

# Q3 2022 Earnings Call

### **AGENDA**



### INTRODUCTION AND KEY RECENT EVENTS

Dave Ricks, Chair and Chief Executive Officer

### Q3 2022 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**

# **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; the extent and duration of the effects of the COVID-19 pandemic; 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



### **Grow Revenue**



- 2% revenue growth in Q3, or 7% growth on a constant currency basis
- Q3 revenue driven by 14% volume growth
- Key growth products<sup>2</sup> grew 19% and represented 70% of revenue, excluding sales from COVID-19 antibodies<sup>1</sup>

### **Improve Productivity**



- Non-GAAP gross margin: 79.0% in Q3 and 78.2% YTD
- Non-GAAP operating margin:
  - 28.9% in Q3 (incl. negative impact of 90 basis points from acquired IPR&D and development milestone charges)
  - 28.0% YTD (incl. negative impact of 315 basis points from acquired IPR&D and development milestone charges)

### **Create Long-Term Value**



- Announced the agreement to acquire Akouos, a precision genetic medicine company aiming to discover and develop treatments for hearing loss
- Distributed nearly \$900 million via dividends in Q3

### **Speed Life-Changing Medicines**



- FDA granted Fast Track designation for **tirzepatide** in obesity. Rolling submission expected to initiate in 2022, primarily based on results from the completed SURMOUNT-1 trial as well as SURMOUNT-2, which is expected to be complete by the end of April 2023
- EU and Japan approval for Mounjaro® in type 2 diabetes
- Submission of **lebrikizumab** for moderate-to-severe atopic dermatitis in the U.S. and EU
- FDA accelerated approval for Retevmo® in tumor-agnostic RET fusion-positive advanced or metastatic solid tumors and traditional approval in locally advanced or metastatic RET fusion-positive NSCLC

1-Sales for COVID-19 antibodies include bamlanivimab, etesevimab and bebtelovimab sold pursuant to Emergency Use Authorization or similar regulatory authorizations 2-Refer to slide 9 for presentation of key growth products

# KEY EVENTS SINCE THE LAST EARNINGS CALL



#### **REGULATORY**

- The U.S. Food and Drug Administration (FDA) granted Fast Track designation for tirzepatide for the treatment of adults with obesity, or overweight with weight-related comorbidities. Rolling submission is expected to initiate in 2022, primarily based on results from the completed SURMOUNT-1 trial as well as SURMOUNT-2, which is expected to be complete by the end of April 2023;
- Regulatory authorities in Europe and Japan approved Mounjaro for the treatment of adults with type 2 diabetes;
- Submitted **lebrikizumab** for the treatment of moderate-to-severe atopic dermatitis to the FDA. Almirall submitted in the EU; and
- The FDA granted accelerated approval for Retevmo in adults with advanced or metastatic solid tumors with a RET gene fusion regardless of tumor type and simultaneously granted traditional approval in adults with locally advanced or metastatic non-small cell lung cancer with a RET gene fusion, as detected by an FDAapproved test.

#### **CLINICAL**

 Presented results from the maintenance study of lebrikizumab for the treatment of patients with moderate-to-severe atopic dermatitis showing robust and durable improvements in skin clearance and itch when dosed once every four weeks or once every two weeks after Week 16.

#### COVID-19

- Made bebtelovimab available for purchase to states, hospitals and certain other providers; and
- Supplied an additional 60,000 doses of bebtelovimab to the U.S.
   Government in Q3 2022 for approximately \$110 million to be used for financially vulnerable patients.

#### **OTHER**

- Announced the agreement to acquire **Akouos**, a precision genetic medicine company developing a portfolio of first-in-class adenoassociated viral gene therapies for the treatment of inner ear conditions, including sensorineural hearing loss;
- Announced the retirement of Stephen Fry, executive vice president, human resources and diversity, at the end of 2022, and the appointment of his successor, Eric Dozier, currently senior vice president and chief commercial officer for Loxo@Lilly; and
- Published the inaugural Sustainability Bond Allocation and Impact Report highlighting allocation of approximately €128 million across a range of projects since the issuance of the sustainability bonds in September 2021.

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



Millions; except per share data

Q3 2022

	GAAP Reported	Adjustments	Non-GAAP Adjusted	Non-GAAP Adjusted Change
TOTAL REVENUE	\$6,942	_	\$6,942	2%
GROSS MARGIN	77.3%	1.7pp	79.0%	(0.0)pp
<b>TOTAL OPERATING EXPENSE</b>	3,686	(206)	3,480	1%
OPERATING INCOME	1,676	331	2,007	6%
OPERATING MARGIN	24.2%	4.7pp	28.9%	1.0pp
OTHER INCOME (EXPENSE)	(111)	108	(3)	(55)%
EFFECTIVE TAX RATE	7.3%	3.4pp	10.7%	(3.6)pp
NET INCOME	\$1,452	\$337	\$1,789	11%
EPS	\$1.61	\$0.37	\$1.98	12%
Acquired IPR&D and Development Milestone Charges per share*	\$0.06	-	\$0.06	(63)%

<sup>\*</sup>Acquired IPR&D and development milestone charges of \$62 million (pre-tax) Numbers may not add due to rounding; see slide 23 for a complete list of adjustments.

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



Millions; except per share data

### YTD 2022

	GAAP Reported	Adjustments	Non-GAAP Adjusted	Non-GAAP Adjusted Change
TOTAL REVENUE	\$21,240	_	\$21,240	5%
GROSS MARGIN	76.1%	2.1pp	78.2%	0.3pp
<b>TOTAL OPERATING EXPENSE</b>	10,867	(207)	10,660	2%
OPERATING INCOME	5,291	656	5,947	10%
OPERATING MARGIN	24.9%	3.1pp	28.0%	1.3pp
OTHER INCOME (EXPENSE)	(581)	603	22	(33)%
EFFECTIVE TAX RATE	8.6%	2.7pp	11.3%	(1.4)pp
NET INCOME	\$4,307	\$986	\$5,293	11%
EPS	\$4.76	\$1.09	<b>\$5.85</b>	12%
Acquired IPR&D and Development Milestone Charges per share*	\$0.67	-	\$0.67	41%

<sup>\*</sup>Acquired IPR&D and development milestone charges of \$668 million (pre-tax) Numbers may not add due to rounding; see slide 24 for a complete list of adjustments.

# PRICE/RATE/VOLUME EFFECT ON REVENUE



Millions	Q3 2022
116610110	

Millions	Q3 2022					
	Amount	<b>Price</b>	FX Rate	<u>Volume</u>	Total	CER
U.S.	\$4,422	(4)%	_	15%	11%	11%
EUROPE	1,056	(3)%	(15)%	14%	(4)%	11%
JAPAN	488	(4)%	(16)%	3%	(18)%	(2)%
CHINA	343	(67)%	(4)%	57%	(14)%	(10)%
<b>REST OF WORLD</b>	632	(1)%	(3)%	(4)%	(8)%	(6)%
TOTAL REVENUE	\$6,942	(7)%	(4)%	14%	2%	7%

### **YTD 2022**

	Amount	<u>Price</u>	FX Rate	Volume	Total	CER
U.S.	\$13,531	(4)%	_	20%	16%	16%
EUROPE	3,225	(2)%	(10)%	1%	(11)%	(1)%
JAPAN	1,352	(4)%	(11)%	(11)%	(26)%	(15)%
CHINA	1,102	(61)%	(1)%	47%	(14)%	(13)%
<b>REST OF WORLD</b>	2,029	(2)%	(3)%	10%	5%	8%
TOTAL REVENUE	\$21,240	(7)%	(3)%	15%	5%	8%

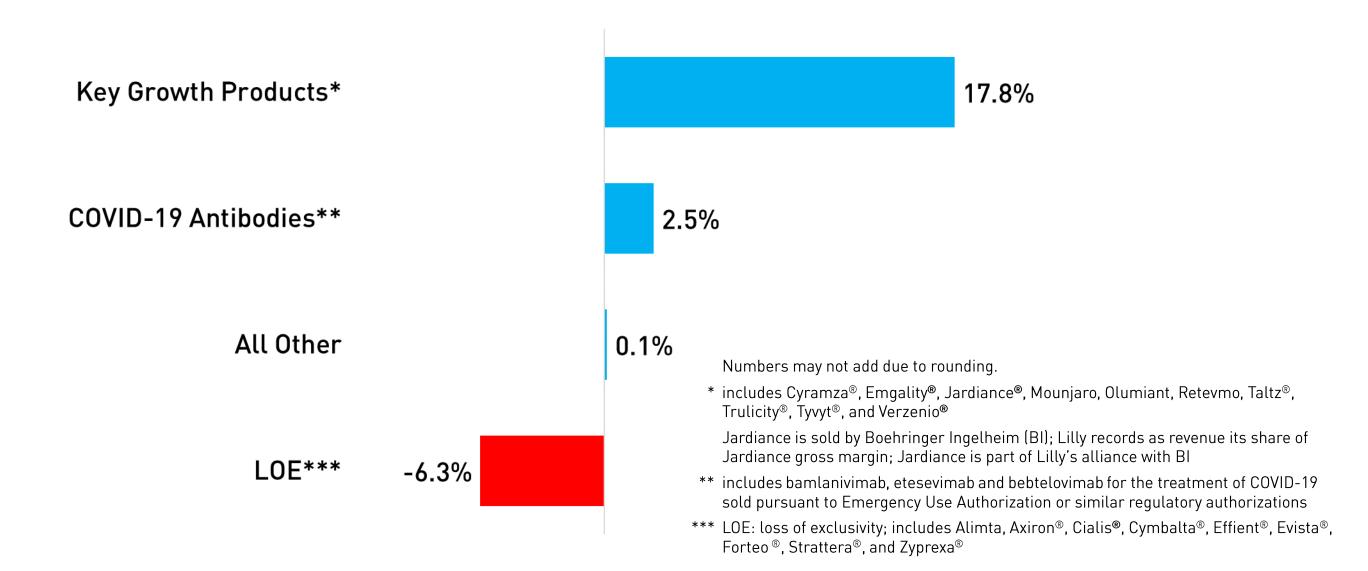
Numbers may not add due to rounding

CER = price change + volume change

# **KEY PRODUCTS DRIVING WW VOLUME GROWTH**

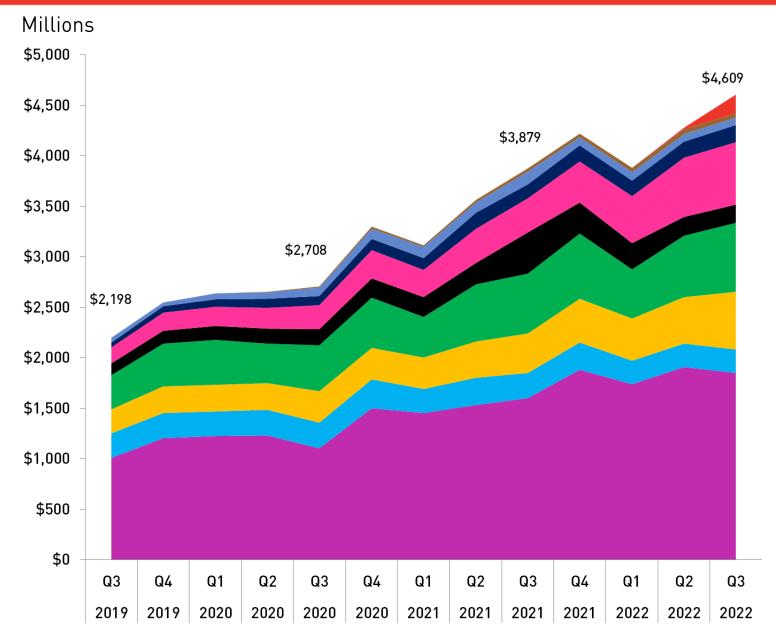


### Contribution to 14% Q3 WW Volume Growth



# **UPDATE ON KEY GROWTH PRODUCTS**





Jardiance is part of Lilly's alliance with Boehringer Ingelheim. Source: IQVIA weekly data September 30, 2022

MOUNJARO

• U.S. T2D launch in Q2 2022

RETEVMO

• Growth driven by indications in advanced RET lung and thyroid cancer

TYVYT

• Continued penetration via China's National Reimbursement Drug List (NRDL)

**EMGALITY** 

• U.S. injectable calcitonin gene-related peptide (CGRP) TRx SOM nearly 43%

VERZENIO

• U.S. TRx grew nearly 111% vs. Q3 2021

• Strong uptake in adjuvant breast cancer indication

OLUMIANT

• WW sales declined 55% vs. Q3 2021

• Decline primarily driven by lower utilization for the treatment of COVID-19

TALTZ

• IL-17 dermatology leader in U.S. TRx SOM 20%

• U.S. TRx grew 21% vs. Q3 2021, outpacing the market

JARDIANCE

• Market leader in U.S. TRx SOM 62%

• U.S. TRx grew nearly 34% vs Q3 2021, outpacing the market

CYRAMZA

• WW sales declined 8% vs Q3 2021

TRULICITY

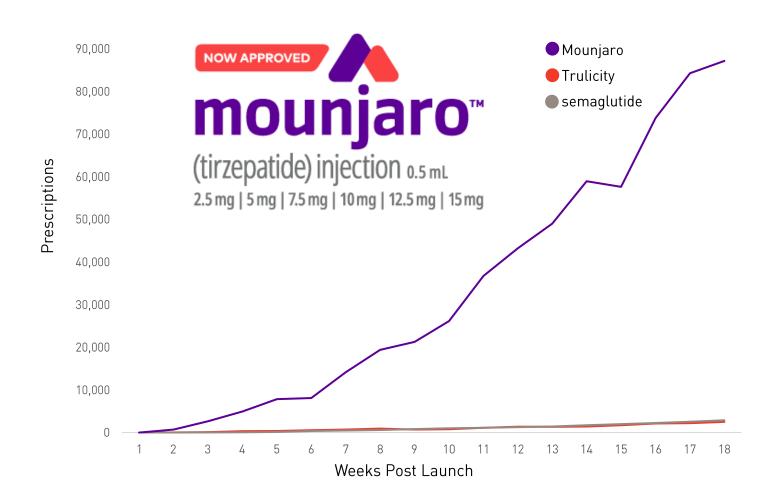
• U.S. injectable incretins TRx SOM 39%

• U.S. TRx grew nearly 23% vs Q3 2021

# **MOUNJARO LAUNCH PROGRESS**



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

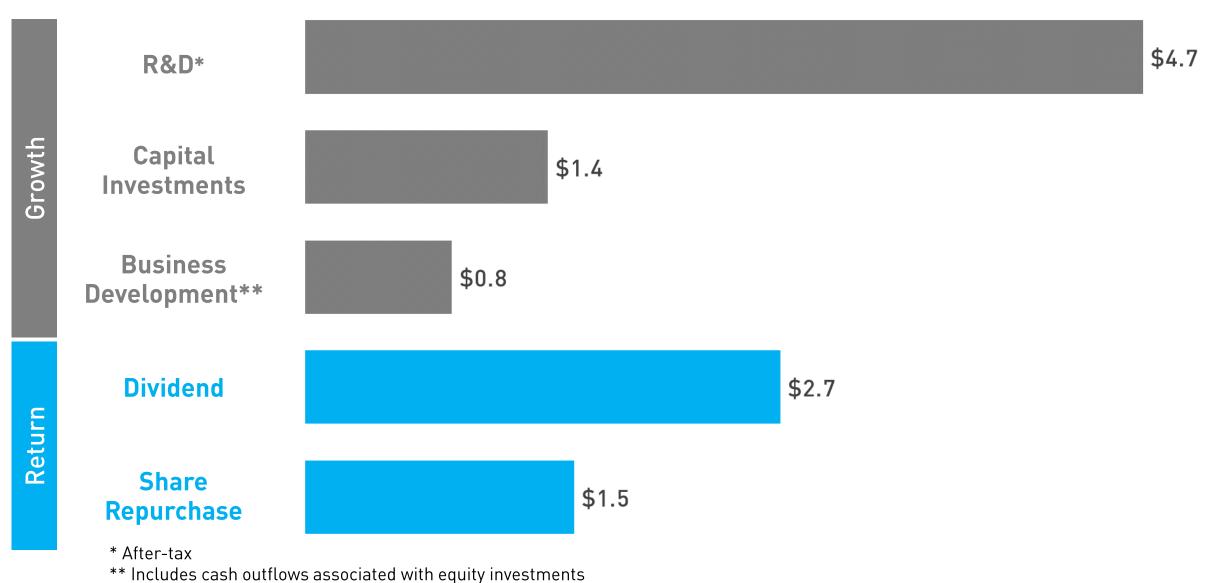
- Robust U.S. uptake bolstered by strong efficacy and a positive customer experience
- Approximately 70% of Mounjaro new therapy starts are naïve to the type 2 diabetes injectable GLP-1 class and under 10% are switches from Trulicity
- Access is now ~45% of total commercial and Part D lives
- Focused on expanding access and increasing paid prescriptions for type 2 diabetes in the U.S.

# **CAPITAL ALLOCATION**





### YTD 2022 Capital Allocation



Not for promotional use

# **2022 GUIDANCE**



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	Prior	<u>Updated</u>	Comments
TOTAL REVENUE	\$28.8 – \$29.3 billion	\$28.5 – \$29.0 billion	Reflects \$300 million in incremental headwinds from foreign exchange rates
GROSS MARGIN % (GAAP) GROSS MARGIN % (NON-GAAP)	Approx. 76% Approx. 78%	Unchanged	
MKTG, SELLING & ADMIN.	\$6.4 – \$6.6 billion	Unchanged	
RESEARCH & DEVELOPMENT	\$7.1 – \$7.3 billion	Unchanged	
ACQUIRED IPR&D & DEVT MILESTONES	Approx. \$610 million	Approx. \$670 million	Reflects total IPR&D charges in the first 9 months of the year; does not include any impact from potential business development transactions, such as the pending acquisition of Akouos
OTHER INCOME/(EXPENSE) (GAAP) OTHER INCOME/(EXPENSE) (NON-GAAP)	\$(600) – \$(500) million \$(100) – \$0 million	\$(700) — \$(600) million Unchanged	GAAP change reflects the impact of net losses on investments in equity securities during Q3 2022
TAX RATE	Approx. 13% – 14%	Unchanged	Assumes the provision in the 2017 Tax Act requiring capitalization of R&D expenses will be deferred or repealed by Congress effective for 2022
EARNINGS PER SHARE (GAAP) EARNINGS PER SHARE (NON-GAAP)	\$6.96 – \$7.11 \$7.90 – \$8.05	\$6.50 - \$6.65 \$7.70 - \$7.85	Non-GAAP EPS change driven by the negative impact of foreign exchange rates and increased acquired IPR&D and development milestone charges
OPERATING INCOME % (GAAP) OPERATING INCOME % (NON-GAAP)	Approx. 27% Approx. 29%	Approx. 26% Unchanged	GAAP change reflects the intangible asset impairment for GBA1 Gene Therapy (PR001) due to changes in estimated launch timing

2022 assumes GAAP and non-GAAP shares outstanding of 904 million

Updated FX assumptions of 0.97 (Euro), 145 (Yen) and 7.11 (Renminbi)

### LILLY SELECT NME AND NILEX PIPELINE

OCTOBER 28, 2022

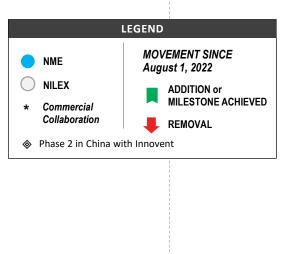


SARM1 INHIBITOR Neurodegeneration		
RET INHIBITOR II Cancer	RIPK1 INHIBITOR Immunology	GITR ANTAGONIST Immunology
PNPLA3 siRNA NASH	PYY ANALOG Diabetes	RELAXIN-LA Heart Failure
NRG4 AGONIST Heart Failure	P2X7 INHIBITOR Pain	PI3K SELECTIVE Cancer
LP(a) siRNA CVD	MAZDUTIDE � Diabetes	NOT DISCLOSED Diabetes
KRAS G12C II Cancer	KV1.3 ANTAGONIST Immunology	LP(a) INHIBITOR CVD
GIP/GLP COAGONIST PEPTIDE Diabetes	IDH1/2 INHIBITOR Cancer	KHK INHIBITOR II Diabetes / NASH
DACRA QW II Obesity	GIPR AGONIST LA Diabetes	GIPR AGONIST LA II Diabetes
AMYLIN AGONIST LA Obesity	CD19 ANTIBODY Immunology	CD200R MAB AGONIST Immunology
	PHASE 1	
BCL2 INHIBITOR		

Cancer

RETATRUTIDE Obesity	TIRZEPATIDE NASH			
ORFORGLIPRON (GLP-1R NPA) Obesity	PIRTOBRUTINIB B-Cell Malignancies			
ANGPTL3 siRNA CVD	GBA1 GENE THERAPY Gaucher Disease Type 2			
SSTR4 AGONIST Pain	TRPA1 ANTAGONIST Pain			
RETATRUTIDE Diabetes	REZPEGALDESLEUKIN Systemic Lupus Erythematosus			
ORFORGLIPRON (GLP-1R NPA) Diabetes	PERESOLIMAB Rheumatoid Arthritis			
MEVIDALEN Symptomatic LBD	O-GLCNACASE INH Alzheimer's Disease			
GBA1 GENE THERAPY Parkinson's Disease	GRN GENE THERAPY Frontotemporal Dementia			
BTLA MAB AGONIST Systemic Lupus Erythematosus	CXCR1/2L MAB Hidradenitis Suppurativa			
PHASE 2				
PACAP38 MAB Migraine				







**REG REVIEW** 



# **POTENTIAL KEY EVENTS 2022**

New since last update



#### **Phase 3 Initiations**

- ★ Abemaciclib for early prostate cancer (CYCLONE-3)
   Basal Insulin-Fc for type 2 diabetes (QWINT-1)
- Basal Insulin-Fc for type 2 diabetes (QWINT-2)
- Basal Insulin-Fc for type 2 diabetes (QWINT-3)
- Basal Insulin-Fc for type 2 diabetes (QWINT-4)
- ◆ Basal Insulin-Fc for type 1 diabetes (QWINT-5)
- **Remternetug (N3PG 4)** for early Alzheimer's disease
- Pirtobrutinib for CLL BTKi naïve H2H vs ibrutinib
- Tirzepatide for morbidity/mortality in obesity (SURMOUNT-MMO)
- Tirzepatide for obstructive sleep apnea (SURMOUNT-OSA)

  Tirzepatide for obesity (H2H vs semaglutide 2.4 mg)
- Tirzepatide for early diabetes (SURPASS-EARLY)

  Imlunestrant for adjuvant breast cancer

### Phase 3 & Other Key Data Disclosures

Empagliflozin for chronic kidney disease<sup>23</sup>

- Lebrikizumab for atopic dermatitis (maintenance data)
- Tirzepatide for obesity (SURMOUNT-1)

### **Medical Meeting Presentations**

- Lebrikizumab for atopic dermatitis (combination with TCS)
- ✓ Mirikizumab for ulcerative colitis (induction ✓ /maintenance ✓ )
- Tirzepatide for obesity (SURMOUNT-1)

### **Regulatory Submissions**

- Bebtelovimab EUA for COVID-19
- Donanemab for early Alzheimer's disease<sup>1</sup>
- 4 Lebrikizumab for atopic dermatitis
- Mirikizumab for ulcerative colitis (US

  √

  /EU

  √

  /J

  √

  )
- Pirtobrutinib for MCL prior BTKi1
- Selpercatinib for metastatic tumor agnostic RET fusion+ (US)

### **Regulatory Actions**

- Bebtelovimab EUA for COVID-19
- 4 Abemaciclib for high-risk HR+, HER2- early breast cancer (EU)
- Baricitinib for atopic dermatitis (US)
- ✓ Baricitinib for alopecia areata (US ✓ /EU ✓ /J ✓ )
- Selpercatinib for metastatic RET fusion-positive NSCLC (US)4
- Sintilimab for 1L NSCLC (US)
- Tirzepatide for type 2 diabetes (US4/EU4/J4)

<sup>&</sup>lt;sup>1</sup> FDA acceptance and priority review designation

<sup>&</sup>lt;sup>2</sup> Stopped early based on an interim assessment that met prespecified criteria for clear positive efficacy

<sup>&</sup>lt;sup>3</sup> In collaboration with Boehringer Ingelheim

<sup>&</sup>lt;sup>4</sup> Full NDA approval

# Q3 2022 PERFORMANCE SUMMARY



- Revenue grew 2%, or 7% on a constant currency basis; revenue driven by 14% volume growth
- Non-GAAP operating margin was 28.9%, including the negative impact of 90 basis points from acquired IPR&D and development milestone charges
- Progressed on our **innovation-based strategy**, including FDA Fast Track designation for tirzepatide in obesity, EU and Japan approval for Mounjaro in T2D and submission of lebrikizumab for moderate-to-severe atopic dermatitis in the U.S. and EU
- Deployed nearly \$900 million to shareholders via the dividend

#### **Grow Revenue**



Expect to deliver top-tier revenue growth

#### **Improve Productivity**



Non-GAAP operating margin expansion to the mid-to-high 30%s\*

#### **Speed Life-Changing Medicines**



- Potential to launch 20+ new molecules in 10 years (2014-2023)
- On average, could launch 2+ new indications or line extensions per year

#### **Create Long-Term Value**



- Fund existing marketed and pipeline products
- Bolster growth prospects via business development
- Annual dividend increases

<sup>\*</sup>Excludes impact of future IPR&D and development milestone charges

# **SUPPLEMENTARY SLIDES**



# **2022 INCOME STATEMENT – REPORTED**



Millions; except per share data

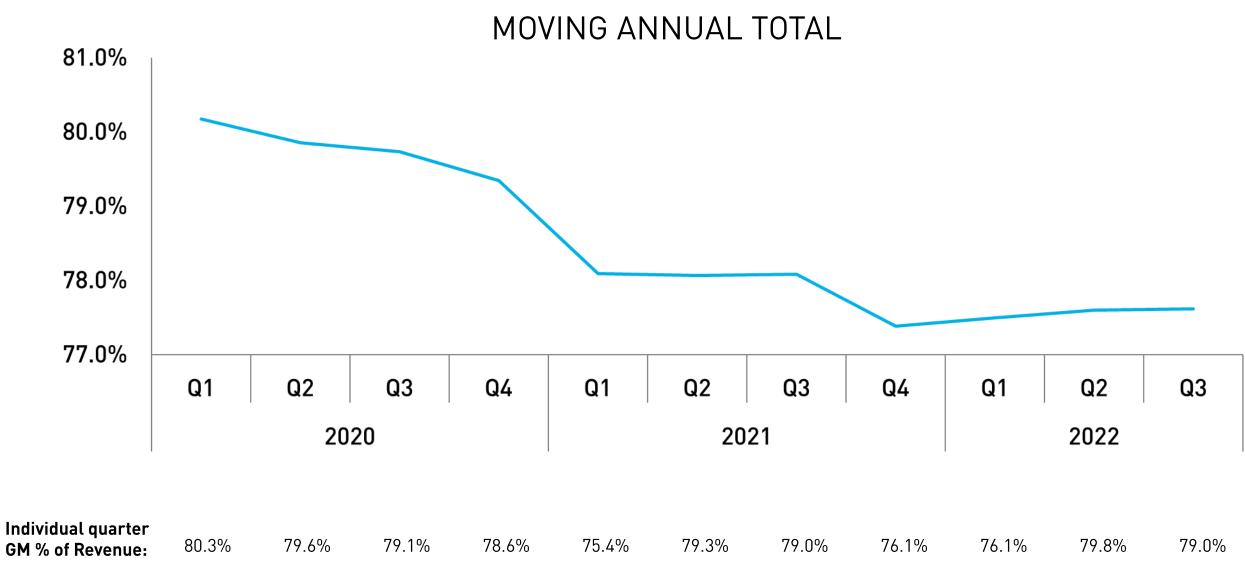
	Q3 2022	Change	YTD 2022	Change
TOTAL REVENUE	\$6,942	2%	\$21,240	5%
GROSS MARGIN	77.3%	(1.6)pp	76.1%	2.0pp
TOTAL OPERATING EXPENSE*	3,686	7%	10,867	2%
OPERATING INCOME	1,676	(11)%	5,291	19%
OPERATING MARGIN	24.2%	(3.6)pp	24.9%	3.1pp
OTHER INCOME (EXPENSE)	(111)	(83)%	(581)	NM
EFFECTIVE TAX RATE	7.3%	(3.6)pp	8.6%	(2.1)pp
NET INCOME	\$1,452	31%	\$4,307	12%
EARNINGS PER SHARE	\$1.61	32%	\$4.76	13%

<sup>\*</sup> Includes research and development expense, marketing, selling and administrative expense, acquired in-process research and development milestone charges, and asset impairment, restructuring and other special charges.

NM – not meaningful

# **NON-GAAP GROSS MARGIN % OF REVENUE**



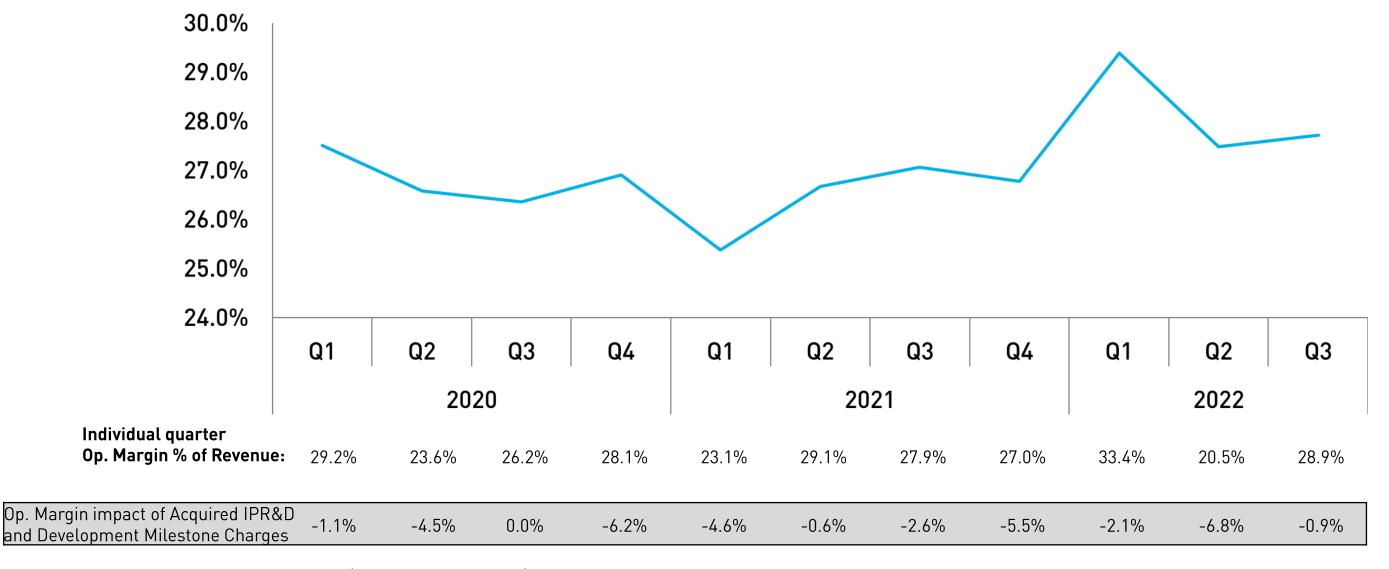


The line in the graph is a moving annual total (i.e. trailing 4 quarters) while the row of numbers is from specific quarters.

# **NON-GAAP OPERATING MARGIN % OF REVENUE**



### MOVING ANNUAL TOTAL



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

# **EFFECT OF FX ON 2022 RESULTS**



Year-on-Year Change Q3 2022 YTD 2022

REPORTED	With FX	w/o FX	With FX	w/o FX
TOTAL REVENUE	2%	7%	5%	8%
COST OF SALES	10%	18%	(3)%	5%
<b>GROSS MARGIN</b>	0%	4%	7%	9%
OPERATING EXPENSE	7%	9%	2%	4%
<b>OPERATING INCOME</b>	(11)%	(6)%	19%	18%
EARNINGS PER SHARE	32%	38%	13%	12%

NON-GAAP	With FX	w/o FX	With FX	w/o FX
TOTAL REVENUE	2%	7%	5%	8%
COST OF SALES	2%	10%	3%	14%
<b>GROSS MARGIN</b>	3%	6%	5%	6%
OPERATING EXPENSE	1%	3%	2%	4%
OPERATING INCOME	6%	11%	10%	9%
EARNINGS PER SHARE	12%	17%	12%	12%

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

# **EPS RECONCILIATION**



	Q3 2022	Q3 2021	% Change	YTD 2022	YTD 2021	% Change
EPS (REPORTED)	\$1.61	\$1.22	32%	\$4.76	\$4.23	13%
NET LOSSES (GAINS) ON INVESTMENTS IN EQUITY SECURITIES	0.09	0.19	-	0.52	(0.22)	-
AMORTIZATION OF INTANGIBLE ASSETS	0.11	0.12	-	0.39	0.34	-
ASSET IMPAIRMENT, RESTUCTURING AND OTHER SPECIAL CHARGES	0.17	-	-	0.17	0.19	-
CHARGE RELATED TO REPURCHASE OF HIGHER-COST DEBT	-	0.35	-	-	0.35	-
COVID-19 ANTIBODIES INVENTORY CHARGES	-	(0.11)	-	-	0.33	-
EPS (NON-GAAP)	\$1.98	\$1.77	12%	\$5.85	\$5.22	12%
Acquired IPR&D and development milestone charges	\$0.06	\$0.17	(63)%	\$0.67	\$0.48	41%

Numbers may not add due to rounding; see slides 23 and 24 for more details on these significant adjustments.

# Q3 2022 INCOME STATEMENT NOTES



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

- 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).

#### Q3 2021 NON-GAAP INFORMATION HAS BEEN ADJUSTED TO ELIMINATE:

- a charge related to the repurchase of higher-cost debt totaling \$405.2 million (pretax), or \$0.35 per share (after-tax);
- net losses on investments in equity securities totaling \$223.4 million (pretax), or \$0.19 per share (after-tax);
- amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties totaling \$137.1 million (pretax), or \$0.12 per share (after-tax); and
- partial reversal of charges resulting from excess inventory related to COVID-19 antibodies totaling (\$128.1) million (pretax), or (\$0.11) per share (after-tax).

# YTD 2022 INCOME STATEMENT NOTES



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

- 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).

#### YTD 2021 NON-GAAP INFORMATION HAS BEEN ADJUSTED TO ELIMINATE:

- a charge related to the repurchase of higher-cost debt totaling \$405.2 million (pretax), or \$0.35 per share (after-tax);
- amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties totaling \$395.0 million (pretax), or \$0.34 per share (after-tax);
- charges resulting from excess inventory related to COVID-19 antibodies totaling \$376.4 million (pretax), or \$0.33 per share (after-tax);
- asset impairment, restructuring and other special charges, primarily an intangible asset impairment resulting from the decision to sell the
  rights to Qbrexza® and acquisition and integration costs recognized as part of the closing of the acquisition of Prevail Therapeutics Inc. totaling
  \$211.6 million (pre-tax), or \$0.19 per share (after-tax); and
- net gains on investments in equity securities totaling (\$248.5) million (pretax), or (\$0.22) per share (after-tax).

# **COMPARATIVE EPS SUMMARY 2021/2022**



	1Q21	2Q21	3Q21	4Q21	2021	1Q22	2Q22	3Q22	4Q22	2022
Reported	1.49	1.53	1.22	1.90	6.12	2.10	1.05	1.61		
Non-GAAP	1.61	1.85	1.77	2.17	7.39	2.62	1.25	1.98		

Numbers may not add due to rounding.

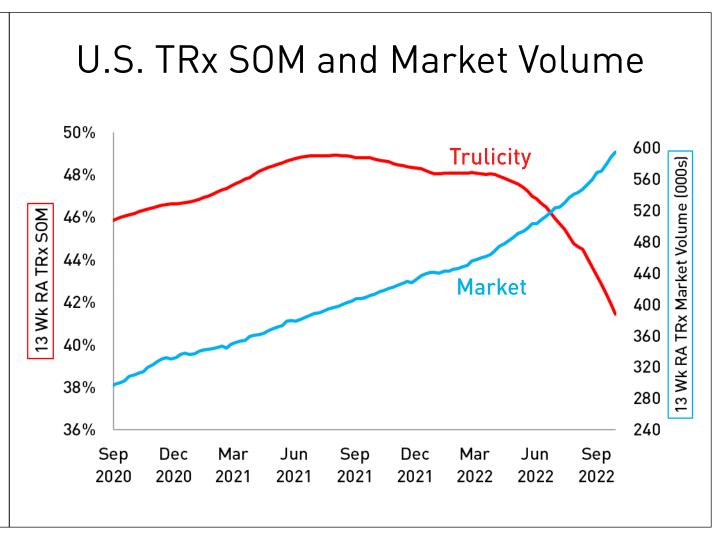
For a complete reconciliation to reported earnings, see slide 22 and our earnings press release dated November 1st, 2022.

# Q3 2022 TRULICITY SALES INCREASED 16%



### Millions



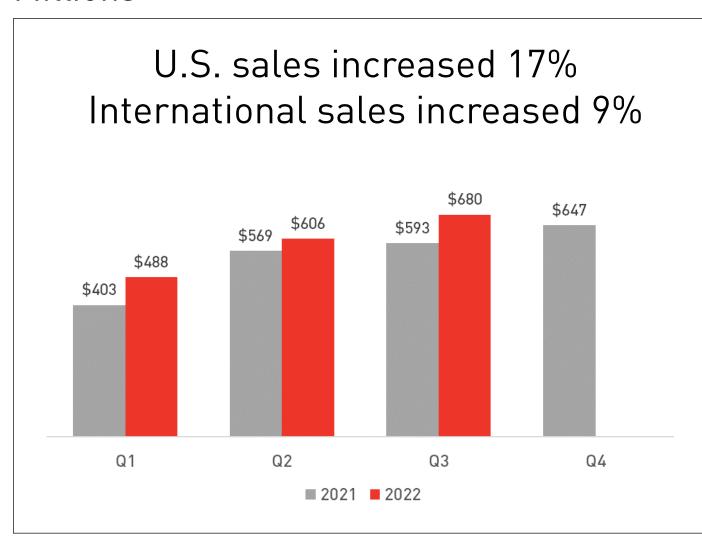


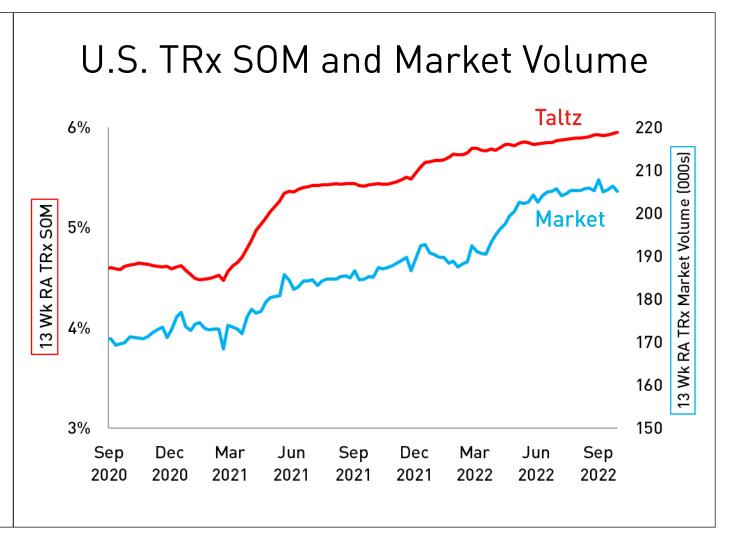
Source: IQVIA NPA TRx 3MMA, weekly data September 30, 2022; RA = rolling average TRx data is representative of the injectable incretin market

# Q3 2022 TALTZ SALES INCREASED 15%



### Millions



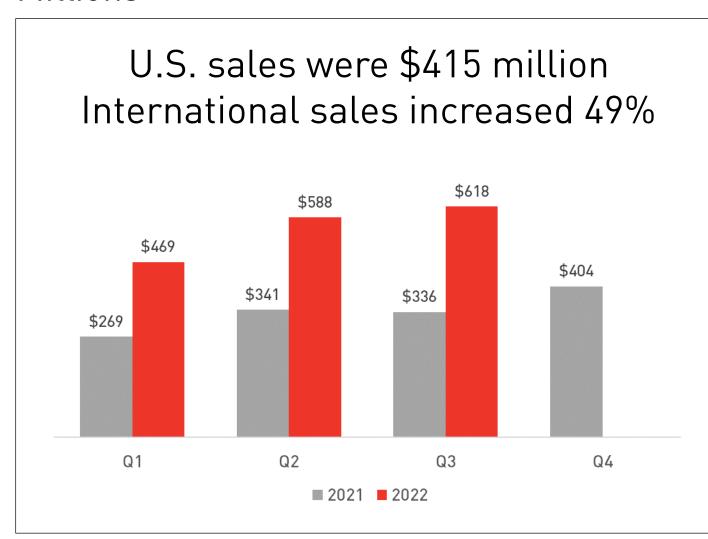


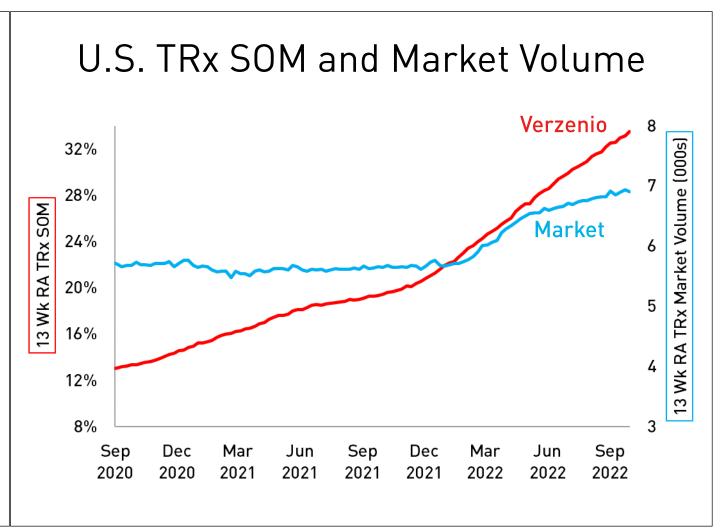
Source: IQVIA NPA TRx 3MMA, weekly data September 30, 2022; RA = rolling average TRx data is representative of the full molecule market

# Q3 2022 VERZENIO SALES INCREASED 84%



### Millions



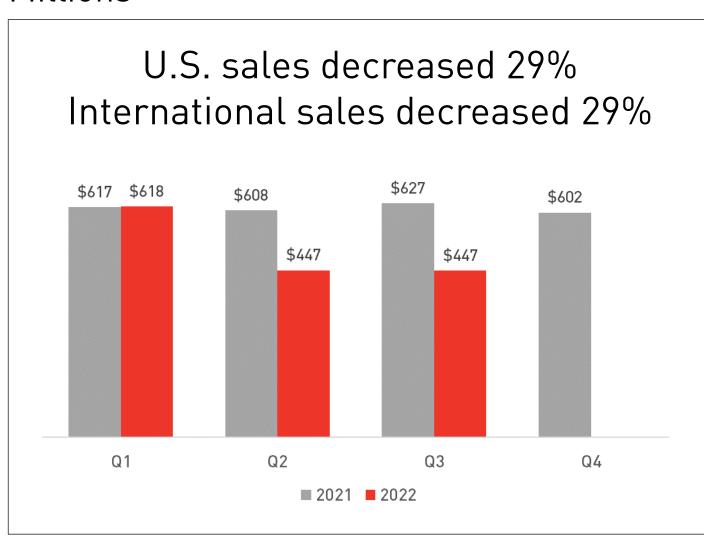


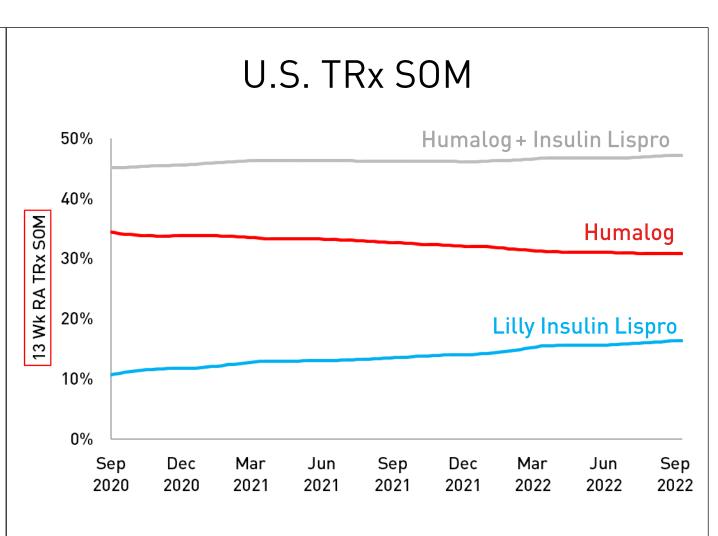
Source: IQVIA NPA TRx 3MMA, weekly data September 30, 2022; RA = rolling average

# Q3 2022 HUMALOG SALES DECREASED 29%



### Millions



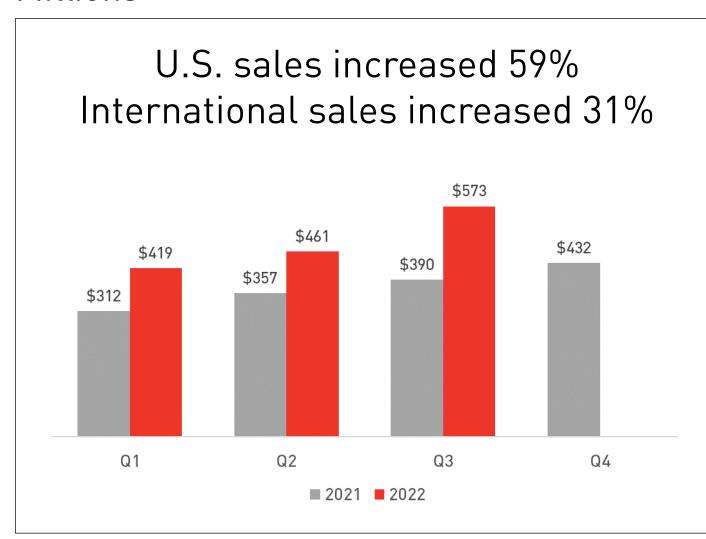


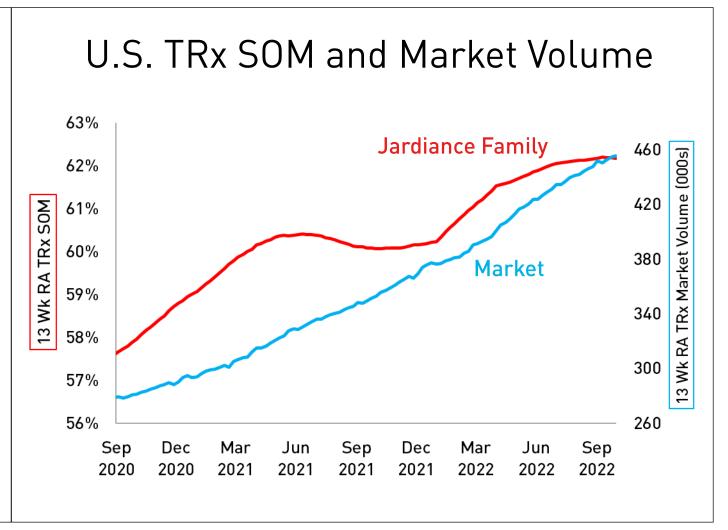
Source: IQVIA NPA TRx 3MMA, weekly data September 30, 2022; RA = rolling average

# Q3 2022 JARDIANCE SALES INCREASED 47%



### Millions

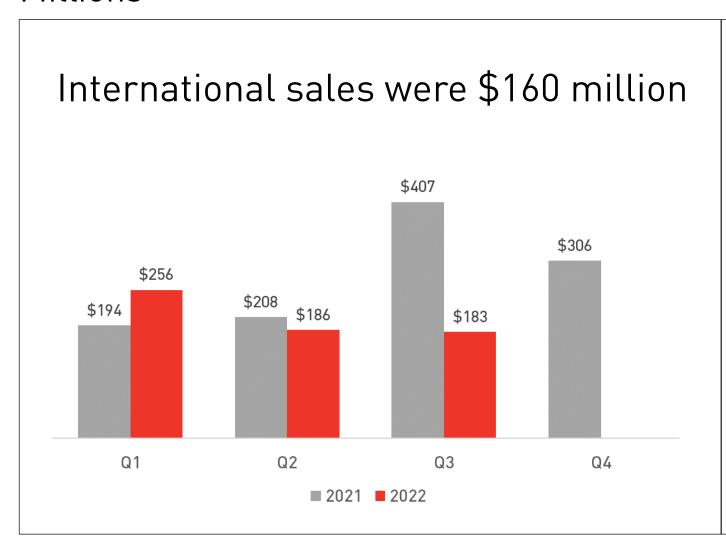




Source: IQVIA NPA TRx 3MMA, weekly data September 30, 2022; RA = rolling average Jardiance is part of Lilly's alliance with Boehringer Ingelheim.

# Q3 2022 OLUMIANT SALES DECREASED 55%



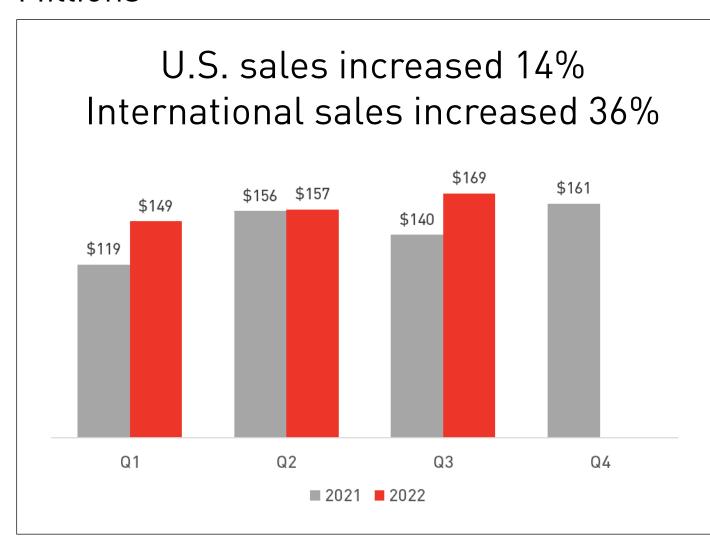


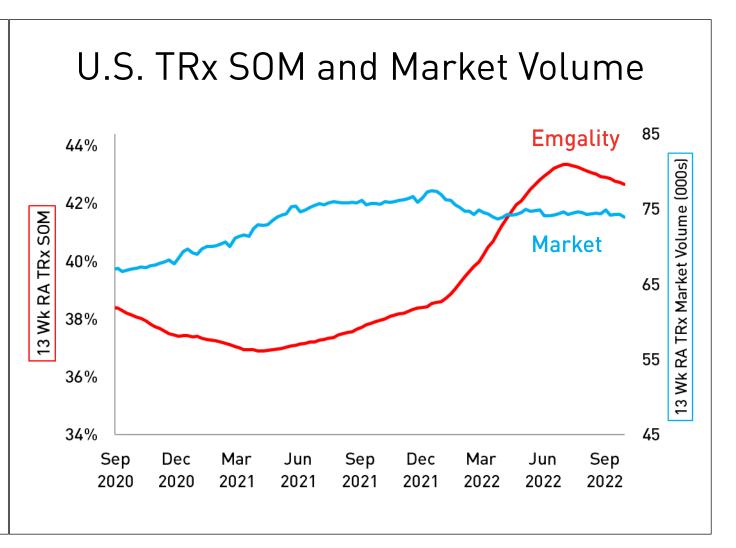
- In the U.S., launched in rheumatoid arthritis in Q3 2018 and in alopecia areata in Q2 2022
- Q3 sales driven by Germany, Japan, and U.S.
- Q3 decline primarily driven by lower utilization for the treatment of COVID-19

# Q3 2022 EMGALITY SALES INCREASED 20%



### Millions





Source: IQVIA NPA TRx 3MMA, weekly data September 30, 2022; RA = rolling average TRx data is representative of the injectable CGRP market

# Q3 2022 TYVYT SALES IN CHINA DECREASED 39%

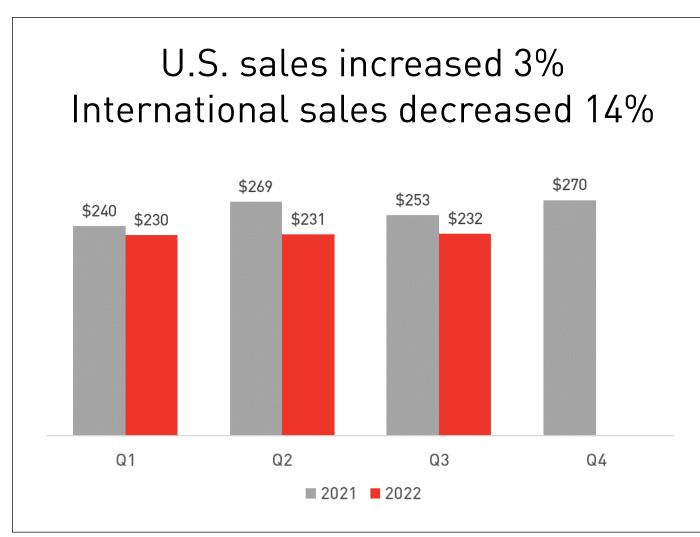


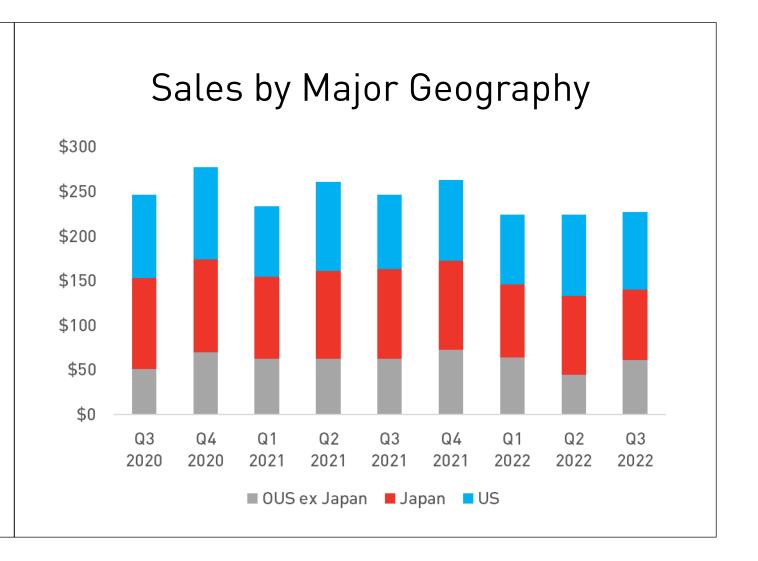


- Launched in China in Q1 2019
- Part of Lilly collaboration with Innovent
- Q3 decline due to the impact of NRDL formulary, resulting in lower realized prices partially offset by increased volume, as well as increased competitive pressures

# Q3 2022 CYRAMZA SALES DECREASED 8%

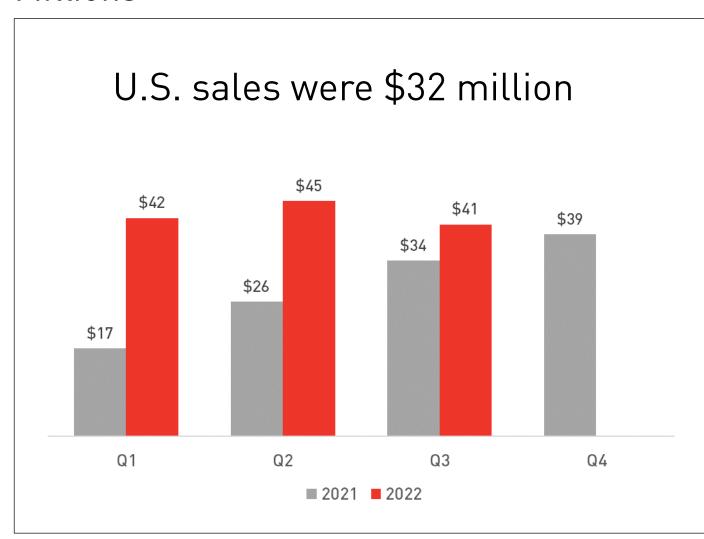






# Q3 2022 RETEVMO SALES WERE \$41 MILLION





- First RET inhibitor approved for certain lung and thyroid cancers with RET fusions and mutations
- Q3 2022 U.S accelerated approval in tumoragnostic RET fusion-positive advanced or metastatic solid tumors
- Continued focus on diagnostics utilization

# **SELECT TRIALS – BASAL INSULIN-FC**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT05462756	Type 2 Diabetes	A Study of LY3209590 as a Weekly Basal Insulin Compared to Insulin Glargine in Adult Participants With Type 2 Diabetes on Multiple Daily Injections (QWINT-4)	3	670	Change from Baseline in HbA1c	Oct 2023	Oct 2023
NCT05275400	Type 2 Diabetes	A Study of LY3209590 Compared With Insulin Degludec in Participants With Type 2 Diabetes Currently Treated With Basal Insulin (QWINT-3)	3	939	Change from Baseline in Hemoglobin A1c (HbA1c)	Apr 2024	May 2024
NCT05362058	Type 2 Diabetes	A Study of LY3209590 Compared to Degludec in Adults With Type 2 Diabetes Who Are Starting Basal Insulin for the First Time (QWINT-2)		912	Change from Baseline in Hemoglobin A1c (HbA1c)	Apr 2024	Jun 2024
NCT05463744	Type 1 Diabetes	A Study of LY3209590 Compared With Insulin Degludec in Participants With Type 1 Diabetes Treated With Multiple Daily Injection Therapy (QWINT-5)	3	670	Change from Baseline in Hemoglobin A1c (HbA1c)	Sep 2023	Apr 2024

Source: clinicaltrials.gov, October 20, 2022

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **SELECT TRIALS – DONANEMAB**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT05108922	Alzheimer Disease	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	Jul 2024
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)	Sep 2023	Mar 2024
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

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **SELECT TRIALS – EMGALITY**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT05127486	Migraine	A Study of Galcanezumab (LY2951742) in Adult Participants With Episodic Migraine (CHALLENGE-MIG)	4	575	Mean Monthly Percentage of Participants with a 50% Response Rate	Mar 2023	Mar 2023

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **SELECT TRIALS - IMLUNESTRANT**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04975308	ER+ HER2- mBC	A Study of Imlunestrant, Investigator's Choice of Endocrine Therapy, and Imlunestrant Plus Abemaciclib in Participants With ER+, HER2- Advanced Breast Cancer (EMBER-3)		800	Progression Free Survival (PFS) in the Intent-to-Treat (IIT) Population	Jun 2023	Sep 2026
NCT05514054	Adjuvant Breast Cancer	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

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **SELECT TRIALS – JARDIANCE**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03594110 <sup>1</sup>	Chronic Kidney Disease	EMPA-KIDNEY (The Study of Heart and Kidney Protection With Empagliflozin)	3	6609	Interventional part: Time to first occurrence of kidney disease progression (defined as ESKD, a sustained decline in eGFR to <10 mL/min/1.73m², renal death, or a sustained decline of >40% in eGFR from randomization) or cardiovascular death		Jan 2025
			_	-			
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	6500	Composite of time to first heart failure hospitalisation or all-cause mortality	Mar 2023	Mar 2023

In collaboration with Boehringer Ingelheim

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

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **SELECT TRIALS – LEBRIKIZUMAB**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04760314	Atopic Dermatitis	A Study of Lebrikizumab (LY3650150) in Combination With Topical Corticosteroids in Japanese Participants With Moderate-to-Severe Atopic Dermatitis (Adhere-J)	3	280	Percentage of Participants with an Investigators Global Assessment (IGA) score of 0 or 1 and a reduction ≥2 points from Baseline to Week 16	Jul 2022	Jan 2023
NCT05369403	Atopic Dermatitis	A Study of Lebrikizumab (LY3650150) in Adult and Adolescent Participants With Moderate-to-Severe Atopic Dermatitis Previously Treated With Dupilumab	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	3	80	Percentage of Participants Achieving Eczema Area and Severity Index-75 (EASI-75) (>75% reduction from baseline in EASI)	Mar 2024	Aug 2024
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

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **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	Nov 2021	Mar 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	Jul 2025

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **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)	Jan 2024	Jun 2024
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

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **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	400	Percentage of Participants Who Reach Amyloid Plaque Clearance on Amyloid PET Scan for Remternetug versus Placebo	Mar 2024	Mar 2025

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **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 (LIBRETT0-531)	3	400	Progression Free Survival (PFS) by Blinded Independent Central Review (BICR)	May 2024	Nov 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 (LIBRETT0-431)	. 3	250	Progression Free Survival (PFS) by Blinded Independent Central Review (BICR) (with Pembrolizumab)	Jan 2023	Aug 2025
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	Mar 2024	Sep 2024
NCT04819100	Non- Small Cell Lung Cancer	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

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **SELECT TRIALS – SOLANEZUMAB**



Study	Indication	Title	Phase	Patients	Primary Outcome*	Primary Completion	Completion
NCT02008357 <sup>1</sup>	Cognition Disorders	Clinical Trial of Solanezumab for Older Individuals Who May be at Risk for Memory Loss (A4)	3	1150	Change from Baseline of the Preclinical Alzheimer Cognitive Composite (PACC)	Dec 2022	Jun 2023

Source: clinicaltrials.gov, August 19, 2022

<sup>&</sup>lt;sup>1</sup> Also lists Alzheimer's Therapeutic Research Institute

<sup>\*</sup> Trial may have additional primary and other secondary outcomes

## **SELECT TRIALS – TIRZEPATIDE**



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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	Nov 2023	Dec 2023
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	May 2024
NCT05024032	Obesity	A Study of Tirzepatide (LY3298176) in Chinese Participants Without Type 2 Diabetes Who Have Obesity or Overweight (SURMOUNT-CN)	3	210	Mean Percent Change from Randomization in Body Weight	Dec 2022	Dec 2022
NCT04657003	Obesity	A Study of Tirzepatide (LY3298176) in Participants With Type 2 Diabetes Who Have Obesity or Are Overweight (SURMOUNT-2)	3	900	Percent Change from Randomization in Body Weight	Mar 2023	Apr 2023
NCT04657016	Obesity	A Study of Tirzepatide (LY3298176) In Participants After A Lifestyle Weight Loss Program (SURMOUNT-3)	3	800	Percent Change from Randomization in Body Weight	Apr 2023	May 2023
NCT04660643	Obesity	A Study of Tirzepatide (LY3298176) in Participants With Obesity or Overweight for the Maintenance of Weight Loss (SURMOUNT-4)	3	750	Percent Change from Randomization (Week 36) in Body Weight	Apr 2023	May 2023
NCT04844918	Obesity	A Study of Tirzepatide (LY3298176) in Participants With Obesity Disease (SURMOUNT-J)	3	261	Percentage of Participants who Achieve ≥5% Body Weight Reduction	Jun 2023	Jun 2023
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

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **SELECT TRIALS - TIRZEPATIDE (CONT.)**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04537923	Type 2 Diabetes	A Study of Tirzepatide (LY3298176) Versus Insulin Lispro (U100) in Participants With Type 2 Diabetes Inadequately Controlled on Insulin Glargine (U100) With or Without Metformin (SURPASS-6)	3	1182	Change from Baseline in Hemoglobin A1c (HbA1c) (Pooled Doses)	Oct 2022	Nov 2022
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
NCT05433584	Type 2 Diabetes	A Study of Tirzepatide Compared With Intensified Conventional Care in Adult Participants With Type 2 Diabetes (SURPASS-EARLY)	4	780	Change from Baseline in Hemoglobin A1c (HbA1c)	May 2025	Jun 2027
NCT05260021	Type2 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)	2	90	Change From Baseline in Hemoglobin A1c (HbA1c)	Nov 2027	Dec 2027
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	Nov 2023	Nov 2023
NCT05412004	Obstructive Sleep Apnea	Obstructive Sleep Apnea Master Protocol GPIF: A Study of Tirzepatide (LY3298176) in Participants With Obstructive Sleep Apnea (SURMOUNT-OSA)	3	412	Percent Change from Baseline in Apnea-Hypopnea Index (AHI)	Feb 2024	Feb 2024

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **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	Jun 2029
NCT05169567	Breast Cancer	Abemaciclib (LY2835219) Plus Fulvestrant Compared to Placebo Plus Fulvestrant in Previously Treated Breast Cancer (postMonarch)	3	350	Progression-Free Survival (PFS)	Aug 2023	Feb 2026
NCT03706365	Prostate	A Study of Abiraterone Acetate Plus Prednisone With or Without Abemaciclib (LY2835219) in Participants With	2 3	350	Radiographic Progression Free Survival (rPFS)	Dec 2023	Jun 2026
110103700303	Cancer	Prostate Cancer (CYCLONE 2)	2 3	350	Radiographic Progression Free Survival (1775)	Dec 2023	Jun 2026
NCT05288166	Prostate Cancer	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)		900	Radiographic Progression-Free Survival (rPFS) Assessed by Investigator	Oct 2025	Oct 2027

<sup>&</sup>lt;sup>1</sup> Also lists NSABP Foundation Inc

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **SELECT TRIALS – EARLY PHASE DIABETES**

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Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
Retatrutide	NCT04881760	Obesity	A Study of LY3437943 in Participants Who Have Obesity or Are Overweight	2	494	Mean Percent Change in Body Weight	May 2022	Nov 2022
Retatrutide	NCT04867785	Type 2 Diabetes	A Study of LY3437943 in Participants With Type 2 Diabetes	2	300	Change from Baseline in Hemoglobin A1c (HbA1c)	Jul 2022	Oct 2022
Orforglipron	NCT05051579	Obesity	A Study of LY3502970 in Participants With Obesity or Overweight With Weight-related Comorbidities	2	270	Percent Change From Baseline in Body Weight	Aug 2022	Nov 2022
Orforglipron	NCT05048719	Type 2 Diabetes	A Study of LY3502970 in Participants With Type 2 Diabetes Mellitus	2	370	Change from Baseline in Hemoglobin A1c (HbA1c) in LY3502970 and Placebo	Sep 2022	Sep 2022
ANGPLT3 siRNA	NCT05256654	Dyslipidemias	A Study of LY3561774 in Participants With Mixed Dyslipidemia (PROLONG-ANG3)	2	175	Percent Change from Baseline for Apolipoprotein B (ApoB)	Sep 2023	Dec 2023
LP(a) 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	Nov 2024
LP(a) Inhibitor	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
Relaxin-LA	NCT05592275	HFpEF	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)	Aug 2024	Sep 2024

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **SELECT TRIALS - EARLY PHASE DIABETES (CONT.)**



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
GIPR Agonist LA	NCT05444569	Healthy	A Study of LY3537021 in Healthy Participants	1	60	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	Feb 2023	Feb 2023
PYY Analog Agonist	NCT05582096	Obesity	A Study of LY3457263 in Obese Participants	1	45	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	May 2023	May 2023
DACRA QW II	NCT05380323	Obesity	A Study of LY3541105 in Healthy and Overweight Participants	1	160	Number of Participants with One or More Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Aug 2023	Aug 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	Sep 2023	Sep 2023
PYY Analog Agonist	NCT05377333	Type 2 Diabetes	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	Sep 2023	Sep 2023
GIPR Agonist LA II	NCT05407961	Type 2 Diabetes	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

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **SELECT TRIALS - EARLY PHASE DIABETES (CONT.)**



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
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

Source: clinicaltrials.gov, September 9, 2022

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **SELECT TRIALS – EARLY PHASE IMMUNOLOGY**



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Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
CXCR1/2L mAb	NCT04493502	Hidradenitis Suppurativa	1	2	52	Percentage of Participants Achieving Hidradenitis Suppurativa Clinical Response (HiSCR)	Mar 2022	Nov 2022
Rezpegaldesleukin <sup>1</sup>	NCT04433585	Systemic Lupus Erythematosus	A Study of LY3471851 in Adults With Systemic Lupus Erythematosus (SLE) (ISLAND-SLE)	2	280	Percentage of Participants who Achieve a ≥4 Point Reduction in Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) 2000 (2K) Score	Dec 2022	Mar 2023
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	Oct 2024
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

<sup>&</sup>lt;sup>1</sup> Also lists Nektar Therapeutics

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

# SELECT TRIALS - EARLY PHASE IMMUNOLOGY (CONT.) Liley



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
Rezpegaldesleukin <sup>1</sup>	NCT04081350	Atopic Dermatitis	A Study of LY3471851 in Participants With Eczema	1	40	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Jun 2022	Jun 2022
BTLA MAB Agonist	NCT04975295	Psoriasis	A Study of LY3361237 in Participants With Psoriasis	1	24	Number of Participants with One or More Treatment-Emergent Adverse Event(s) (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Feb 2023	Feb 2023
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 2023	Jun 2023
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	Apr 2024	Apr 2024

<sup>&</sup>lt;sup>1</sup> Also lists Nektar Therapeutics

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

# SELECT TRIALS - EARLY PHASE NEURODEGENERATION Liley

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)	May 2024	Jun 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 2023
GRN Gene Therapy	NCT04408625	Frontotempo ral 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	Sep 2027	Sep 2027
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 (PR0PEL)	1 2	24	Number of Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)	Apr 2028	Apr 2028
GBA1 Gene Therapy	NCT04411654	Gaucher Disease, Type 2	Phase 1/2 Clinical Trial of PR001 in Infants With Type 2 Gaucher Disease (PR0VIDE)	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	NCT05487599	Gaucher Disease	A Clinical Trial of PR001 (LY3884961) in Patients With Peripheral Manifestations of Gaucher Disease (PR0CEED)	1 2	15	Incidence and severity of Treatment-emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)	Sep 2030	Sep 2030

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **SELECT TRIALS – EARLY PHASE ONCOLOGY**



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Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
IDH1/2 Inhibitor	NCT04521686	Cholangiocarcinoma	Study of LY3410738 Administered to Patients With Advanced Solid Tumors With IDH1 or IDH2  Mutations	1	200	Recommended Phase 2 dose (RP2D)	May 2023	May 2023
KRAS G12C <sup>1</sup>	NCT04956640	NSCLC and CRC	Study of LY3537982 in Cancer Patients With a Specific Genetic Mutation (KRAS G12C)	1	360	Phase 1a: To determine the recommended phase 2 dose (RP2D) of LY3537982 monotherapy   Phase 1b: To assess the safety and tolerability of LY3537982 when administered alone or in combination with other investigational agents	Nov 2023	Nov 2023
IDH1/2 Inhibitor	NCT04603001	Acute Myeloid Leukemia (AML)	Study of Oral LY3410738 in Patients With Advanced Hematologic Malignancies With IDH1 or IDH2 Mutations	1	260	To determine the maximum tolerated dose (MTD)/recommended Phase 2 dose (RP2D)	May 2024	May 2024
PI3K Selective	NCT05307705	Breast Cancer	A Study of LOXO-783 in Patients With Breast Cancer/Other Solid Tumors (PIKASSO-01)	1	300	Phase 1 a: To determine the MTD/RP2D of LOX0-783: Number of patients with dose-limiting toxicities (DLTs)	May 2025	May 2025
RET Inhibitor	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	140	Phase 1 a: To determine the MTD/RP2D of LOX0- 260: Dose limiting toxicity (DLT) rate	Apr 2026	Apr 2026

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

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes

## **SELECT TRIALS – EARLY PHASE PAIN**



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
TRPA1 Antagonist	NCT05177094	Diabetic Peripheral Neuropathic Pain	Chronic Pain Master Protocol (CPMP): A Study of LY3526318 in Participants With Diabetic Peripheral Neuropathic Pain	2	150	Change from Baseline in Average Pain Intensity as Measured by the Numeric Rating Scale (NRS)	Nov 2022	Nov 2022
P2X7 Inhibitor	NCT05292040	Healthy	A Study of LY3857210 in Healthy Participants	1	25	Change from baseline in brain receptor occupancy (RO) of LY3857210 measured by [18F]-LY3818850 PET scan		Dec 2022

<sup>\*</sup> Molecule may have multiple indications

<sup>\*\*</sup> Trial may have additional primary and other secondary outcomes