

# Q1 2022 Earnings Call

### **AGENDA**



### INTRODUCTION AND KEY RECENT EVENTS

Dave Ricks, Chair and Chief Executive Officer

### **Q1 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**



- 15% revenue growth in Q1; 10% growth excluding revenue from COVID-19 antibodies\* and Alimta®
- Q1 revenue growth driven by:
  - 20% volume growth
  - Key growth products, which contributed 13 percentage points of revenue growth and represented 61% of core revenue, excluding revenue from COVID-19 antibodies

### **Improve Productivity**



- Non-GAAP gross and operating margin:
  - Gross margin in Q1 was 76.1% (76.0% excluding FX impact on international inventories sold)
  - Operating margin in Q1 was 33.4%\*\* (33.3% excluding FX impact on international inventories sold)

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



- Announced the launch of the Lilly Institute for Genetic Medicine and an investment of approximately \$700 million to establish a new site in the Boston Seaport
- Distributed nearly \$900 million via dividends in Q1
- Completed \$1.5 billion in share repurchases in Q1

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



- U.S. and EU approval for **Jardiance**® in heart failure with preserved ejection fraction and announced **Jardiance** Phase 3 EMPA-KIDNEY trial will stop early due to clear positive efficacy in people with chronic kidney disease
- U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for **bebtelovimab** for COVID-19 treatment
- Submitted **mirikizumab** to the FDA for ulcerative colitis
- Positive results from SURMOUNT-1 trial of tirzepatide in obesity

\*Sales for COVID-19 antibodies include bamlanivimab, etesevimab and bebtelovimab sold pursuant to Emergency Use Authorization or similar regulatory authorizations

\*\*Includes upfront charges related to acquired in-process research and development (IPR&D) and development milestone charges

Note: Jardiance is part of the Boehringer Ingelheim (BI) and Lilly Alliance, and BI holds the marketing authorization for Jardiance

Not for promotional use 2022 Q1 EARNINGS

### KEY EVENTS SINCE THE LAST EARNINGS CALL



#### **REGULATORY**

- Submitted mirikizumab to the U.S. Food and Drug Administration (FDA) for the treatment of ulcerative colitis;
- The FDA granted priority review for Olumiant® in severe alopecia areata as a potential first-in-disease medicine;
- The FDA and European Medicines Agency (EMA) approved Jardiance to treat adults with heart failure, regardless of left ventricular ejection fraction; and
- The FDA issued complete response letters for sintilimab in combination with pemetrexed and platinum chemotherapy for the first-line treatment of nonsquamous non-small cell lung cancer and Olumiant for the treatment of atopic dermatitis.

#### **CLINICAL**

- Presented lebrikizumab combination therapy data at the Revolutionizing Atopic Dermatitis (RAD) conference. Lebrikizumab, when combined with topical corticosteroids, showed 70% of patients with moderate-to-severe atopic dermatitis experienced at least 75% reduction in disease severity at 16 weeks;
- Presented lebrikizumab monotherapy induction data at the American Academy of Dermatology (AAD) meeting. More than 50% of patients with moderate-to-severe atopic dermatitis experienced at least 75% reduction in disease severity at 16 weeks;

#### **CLINICAL (CONT)**

- Published Olumiant data for alopecia areata in the New England Journal of Medicine (NEJM). Nearly 40% of adults with alopecia areata taking Olumiant 4-mg saw at least 80% scalp hair coverage at 52 weeks in Lilly's pivotal Phase 3 studies;
- Presented mirikizumab induction data at the European Crohn's and Colitis Organisation (ECCO) congress. Nearly two-thirds of patients responded to mirikizumab treatment at 12 weeks in Lilly's first-in-class ulcerative colitis Phase 3 LUCENT-1 study;
- Announced Jardiance Phase 3 EMPA-KIDNEY trial will stop early due to clear positive efficacy in people with chronic kidney disease; and
- Tirzepatide met both co-primary endpoints of superior mean percent change in body weight from baseline and greater percentage of participants achieving body weight reductions of at least 5% compared to placebo in adults with obesity or overweight in the 72-week Phase 3 SURMOUNT-1 study.

### KEY EVENTS SINCE THE LAST EARNINGS CALL



#### COVID-19

- Received Emergency Use Authorization (EUA) for **bebtelovimab** for the treatment of mild-to-moderate COVID-19. Bebtelovimab neutralizes Omicron as demonstrated by pseudovirus and authentic virus data; and
- Signed an agreement with the U.S. government (USG) that resulted in purchase of 600,000 vials of **bebtelovimab** for \$1.08 billion. There is a USG option to order 500,000 additional doses no later than July 31, 2022, but it is uncertain whether the option will be exercised.

#### **OTHER**

- Announced the launch of the Lilly Institute for Genetic Medicine and an investment of approximately \$700 million to establish a state-of-the-art facility at a new site in the Boston Seaport as part of Lilly's strategy to advance RNA-based therapeutics;
- Purchased a priority review voucher during the first quarter of 2022; and
- Expect to incur a Q2 charge of approximately \$335 million tied to the acquisition of rights to receive future milestone payments related to our mutant-selective PI3Ka inhibitor.

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



Millions; except per share data

Q1 2022

	GAAP Reported Adjustments		Non-GAAP Adjusted	Non-GAAP Adjusted Change
TOTAL REVENUE	\$7,810	_	\$7,810	15%
GROSS MARGIN	73.5%	2.6%	76.1%	0.7pp
<b>TOTAL OPERATING EXPENSE</b>	3,334	_	3,334	(6)%
OPERATING INCOME	2,404	205	2,609	66%
OPERATING MARGIN	30.8%	2.6%	33.4%	10.3pp
OTHER INCOME (EXPENSE)	(351)	388	38	9%
EFFECTIVE TAX RATE	7.3%	3.0%	10.3%	1.4pp
NET INCOME	\$1,903	\$470	\$2,373	62%
EPS	\$2.10	\$0.52	\$2.62	63%
Acquired IPR&D and Development Milestone Charges	\$0.15		\$0.15	(44)%

Note: Acquired IPR&D and development milestone charges of \$166 million (pre-tax) Numbers may not add due to rounding; see slide 26 for a complete list of adjustments.

# PRICE/RATE/VOLUME EFFECT ON REVENUE



Millions

Q1 2022

	Amount	<b>Price</b>	Price FX Rate		<b>Total</b>	CER
U.S.	\$5,175	(1)%	_	32%	31%	31%
EUROPE	1,067	(3)%	(6)%	(10)%	(19)%	(13)%
JAPAN	410	(3)%	(7)%	(18)%	(28)%	(21)%
CHINA	406	(36)%	2%	46%	12%	10%
REST OF WORLD	751	(3)%	(6)%	32%	23%	29%
TOTAL REVENUE	\$7,810	(3)%	(2)%	20%	15%	17%
				1	 	1

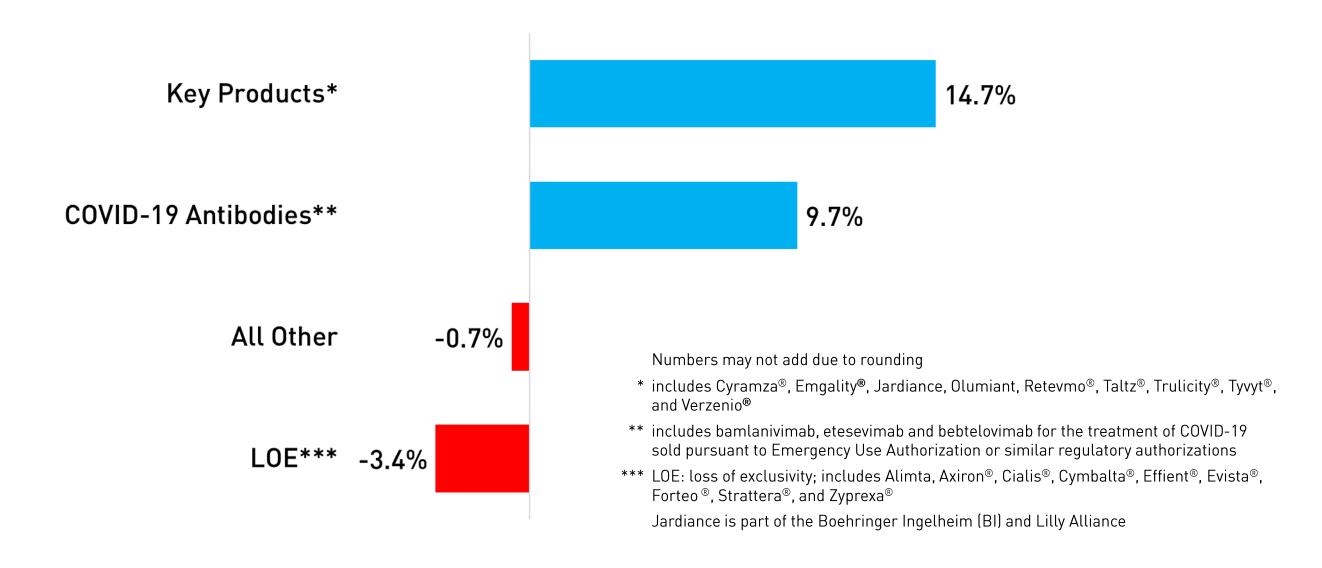
Note: Numbers may not add due to rounding

CER = price change + volume change

### **KEY PRODUCTS DRIVING WW VOLUME GROWTH**

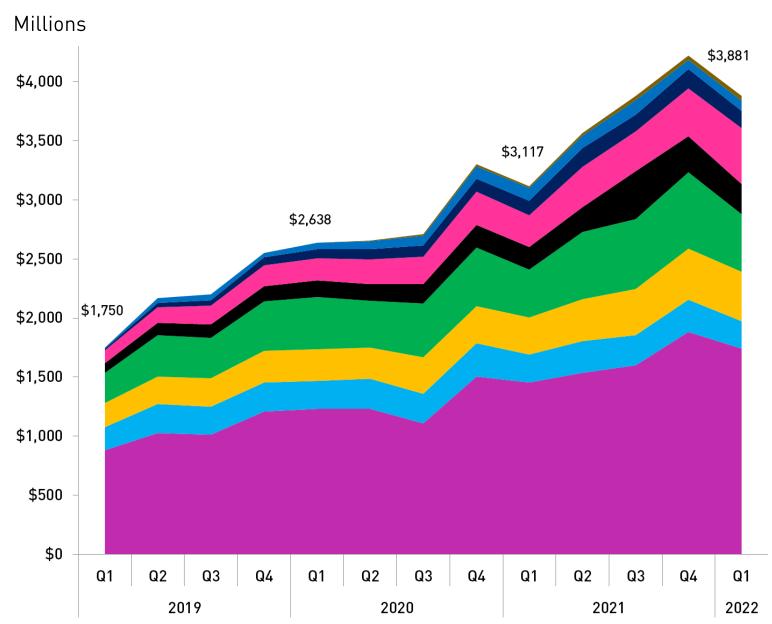


### Contribution to 20% Q1 WW Volume Growth



### **UPDATE ON KEY GROWTH PRODUCTS**





Note: Jardiance is sold by Boehringer Ingelheim (BI); Lilly records as revenue its share of Jardiance gross margin; Jardiance is part of the BI and Lilly Alliance

#### RETEVMO

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

#### TYVYT

• Continued penetration via China's National Drug Reimbursement List

#### EMGALITY

• U.S. TRx SOM nearly 43% at end of Q1 2022 (injectable CGRP)

#### VERZENIO

- U.S. TRx grew 70% vs. Q1 2021, outpacing the market
- Strong uptake in new adjuvant breast cancer indication

#### OLUMIANT

• WW sales increased 32% vs. Q1 2021

#### TALTZ

- IL-17 dermatology leader in U.S. TRx SOM 20%
- U.S. TRx grew nearly 33% vs. Q1 2021, outpacing the market

#### JARDIANCE

- Market leader in U.S. TRx SOM nearly 62%
- U.S. TRx grew nearly 30% vs Q1 2021, outpacing the market

#### CYRAMZA

• WW sales slightly declined vs Q1 2021

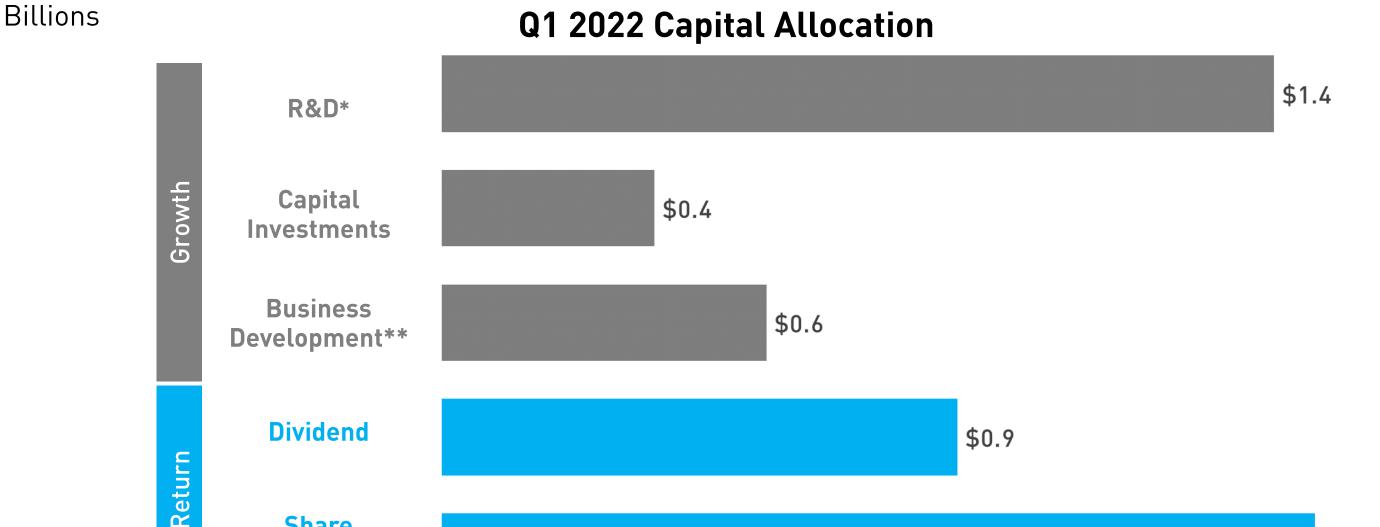
#### TRULICITY

- U.S. TRx SOM nearly 48% (injectable GLP-1)
- U.S. TRx grew nearly 30% vs Q1 2021, outpacing the market

## **CAPITAL ALLOCATION**



\$1.5



Share
Repurchase

<sup>\*</sup> After-tax

<sup>\*\*</sup> Includes cash outflows associated with equity investments

# **2022 GUIDANCE**



	<u>Prior</u>	<u>Updated</u>	Comments
TOTAL REVENUE	\$27.8 – \$28.3 billion	\$28.8 – \$29.3 billion	Reflects ~\$1B of additional revenue from bebtelovimab in Q1. Unfavorable impact from foreign exchange rates offset by strength of core business.
GROSS MARGIN % (GAAP) GROSS MARGIN % (NON-GAAP)	Approx. 78% Approx. 80%	Approx. 76% Approx. 78%	Change driven by the impact of Q1 bebtelovimab sales and, to a lesser extent, increased manufacturing costs due to inflation.
MKTG, SELLING & ADMIN.	\$6.4 – \$6.6 billion	Unchanged	
RESEARCH & DEVELOPMENT	\$7.0 – \$7.2 billion	\$7.1 – \$7.3 billion	Change driven by investment in late-stage pipeline.
ACQUIRED IPR&D & DEVT MILESTONES	n.a.	Approx. \$520M	Reflects Q1 charges and an expected charge for the buy-out of future obligations associated with our mutant-selective PI3Ka inhibitor.
OTHER INCOME/(EXPENSE) (GAAP) OTHER INCOME/(EXPENSE) (NON-GAAP)	\$(100) – \$0 million \$(100) – \$0 million	\$(500) to \$(400) million Unchanged	Change to GAAP guidance reflects the impact of net losses on investments in equity securities during Q1 2022.
TAX RATE	Approx. 13 – 14%	Unchanged	Assumes the provision in the 2017 Tax Act will be deferred or repealed by Congress effective for 2022.
EARNINGS PER SHARE (GAAP) EARNINGS PER SHARE (NON-GAAP)	\$8.00 - \$8.15 \$8.50 - \$8.65	\$7.30 - \$7.45 \$8.15 - \$8.30	Change driven by items cited above. Includes acquired IPR&D and development milestone charges totaling \$0.55.
OPERATING INCOME % (GAAP) OPERATING INCOME % (NON-GAAP)	Approx. 30% Approx. 32%	Approx. 28% Approx. 30%	Includes a negative impact of nearly 200 basis points primarily due to acquired IPR&D and development milestone charges.

# **SURMOUNT PROGRAM**

#### TIRZEPATIDE EVALUATED ACROSS A BROAD PATIENT POPULATION



	Expected Read-out Date	Study Size (pts)	Studied Doses	Study Duration	Primary Endpoint	Key Inclusion Criteria	
SURMOUNT-1 Weight Management in Participants with Obesity/Overweight*		2,539	5/10/15 mg	72 weeks (2-year additional treatment period**)		BMI > 30 kg/m <sup>2</sup> or > 27 kg/m <sup>2</sup> with >1 weight-related comorbidity	
SURMOUNT-2 Weight Management in Participants with Obesity/Overweight with T2DM		~900	~900 10/15 mg	72 weeks	1) Percent change in body weight 2) Percentage of participants who achieve >5% body weight reduction	BMI ≥ 27 kg/m² with T2D (A1c 7-10%), treated with diet/exercise alone or any oral agent except DPP-4 inhibitors or GLP-1R agonists	
SURMOUNT-3  Maximizing Weight Loss Following Intensive Lifestyle Program in Participants with Obesity/Overweight*	Mid-2023	~800	MTD	84 weeks (incl. 12-wk intensive lifestyle lead-in)		BMI > 30 kg/m <sup>2</sup> or > 27 kg/m <sup>2</sup> with >1 weight-related comorbidity	
SURMOUNT-4  Maintaining Weight Loss with Maximal Tolerated Dose Therapy in Participants with Obesity/Overweight*		~750	(10 or 15 mg)	88 weeks (incl. 36-wk open- label TZP lead-in)	Percent change in body weight from randomization (week 36) to week 88		

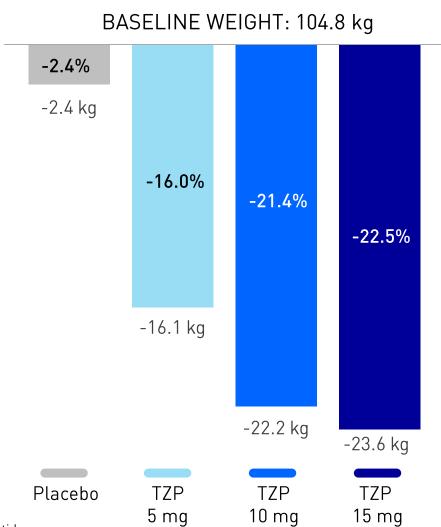
Note: Separate on-going trials in Japan (SURMOUNT-J) and China (SURMOUNT-CN)
MTD = Maximum Tolerated Dose; BMI = Body Mass Index; T2DM = Type 2 Diabetes Mellitus; TZP = tirzepatide
\* Participants without T2DM; \*\* For those with pre-diabetes at randomization

### **SURMOUNT-1: EFFICACY**

#### PARTICIPANTS ON HIGHEST DOSE ACHIEVED 22.5% WEIGHT LOSS ON AVERAGE



### MEAN BODY WEIGHT CHANGE AT 72 WEEKS



### **KEY EFFICACY RESULTS**

- All tirzepatide treatment arms demonstrated statistically superior and clinically meaningful weight loss compared to placebo
- In the 15mg treatment arm, mean weight loss was 24kg (52lb)
- In the 10 and 15mg treatment arms, tirzepatide becomes the first investigational medicine to deliver more than 20% weight loss on average in a Phase 3 study
- In the 5mg treatment arm, strong results were demonstrated, with 16.0% mean weight loss

IZP = tirzepatide

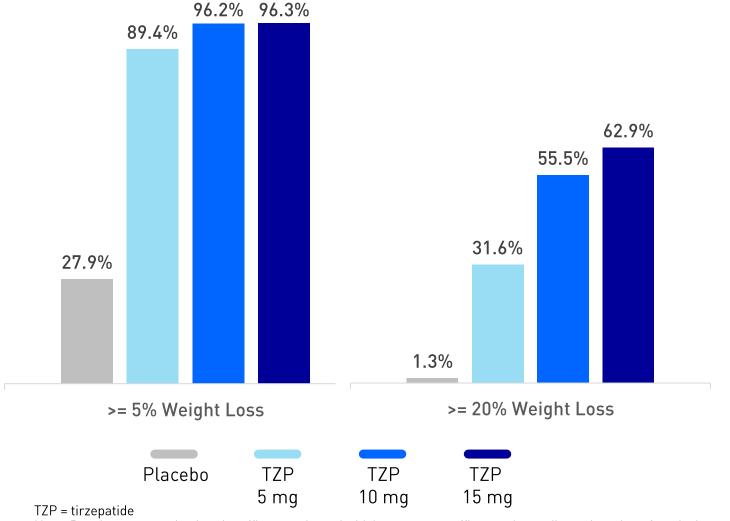
### **SURMOUNT-1: EFFICACY**

GREATER THAN 96% IN 10 AND 15 MG TREATMENT ARMS ACHIEVED AT LEAST 5% BODY WEIGHT LOSS.



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# PERCENTAGE OF PATIENTS ACHIEVING WEIGHT LOSS (%) TARGET



### **KEY EFFICACY RESULTS**

- Met the co-primary endpoint of achieving at least 5% body weight loss in all treatment arms taking tirzepatide as an adjunct to diet and exercise
- 63% of participants achieved at least 20% body weight loss in the 15mg treatment arm as a key secondary endpoint
- In the placebo group (placebo as an adjunct to diet and exercise), only 1% of participants achieved greater than 20% weight loss

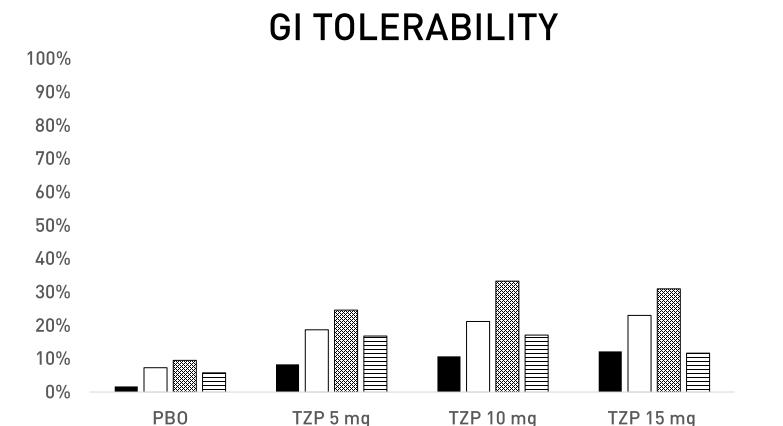
Note: Results presented using the efficacy estimand which represents efficacy prior to discontinuation of study drug

Not for promotional use 2022 Q1 EARNINGS

### **SURMOUNT-1: SAFETY AND TOLERABILITY DATA**

OVERALL SAFETY PROFILE SIMILAR TO INCRETIN-BASED THERAPIES APPROVED FOR OBESITY



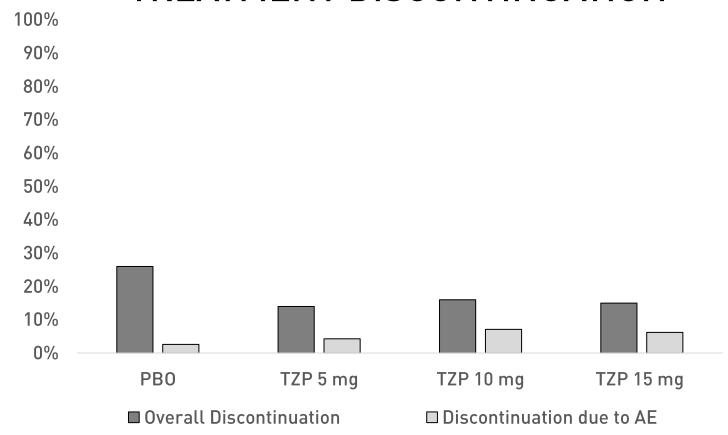


Nausea was most common reported adverse event and ranged from ~25-33% on tirzepatide vs ~10% on placebo.

■ Nausea

Most common reported AEs were GI-related, generally mild-to-moderate in severity, and usually occurred during dose escalation.

### TREATMENT DISCONTINUATION



Treatment discontinuation due to adverse events was between 4.3% and 7.1% for each tirzepatide treatment arm compared to 2.6% for placebo.

□Diarrhea

■ Vomiting

**■** Constipation

### LILLY SELECT NME AND NILEX PIPELINE

APRIL 27, 2022

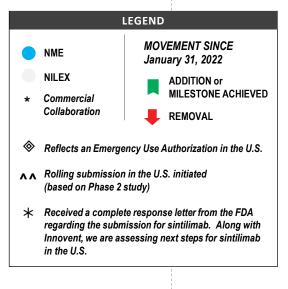
**INHIBITOR** Cancer



AMYLIN AGONIST LA Obesity	RET INHIBITOR II Cancer	
PYY ANALOG Diabetes	RELAXIN-LA Heart Failure	RIPK1 INHIBITOR Immunology
NRG4 AGONIST Heart Failure	OXYNTOMODULIN Diabetes	P2X7 INHIBITOR Pain
LP(a) siRNA CVD	N3pG 4 Alzheimer's Disease	NOT DISCLOSED Diabetes
KHK INHIBITOR II Diabetes / NASH	KRAS G12C II Cancer	LP(a) INHIBITOR CVD
GIPR AGONIST LA Diabetes	GIPR AGONIST LA II Diabetes	IDH1/2 INHIBITOR Cancer
CD19 ANTIBODY Immunology	CD200R MAB AGONIST Immunology	GIP/GLP COAGONIST PEPTIDE Diabetes
ANGPTL3 siRNA CVD	BCL2 (LOXO-338) Cancer	BTLA MAB AGONIST Immunology
	PHASE 1	
AUR A KINASE		











### **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)

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)

#### **Phase 3 & Other Key Data Disclosures**

**Donanemab** for plaque clearance in early AD (H2H vs aducanumab)

**Empagliflozin** for chronic kidney disease<sup>3</sup> <sup>4</sup>

**Galcanezumab** for episodic migraine (H2H vs rimegepant)

Lebrikizumab for atopic dermatitis (maintenance data)

Tirzepatide for obesity (SURMOUNT-1)

#### <sup>1</sup> Initiated rolling U.S. submission

#### **Medical Meeting Presentations**

- ✓ Lebrikizumab for atopic dermatitis (induction
  ✓ /maintenance)
- 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 2</sup>
  Lebrikizumab for atopic dermatitis
- Mirikizumab for ulcerative colitis (US) /EU/J)
  Pirtobrutinib for MCL prior BTKi<sup>1</sup>
  Selpercatinib for metastatic tumor agnostic RET fusion+

#### **Regulatory Actions**

- Bebtelovimab EUA for COVID-19
- ◆ Abemaciclib for high-risk HR+, HER2- early breast cancer (EU)
- Baricitinib for atopic dermatitis (US)
  Baricitinib for alopecia areata (US/EU/J)
- Empagliflozin for HFpEF (US→/EU→/J→)<sup>4</sup>

   Selpercatinib for metastatic RET fusion-positive NSCLC (US)<sup>5</sup>
- Sintilimab for 1L NSCLC (US)

Tirzepatide for type 2 diabetes (US /EU/J)

<sup>&</sup>lt;sup>2</sup> Removed donanemab from Regulatory Actions section as decision is now expected in early 2023

<sup>&</sup>lt;sup>3</sup> Stopped early based on an interim assessment that met prespecified criteria for clear positive efficacy

<sup>&</sup>lt;sup>4</sup> In collaboration with Boehringer Ingelheim

<sup>&</sup>lt;sup>5</sup> Full NDA approval Not for promotional use

### **Q1 2022 PERFORMANCE SUMMARY**



- Volume-driven revenue growth of 10% excluding revenue from COVID-19 antibodies and Alimta,
   with key growth products comprising 61% of core business revenue
- Non-GAAP operating margin of 33.4%, with year-over-year expansion primarily driven by both higher gross margin and lower R&D expenses for COVID-19 antibodies
- Progress on our **innovation-based strategy**, including tirzepatide's positive data readout in obesity, Jardiance's positive development in chronic kidney disease and approvals in heart failure with preserved ejection fraction and EUA authorization for bebtelovimab for COVID-19
- Deployed nearly \$2.4 billion to shareholders via the dividend and share repurchases

#### **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

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<sup>\*</sup> Excludes the adjustments for upfront charges and development milestones related to in-process research and development EUA = emergency use authorization

# **SUPPLEMENTARY SLIDES**



## 2022 INCOME STATEMENT – REPORTED



Millions; except per share data

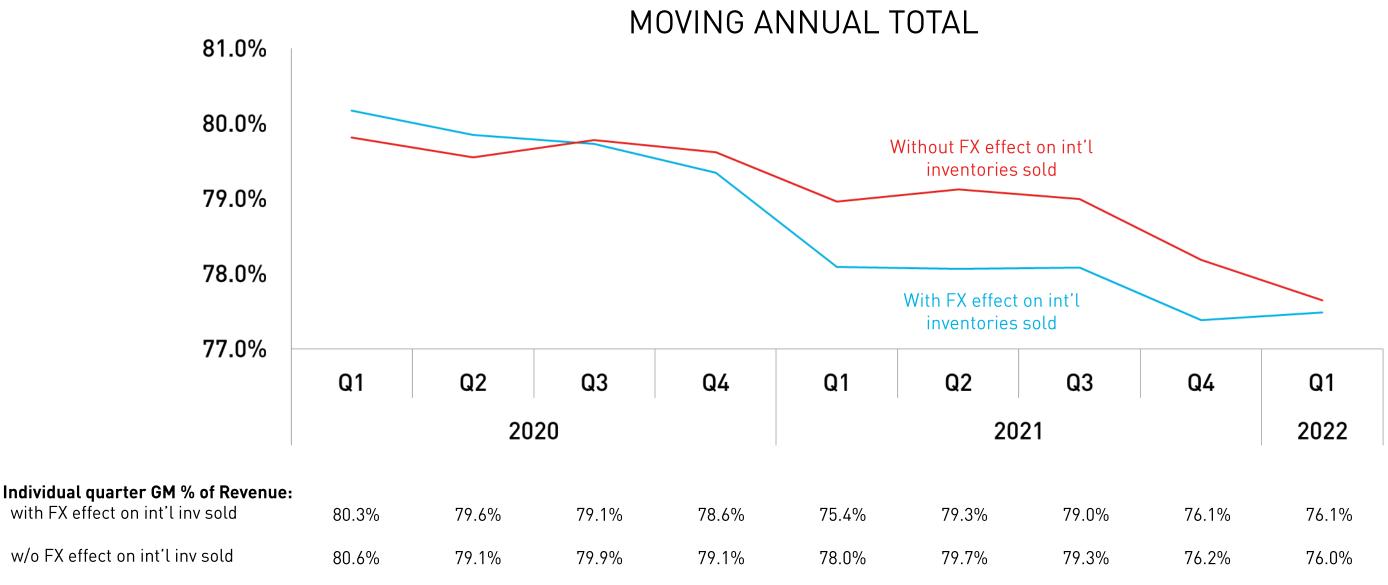
	Q1 2022	<b>Change</b>
TOTAL REVENUE	\$7,810	15%
GROSS MARGIN	73.5%	1.1pp
TOTAL OPERATING EXPENSE*	3,334	(12)%
OPERATING INCOME	2,404	NM
OPERATING MARGIN	30.8%	13.8pp
OTHER INCOME (EXPENSE)	(351)	NM
EFFECTIVE TAX RATE	7.3%	(0.9)pp
NET INCOME	\$1,903	40%
EARNINGS PER SHARE	\$2.10	41%

<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**

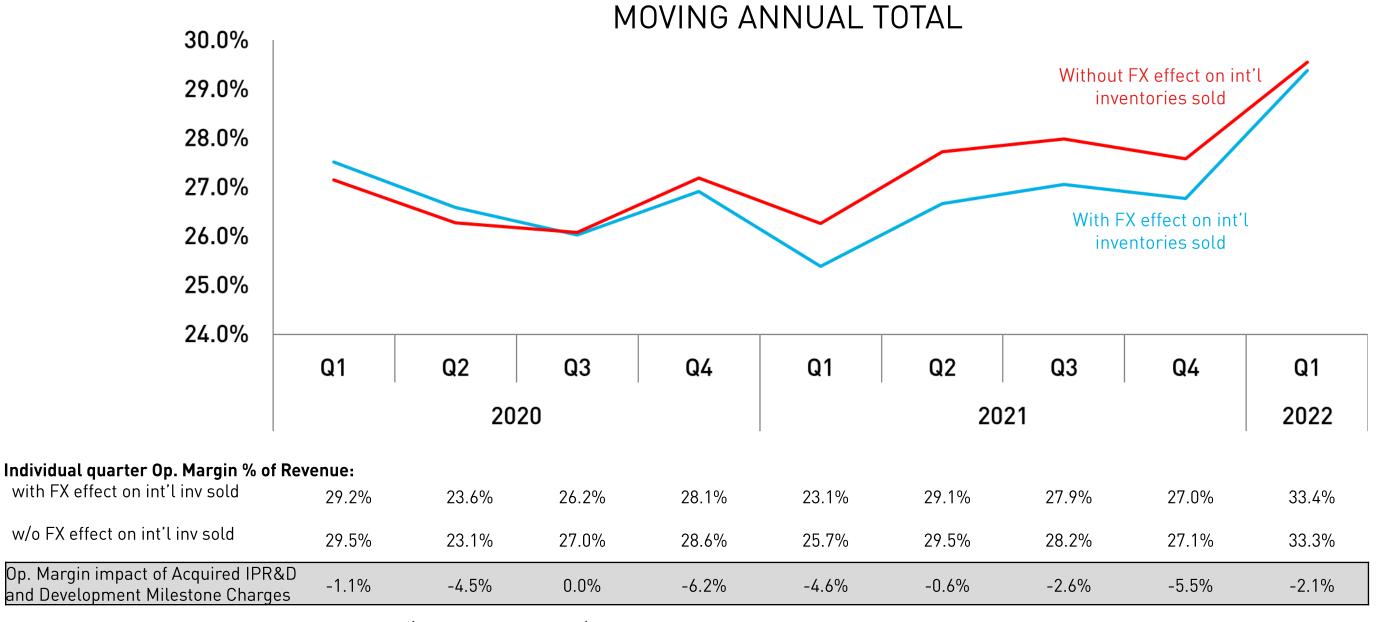




Note: The lines in the graph are moving annual totals (i.e. trailing 4 quarters) while the two rows of numbers are from specific quarters.

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





Note: The lines in the graph are moving annual totals (i.e. trailing 4 quarters) while the two rows of numbers are from specific quarters.

# **EFFECT OF FX ON 2022 RESULTS**



Year-on-Year Growth

Q1 2022
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REPORTED	With FX	w/o FX
TOTAL REVENUE	15%	17%
COST OF SALES	10%	24%
<b>GROSS MARGIN</b>	16%	15%
OPERATING EXPENSE	(12)%	(10)%
OPERATING INCOME	NM	85%
EARNINGS PER SHARE	41%	30%

NON-GAAP	With FX	w/o FX
TOTAL REVENUE	15%	17%
COST OF SALES	12%	28%
<b>GROSS MARGIN</b>	16%	14%
OPERATING EXPENSE	(6)%	(5)%
OPERATING INCOME	66%	53%
EARNINGS PER SHARE	63%	51%

## **EPS RECONCILIATION**



	Q1 2022	Q1 2021	% Change
EPS (REPORTED)	\$2.10	\$1.49	41%
NET LOSSES (GAINS) ON INVESTMENTS IN EQUITY SECURITIES	.34	(.25)	-
AMORTIZATION OF INTANGIBLE ASSETS	.18	.11	-
ASSET IMPAIRMENT, RESTUCTURING AND OTHER SPECIAL CHARGES	-	.19	_
PARTIAL REVERSAL OF COVID-19 ANTIBODIES INVENTORY CHARGE	-	.07	-
EPS (NON-GAAP)	\$2.62	\$1.61	63%

Acquired IPR&D and	<b>¢</b> 0.15	\$0.27	(44)%
development milestone charges	\$0.15	<b>Ψ</b> 0.27	(44)%

Note: Numbers may not add due to rounding; see slide 26 for more details on these significant adjustments.

### Q1 2022 INCOME STATEMENT NOTES



#### Q1 2022 NON-GAAP INFORMATION HAS BEEN ADJUSTED TO ELIMINATE:

- amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties totaling \$204.6 million (pretax), or \$0.18 per share (after-tax); and
- net losses on investments in equity securities totaling \$388.4 million (pretax), or \$0.34 per share (after-tax).

#### Q1 2021 NON-GAAP INFORMATION HAS BEEN ADJUSTED TO ELIMINATE:

- amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties totaling \$125.7 million (pretax), or \$0.11 per share (after-tax);
- net gains on investments in equity securities totaling \$286.5 million (pretax), or (\$0.25) 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
- charges resulting from excess inventory due in part to the discontinuation of bamlanivimab for use on its own totaling \$81.5 million (pretax), or \$0.07 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				
Non-GAAP	1.61	1.85	1.77	2.17	7.39	2.62				

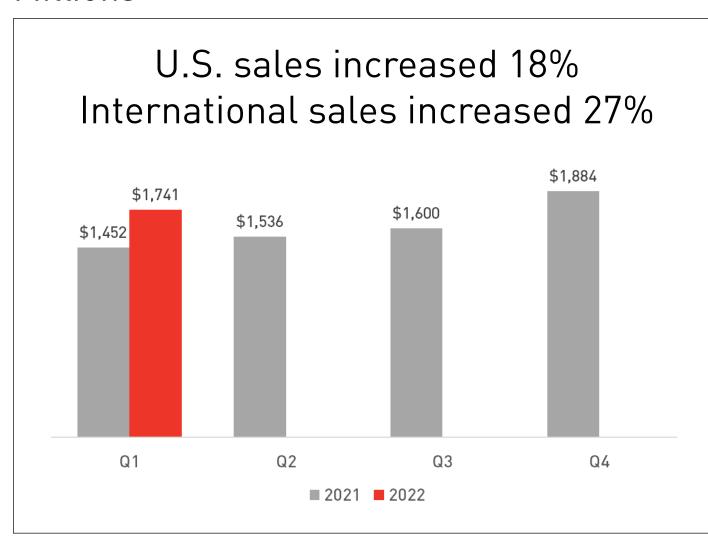
Note: Numbers may not add due to rounding.

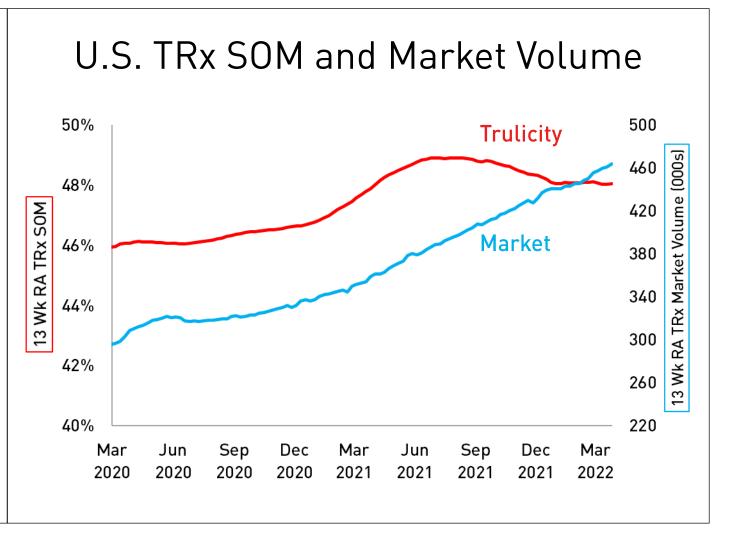
For a complete reconciliation to reported earnings, see slide 25 and our earnings press release dated April 28th, 2022

### **Q1 2022 TRULICITY SALES INCREASED 20%**



### Millions



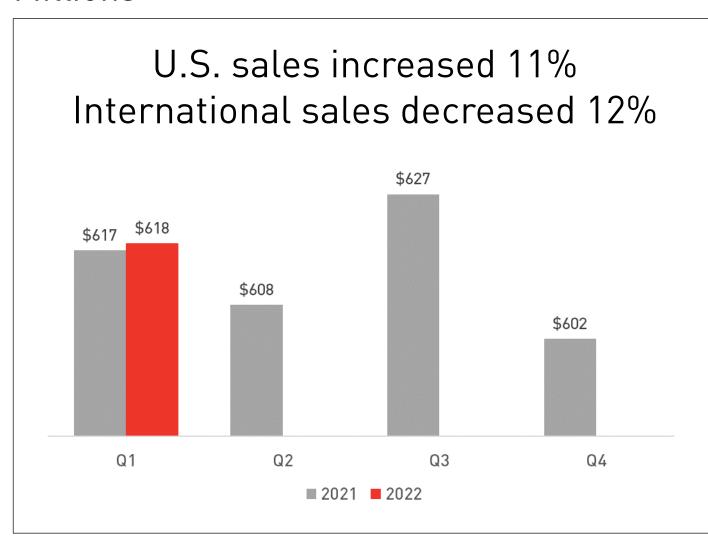


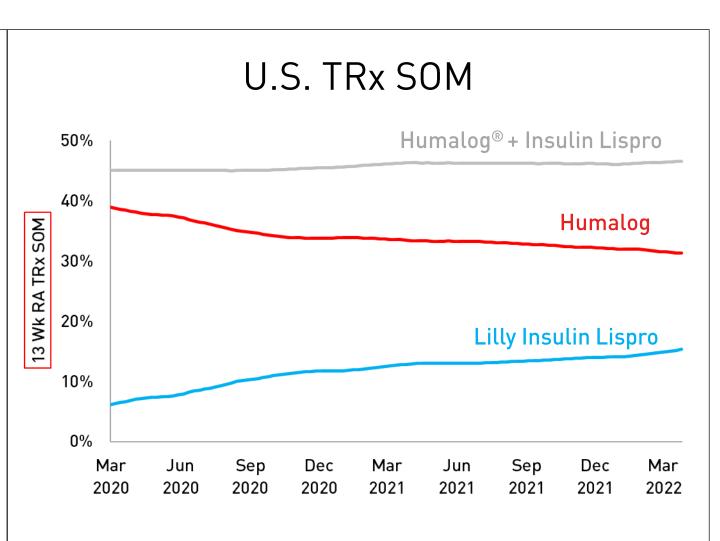
Source: IQVIA NPA TRx 3MMA, weekly data March 25, 2022; RA = rolling average Note: TRx data is representative of the injectable GLP-1 market

### Q1 2022 HUMALOG SALES WERE FLAT



### Millions



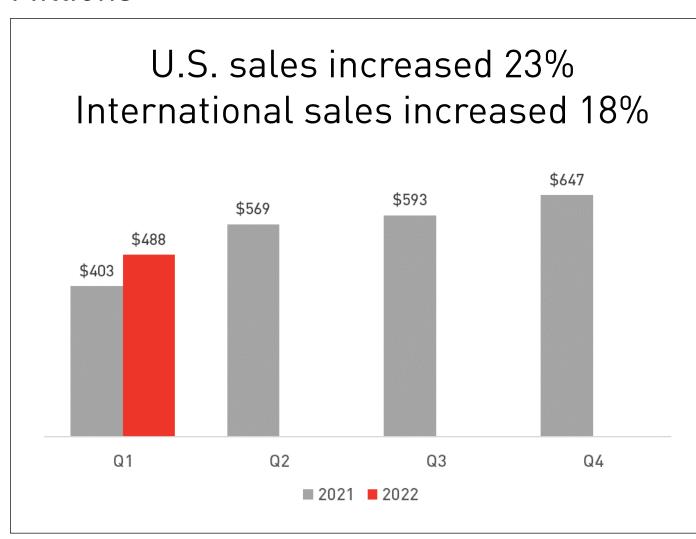


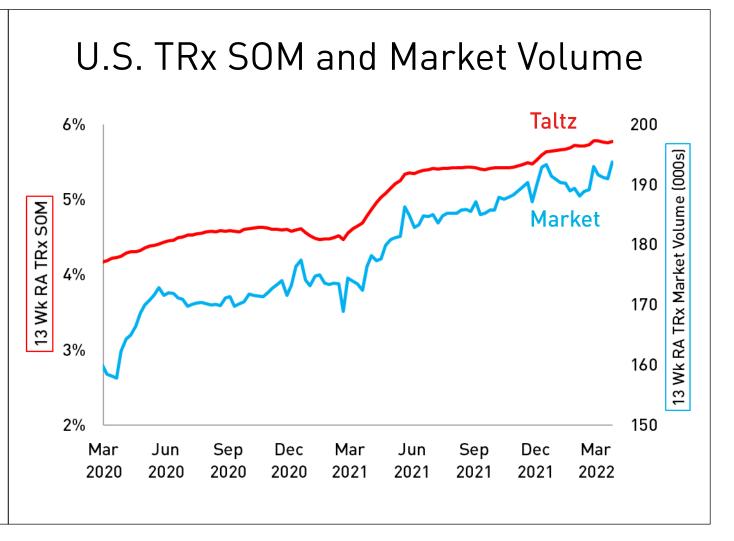
Source: IQVIA NPA TRx 3MMA, weekly data March 25, 2022; RA = rolling average

### Q1 2022 TALTZ SALES INCREASED 21%



### Millions



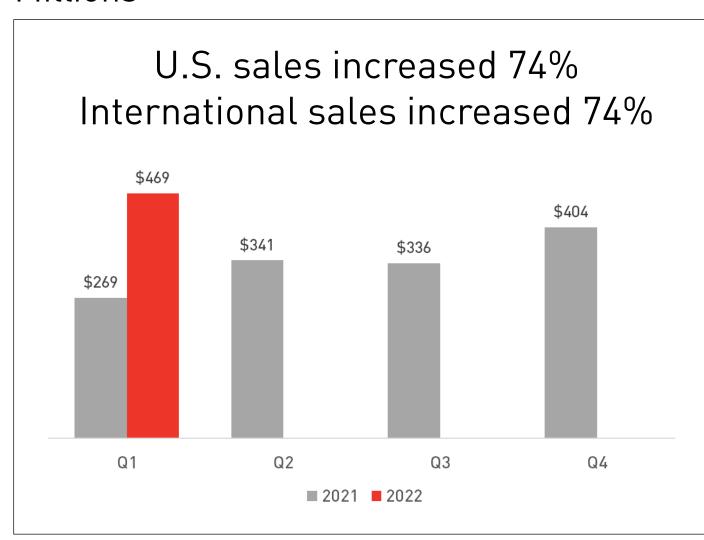


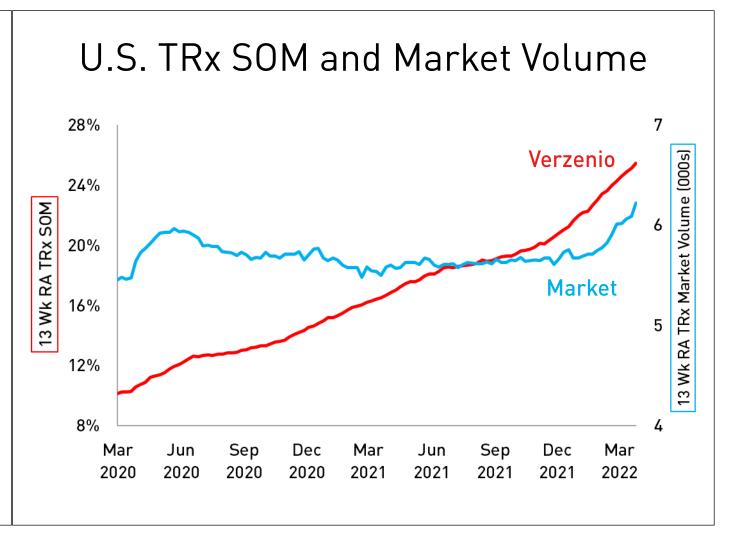
Source: IQVIA NPA TRx 3MMA, weekly data March 25, 2022; RA = rolling average Note: TRx data is representative of the full molecule market

### Q1 2022 VERZENIO SALES INCREASED 74%



### Millions



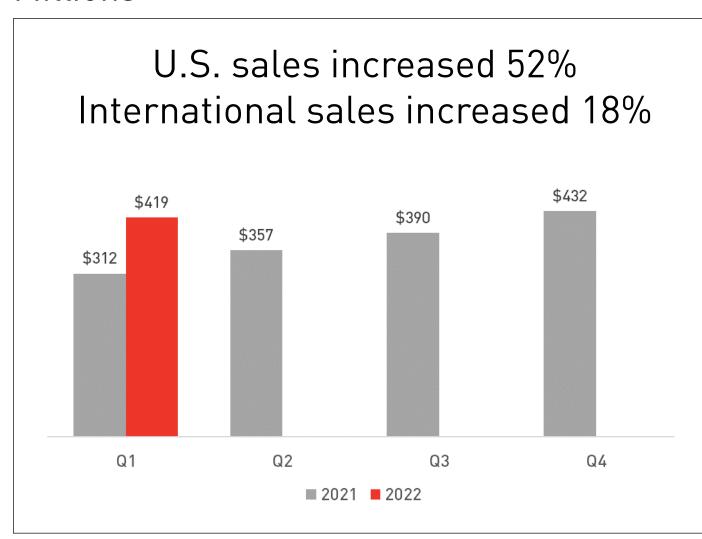


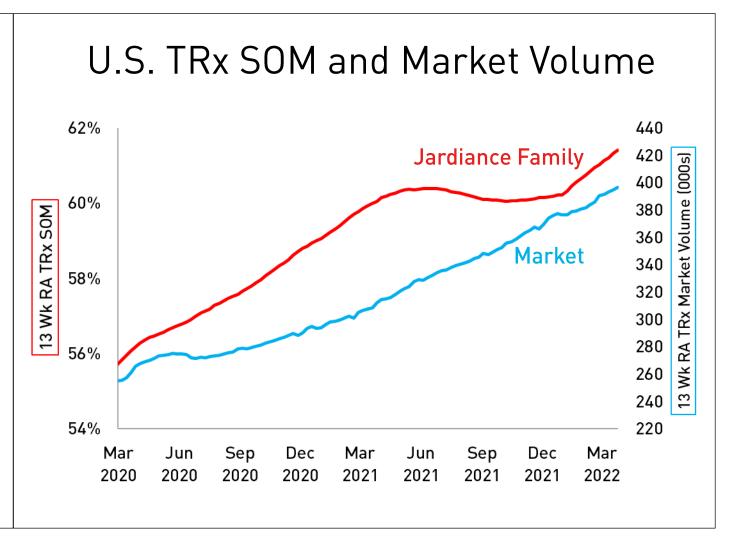
Source: IQVIA NPA TRx 3MMA, weekly data March 25, 2022; RA = rolling average Note: Q2 2020 IQVIA data was impacted by an addition of data for Verzenio

### **Q1 2022 JARDIANCE SALES INCREASED 34%**



### Millions



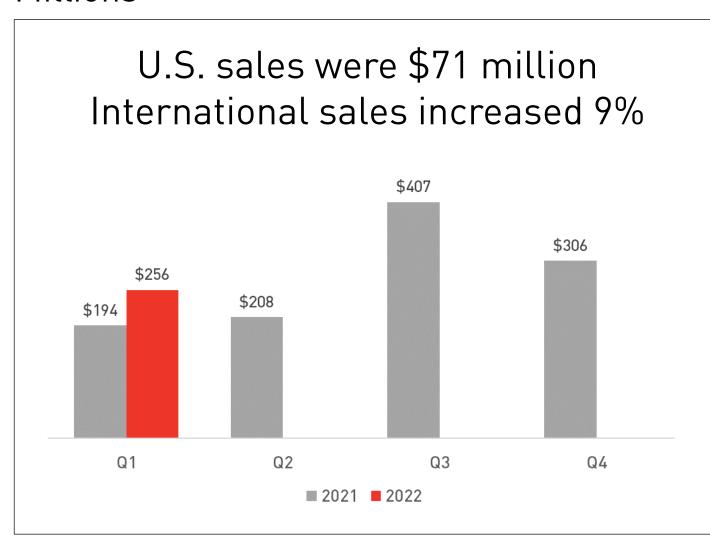


Source: IQVIA NPA TRx 3MMA, weekly data March 25, 2022; RA = rolling average Note: Jardiance is part of the Boehringer Ingelheim and Lilly Alliance

### Q1 2022 OLUMIANT SALES INCREASED 32%



### Millions

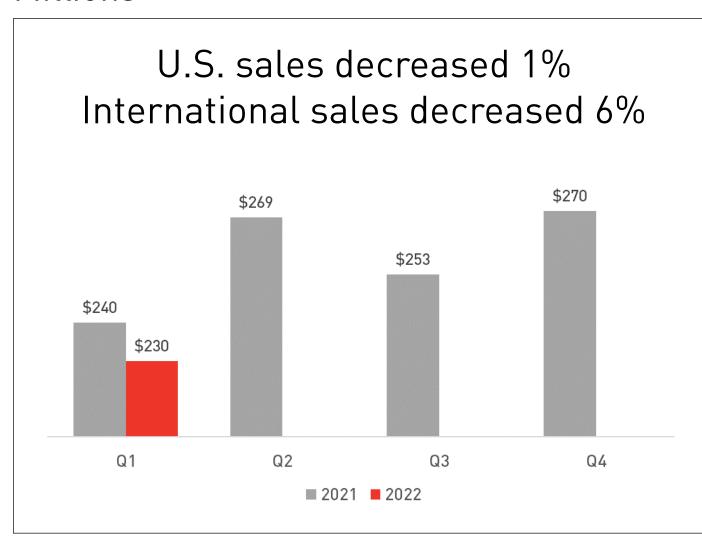


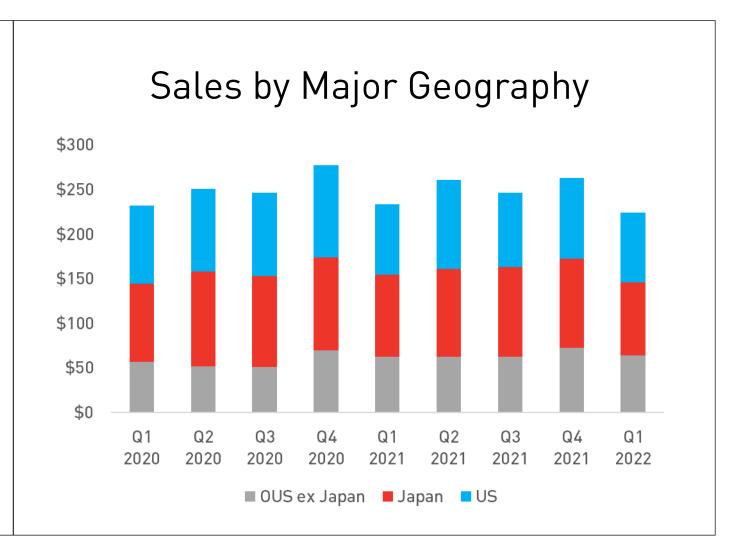
- Launched in the U.S. in July 2018
- Q1 sales driven by the U.S., Germany and Japan
- Contributed ~110bps to Q1 WW volume growth

### Q1 2022 CYRAMZA SALES DECREASED 4%



### Millions

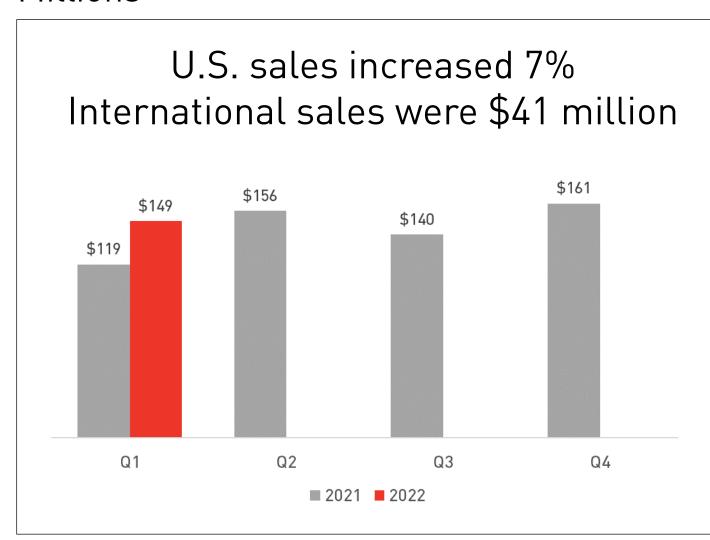


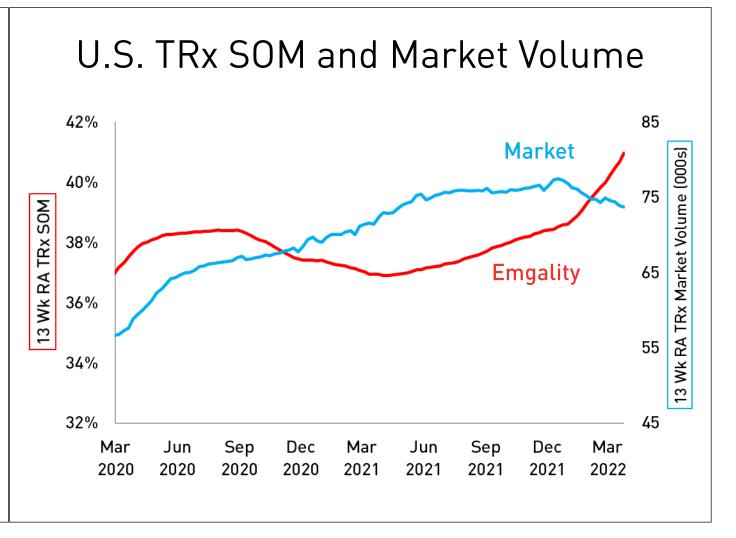


### **Q1 2022 EMGALITY SALES INCREASED 25%**



### Millions



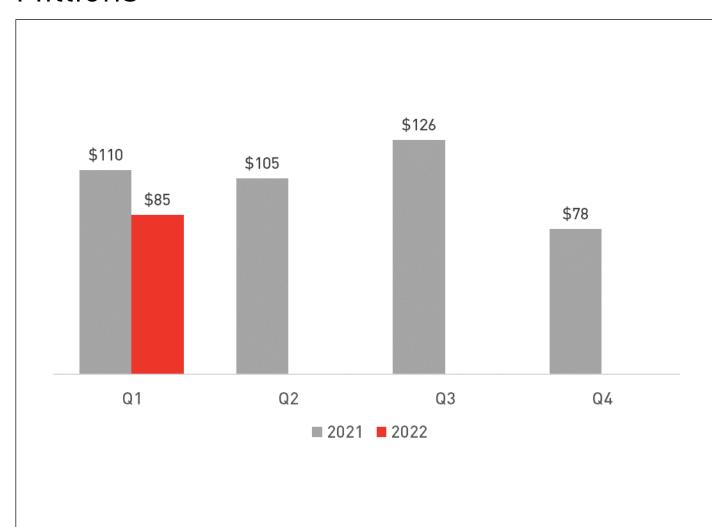


Source: IQVIA NPA TRx 3MMA, weekly data March 25, 2022; RA = rolling average Note: TRx data is representative of the injectable CGRP market

# Q1 2022 TYVYT SALES WERE \$85 MILLION IN CHINA



### Millions

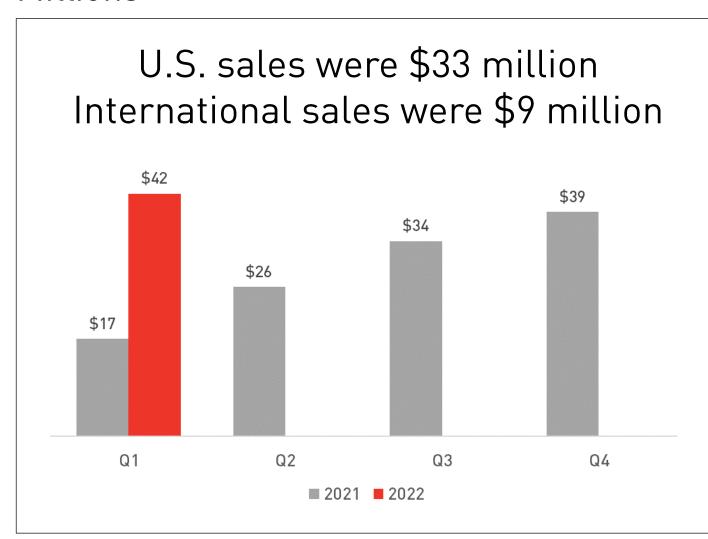


- Launched in China in Q1 2019
- Part of Lilly collaboration with Innovent
- Contributed ~110bps to Q1 WW volume growth
- Q1 sales decline due to updated NRDL access and corresponding lower price

### Q1 2022 RETEVMO SALES WERE \$42M



#### Millions



- First RET inhibitor approved for certain lung and thyroid cancers with RET fusions and mutations
- Positive uptake since 2020 launch
- Continued focus on diagnostics utilization

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



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
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	Apr 2024

<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	Aug 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)	Aug 2023	Jan 2024
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	700	Mean Monthly Percentage of Participants with a 50% Response Rate	Dec 2022	Dec 2022

<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 Completion	Completion
NCT04975308	Breast Cancer	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	800	Progression Free Survival (PFS)	Jun 2023	Sep 2026

<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	Composite primary outcome: Time to first occurrence of (i) 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 (ii) Cardiovascular death	Jun 2022	Jul 2022
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	5000	Composite of time to first heart failure hospitalisation or all-cause mortality	Mar 2023	Mar 2023

In collaboration with Boehringer Ingelheim

<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**



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Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04146363	Atopic Dermatitis	Evaluation of the Efficacy and Safety of Lebrikizumab (LY3650150) in Moderate to Severe Atopic Dermatitis (ADvocate1)	3	400	Percentage of participants with an IGA score of 0 or 1 and a reduction >2 points from Baseline to Week 16	Jun 2021	May 2022
NCT04178967	Atopic Dermatitis	Evaluation of the Efficacy and Safety of Lebrikizumab (LY3650150) in Moderate to Severe Atopic Dermatitis (ADvocate2)	3	400	Percentage of participants with an IGA score of 0 or 1 and a reduction ≥2 points from Baseline to Week 16	Jul 2021	Jun 2022
NCT04250350	Atopic Dermatitis	Study to Assess the Safety and Efficacy of Lebrikizumab (LY3650150) in Adolescent Participants With Moderate-to- Severe Atopic Dermatitis (ADore)	3	200	Percentage of Participants Discontinued from Study Treatment Due to Adverse Events	Apr 2022	Jul 2022
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
NCT04626297	Atopic Dermatitis	A Study of Lebrikizumab (LY3650150) on Vaccine Response in Adults With Atopic Dermatitis (ADopt-VA)	3	240	Percentage of Participants who Develop a Booster Response to Tetanus Toxoid 4 Weeks after Vaccine Administration	Aug 2022	Oct 2022
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	May 2024	May 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	1150	Percentage of Participants Achieving Endoscopic Response	Dec 2023	Apr 2024
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
	<u> </u>						1
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	Oct 2022
NCT03524092	Ulcerative Colitis	A Maintenance Study of Mirikizumab in Participants With Moderately to Severely Active Ulcerative Colitis (LUCENT 2)	3	1044	Percentage of Participants in Clinical Remission	Nov 2021	Aug 2023
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
NCT04844606	Ulcerative Colitis	A Master Protocol (AMAZ): A Study of Mirikizumab (LY3074828) in Pediatric Participants With Ulcerative Colitis or Crohn's Disease (SHINE-ON)	3	185	Percentage of Participants with UC in Modified Mayo Score (MMS) Clinical Remission	Sep 2025	Sep 2027

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

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

#### **SELECT TRIALS – OLUMIANT**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03899259	Alopecia Areata	A Study of Baricitinib (LY3009104) in Adults With Severe or Very Severe Alopecia Areata (BRAVE-AA2)	3	546	Percentage of Participants Achieving Severity of Alopecia Tool (SALT) ≤20	Jan 2021	May 2024
NCT03570749	Alopecia Areata	A Study of Baricitinib (LY3009104) in Participants With Severe or Very Severe Alopecia Areata (BRAVE-AA1)	2 3	764	Percentage of Participants Achieving Severity of Alopecia Tool (SALT) ≤20	Feb 2021	Jun 2024

In collaboration with Incyte

<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)	Jul 2024	Jul 2024

<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 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
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
	<u> </u>		ı	· · · · · · · · · · · · · · · · · · ·		T	T 1
NCT04280081	Solid Tumor	A Study of Selpercatinib (LY3527723) in Participants With Advanced Solid Tumors Including RET Fusion-positive Solid Tumors, Medullary Thyroid Cancer and Other Tumors With RET Activation (LIBRETTO-321)	2	75	Overall Response Rate (ORR): Percentage of Participants with Complete Response (CR) or Partial Response (PR) by Independent Review Committee	Mar 2021	Nov 2025

<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

<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**



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	Nov 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

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

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

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



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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	12500	Time to First Occurrence of Death from Cardiovascular (CV) Causes, Myocardial Infarction (MI), or Stroke (MACE-3)	Oct 2024	Oct 2024
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)	)	90	Change From Baseline in Hemoglobin A1c (HbA1c)	Nov 2027	Dec 2027
					A Hierarchical Composite of All-Cause Mortality, Heart		
NCT04847557	HFpEF	A Study of Tirzepatide (LY3298176) in Participants With Heart Failure With Preserved Ejection Fraction and Obesity (SUMMIT)	3	700	Failure Events, 6-minute Walk Test Distance (6MWD) and Kansas City Cardiomyopathy Questionnaire (KCCQ) Clinical Summary Score (CSS) Category	Nov 2023	Nov 2023

Not for promotional use

**2022 Q1 EARNINGS** 

<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
		A Study of Abiratorona Acatata Dluc Dradnicana With an					
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)	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**

Lilly

Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
GGG Tri- Agonist	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
GLP-1R NPA	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	May 2022	Sep 2022
GGG Tri- Agonist	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
GLP-1R NPA	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
ANGPLT3- siRNA	NCT05256654	Dyslipidemias	A Study of LY3561774 in Participants With Mixed Dyslipidemia (PROLONG-ANG3)	2	225	Percent Change from Baseline for Non-High Density Lipoprotein-Cholesterol (non-HDL-C)	May 2023	Nov 2023
LP(a) Disrupter Inhibitor	NCT05038787	Healthy	A Study of LY3473329 in Healthy Japanese Participants	1	24	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 2022

<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
Relaxin-LA	NCT04768855	Healthy	A Study of LY3540378 in Healthy Participants	1	132	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	May 2022	May 2022
LP(a)-siRNA	NCT04914546	Healthy	A Study of LY3819469 in Healthy Participants	1	66	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Nov 2022	Nov 2022
NRG4 Agonist	NCT04840914	Chronic 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	Jul 2023	Jul 2023
LA Amylin Receptor Agonist	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

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

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

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



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
Peresolimab	NCT04634253	Rheumatoid Arthritis	A Study of LY3462817 in Participants With Rheumatoid Arthritis	2	80	Change from Baseline on the Disease Activity Score Modified to Include the 28 Diarthrodial Joint Count- High-Sensitivity C-Reactive Protein (DAS28-hsCRP)		Jun 2022
CXCR1/2L mAb	NCT04493502	Hidradenitis Suppurativa	A Study of LY3041658 in Adults With Hidradenitis Suppurativa	2	52	Percentage of Participants Achieving Hidradenitis Suppurativa Clinical Response (HiSCR)	Mar 2022	Nov 2022
IL-2 CONJUGATE <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	Nov 2022	Feb 2023
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	Apr 2023	Aug 2023

<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
IL-2 CONJUGATE <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
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	Nov 2022	Nov 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

<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
N3PG AB MAB	NCT04451408	Alzheimer Disease	A Study of LY3372993 in Participants With Alzheimer's Disease (AD) and Healthy Participants	1	209	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Sep 2023	Sep 2023
GBA1 Gene Therapy	NCT04127578	Parkinson Disease	Phase 1/2a Clinical Trial of PR001 in Patients With Parkinson's Disease With at Least One GBA1 Mutation (PR0PEL)	1 2	12	Number of Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)	Jun 2027	Jun 2027
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	Sep 2027	Sep 2027
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

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

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

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



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
IDH1 Inhibitor	NCT04521686	Cholangiocarcinoma	Study of LY3410738 Administered to Patients With Advanced Solid Tumors With IDH1 or IDH2  Mutations	1	180	Recommended Phase 2 dose (RP2D)	Feb 2023	Sep 2023
IDH1 Inhibitor	NCT04603001	Acute Myeloid Leukemia (AML)	Study of Oral LY3410738 in Patients With Advanced Hematologic Malignancies With IDH1 or IDH2 Mutations	1	220	To determine the maximum tolerated dose (MTD)/recommended Phase 2 dose (RP2D)	Mar 2023	Mar 2023
KRAS G12C	NCT04956640	NSCLC and CRC	Study of LY3537982 in Cancer Patients With a Specific Genetic Mutation (KRAS G12C)	1	300	Phase 1a: To determine the recommended phase 2 dose (RP2D) of LY3537982 monotherapy	Oct 2023	Oct 2023
BCL2	NCT05024045	Leukemia, Lymphocytic, Chronic, B-Cell	Study of Oral LOXO-338 in Patients With Advanced Blood Cancers	1	316	Part 1 - To determine the maximum tolerated dose (MTD)/recommended phase 2 dose (RP2D) of oral LOXO-338	Apr 2024	Apr 2024
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> 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	NCT05080660	Osteoarthritis	Chronic Pain Master Protocol (CPMP): A Study of LY3526318 in Participants With Osteoarthritis	2	150	Change from Baseline in Average Pain Intensity as Measured by the Numeric Rating Scale (NRS)	Jun 2022	Jun 2022
TRPA1 Antagonist	NCT05086289	Chronic Low-back Pain	Chronic Pain Master Protocol (CPMP): A Study of LY3526318 in Participants With Chronic Low Back Pain	2	150	Change from Baseline for Average Pain Intensity as Measured by the Numeric Rating Scale (NRS)	Jun 2022	Jun 2022
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)	Sep 2022	Sep 2022
PACAP38 MAB	NCT04498910	Migraine	A Study of LY3451838 in Participants With Migraine	2	120	Change from Baseline in the Number of Monthly Migraine Headache Days	Sep 2022	Sep 2022
SSTR4 Agonist	NCT04707157	Diabetic Peripheral Neuropathic Pain	Chronic Pain Master Protocol (CPMP): A Study of LY3556050 in Participants With Diabetic Peripheral Neuropathic Pain	2	150	Change from Baseline in Average Pain Intensity as Measured by the Numeric Rating Scale (NRS)	May 2023	May 2023
						Change from baseline in brain receptor occupancy		
P2X7	NCT05292040	Healthy	A Study of LY3857210 in Healthy Participants	1	25	(RO) of LY3857210 measured by [18F]-LY3818850 PET scan	Jun 2022	Jun 2022

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

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