57%



Millions

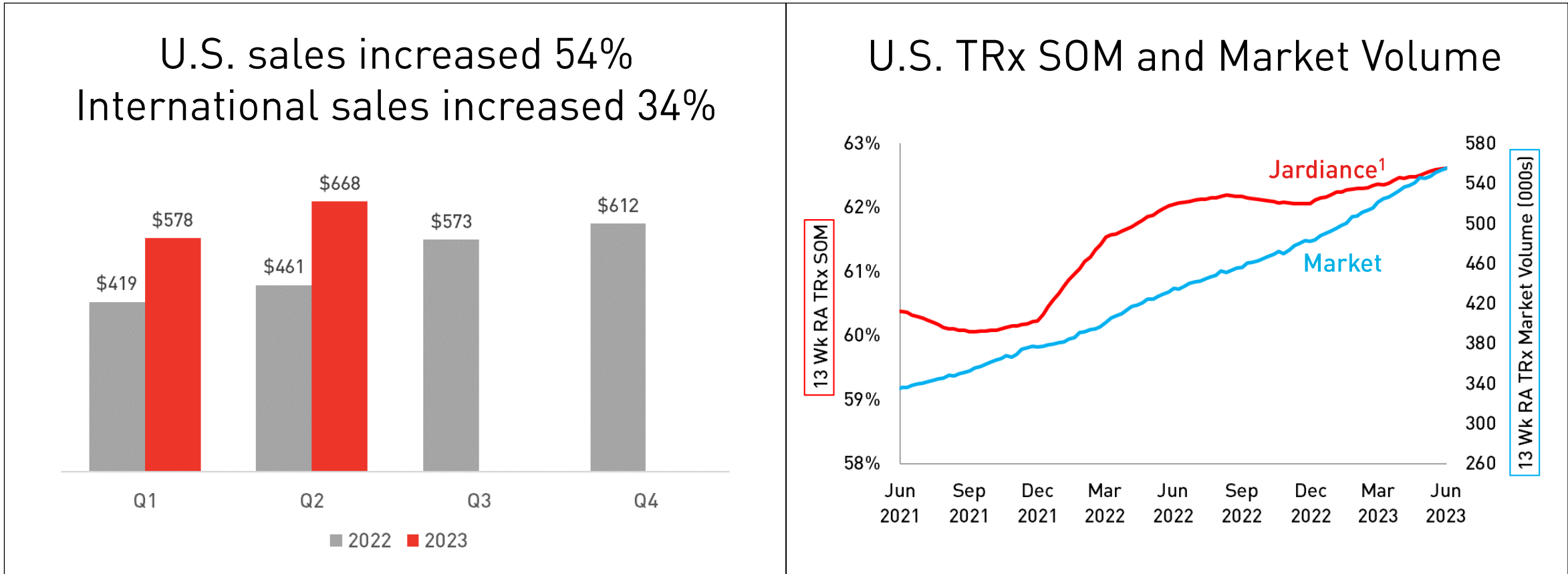


Source: IQVIA NPA TRx 3MMA, weekly data June 30, 2023; RA = rolling average

# Q2 2023 JARDIANCE SALES INCREASED 45%



Millions



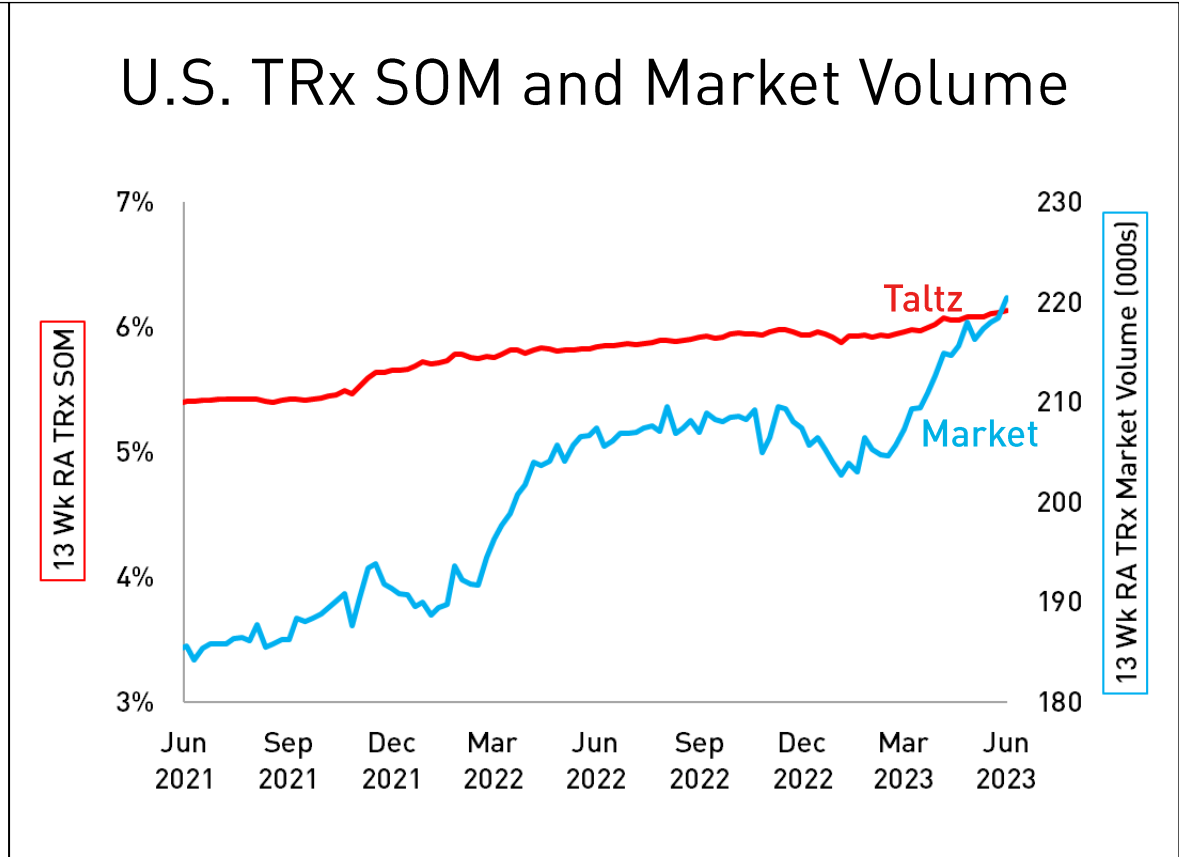
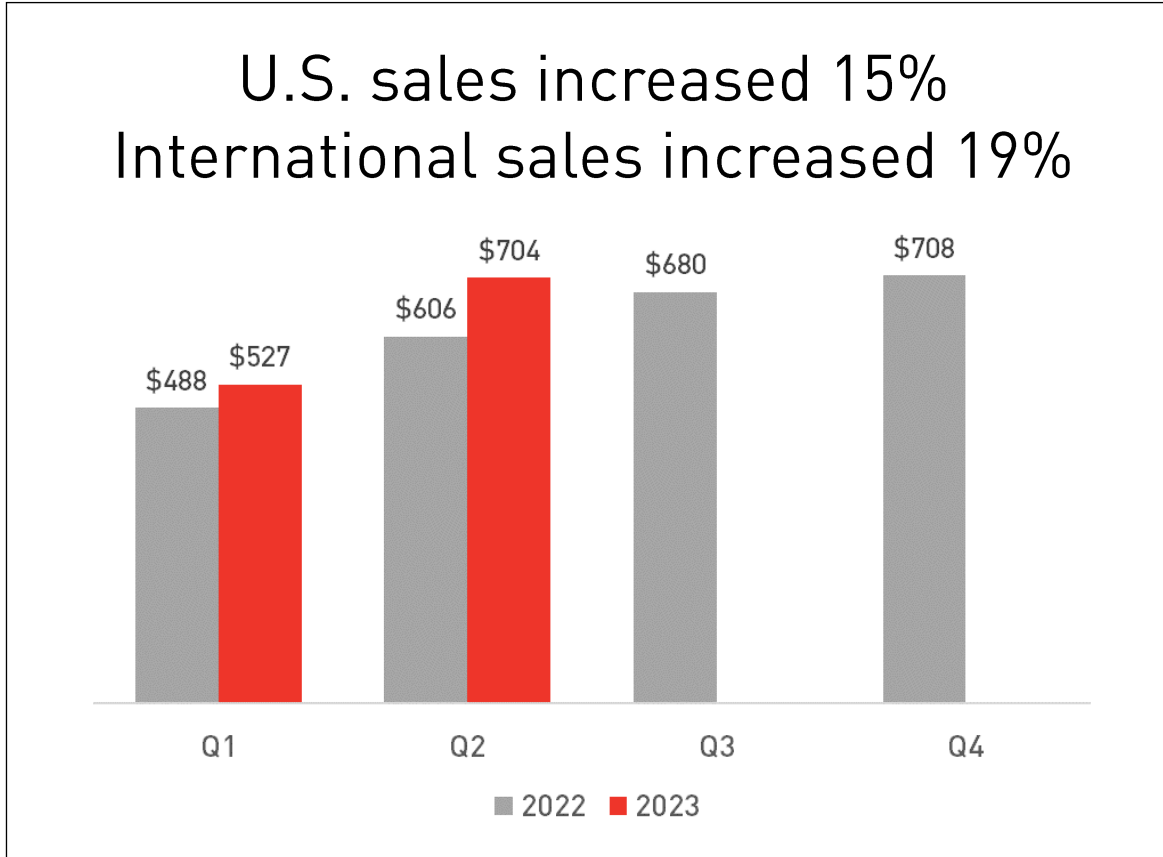
Source: IQVIA NPA TRx 3MMA, weekly data June 30, 2023; RA = rolling average  
 Jardiance is part of Lilly's alliance with Boehringer Ingelheim.

<sup>1</sup> Jardiance includes Glyxambi and Synjardy

# Q2 2023 TALTZ SALES INCREASED 16%



Millions



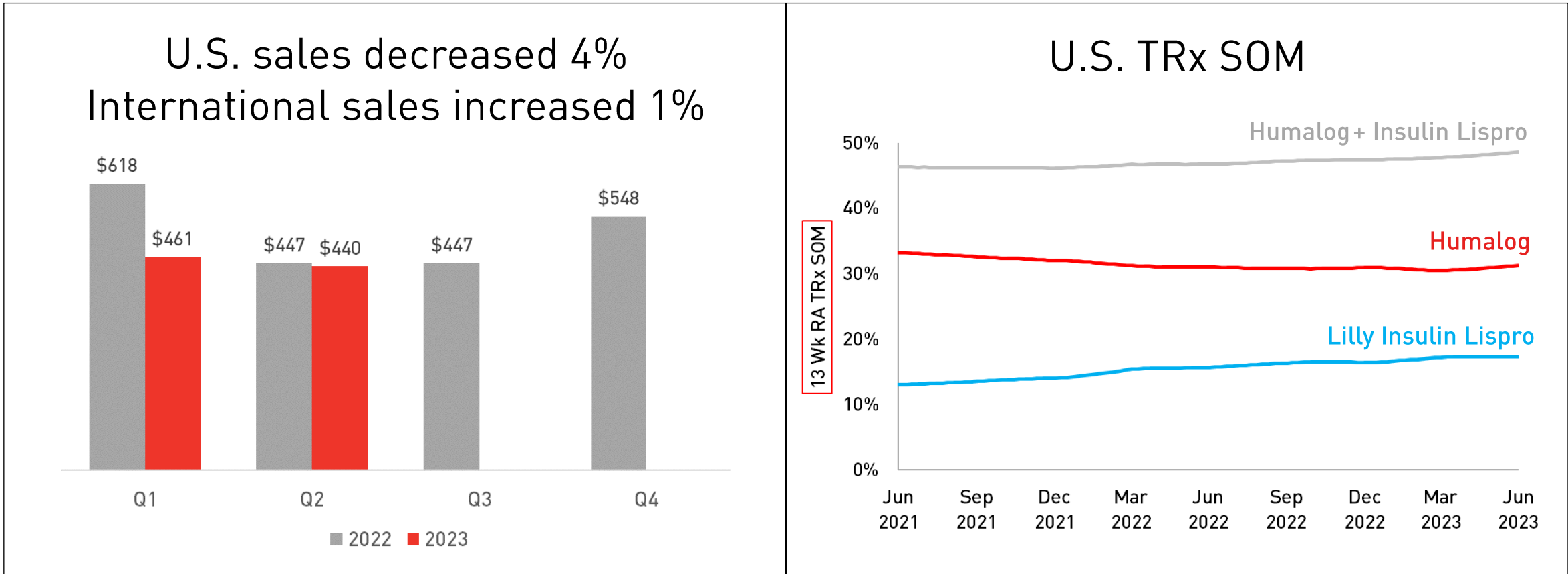
Source: IQVIA NPA TRx 3MMA, weekly data June 30, 2023; RA = rolling average  
TRx data is representative of the full molecule market



# Q2 2023 HUMALOG SALES DECREASED 1%



Millions

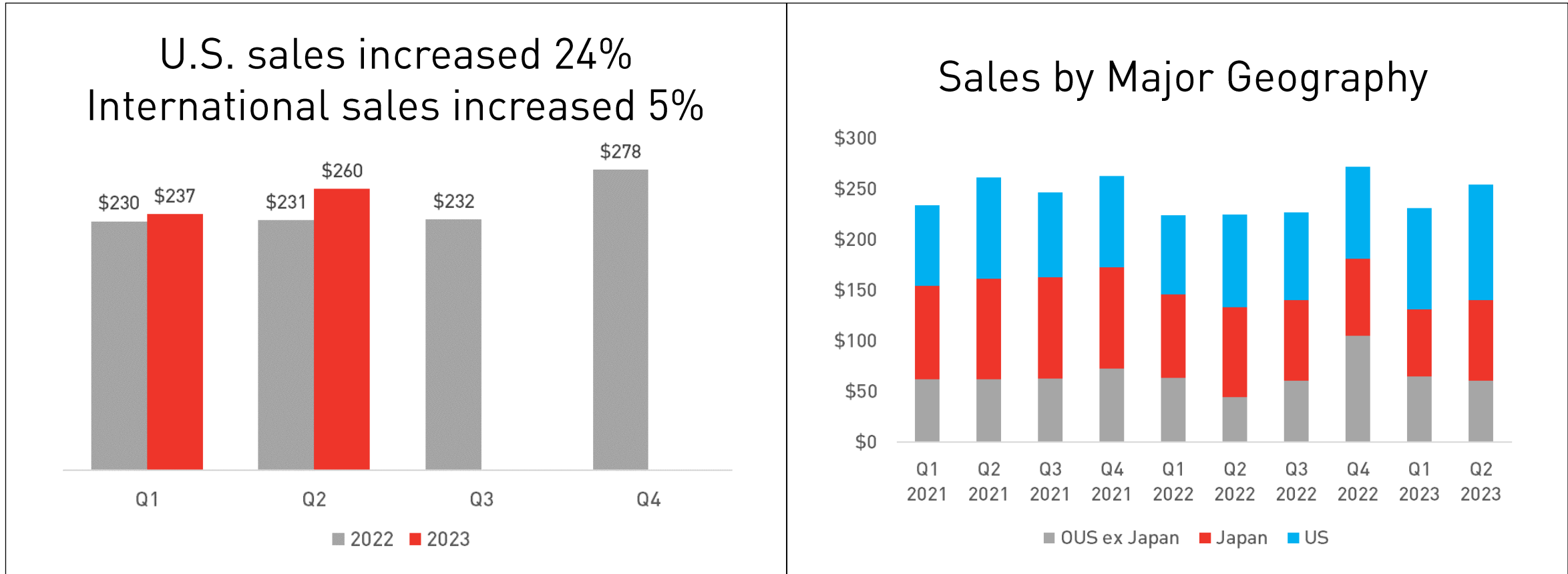


Source: IQVIA NPA TRx 3MMA, weekly data June 30, 2023; RA = rolling average

# Q2 2023 CYRAMZA SALES INCREASED 13%



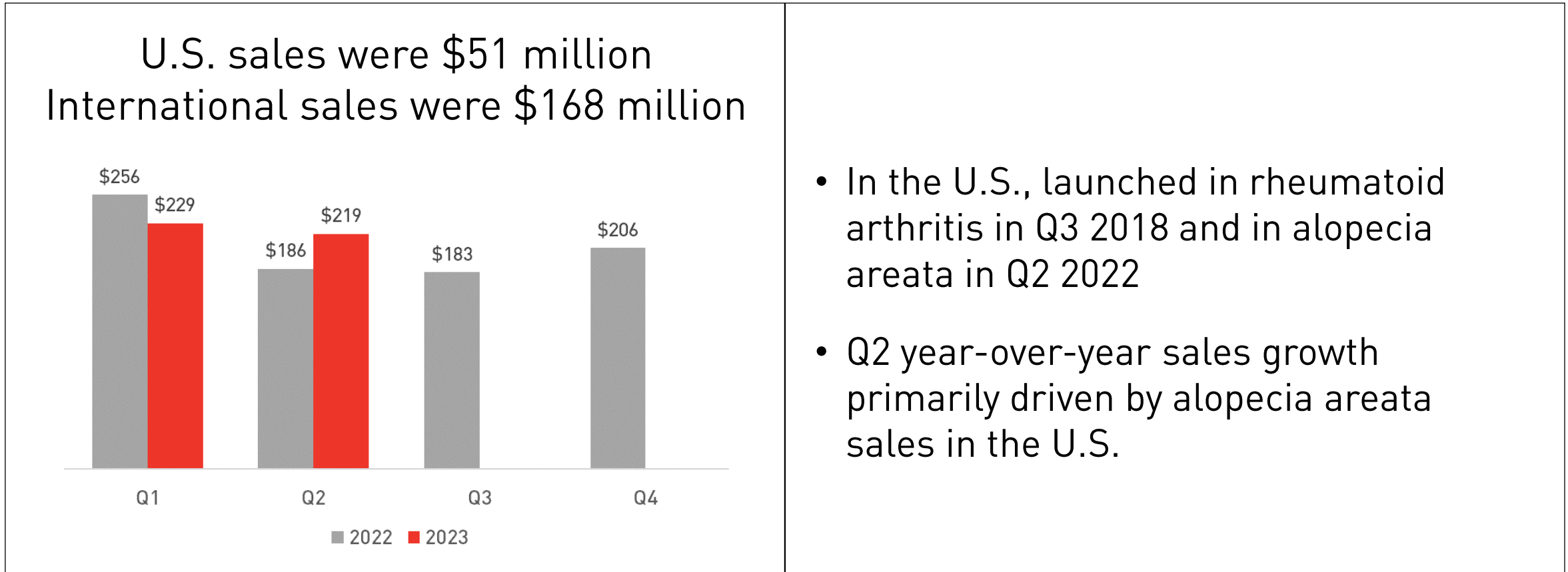
Millions



# Q2 2023 OLUMIANT SALES INCREASED 18%



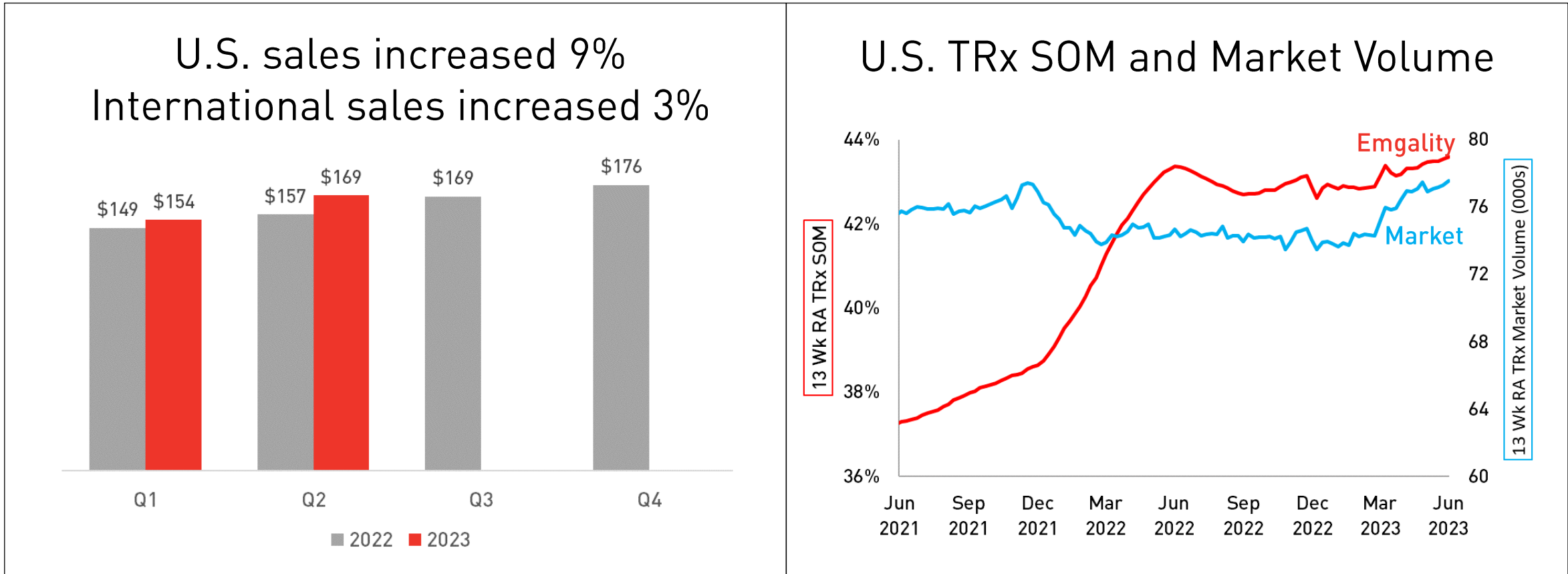
Millions



# Q2 2023 EMGALITY SALES INCREASED 8%



Millions



Source: IQVIA NPA TRx 3MMA, weekly data June 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, July 13, 2023

# SELECT TRIALS – DONANEMAB



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT05108922	Mild Cognitive Impairment	A Study of Donanemab (LY3002813) Compared With Aducanumab in Participants With Early Symptomatic Alzheimer's Disease (TRAILBLAZER-ALZ 4)	3	200	Percentage of Participants Who Reach Complete Amyloid Plaque Clearance on Florbetapir F18 Positron Emission Tomography (PET) Scan (Superiority) on donanemab versus aducanumab	Sep 2022	Sep 2023
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	3300	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, July 20, 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 (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, July 17, 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 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	Aug 2023	Aug 2023

In collaboration with Boehringer Ingelheim

<sup>1</sup> Also lists Medical Research Council Population Health Research Unit, CTSU, University of Oxford (academic lead)

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, July 27, 2023



# 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	Oct 2023	Mar 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	Aug 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	Aug 2024	Jul 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, July 24, 2023

# SELECT TRIALS – MIRIKIZUMAB



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03926130	Crohn's Disease	A Study of Mirikizumab (LY3074828) in Participants With Crohn's Disease (VIVID-1)	3	1100	Percentage of Participants Achieving Clinical Response at Week 12 and Endoscopic Response at Week 52	Aug 2023	Dec 2023
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	Apr 2026
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, July 13, 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)	Jan 2025	Jan 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]	Jan 2025	Sep 2025
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, August 2, 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)	Dec 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, July 11, 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, July 24, 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)	Feb 2025	Feb 2025
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	Oct 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	Nov 2025	Dec 2025
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, July 18, 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 2024	Nov 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
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)	Dec 2024	Jul 2027
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, July 13, 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	Dec 2024
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
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 2027	Dec 2027

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, July 14, 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)	Oct 2025	Nov 2025

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, July 25, 2023

# SELECT TRIALS – VERZENIO



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT031559971	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, July 14, 2023

# SELECT TRIALS – EARLY PHASE DIABETES AND OBESITY



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
Lepodisiran (LPA siRNA)	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
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

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, August 1, 2023

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



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
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	Oct 2023	Oct 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	Oct 2023	Oct 2023
Nisotirostide (PYY Analog Agonist)	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
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

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, July 14, 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	Mar 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

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, July 13, 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	420	Percentage of Participants Achieving American College of Rheumatology (ACR)20	Nov 2023	Jan 2025
BTLA MAB Agonist	NCT05123586	Systemic Lupus Erythematosus	A IMMA Master Protocol: A Study of LY3361237 in Participants With at Least Moderately Active Systemic Lupus Erythematosus	2	90	Percentage of Participants with Arthritis and/or Rash at Baseline Who Achieve Remission of Arthritis and/or Rash	Jan 2024	Apr 2024
Ucenprubart (CD200R MAB Agonist)	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	Jul 2025
RIPK1 Inhibitor	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
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	Jan 2024	Jan 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, July 27, 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	Apr 2024	Apr 2024
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	15	Number of Adverse Events (AEs), Serious Adverse Events (SAEs), and Adverse Events Leading to discontinuation	Dec 2027	Dec 2027
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
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, July 13, 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 Patients With Cancer With a Change in a Gene Called FGFR3	1	140	Phase 1a: To determine the maximum tolerated dose/recommended phase 2 dose (MTD/RP2D) of LOXO-435: Number of patients 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, July 21, 2023



# SELECT TRIALS – EARLY PHASE PAIN



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
P2X7 Inhibitor	NCT05620576	Chronic Pain	A Chronic Pain Master Protocol (CPMP): A Study of LY3857210 in Participants With Diabetic Peripheral Neuropathic Pain (NP05)	2	125	Change from Baseline for Average Pain Intensity as measured by the Numeric Rating Scale (NRS)	Jul 2023	Aug 2023

\* Molecule may have multiple indications

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

Source: clinicaltrials.gov, July 12, 2023

*Lilly*