## Powered By Purpose



Q1 2021 Earnings Call April 27, 2021

## **AGENDA**



#### INTRODUCTION AND KEY RECENT EVENTS

Dave Ricks, Chairman and Chief Executive Officer

#### **Q1 2021 FINANCIAL RESULTS**

Anat Ashkenazi, Chief Financial Officer

#### **R&D UPDATE**

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

#### **CLOSING REMARKS**

Dave Ricks, Chairman 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**



- 16% revenue growth in Q1; 7% growth excluding COVID-19 antibody revenue and Q1 2020 COVID-19 related stocking benefit
- Revenue growth driven by:
  - 17% volume growth
  - Key growth products, which accounted for 52% of revenue excluding COVID-19 antibodies

#### **Improve Productivity**



- Non-GAAP:
  - Gross margin in Q1 was 75.4% (78.0% excluding FX impact on international inventories sold)
  - Operating margin in Q1 was 27.5% (30.1% excluding FX impact on international inventories sold)

## **Create Long-Term Value**



- In-licensed RIPK1 inhibitor from Rigel Pharmaceuticals
- Agreed to sell the rights to QBREXZA, completing planned integration strategy of Dermira
- Distributed nearly \$800 million via dividends in Q1

## **Speed Life-Changing Medicines**



- Positive results from SURPASS-2, 3 & 5 trials of tirzepatide in type 2 diabetes
- Positive results from LUCENT-1 trial of mirikizumab in ulcerative colitis
- Positive results from BRAVE-AA1 & AA2 of baricitinib in alopecia areata
- Phase 3 initiations for pirtobrutinib, formerly LOXO-305, in chronic lymphocytic leukemia and mantle cell lymphoma
- U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) for bamlanivimab and etesevimab together for COVID-19

## KEY EVENTS SINCE THE LAST EARNINGS CALL



#### REGULATORY

- The FDA extended the review period for the supplemental New Drug Application (sNDA) for **baricitinib** for the treatment of adults with moderate to severe atopic dermatitis which shifted The Prescription Drug User Fee Act action date by three months to early Q3; and
- Announced the outcome of the FDA Joint Arthritis Advisory Committee and Drug Safety and Risk Management Advisory Committee on tanezumab where the Committee voted 1 in favor and 19 against tanezumab on whether the proposed risk evaluation and mitigation strategy will ensure its benefits outweigh its risks.

#### **CLINICAL**

- Announced positive top-line results from three Phase 3 clinical trials of
  tirzepatide in adults with type 2 diabetes in terms of A1C and body weight
  reductions from baseline. The three trials compared tirzepatide to titrated insulin
  degludec, to placebo, both as an add-on to titrated insulin glargine, and to
  injectable semaglutide 1 mg;
- Presented positive Phase 2 results for **donanemab** that expanded on previously reported top-line data that found donanemab met its primary endpoint and showed significant slowing of decline compared to placebo on the integrated Alzheimer's Disease Rating Scale (iADRS), a composite measure of cognition and daily function, in patients with early symptomatic Alzheimer's disease;
- Announced the expansion of the Phase 3 TRAILBLAZER-ALZ 2 study for donanemab in early Alzheimer's disease and the plan to initiate a new Phase 3 study, TRAILBLAZER-ALZ 3, for donanemab in asymptomatic Alzheimer's disease;

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

- Announced positive top-line results for **mirikizumab** in a Phase 3 induction study for the treatment of patients with moderate to severe ulcerative colitis which met the primary and all key secondary endpoints evaluating the efficacy and safety of mirikizumab;
- Announced the development program for **mirikizumab** will focus only on ulcerative colitis and Crohn's disease with no plan to submit mirikizumab for regulatory approval in psoriasis in any geography; and
- Announced positive top-line results from two Phase 3 studies for **baricitinib** in adults with severe alopecia areata, where baricitinib met the primary efficacy endpoint at week 36, demonstrating a statistically significant improvement in scalp hair regrowth compared to those randomized to placebo.

#### **BUSINESS DEVELOPMENT**

- Announced a global exclusive license agreement and strategic collaboration
  with Rigel Pharmaceuticals to co-develop and commercialize Rigel's R552, a
  receptor-interacting serine/threonine-protein kinase 1 (RIPK1) inhibitor, for all
  indications, and Lilly will also lead all clinical development of brain penetrating
  RIPK1 inhibitors in central nervous system (CNS);
- Announced a collaboration and licensing agreement with Welldoc to integrate
  Welldoc's software into Lilly's connected insulin solutions, currently in
  development. Lilly will commercialize the pen platform, which will include the
  new app and Lilly's connected insulin pen solutions; and
- Announced a research collaboration and license agreement with **Biolojic Design** that will leverage Biolojic's Al-based multibody platform to discover and develop a potential novel antibody-based therapy for the treatment of diabetes.

## KEY EVENTS SINCE THE LAST EARNINGS CALL



#### **COVID-19 & OTHER**

- The FDA granted EUA for investigational bamlanivimab and etesevimab together for the treatment of mild to moderate COVID-19 patients who are at high risk for progressing to severe COVID-19 and/or hospitalization. As part of the previously reported collaboration with the company, Amgen began manufacturing etesevimab;
- Announced a purchase agreement with the U.S. government to purchase up to 1.2 million doses of **bamlanivimab and etesevimab together** by November 2021, with 100k doses ordered for shipment by March 31, 2021 at a value of \$210M;
- Modified the purchase agreement for COVID-19 antibodies with the U.S. government to focus on supply of bamlanivimab and etesevimab together to enable the supply of etesevimab alone to complement doses of bamlanivimab the U.S. government already purchased. This terminated the purchase agreement for bamlanivimab alone and cancelled the remaining 350,856 doses that were scheduled to be delivered by the end of March 2021;
- Requested revocation of EUA for bamlanivimab alone to complete the transition to only supply bamlanivimab and etesevimab together for treatment of COVID-19 in the U.S. The FDA subsequently revoked the EUA for bamlanivimab alone;
- The European Medicines Agency's Committee for Medicinal Products for Human Use issued a positive scientific opinion for **bamlanivimab alone** and **bamlanivimab and etesevimab together** for the treatment of COVID-19 patients who are at high risk for progressing to severe COVID-19;
- Shared data from a new Phase 3 cohort of BLAZE-1 which showed treatment with COVID-19 antibodies **bamlanivimab and etesevimab together** significantly reduced risk of COVID-19 related hospitalizations and death by 87% in high-risk patients;

#### COVID-19 & OTHER (CONT.)

- Announced positive top-line data from the expanded Phase 2 trial which showed that investigational bamlanivimab co-administered with VIR-7831 (also known as GSK4182136) 500 mg demonstrated a 70 percent relative reduction in persistently high viral load at day 7 compared to placebo;
- Announced top-line data for a Phase 3 study evaluating **baricitinib** plus standard of care (SoC) versus placebo plus SoC, which did not meet statistical significance on the primary endpoint but showed that treatment with baricitinib in addition to SoC resulted in a significant reduction in death from any cause by 38 percent by day 28;
- Announced several recent and upcoming executive leadership transitions, including the appointment of **Anat Ashkenazi** as senior vice president and chief financial officer, the appointment of **Edgardo Hernandez** as senior vice president and president of manufacturing operations, the appointment of **Diogo Rau** as senior vice president and chief information and digital officer, and the appointment of **Alonzo Weems** as senior vice president, enterprise risk management and chief ethics and compliance officer;
- The Board of Directors elected Kimberly H. Johnson as a new member, serving on both the Compensation and Ethics and Compliance Committees; and
- Announced plans to host a webcast to provide an overview of the company's sustainability efforts in the areas of **Environmental, Social, and Governance** for the investment community, media, and the general public on May 4, 2021.

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



Millions; except per share data

Q1 2021

	GAAP Reported	Adjustments	Non-GAAP Adjusted	Non-GAAP Adjusted Change
TOTAL REVENUE	\$6,806	_	\$6,806	16%
GROSS MARGIN	72.4%	3.0%	<b>75.4</b> %	(4.9pp)
<b>TOTAL OPERATING EXPENSE</b>	3,772	(511)	3,261	11%
OPERATING INCOME	1,155	718	1,873	6%
OPERATING MARGIN	17.0%	10.5%	<b>27.5</b> %	(2.5pp)
OTHER INCOME (EXPENSE)	321	(287)	35	NM
EFFECTIVE TAX RATE	8.2%	2.6%	10.8%	(2.1pp)
NET INCOME	\$1,355	347	\$1,702	16%
EPS	\$1.49	\$0.38	<b>\$1.87</b>	16%

Note: Numbers may not add due to rounding; see slide 26 for a complete list of significant adjustments.

## PRICE/RATE/VOLUME EFFECT ON REVENUE



Millions

Q1 2021

	<del>4</del>						
	Amount	<b>Price</b>	FX Rate	Volume	Total	CER	
U.S.	\$3,941	(6)%	-%	24%	18%	18%	
EUROPE	1,321	(0)%	10%	15%	24%	15%	
JAPAN	572	(2)%	4%	(6)%	(3)%	(8)%	
CHINA	362	(6)%	9%	32%	35%	26%	
REST OF WORLD	609	(2)%	1%	2%	(0)%	(1)%	
TOTAL REVENUE	\$6,806	(4)%	3%	17%	16%	13%	

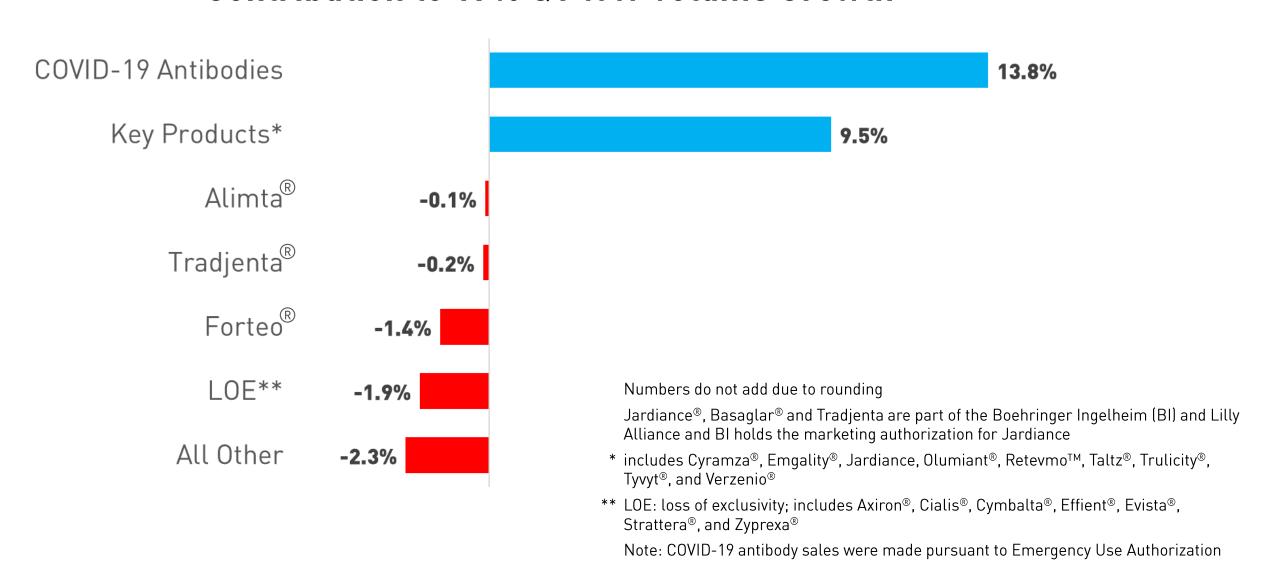
Note: Numbers may not add due to rounding

CER = price change + volume change

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

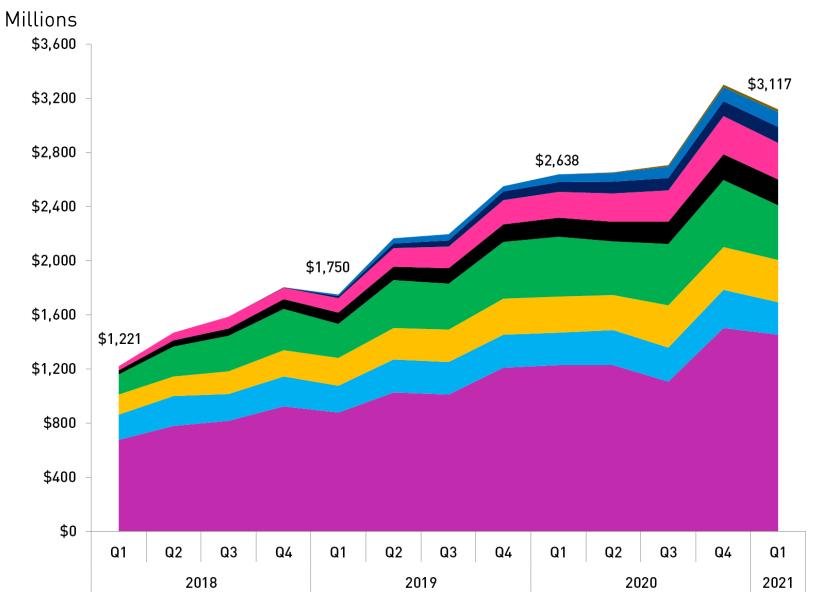


#### Contribution to 17% Q1 WW Volume Growth



## **UPDATE ON KEY GROWTH PRODUCTS**





Note: Jardiance is sold by Boehringer Ingelheim; Lilly records as revenue its share of Jardiance gross margin; Jardiance, Basaglar and Tradjenta are part of the Boehringer Ingelheim and Lilly Alliance \*Verzenio TRx growth normalized for additional prescription data capture in the base period

RETEVMO

• U.S. approval May 2020 in advanced RET-driven lung and thyroid cancers

TYVYT

Added to China's National Drug Reimbursement List in 2020

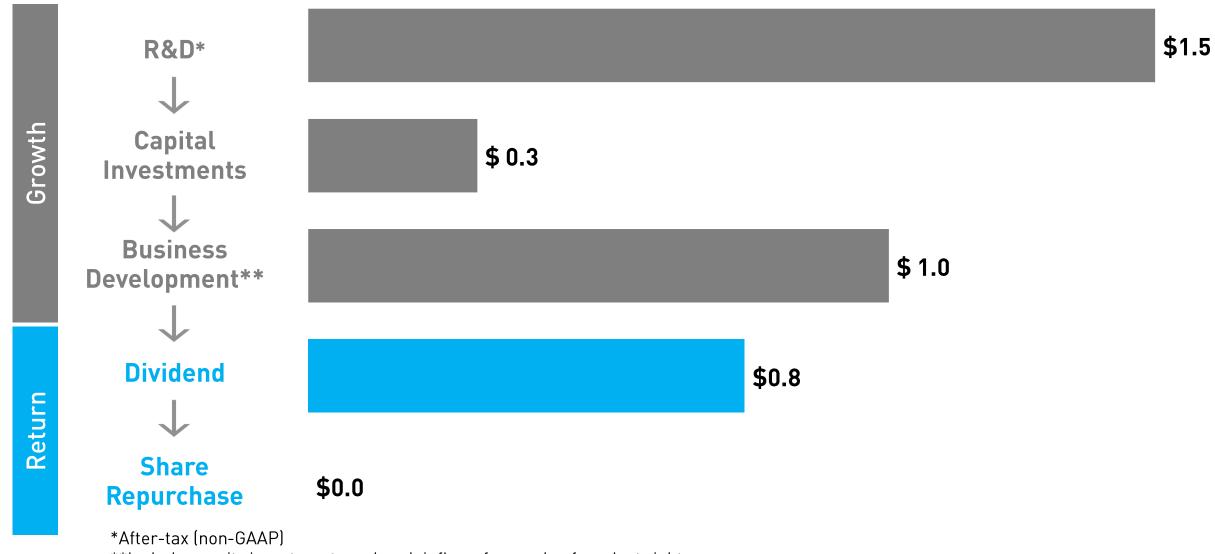
EMGALITY

- U.S. NBRx SOM 39% at the end of Q1 2021
- U.S. TRx 37% SOM at end of Q1 2021
- VERZENIO
  - U.S. NBRx SOM nearly 28% at end of Q1 2021
  - U.S. TRx grew 30%\* vs. Q1 2020, outpacing the market
  - OLUMIANT
    - OUS sales grew 32% vs. Q1 2020
- TALTZ
  - IL-17 dermatology leader in U.S. TRx SOM 19%
  - U.S. TRx grew nearly 21% vs. Q1 2020
  - JARDIANCE
    - Market leader in U.S. TRx SOM 60% and NTS SOM 63%
    - U.S. SGLT2 class grew nearly 18% vs. Q1 2020
  - CYRAMZA
    - WW sales growth +1% vs. Q1 2020
    - **TRULICITY**
    - Market leader in U.S. TRx SOM 48% (injectable GLP-1)
    - U.S. injectable GLP-1 class grew 16% vs. Q1 2020

## **CAPITAL ALLOCATION**







<sup>\*\*</sup>Includes equity investments and cash inflows from sale of product rights

## **2021 GUIDANCE**



	Prior	<b>Updated</b>	Comments
TOTAL REVENUE	\$26.5 – \$28.0 billion	\$26.6 – \$27.6 billion	Reflects \$100M increase to the core business for FX benefits; COVID-19 antibodies revenue range narrowed to \$1-\$1.5B
GROSS MARGIN % (GAAP)	approx. 77%	Unchanged	
GROSS MARGIN % (NON-GAAP)	approx. 79%	Unchanged	
MKTG, SELLING & ADMIN.	\$6.2 – \$6.4 billion	Unchanged	
RESEARCH & DEVELOPMENT	\$6.5 – \$6.7 billion	\$6.9 – \$7.1 billion	Reflects an increase for investments in donanemab; COVID-19 antibodies range increased to \$400-\$500M
OTHER INCOME/(EXPENSE) (GAAP)	\$(300) – \$(200) million	\$150 – \$250 million	Reflects Q1 2021 equity investment gains and Alimta patent settlement in Europe
OTHER INCOME/(EXPENSE) (NON-GAAP)	\$(300) – \$(200) million	\$(200) – \$(100) million	Reflects Alimta patent settlement in Europe
TAX RATE	approx. 15%	approx. 13%	Reflects higher discrete tax items in Q1 2021 and a lower base rate
EARNINGS PER SHARE (GAAP)	\$7.10 – \$7.75	\$7.03 – \$7.23	Reflects increases to acquired IPR&D, other specified items and equity investment gains
EARNINGS PER SHARE (NON-GAAP)	\$7.75 – \$8.40	\$7.80 – \$8.00	Reflects adjustments to revenue, research & development expense, other income/(expense) and tax rate
OPERATING INCOME % (GAAP)	approx. 30%	approx. 26%	Reflects increases to acquired IPR&D and other specified items
OPERATING INCOME % (NON-GAAP)	approx. 32%	approx. 31%	Reflects adjustments to revenue and research & development expense

Assumes GAAP and non-GAAP shares outstanding 909 million

Updated FX assumptions of 1.17 (Euro), 110 (Yen) and 6.59 (Renminbi)

Not for promotional use 2021 Q1 EARNINGS

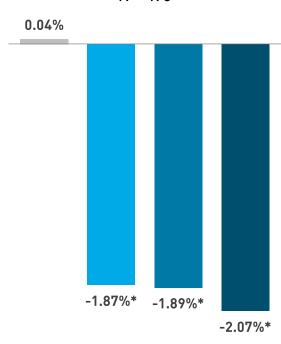
### **SURPASS HIGHLIGHTS: SIGNIFICANT HBA1C REDUCTION**

TIRZEPATIDE SIGNIFICANTLY REDUCED HBA1C ACROSS DOSES DEMONSTRATING SUPERIORITY VS. ALL COMPARATORS





Baseline HbA1c: 7.9%N = 478



#### No background OAMs

TZP

10 ma

TZP

15 ma

TZP

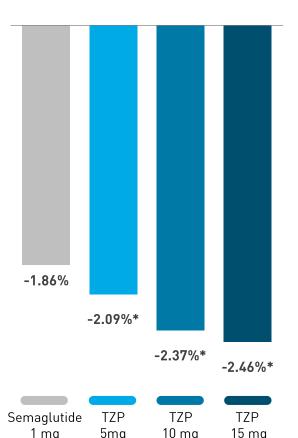
5ma

Placebo

#### **SURPASS-2**

(40 Weeks)

Baseline HbA1c: 8.3% N = 1,879

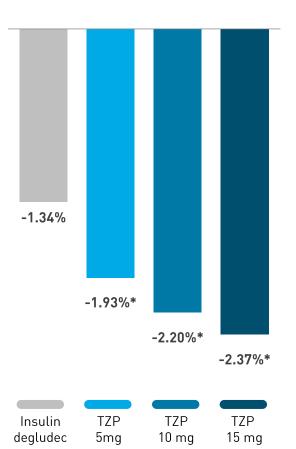


#### **Background Metformin**

## SURPASS-3 (52 Weeks)

asalina HhA1c, 8 2

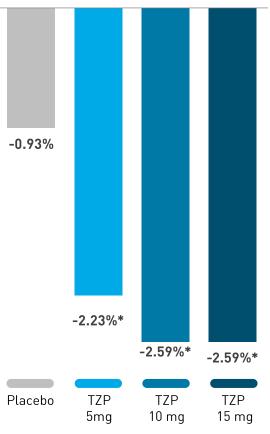
Baseline HbA1c: 8.2% N = 1,444



#### Background Metformin, or Metformin + SGLT-2i

## SURPASS-5 (40 Weeks)

Baseline HbA1c: 8.3% N = 475



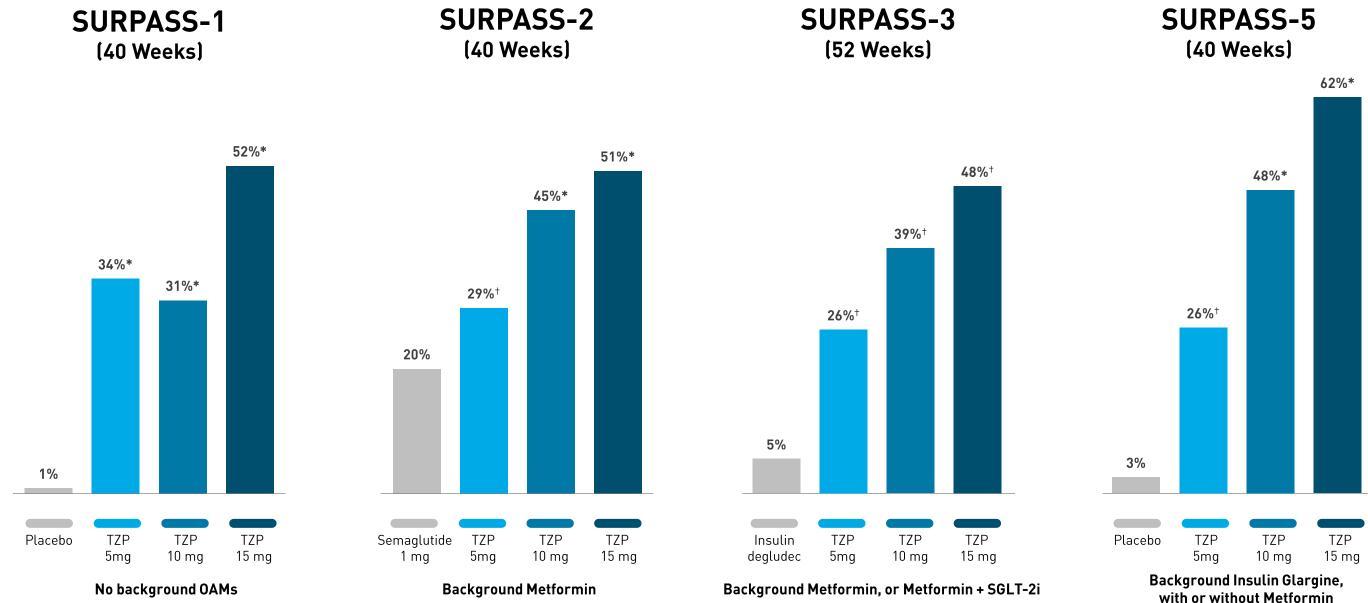
Background Insulin Glargine, with or without Metformin

<sup>\*</sup>denotes statistical significance to comparator; TZP = tirzepatide; OAM = Oral Antidiabetic Medication; SGLT-2i = sodium-glucose co-transporter-2 inhibitor
Results presented using the efficacy estimand, which represents efficacy prior to discontinuation of study drug or initiating rescue therapy for persistent severe hyperglycemia

## **SURPASS HIGHLIGHTS: HBA1C < 5.7%**

BETWEEN 26% AND 62% OF TIRZEPATIDE-TREATED PATIENTS ACHIEVED A NORMAL HBA1C LEVEL (<5.7%)





<sup>\*</sup> denotes statistical significance to comparator; †Not controlled for type I error; TZP = tirzepatide; OAM = Oral Antidiabetic Medication; SGLT-2i = sodium-glucose co-transporter-2 inhibitor Results presented using the efficacy estimand, which represents efficacy prior to discontinuation of study drug or initiating rescue therapy for persistent severe hyperglycemia

## SURPASS HIGHLIGHTS: SIGNIFICANT WEIGHT REDUCTION

AT THE HIGHEST DOSE OF TIRZEPATIDE, PARTICIPANTS LOST UP TO 12.9 KG (28.4 LBS)



#### **SURPASS-1**

(40 Weeks)

Baseline Weight: 85.9 kg

#### **SURPASS-2**

(40 Weeks)

Baseline Weight: 93.7 kg

-8.5%

-7.8 kg\*

-11.0%

-10.3 kg\*

TZP

10 mg

-13.1%

-12.4 kg\*

TZP

15 mg

-6.7%

-6.2 kg

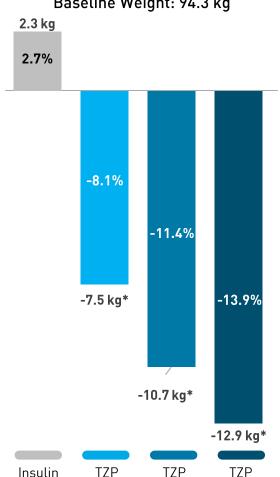
Semaglutide

1 mg

#### **SURPASS-3**

(52 Weeks)

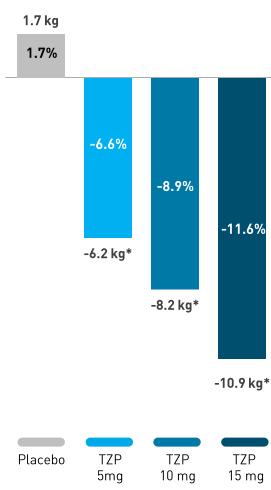
Baseline Weight: 94.3 kg

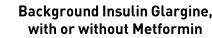


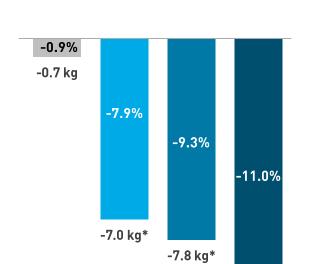
(40 Weeks)

**SURPASS-5** 

Baseline Weight: 95.2 kg









No background OAMs

Placebo

-9.5 kg\*

#### **Background Metformin**

Background Metformin, or Metformin + SGLT-2i

10 mg

15 mg

5mg

degludec

\*denotes statistical significance to comparator; TZP = tirzepatide; OAM = Oral Antidiabetic Medication; SGLT-2i = sodium-glucose co-transporter-2 inhibitor Results presented using the efficacy estimand, which represents efficacy prior to discontinuation of study drug or initiating rescue therapy for persistent severe hyperglycemia

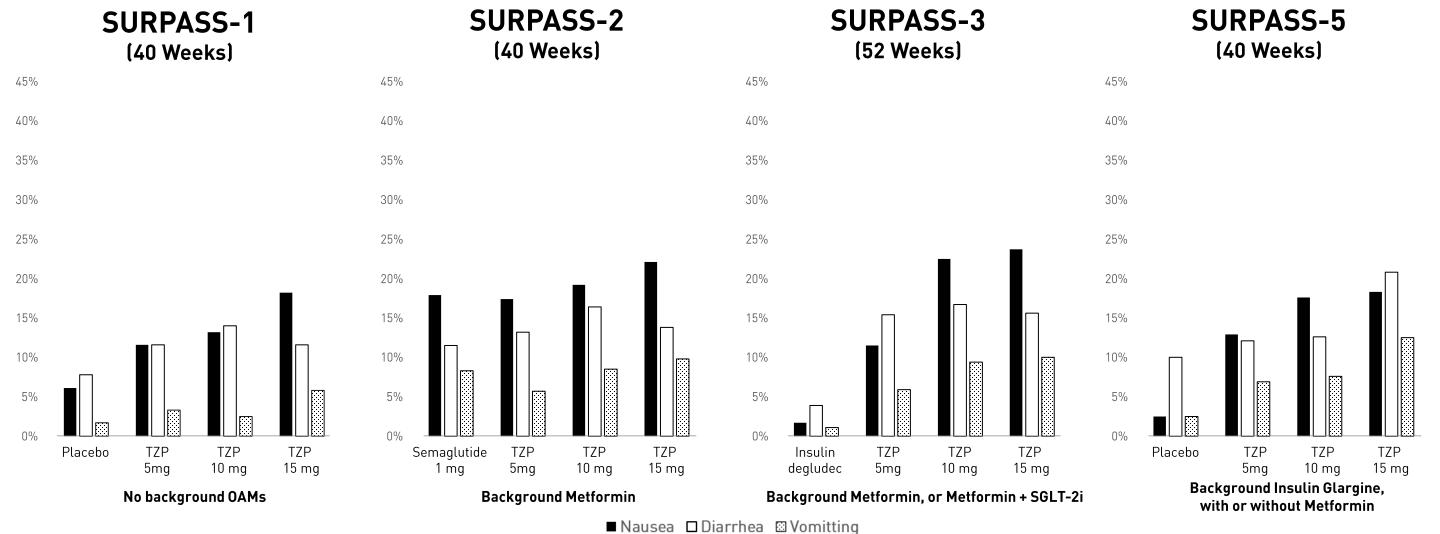
TZP

5mg

## **SURPASS HIGHLIGHTS: TOLERABILITY**

TIRZEPATIDE SAFETY PROFILE WAS SIMILAR TO WELL ESTABLISHED GLP-1 RECEPTOR AGONIST CLASS





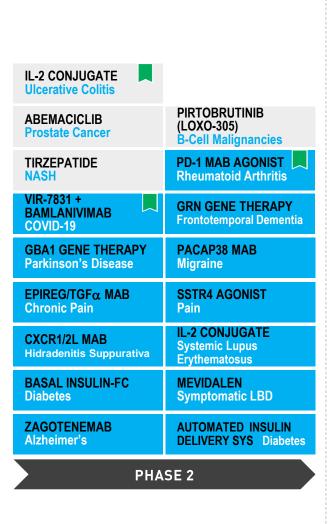
#### DISCONTINUATION RATES DUE TO ADVERSE EVENTS WERE BETWEEN 3% AND 11% ACROSS DOSES

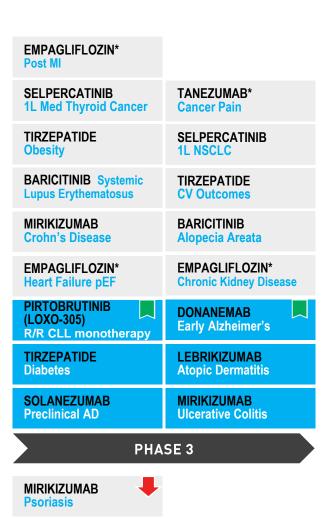
## LILLY SELECT NME AND NILEX PIPELINE

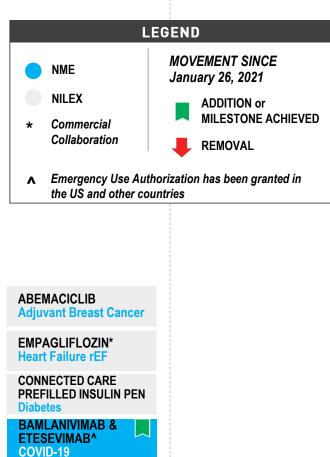
**APRIL 23, 2021** 



RELAXIN-LA Heart Failure	NOT DISCLOSED Diabetes	
LY-CoV1404 MAB COVID-19	RIPK1 INHIBITOR Immunology	P2X7 INHIBITOR Pain
GIP/GLP COAGONIST PEPTIDE II Diabetes	IL-17A SMALL MOL INHIBITOR Immunology	PYY ANALOG Diabetes
KHK INHIBITOR II Diabetes / NASH	ANGPTL3 siRNA CVD	LP(a) INHIBITOR CVD
GIPR AGONIST LA Diabetes	GLP-1R NPA Diabetes	NRG4 AGONIST Heart Failure
IDH1 INHIBITOR Cancer	CD200R MAB AGONIST Immunology	KHK INHIBITOR Diabetes / NASH
GGG TRI-AGONIST Diabetes	N3PG Aβ MAB Alzheimer's	TRPA1 ANTAGONIST Pain
O-GLCNACASE INH Alzheimer's	GIP/GLP COAGONIST PEPTIDE Diabetes	SERD Cancer
BTLA MAB AGONIST Immunology	AUR A KINASE INHIBITOR Cancer	OXYNTOMODULIN Diabetes
	PHASE 1	
CD73 INHIBITOR Cancer	ANGPTL3/8 MAB	







**BARICITINIB**<sup>^</sup>

**APPROVED** 

COVID-19

**TANEZUMAB\*** 

**Osteoarthritis Pain** 

**REG REVIEW** 

Not for promotional use 2021 Q1 EARNINGS

New since last update

## **POTENTIAL KEY EVENTS 2021**

## Lilly

#### **Phase 3 Initiations**

**Abemaciclib** for HR+, HER2+ early breast cancer **Pirtobrutinib (LOX0-305)** for MCL monotherapy

Pirtobrutinib (LOXO-305) for CLL monotherapy

Pirtobrutinib (LOXO-305) for CLL combination therapy

Pirtobrutinib (LOXO-305) for CLL first-line

Tirzepatide for obesity (3 additional studies)

Tirzepatide for HFpEF

Donanemab for asymptomatic Alzheimer's disease

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

Baricitinib for alopecia areata

Baricitinib for systemic lupus erythematosus

Mirikizumab for ulcerative colitis (induction data)
Mirikizumab for ulcerative colitis (maintenance data)

✓ Tirzepatide for type 2 diabetes (SURPASS-2)

Tirzepatide for type 2 diabetes (SURPASS-3)

Tirzepatide for type 2 diabetes (SURPASS-4)

Tirzepatide for type 2 diabetes (SURPASS-5)

Zagotenemab for early Alzheimer's disease

#### **Medical Meeting Presentations**

✓ Donanemab for early Alzheimer's disease
Oral SERD for metastatic breast cancer
Tirzepatide for type 2 diabetes

#### **Regulatory Submissions**

Abemaciclib for high-risk HR+, HER2- early breast cancer (J)

Baricitinib for alopecia areata

Bamlanivimab + Etesevimab for COVID-19 (EU 46 / US)
Sintilimab for NSCLC (US)
Tirzepatide for type 2 diabetes (US/EU/J)

#### **Regulatory Actions**

**Abemaciclib** for high-risk HR+, HER2- early breast cancer (US/EU/J) **Baricitinib** for atopic dermatitis (US/J )<sup>3</sup> **Empagliflozin** for HFrEF (US/EU/J)<sup>1</sup>

Selpercatinib for NSCLC and thyroid cancers (EU / / / )

Tanezumab for osteoarthritis pain (US)<sup>2</sup>

Bamlanivimab + Etesevimab EUA for COVID-19

◆Baricitinib for COVID-19 (J
◆)

<sup>&</sup>lt;sup>1</sup> in collaboration with Boehringer Ingelheim

<sup>&</sup>lt;sup>2</sup> in collaboration with Pfizer

<sup>&</sup>lt;sup>3</sup> Japan approval occurred in Q4 2020

## **Q1 2021 PERFORMANCE SUMMARY**



- Volume-driven revenue growth of 17%, with key growth products comprising the majority of revenue excluding COVID-19 antibodies
- Operating margin of 30.1%, excluding FX impact on international inventories sold with continued expansion expected throughout the year
- Progress on our innovation-based strategy, including positive data readouts for tirzepatide, mirikizumab and baricitinib, Phase 3 initiations for pirtobrutinib and EUA authorization for bamlanivimab and etesevimab together for COVID-19
- Deployed nearly \$800 million to shareholders via the dividend

# Grow Revenue Expect to deliver top-tier revenue growth





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

## **SUPPLEMENTARY SLIDES**



## 2021 INCOME STATEMENT – REPORTED



Millions; except per share data

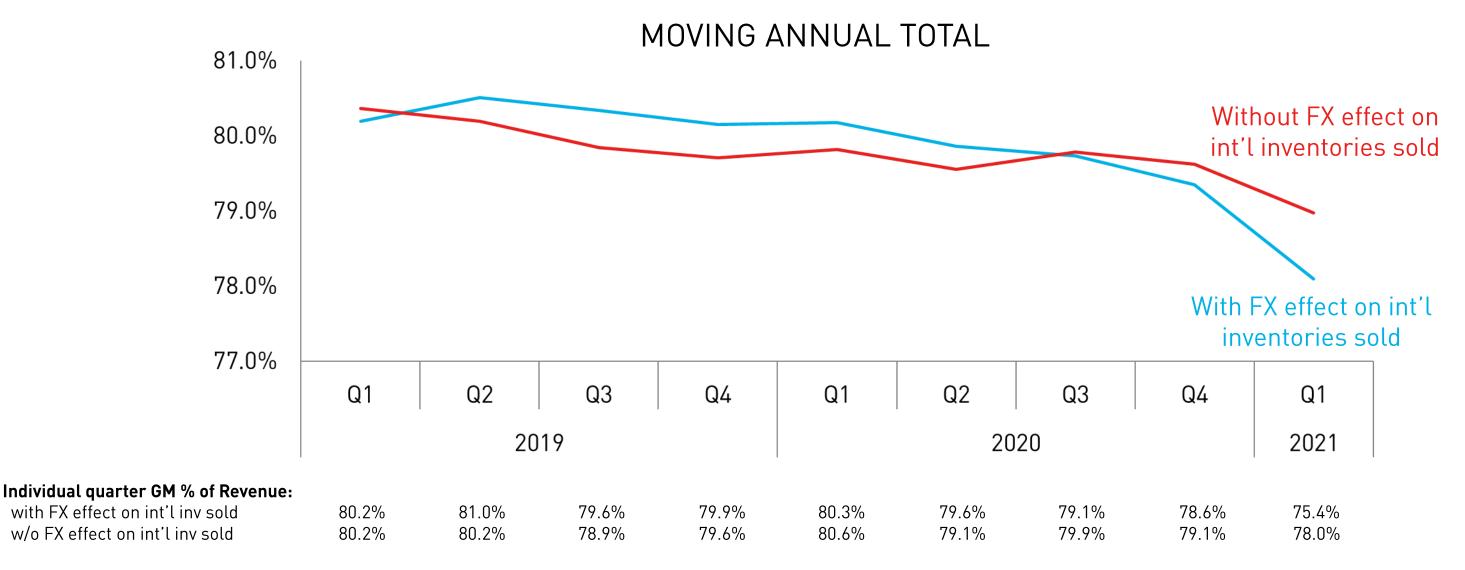
	Q1 2021	<b>Change</b>
TOTAL REVENUE	\$6,806	16%
GROSS MARGIN	72.4%	(6.9pp)
TOTAL OPERATING EXPENSE*	3,772	24%
OPERATING INCOME	1,155	(27%)
OPERATING MARGIN	17.0%	(10.2pp)
OTHER INCOME (EXPENSE)	321	NM
EFFECTIVE TAX RATE	8.2%	(5.1pp)
NET INCOME - CONTINUING OPERATIONS	\$1,355	(7%)
EARNINGS PER SHARE	\$1.49	(7%)

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

NM – not meaningful

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

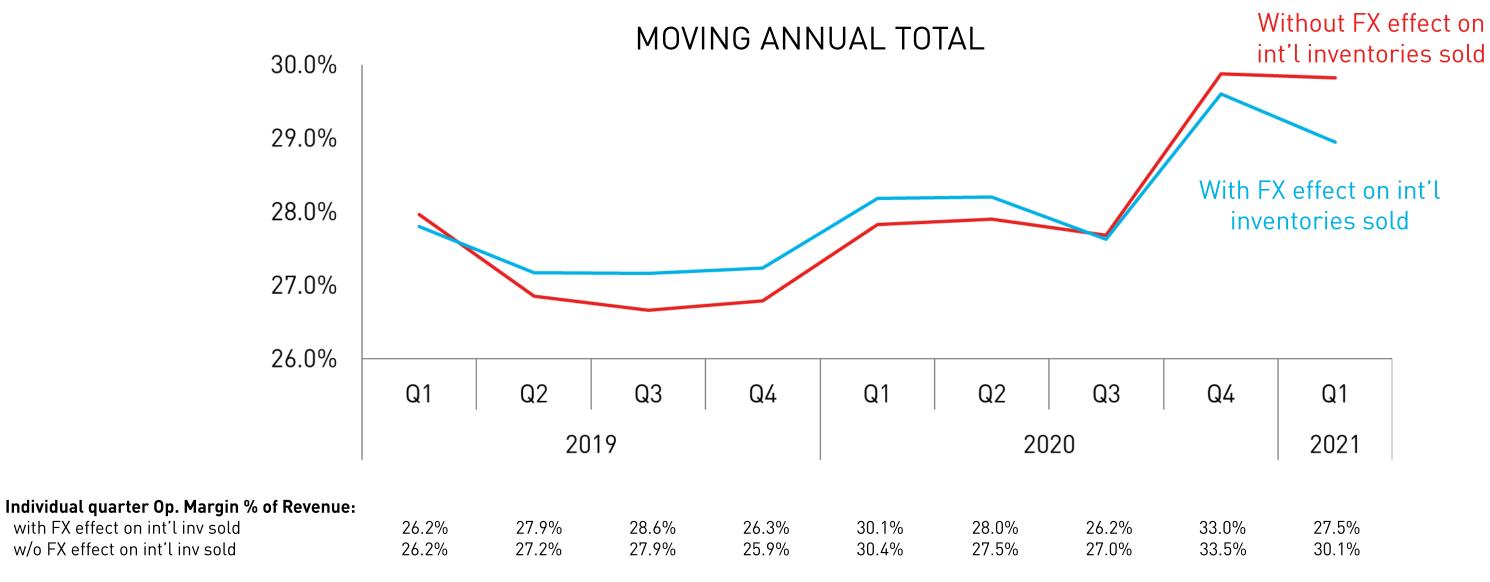




Note: The lines in the graph are moving annual totals (i.e. trailing 4 quarters) while the two rows of numbers are from specific quarters.

## **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 2021 RESULTS**



Year-on-Year Growth Q1 2021

REPORTED	With FX	w/o FX		
TOTAL REVENUE	16%	13%		
COST OF SALES	55%	39%		
<b>GROSS MARGIN</b>	6%	7%		
OPERATING EXPENSE	24%	22%		
OPERATING INCOME	(27%)	(23%)		
EARNINGS PER SHARE	(7%)	(2%)		

NON-GAAP	With FX	w/o FX
TOTAL REVENUE	16%	13%
COST OF SALES	45%	29%
GROSS MARGIN	9%	10%
OPERATING EXPENSE	11%	10%
OPERATING INCOME	6%	10%
EARNINGS PER SHARE	16%	20%

## **EPS RECONCILIATION**



	Q1 2021	Q1 2020	% Change
EPS (REPORTED)	\$1.49	\$1.60	(7%)
ACQUIRED IN-PROCESS RESEARCH AND DEVELOPMENT	0.26	0.05	
OTHER SPECIFIED ITEMS	0.26	0.06	
AMORTIZATION OF INTANGIBLE ASSETS	0.11	0.05	
EQUITY INVESTMENT GAINS/LOSSES	(0.25)	(0.14)	
EPS (NON-GAAP)	\$1.87	\$1.61	16%

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

## Q1 2021 INCOME STATEMENT NOTES



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

- amortization of intangible assets 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);
- acquired in-process R&D charges totaling \$299.3 million (pretax), or \$0.26 per share (after-tax), related to business development transactions with Rigel Pharmaceuticals, Inc., Precision BioSciences, Inc., Merus N.V., and Asahi Kasei Pharma Corporation;
- asset impairment, restructuring and other special charges, primarily an intangible asset impairment resulting from the decision to sell the rights to QBREXZA, charges resulting from excess inventory due in part to the discontinuation of bamlanivimab for use on its own, as well as acquisition and integration costs recognized as part of the closing of the acquisition of Prevail Therapeutics Inc., totaling \$293.1 million (pretax), or \$0.26 per share (after-tax); and
- gains and losses on investments in equity securities totaling \$286.5 million (pretax), or (\$0.25) per share (after-tax).

#### Q1 2020 NON-GAAP INFORMATION HAS BEEN ADJUSTED TO ELIMINATE:

- amortization of intangible assets primarily associated with costs of marketed products acquired or licensed from third parties totaling \$54.4 million (pretax), or \$0.05 per share (after-tax);
- acquired in-process R&D charges totaling \$52.3 million (pretax), or \$0.05 per share (after-tax), related to business development activity other than a business combination, related to Sitryx;
- asset impairment, restructuring and other special charges, primarily acquisition and integration costs associated with the acquisition of Dermira, Inc., totaling \$64.1 million (pretax), or \$0.06 per share (after-tax); and
- gains and losses on investments in equity securities totaling \$161.7 million (pretax), or (\$0.14) per share (after-tax).

## **COMPARATIVE EPS SUMMARY 2020/2021**



	1Q20	2Q20	3Q20	4Q20	2020	1Q21	2Q21	3Q21	4Q21	2021
Reported	1.60	1.55	1.33	2.32	6.79	1.49				
Non-GAAP	1.61	1.45	1.41	2.31	6.78	1.87				

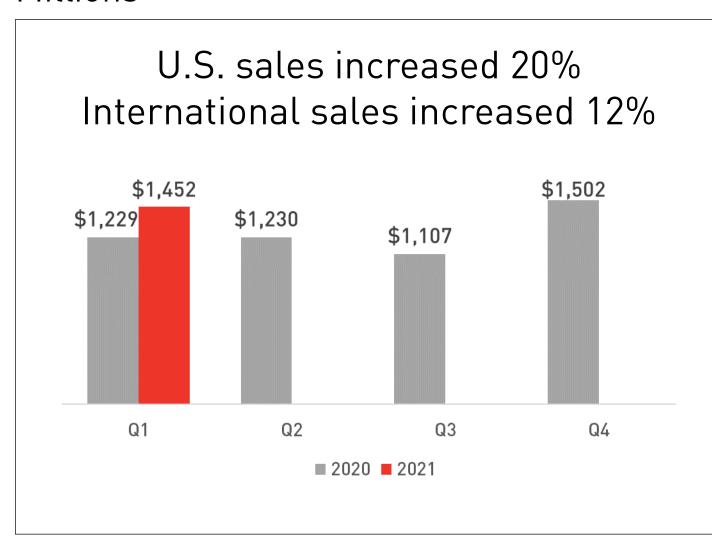
Note: Numbers may not add due to rounding.

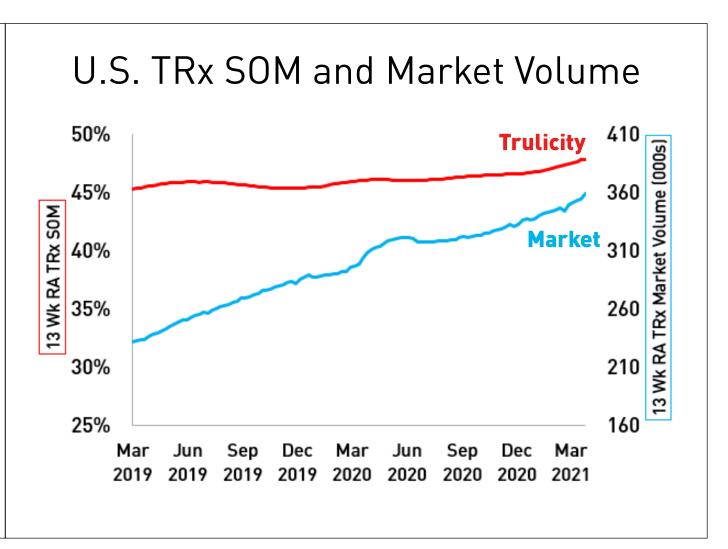
For a complete reconciliation to reported earnings, see slide 26 and our earnings press release dated April 27, 2021

## Q1 2021 TRULICITY SALES INCREASED 18%



#### Millions





Note: Numbers may not add due to rounding.

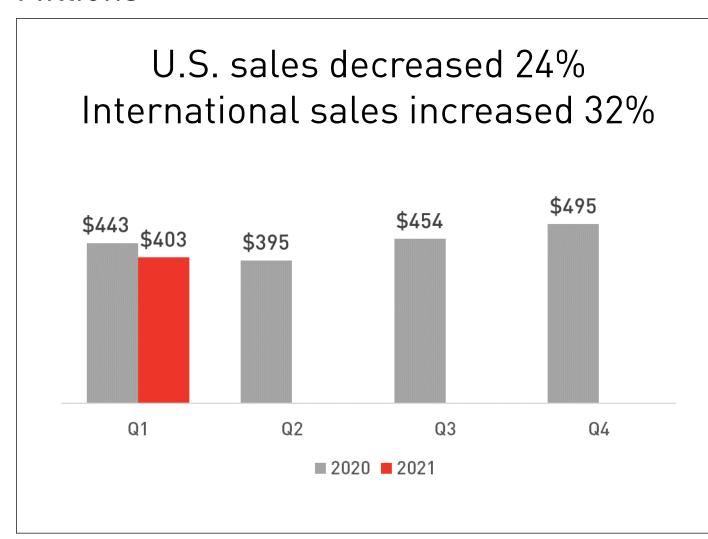
Source: IQVIA NPA TRx 3MMA, weekly data March 26, 2021; RA = rolling average

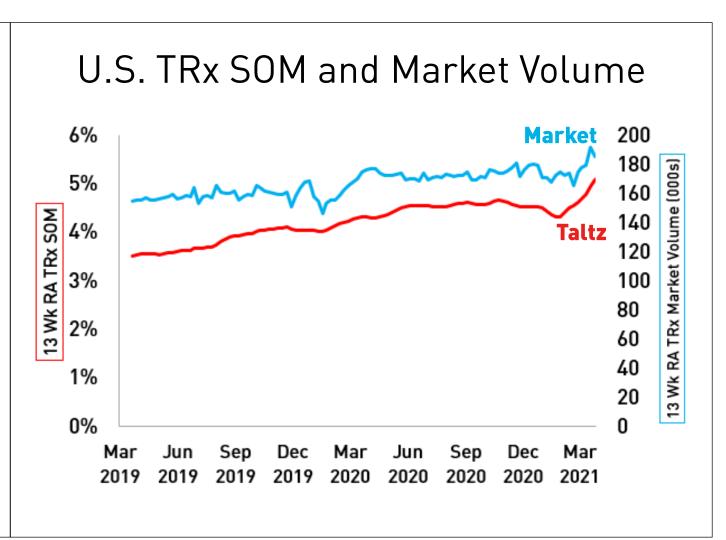
Note: TRx data is representative of the injectable GLP-1 market

## Q1 2021 TALTZ SALES DECREASED 9%



#### Millions





Note: Numbers may not add due to rounding.

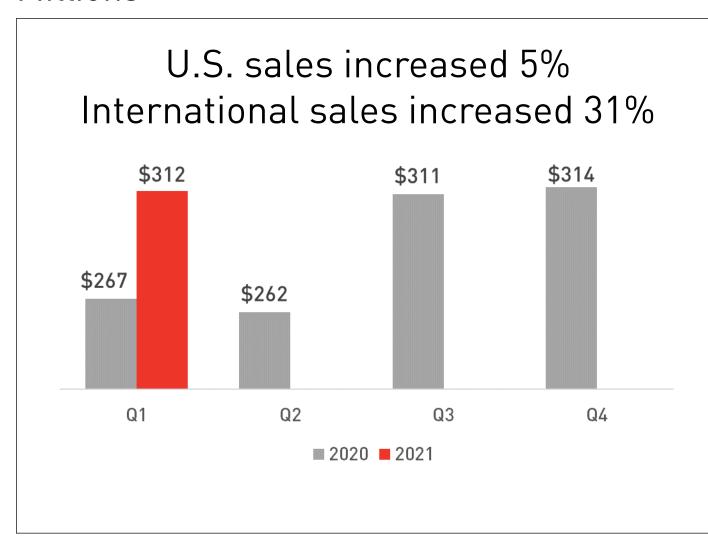
Source: IQVIA NPA TRx 3MMA, weekly data March 26, 2021; RA = rolling average

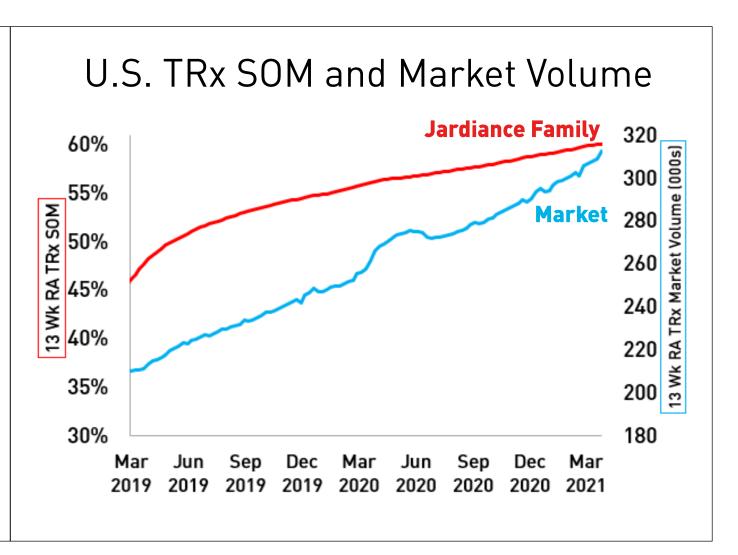
Note: TRx data is representative of the full molecule market

## Q1 2021 JARDIANCE SALES INCREASED 17%



#### Millions





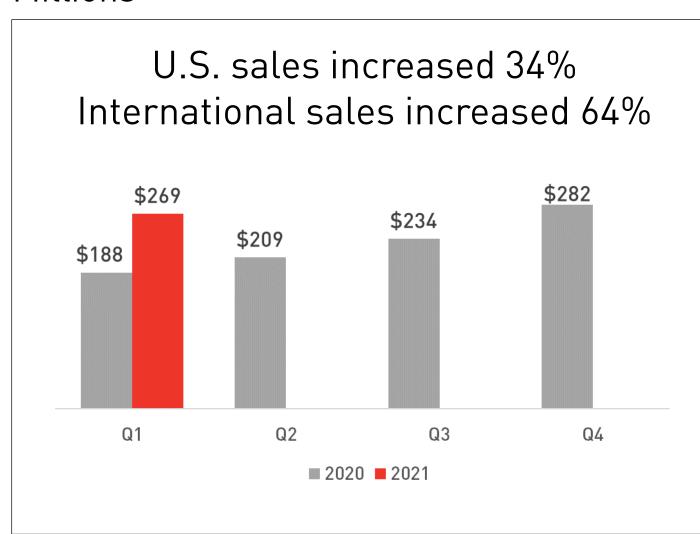
Note: Numbers may not add due to rounding.

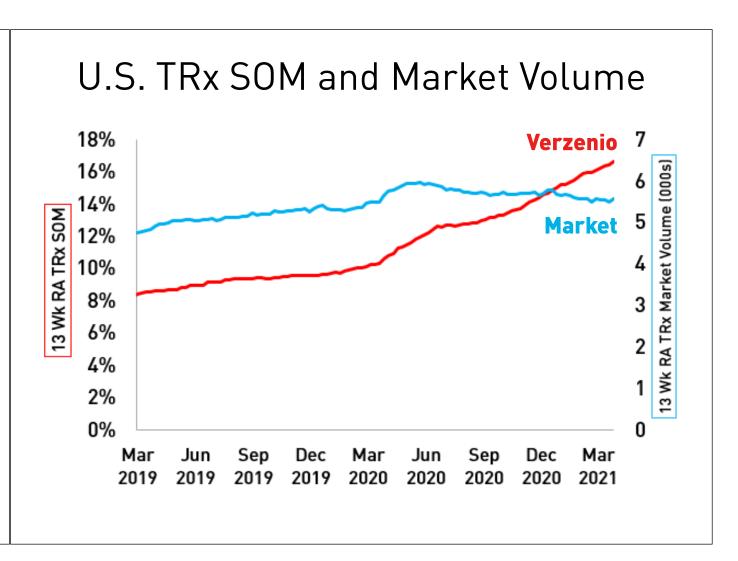
Source: IQVIA NPA TRx 3MMA, weekly data March 26, 2021; RA = rolling average Note: Jardiance is part of the Boehringer Ingelheim and Lilly Alliance

## Q1 2021 VERZENIO SALES INCREASED 43%



#### Millions





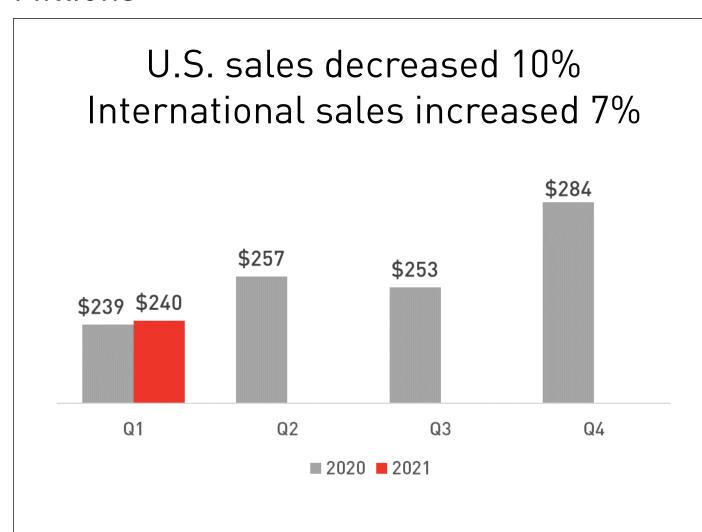
Note: Numbers may not add due to rounding.

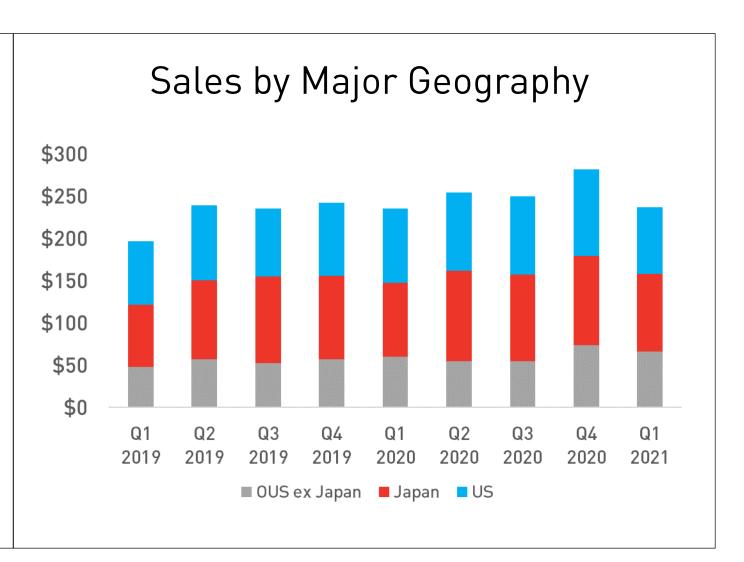
Source: IQVIA NPA TRx 3MMA, weekly data March 26, 2021; RA = rolling average Note: Q2 2020 IQVIA data was impacted by an addition of data for Verzenio

## Q1 2021 CYRAMZA SALES INCREASED 1%



#### Millions





Note: Numbers may not add due to rounding.

## Q1 2021 OLUMIANT SALES INCREASED 39%



#### Millions



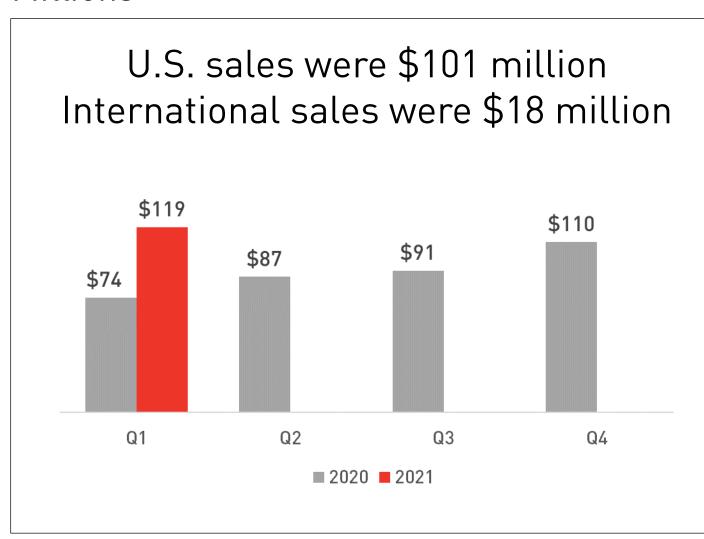
- Launched in the U.S. in July 2018
- Q1 sales driven by Germany and Japan
- Contributed ~80bps to Q1 WW volume growth

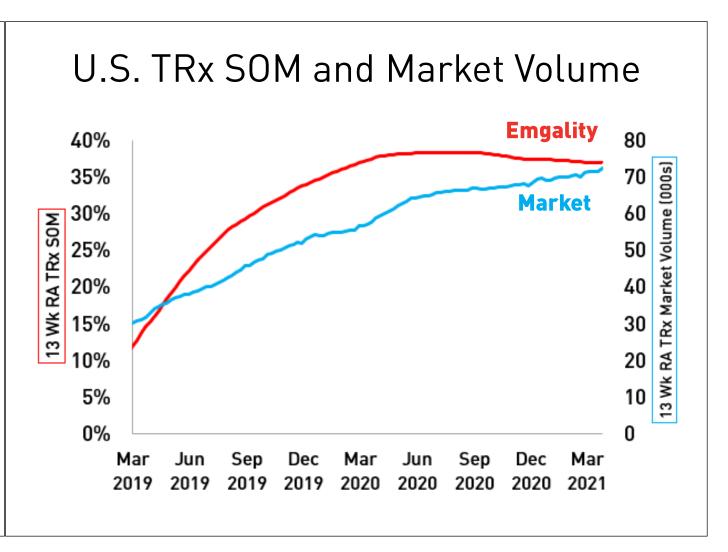
Note: Numbers may not add due to rounding.

## Q1 2021 EMGALITY SALES WERE \$119 MILLION



#### Millions





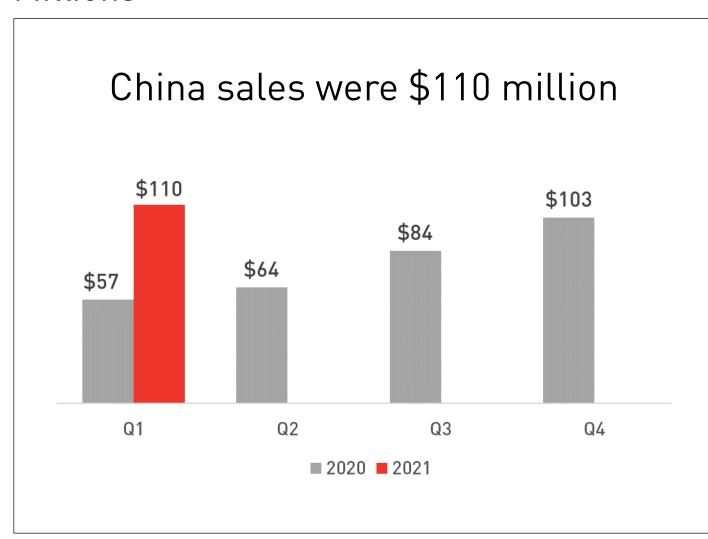
Note: Numbers may not add due to rounding.

Source: IQVIA NPA TRx 3MMA, weekly data March 26, 2021; RA = rolling average

## Q1 2021 TYVYT SALES WERE \$110 MILLION



#### Millions



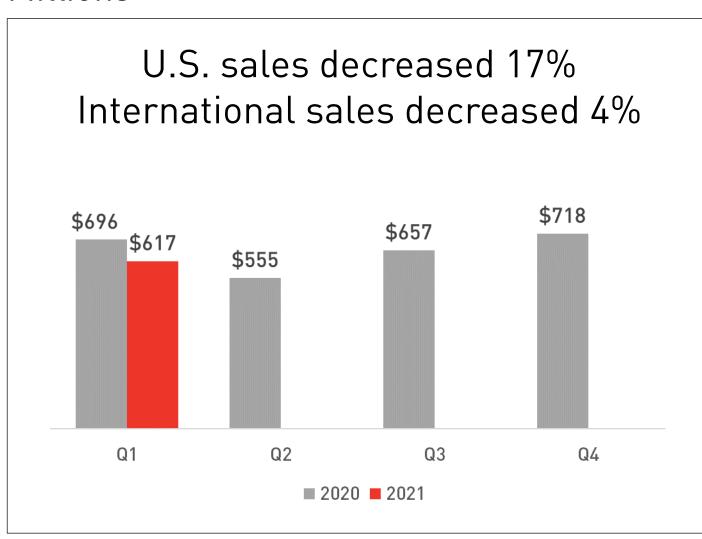
- Launched in China in Q1 2019
- Part of Lilly collaboration with Innovent
- Contributed ~60bps to Q1 WW volume growth

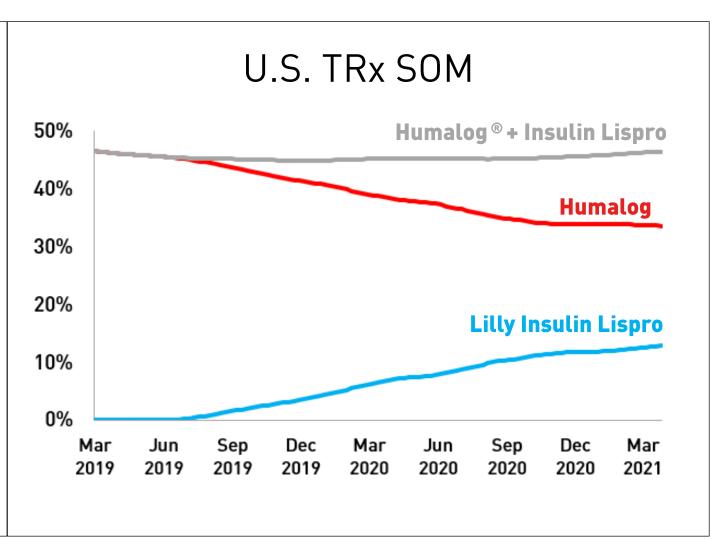
Note: Numbers may not add due to rounding.

## Q1 2021 HUMALOG SALES DECREASED 11%



#### Millions





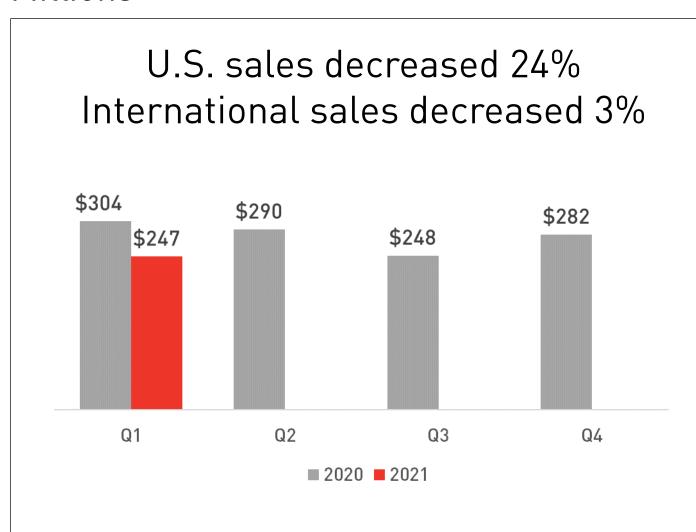
Note: Numbers may not add due to rounding.

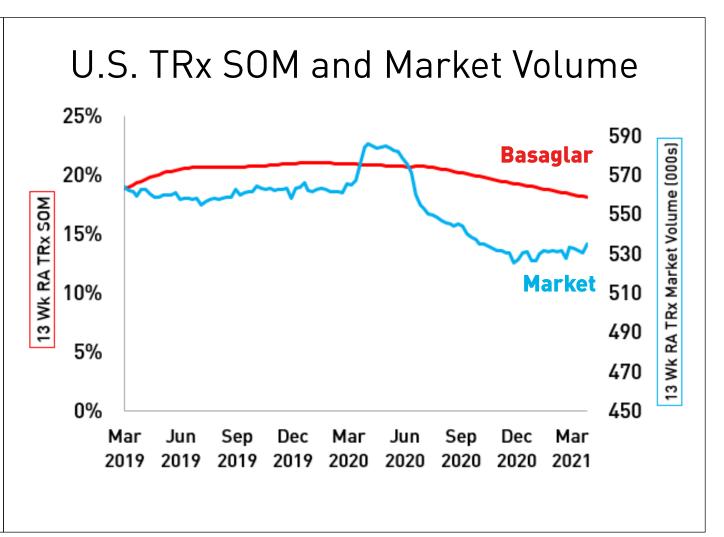
Source: IQVIA NPA TRx 3MMA, weekly data March 26, 2021

#### Q1 2021 BASAGLAR SALES DECREASED 19%



#### Millions





Note: Numbers may not add due to rounding.

Source: IQVIA NPA TRx 3MMA, weekly data March 26, 2021; RA = rolling average Note: Basaglar is part of the Boehringer Ingelheim and Lilly Alliance

#### **SELECT TRIALS – COVID-19 ANTIBODIES**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04427501 <sup>1</sup>	COVID-19	A Study of LY3819253 (LY-CoV555) and LY3832479 (LY-CoV016) in Participants With Mild to Moderate COVID-19 Illness	2 3	3160	Percentage of Participants Who Experience COVID-Related Hospitalization or Death from Any Cause	Sep 2020	Jun 2021
NCT04497987 <sup>2</sup>	COVID-19	A Study of LY3819253 (LY-CoV555) and LY3832479 (LY-CoV016) in Preventing SARS-CoV-2 Infection and COVID-19 in Nursing Home Residents and Staff	3	5000	Percentage of Participants with COVID-19 within 21 Days of Detection	Jan 2021	Jun 2021
NCT04656691 <sup>3</sup>	COVID-19	At-Home Infusion Using Bamlanivimab in Participants With Mild to Moderate COVID-19	4	4000	Efficacy - determining hospitalization rates	May 2021	May 2021
NCT04701658 <sup>4</sup>	COVID-19	A Real World Study of Bamlanivimab in Participants With Mild-to-moderate Coronavirus Disease 2019 (COVID-19)	2	3000	Percentage of Participants who Experience COVID-19 Related Hospitalization or Death	Jun 2021	Aug 2021
NCT04634409 <sup>1</sup>	COVID-19	A Study of Immune System Proteins in Participants With Mild to Moderate COVID-19 Illness	2	700	Percentage of Participants with SARS-CoV-2 Viral Load Greater than 5.27	Aug 2021	Aug 2021
NCT04501978 <sup>5</sup>	COVID-19	ACTIV-3: Therapeutics for Inpatients With COVID-19	3	10000	Time from randomization to sustained recovery	Jul 2022	Jul 2022

<sup>&</sup>lt;sup>1</sup> In collaboration with AbCellera Biologics Inc. and Junshi Bioscience Co., Ltd.

<sup>&</sup>lt;sup>2</sup> In collaboration with NIAID, AbCellera Biologics Inc. and Junshi Bioscience Co., Ltd.

<sup>&</sup>lt;sup>3</sup> Sponsored by United Health Group (UHG), also lists Daniel Griffen and Optum, Inc.

<sup>&</sup>lt;sup>4</sup> In collaboration with AbCellera Biologics Inc.

<sup>&</sup>lt;sup>5</sup> Sponsored by NIAID, also lists INSIGHT, University of Copenhagen, Medical Research Council and more

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

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

# SELECT TRIALS - COVID-19 ANTIBODIES (CONT.)



Stu	udy	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT045	5184106	COVID-19	ACTIV-2: A Study for Outpatients With COVID-19	2 3	2000	Duration of targeted clinical COVID-19 symptoms (Phase 2)	May 2023	May 2023

<sup>&</sup>lt;sup>6</sup> Sponsored by NIAID, and also lists AIDS Clinical Trials Group

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

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

#### **SELECT TRIALS – DONANEMAB**



40

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03367403	Alzheimer Disease	A Study of LY3002813 in Participants With Early Symptomatic Alzheimer's Disease (TRAILBLAZER-ALZ)	2	266	Change from Baseline in the Integrated Alzheimer's Disease Rating Scale (iADRS) Score	Dec 2020	Nov 2021
NCT04640077	Alzheimer Disease	A Follow-On Study of Donanemab (LY3002813) With Video Assessments in Participants With Alzheimer's Disease (TRAILBLAZER-EXT)	2	100	Part A: Correlation between VTC and on-site assessment for PAIR 1 for Alzheimer's Disease Assessment Scale - Cognitive Subscale (ADAS-Cog13)	Oct 2022	Mar 2023
NCT04437511	Alzheimer Disease	A Study of Donanemab (LY3002813) in Participants With Early Alzheimer's Disease (TRAILBLAZER-ALZ 2)	3	1500	Change from Baseline on the integrated Alzheimer's Disease Rating Scale (iADRS)	Feb 2023	Dec 2023

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

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

#### **SELECT TRIALS – JARDIANCE**



Source: clinicaltrials.gov, April 13, 2021

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03594110 <sup>^</sup>	Chronic Kidney Disease	EMPA-KIDNEY (The Study of Heart and Kidney Protection With Empagliflozin)	3	6000	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	Oct 2022	Oct 2022
NCT03057951	Heart Failure	EMPagliflozin outcomE tRial in Patients With chrOnic heaRt Failure With Preserved Ejection Fraction (EMPEROR- Preserved)	3	5988	Composite primary endpoint - Time to first event of adjudicated CV (Cardiovascular) death or adjudicated HHF (Hospitalisation for Heart Failure) in patients with Heart Failure with preserved Ejection Fraction (HFpEF)	Apr 2021	Apr 2021
NCT04157751	Heart Failure	A Study to Test the Effect of Empagliflozin in Patients Who Are in Hospital for Acute Heart Failure	3	500	The clinical benefit, a composite of death, number of HFE (including HHFs), urgent heart failure visits and unplanned outpatient visits), time to first HFE and change from baseline KCCQ-TSS after 90 days of treatment assessed by the win ratio.	May 2021	Jun 2021
	Myocardial	EMPACT-MI: A Study to Test Whether Empagliflozin Can			Composite of time to first heart failure hospitalisation or		
NCT04509674	Infarction	Lower the Risk of Heart Failure and Death in People Who Had a Heart Attack (Myocardial Infarction)	3	3312	all-cause mortality	Dec 2022	Dec 2022

In collaboration with Boehringer Ingelheim

<sup>^</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
NCT04178967	Atopic Dermatitis	Evaluation of the Efficacy and Safety of Lebrikizumab (LY3650150) in Moderate to Severe Atopic Dermatitis	3	400	Percentage of participants with an IGA score of 0 or 1 and a reduction <a>2</a> points from Baseline to Week 16	Jun 2021	Jun 2022
NCT04146363	Atopic Dermatitis	Evaluation of the Efficacy and Safety of Lebrikizumab (LY3650150) in Moderate to Severe Atopic Dermatitis (ADvocate1)	3	424	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
NCT04250337	Atopic Dermatitis	Safety and Efficacy of Lebrikizumab (LY3650150) in Combination With Topical Corticosteroid in Moderate-to- Severe Atopic Dermatitis.	3	225	The primary efficacy endpoint is the percentage of participants with an IGA score of 0 or 1 and a reduction ≥2-points from Baseline to Week 16.	Aug 2021	Oct 2021
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	Nov 2021	Jan 2022
NCT04250350	Atopic Dermatitis	Study to Assess the Safety and Efficacy of Lebrikizumab (LY3650150) in Adolescent Participants With Moderate-to- Severe Atopic Dermatitis	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	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	Oct 2022	May 2023
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 – LYUMJEV**



43

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03740919	Type 1 Diabetes Mellitus	A Study Comparing LY900014 to Insulin Lispro (Humalog) in Children and Adolescents With Type 1 Diabetes	3	945	Change from Baseline in Hemoglobin A1c (HbA1c) (Prandial Dosing)	Jul 2021	Jul 2021
NCT03952130	Type 1 Diabetes Mellitus	A Study of LY900014 Compared to Insulin Lispro (Humalog) in Adults With Type 1 Diabetes	3	350	Change from Baseline in Hemoglobin A1c (HbA1c)	Dec 2021	Dec 2021
NCT04605991	Type 2 Diabetes	A Study of Mealtime Insulin LY900014 in Participants With Type 2 Diabetes Using Continuous Glucose Monitoring (PRONTO-Time in Range)	3	167	Change from Baseline in Percentage of Time with CGM Glucose Values between 70-180 milligrams/deciliter (mg/dL) (3.9-10.0 millimoles/Liter [mmol/L]) (both inclusive) during Daytime Period with 14 Days of CGM Use	Sep 2021	Sep 2021

**2021 Q1 EARNINGS** 

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

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

#### **SELECT TRIALS – MIRIKIZUMAB**



44

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03556202	Psoriasis	A Long-term Study to Evaluate Safety and Maintenance of Treatment Effect of LY3074828 in Participants With Moderate-to-Severe Plaque Psoriasis (OASIS-3)	3	1816	Percentage of Participants with a Static Physician's Global Assessment Among Those who Entered the Study with a sPGA of 0,1(sPGA) of (0,1)	May 2024	May 2024
NCT03926130	Crohn's Disease	A Study of Mirikizumab (LY3074828) in Participants With Crohn's Disease	3	1150	Percentage of Participants Achieving Endoscopic Response	Dec 2022	Apr 2023
NCT04232553	Crohn's Disease	A Long-term Extension Study of Mirikizumab (LY3074828) in Participants With Crohn's Disease	3	778	Percentage of Participants Achieving Endoscopic Response	Jun 2024	Jun 2024
NCT03518086	Ulcerative Colitis	An Induction Study of Mirikizumab in Participants With Moderately to Severely Active Ulcerative Colitis (LUCENT 1)	3	1160	Percentage of Participants in Clinical Remission	Dec 2021	Nov 2022
NCT03524092	Ulcerative Colitis	A Maintenance Study of Mirikizumab in Participants With Moderately to Severely Active Ulcerative Colitis	3	1044	Percentage of Participants in Clinical Remission	Jun 2023	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	Aug 2023	Jul 2025
NCT04469062	Ulcerative Colitis	A Study of Mirikizumab (LY3074828) in Participants With Ulcerative Colitis	3	1100	Percentage of Participants in Histologic Remission	Mar 2024	Jun 2024

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

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

## SELECT TRIALS - MIRIKIZUMAB (CONT.)



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
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 in Modified Mayo Score (MMS) Clinical Remission	Sep 2027	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	3	476	Percentage of Participants Achieving Severity of Alopecia Tool (SALT) <u>&lt;</u> 20	Jan 2021	May 2024
NCT03570749	Alopecia Areata	A Study of Baricitinib (LY3009104) in Participants With Severe or Very Severe Alopecia Areata	2 3	725	Percentage of Participants Achieving Severity of Alopecia Tool (SALT) < 20	Feb 2021	Jun 2024
NCT04421027	COVID-19	A Study of Baricitinib (LY3009104) in Participants With COVID-19	3	1400	Percentage of Participants who Die or Require Non-Invasive Ventilation/High-Flow Oxygen or Invasive Mechanical Ventilation (including extracorporeal membrane oxygenation [ECMO])	May 2021	Jun 2021
NCT03616964	Systemic Lupus Erythematosus	A Study of Baricitinib in Participants With Systemic Lupus Erythematosus	3	750	Percentage of Participants Achieving a Systemic Lupus Erythematosus Responder Index 4 (SRI-4) Response (High Dose)	Oct 2021	Nov 2021
NCT03616912	Systemic Lupus Erythematosus	A Study of Baricitinib (LY3009104) in Participants With Systemic Lupus Erythematosus	3	809	Percentage of Participants Achieving a Systemic Lupus Erythematosus Responder Index 4 (SRI-4) Response (High Dose)	Oct 2021	Jul 2022

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
NCT04849416	Leukemia, Lymphoid	A Study of LOXO-305 in Chinese Participants With Blood Cancer (Including Lymphoma and Chronic Leukemia)	2	126	Overall Response Rate (ORR)	Aug 2022	Apr 2025
NCT03740529	Chronic Lymphocytic Leukemia	A Study of Oral LOXO-305 in Patients With Previously Treated CLL/SLL or NHL	1 2	860	Maximum Tolerated Dose (MTD)	Feb 2023	May 2023
NCT04666038	Chronic Lymphocytic Leukemia	Study of LOXO-305 Versus Investigator's Choice (IdelaR or BR) in Patients With CLL or SLL	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
NCT04662255	Lymphoma, Mantle- Cell	Study of BTK Inhibitor LOXO-305 Versus Approved BTK Inhibitor Drugs in Patients With Mantle Cell Lymphoma (MCL)	3	500	To compare progression-free survival (PFS) of LOXO-305 as monotherapy (Arm A) to investigator choice of covalent BTK inhibitor monotherapy (Arm B) in patients with previously treated mantle cell lymphoma (MCL)		Feb 2025

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

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

#### **SELECT TRIALS – RETEVMO**



48

Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03899792	Medullary Thyroid Cancer	A Study of Oral LOXO-292 (Selpercatinib) in Pediatric Participants With Advanced Solid or Primary Central Nervous System (CNS) Tumors	1 2	100	To Determine the Safety of Oral LOXO-292 in Pediatric Participants with Advanced Solid Tumors: Dose Limiting Toxicities (DLTs)	Mar 2023	Mar 2024
NCT04211337	Medullary Thyroid Cancer	A Study of Selpercatinib (LY3527723) in Participants With RET-Mutant Medullary Thyroid Cancer	3	400	Treatment Failure-Free Survival (TFFS) by Blinded Independent Committee Review (BICR)	May 2024	Nov 2026
NCT03157128	Non- Small Cell Lung Cancer	Phase 1/2 Study of LOXO-292 in Participants With Advanced Solid Tumors, RET Fusion-Positive Solid Tumors, and Medullary Thyroid Cancer	1 2	989	Phase 1: MTD	Nov 2022	Nov 2023
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	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)	3	170	Event-Free Survival (EFS)	Aug 2028	Nov 2032
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	2	75	Overall Response Rate (ORR): Percentage of Participants with Complete Response (CR) or Partial Response (PR) by Independent Review Committee	Mar 2021	Apr 2023

<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
1 1011 1111/11118 35 /	Cognition Disorders	Clinical Trial of Solanezumab for Older Individuals Who May be at Risk for Memory Loss	3	1150	Change from Baseline of the Preclinical Alzheimer Cognitive Composite (PACC)	Dec 2022	Dec 2022

<sup>^</sup> Also lists Alzheimer's Therapeutic Research Institute

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

#### **SELECT TRIALS – TANEZUMAB**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT02609828	Neoplasm Metastasis	Phase 3 Study on the Efficacy and Safety of Tanezumab in Patients With Cancer Pain Due to Bone Metastasis Who Are Taking Background Opioid Therapy.	3	156	Change from baseline in daily average pain intensity in index bone metastasis cancer pain site	Sep 2020	Jul 2021

In collaboration with Pfizer

Source: clinicaltrials.gov, March 23, 2020

<sup>\*</sup>Molecule may have multiple indications; Indication is for pain associated with the condition listed

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

#### **SELECT TRIALS – TIRZEPATIDE**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completio
NCT04166773	Nonalcoholic Steatohepatitis	A Study of Tirzepatide (LY3298176) in Participants With Nonalcoholic Steatohepatitis (NASH)	2	196	Percentage of Participants with Absence of NASH with no Worsening of Fibrosis on Liver Histology	Jun 2022	Jun 2022
NCT04184622	Obesity	A Study of Tirzepatide (LY3298176) in Participants With Obesity or Overweight	3	2400	Percent Change from Baseline in Body Weight	Apr 2022	May 2024
NCT04657003	Obesity	A Study of Tirzepatide (LY3298176) in Participants With Type 2 Diabetes Who Have Obesity or Are Overweight	3	900	Percent Change from Randomization in Body Weight	Jun 2023	Jul 2023
NCT04844918	Obesity	A Study of Tirzepatide (LY3298176) in Participants With Obesity Disease	3	261	Percentage of Participants who Achieve <u>&gt;</u> 5% Body Weight Reduction	Jul 2023	Jul 2023
NCT04660643	Obesity	A Study of Tirzepatide (LY3298176) in Participants With Obesity or Overweight for the Maintenance of Weight Loss	3	750	Percent Change from Randomization (Week 36) in Body Weight	Aug 2023	Aug 2023
NCT04657016	Obesity	A Study of Tirzepatide (LY3298176) In Participants After A Lifestyle Weight Loss Program	3	800	Percent Change from Randomization in Body Weight	Aug 2023	Sep 2023
NCT04847557	Obesity	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

<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
NCT03730662	Type 2 Diabetes Mellitus	A Study of Tirzepatide (LY3298176) Once a Week Versus Insulin Glargine Once a Day in Participants With Type 2 Diabetes and Increased Cardiovascular Risk	3	1878	Change from Baseline in Hemoglobin A1c (HbA1c) (10 mg and 15 mg)	Mar 2021	Jun 2021
NCT04093752	Type 2 Diabetes	A Study of Tirzepatide (LY3298176) in Participants With Type 2 Diabetes on Metformin With or Without Sulfonylurea (SURPASS-AP-Combo)	3	917	Mean Change from Baseline in Hemoglobin A1c (HbA1c) (10 mg and 15 mg)	Oct 2021	Nov 2021
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	3	1182	Change from Baseline in Hemoglobin A1c (HbA1c) (Pooled Doses)	Aug 2022	Sep 2022
NCT04255433	Type 2 Diabetes Mellitus	A Study of Tirzepatide (LY3298176) Compared With Dulaglutide on Major Cardiovascular Events in Participants With Type 2 Diabetes	3	12500	Time to First Occurrence of Death from Cardiovascular (CV) Causes, Myocardial Infarction (MI), or Stroke (MACE-3)	Oct 2024	Oct 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>^</sup>	Breast Cancer	Endocrine Therapy With or Without Abemaciclib (LY2835219) Following Surgery in Participants With Breast Cancer	3	5637	Invasive Disease Free Survival (IDFS)	Mar 2020	Jun 2029

<sup>^</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**



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
Basal Insulin - FC	NCT04450407	Type 1 Diabetes Mellitus	A Study of LY3209590 in Participants With Type 1 Diabetes	2	254	Change from Baseline in Hemoglobin A1c (HbA1c)	Sep 2021	Sep 2021
Basal Insulin - FC	NCT04450394	Type 2 Diabetes Mellitus	A Phase 2 Study of LY3209590 in Participants With Type 2 Diabetes Mellitus	2	264	Change from Baseline in Hemoglobin A1c (HbA1c)	Sep 2021	Sep 2021
GLP-1R NPA	NCT04680767	Healthy	A Study of LY3502970 in Healthy Male Participants	1	8	Fecal Excretion of LY3502970 Radioactivity Over Time Expressed as a Percentage of the Total Radioactive Dose Administered	May 2021	May 2021
GLP-1R NPA	NCT04426474	Diabetes Mellitus, Type 2	A Study of LY3502970 in Participants With Type 2 Diabetes	1	60	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug	Jun 2021	Jun 2021
KHK Inhibitor	NCT04270370	Healthy	A Study of LY3478045 in Healthy Participants	1	90	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Jun 2021	Jun 2021
GIP/GLP-1 Coagonist II	NCT04648865	Healthy	A Study of LY3537031 in Healthy Participants	1	60	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Jun 2021	Jun 2021

<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
Oxyntomodulin	NCT03928379	Diabetes Mellitus, Type 2	A Study of LY3305677 in Participants With Type 2 Diabetes	1	36	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug	Jul 2021	Jul 2021
GIP/GLP Coagonist Peptide	NCT04682106	Healthy	A Study of LY3493269 in Healthy Participants	1	56	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Sep 2021	Sep 2021
Basal Insulin - FC	NCT04768842	Healthy	A Study of Two Different Formulations of LY3209590 in Healthy Participants	1	50	Pharmacokinetics (PK): Maximum Concentration (Cmax) of LY3209590	Sep 2021	Sep 2021
KHK Inhibitor	NCT04559568	Healthy	A Study of LY3522348 in Healthy Participants	1	100	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Sep 2021	Sep 2021
PYY Analog Agonist	NCT04641312	Healthy	A Study of LY3457263 in Healthy Participants and Participants With Type 2 Diabetes	1	90	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Sep 2021	Sep 2021
LP(a) Inhibitor	NCT04472676	Healthy	A Study of LY3473329 in Healthy Participants	1	107	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Oct 2021	Oct 2021

<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	NCT04586907	Healthy	A Study of LY3537021 in Healthy Participants	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	Nov 2021	Nov 2021
GGG Tri- Agonist	NCT04823208	Diabetes Mellitus, Type 2	A Study of LY3437943 in Japanese Participants With Type 2 Diabetes Mellitus (T2DM)	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	Jan 2022	Jan 2022
Relaxin-LA	NCT04768855	Healthy	A Study of LY3540378 in Healthy Participants	1	120	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Mar 2022	Mar 2022
ANGPTL3- siRNA	NCT04644809	Dyslipidemias	A Study of LY3561774 in Participants With Dyslipidemia	1	74	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Apr 2022	Apr 2022
NRG4 Agonist I	NCT04840914	Chronic Heart Failure With Reduced Ejection Fraction	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	Feb 2023	Feb 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	Completio
CD200R MAB Agonist	NCT04159701	Chronic Spontaneous Urticaria	A Study of LY3454738 in Adults With Chronic Spontaneous Urticaria	2	60	Mean Change from Baseline in Urticaria Activity Score Over 7 Days (UAS7)	Mar 2021	Sep 202
CXCR1/2L mAb	NCT04493502	Hidradenitis Suppurativa	,	2	52	Percentage of Participants Achieving Hidradenitis Suppurativa Clinical Response (HiSCR)	Dec 2021	Jul 2022
PD-1 Mab Agonist	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)	I .	Aug 202
IL-2 CONJUGATE^	NCT04433585	Systemic Lupus Erythematosus	A Study of LY3471851 in Adults With Systemic Lupus Erythematosus (SLE)	2	280	Percentage of Participants who Achieve a <u>&gt;</u> 4 Point Reduction in Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) 2000 (2K) Score	Jan 2023	Apr 2023
IL-2 CONJUGATE	NCT04677179	Colitis, Ulcerative	A Study of LY3471851 in Adult Participants With Moderately to Severely Active Ulcerative Colitis (UC)	2	200	Percentage of Participants in Clinical Remission	Jul 2023	Jul 2024
	T	T		I	1		1	
DTI A MAD		Lupus	A Study of IV2241227 in Participants With Systemic			Number of Participants with One or More Serious		

BTLA MAB Agonist	Lupus NCT03933943 Erythematosus Systemic	A Study of LY3361237 in Participants With Systemic Lupus Erythematosus	1	28	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug		Feb 2021
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<sup>^</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
CXCR1/2L mAb	NCT04653168	Healthy	A Study of LY3041658 in Healthy Participants	1	16	Number of Participants With incidence and severity of Injection Site Reaction (ISR)	May 2021	May 2021
CD200R MAB Agonist	NCT03750643	Dermatitis, Atopic	A Study of LY3454738 in Healthy Participants and Participants With Atopic Dermatitis	1	64	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Jun 2021	Aug 2021
IL-17A Small Molecule Inhibitor	NCT04586920	Healthy	A Study of LY3509754 in Healthy Non-Japanese and Japanese Participants	1	121	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Aug 2021	Aug 2021
PD-1 Mab Agonist	NCT04152382	Psoriasis	A Safety Study of LY3462817 in Participants With Psoriasis	1	64	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Oct 2021	Oct 2021
IL-2 CONJUGATE^	NCT04119557	Psoriasis	A Study of LY3471851 in Participants With Psoriasis	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	Dec 2021	Dec 2021
IL-2 CONJUGATE^	NCT04081350	Dermatitis, Atopic	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	Sep 2022	Sep 2022

<sup>^</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
Zagotenemab (Tau MAB)		Alzheimer Disease (AD)	A Study of LY3303560 in Participants With Early Symptomatic Alzheimer's Disease	2	285	Change from Baseline on the integrated Alzheimer's Disease Rating Scale (iADRS)	Aug 2021	Oct 2021
O-GlcNAcase Inh.	NCT04392271	Healthy	A Study of the Effects of Multiple Doses of LY3372689 on the Brain in Healthy Participants	1	4	Percent O-GlcNAcase (OGA) Enzyme Occupancy (EO)	Oct 2020	Oct 2020
Mevidalen (D1 PAM)	NCT04258826	Healthy	A Study to Evaluate LY3154207 on the Brain of Healthy Participants	1	34	Change from Baseline in Intrinsic Functional Connectivity Among Resting-State Networks of the Brain	Nov 2021	Nov 2021
N3PG Aß MAB	NCT04451408	Alzheimer Disease	A Study of LY3372993 in Participants With Alzheimer's Disease (AD)	1	30	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Apr 2022	Apr 2022
GBA1 Gene Therapy	NCT04127578	Parkinson Disease	Phase 1/2a Clinical Trial of PR001A 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)	1 2	15	Number of Adverse Events (AEs), Serious Adverse Events (SAEs), and Adverse Events Leading to discontinuation	Dec 2027	Dec 2027
GBA1 Gene Therapy	NCT04411654	Gaucher Disease, Type 2	Phase 1/2 Clinical Trial of PR001 in Infants With Type 2 Gaucher Disease (PR0VIDE)	1 2	15	Number of Adverse Events (AEs), Serious Adverse Events (SAEs), and Adverse Events leading to discontinuation	Apr 2028	Apr 2028

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

<sup>\*\*</sup>Trial may have additional primary and other secondary outcomes Not for promotional use

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



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
SERD	NCT04840888	Healthy	A Study of LY3484356 in Healthy Female Participants	1	60	Pharmacokinetics (PK): Area Under the Concentration Versus Time Curve From Zero to Infinity (AUC[0-∞]) of LY3484356	Jul 2021	Jul 2021
SERD	NCT04188548	Breast Cancer	A Study of LY3484356 in Participants With Advanced or Metastatic Breast Cancer or Endometrial Cancer	1	460	Number of Participants with Dose Limiting Toxicities (DLTs) and DLT-Equivalent Toxicities	Jul 2021	Apr 2023
SERD	NCT04647487	Breast Cancer	A Study of LY3484356 in Women With Breast Cancer Before Having Surgery	1	60	Change from Baseline in ER Expression	Mar 2022	Mar 2022
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)	Feb 2023	Sep 2023
IDH1 Inhibitor	NCT04521686	Cholangiocarcinoma	Study of LY3410738 Administered to Patients With Advanced Solid Tumors With IDH1 Mutations	1	180	Recommended Phase 2 dose (RP2D)	Feb 2023	Sep 2023
Aur A Kinase Inhibitor <sup>^</sup>	NCT04106219	Neuroblastoma	A Study of LY3295668 Erbumine in Participants With Relapsed/Refractory Neuroblastoma	1	71	Number of Participants with Dose Limiting Toxicities (DLTs)	Apr 2024	Apr 2025

<sup>^</sup> Also lists New Approaches to Neuroblastoma Therapy Consortium (NANT) and Innovative Therapies for Children with Cancer in Europe (ITCC)

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

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

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



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Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
EPIREG/TGFa MAB	NCT04456686	Osteoarthritis	Chronic Pain Master Protocol (CPMP): A Study of LY3016859 in Participants With Osteoarthritis	2	125	Change from Baseline in Average Pain Intensity as Measured by the Numeric Rating Scale (NRS)	Apr 2021	Sep 2022
EPIREG/TGFa MAB	NCT04529096	Chronic Low-back Pain	Chronic Pain Master Protocol (CPMP): A Study of LY3016859 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 2021	Nov 2022
EPIREG/TGFa MAB	NCT04476108	Diabetic Peripheral Neuropathic Pain	Chronic Pain Master Protocol (CPMP): A Study of LY3016859 in Participants With Diabetic Peripheral Neuropathic Pain	2	125	Change from Baseline in Average Pain Intensity as Measured by the Numeric Rating Scale (NRS)	Aug 2021	Jan 2023
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	Nov 2021	Nov 2021
SSTR4 Agonist	NCT04627038	Osteoarthritis	Chronic Pain Master Protocol (CPMP): A Study of LY3556050 in Participants With Osteoarthritis	2	200	Change from Baseline in Average Pain Intensity as Measured by the Numeric Rating Scale (NRS)	Dec 2021	Dec 2021
SSTR4 Agonist	NCT04707157	Diabetic Peripheral Neuropathic Pain	Chronic Pain Master Protocol (CPMP): A Study of LY3556050 in Participants With Diabetic Peripheral Neuropathic Pain	2	200	Change from Baseline in Average Pain Intensity as Measured by the Numeric Rating Scale (NRS)	Apr 2022	Apr 2022

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

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

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



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
TRPA1 Antagonist I	NCT04682119	Healthy	A Safety Study of LY3526318 in Healthy Participants	1	16	Pharmacokinetics (PK): Area Under the Concentration Versus Time Curve (AUC) of LY3526318	Apr 2021	Apr 2021

Source: clinicaltrials.gov, January 22, 2021

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

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