

2020 BUSINESS RESULTS JULY 30, 2020

## **AGENDA**



#### **INTRODUCTION AND KEY RECENT EVENTS**

Dave Ricks, Chairman and Chief Executive Officer

#### **Q2 2020 FINANCIAL RESULTS**

Josh Smiley, 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.

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

## STRATEGIC DELIVERABLES

#### PROGRESS SINCE THE LAST EARNINGS CALL



#### **Grow Revenue**



- 2% revenue decline in Q2; -2% in constant currency
- 6% revenue growth YTD; 7% in constant currency
- YTD revenue growth driven by:
  - 13% volume growth
  - Key growth products, which accounted for over half of total revenue

#### **Improve Productivity**



- Non-GAAP:
  - Gross margin was 79.6% (79.1% excluding FX impact on international inventories sold)
  - Operating margin was 28.0%

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



- Distributed nearly \$0.7 billion via dividends in Q2
- No shares repurchased

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



- Approval of Retevmo™ in the U.S. for patients with advanced RET-driven lung and thyroid cancers
- Approval of Taltz® for the treatment of non-radiographic axial spondyloarthritis (nr-axSpA)
- Positive results from monarchE study of Verzenio<sup>®</sup> in early breast cancer
- Positive results from OASIS-2 study of Mirikizumab in moderate to severe plaque psoriasis
- Positive results from EMPEROR-reduced study of Jardiance<sup>®</sup> in heart failure

Note: Jardiance is part of the Boehringer Ingelheim and Lilly Diabetes Alliance.

## **KEY EVENTS SINCE THE LAST EARNINGS CALL**



#### **COMMERCIAL**

- In the U.S., launched **Retevmo**, the first therapy specifically for patients with advanced RET-driven lung and thyroid cancers. Retevmo is approved for metastatic RET fusion-positive non-small cell lung cancer (NSCLC), advanced or metastatic RET-mutant medullary thyroid cancer and advanced or metastatic RET fusion-positive thyroid cancer; and
- Launched **Lyumjev™** in the U.S., Japan and the EU for use in adults with type 1 and type 2 diabetes to reduce blood glucose.

#### REGULATORY

- The Food and Drug Administration (FDA) approved Taltz for the treatment of nr-axSpA; Taltz is now approved to treat patients across the full axSpA spectrum;
- The FDA approved Cyramza® as a first-line treatment for metastatic EGFR-mutated non-small cell lung cancer;
- The FDA approved **Tauvid** for use in patients being evaluated for Alzheimer's disease, the first and only approved diagnostic agent to image tau neurofibrillary tangles in the brain; and
- The FDA granted Fast Track designation to **tirzepatide** for treatment of non-alcoholic steatohepatitis (NASH).

#### **CLINICAL**

• **Verzenio** demonstrated positive results in a Phase 3 study of people whose early breast cancer is at high risk of recurrence. Verzenio is the only CDK4 & 6 inhibitor to demonstrate statistically significant improvement in invasive disease-free survival in people with high risk HR+, HER2- early breast cancer;

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

- Higher investigational doses (3mg and 4.5mg) of **Trulicity**® meaningfully reduced HbA1C and body weight in people with type 2 diabetes;
- Announced the first patient dose for SURPASS-CVOT, the Phase 3 cardiovascular outcomes trial for tirzepatide. The study will assess both non-inferiority and superiority of tirzepatide in a head-to-head trial against Trulicity 1.5 mg;
- **Mirikizumab** met the primary and all key secondary endpoints versus placebo at week 16 and all key secondary endpoints versus Cosentyx<sup>®</sup> at week 16 and week 52, including superiority in skin clearance at week 52;
- **Jardiance** significantly reduced the time to first event of cardiovascular death or hospitalization for heart failure versus placebo in adults with heart failure with reduced ejection fraction; and
- Initiated a Phase 3 clinical trial with **Olumiant**® for hospitalized COVID-19 patients.

#### **BUSINESS DEVELOPMENT & OTHER**

- Entered into an agreement with Junshi Biosciences to co-develop antibodies against SARS-CoV-2;
- Announced participation in a new antimicrobial resistance action fund, along with 20 leading pharmaceutical companies. The fund expects to invest \$1 billion in the development of novel antibiotics to address the growing threat of antimicrobial resistance; and
- Announced a pledge with the Lilly Foundation of \$25 million and 25,000 volunteer hours over five years to decrease the burden of racial injustice and its effects on local and national communities of color.

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

Millions; except per share data

Q2 2020

	GAAP Reported	Adjustments	Non-GAAP Adjusted	Non-GAAP Adjusted Change
TOTAL REVENUE	\$5,499	-	\$5,499	(2)%
GROSS MARGIN	77.8%	1.8%	79.6%	(1.4pp)
<b>TOTAL OPERATING EXPENSE</b>	3,081	(242)	2,839	(5)%
OPERATING INCOME	1,197	344	1,541	(2)%
OPERATING MARGIN	21.8%	6.2%	28.0%	0.1pp
OTHER INCOME (EXPENSE)	447	_	447	NM
EFFECTIVE TAX RATE	14.1%	(0.7)%	13.4%	3.4pp
NET INCOME	\$1,412	309	\$1,721	24%
EPS	\$1.55	\$0.34	\$1.89	26%

Note: Numbers may not add due to rounding; see slide 27 for a complete list of significant adjustments.

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

Millions; except per share data

#### YTD 2020

	GAAP Reported	Adjustments	Non-GAAP Adjusted	Non-GAAP Adjusted Change
TOTAL REVENUE	\$11,359	-	\$11,359	6%
GROSS MARGIN	78.5%	1.5%	80.0%	(0.6pp)
<b>TOTAL OPERATING EXPENSE</b>	6,134	(354)	5,780	1%
OPERATING INCOME	2,788	515	3,303	14%
OPERATING MARGIN	24.5%	4.6%	<b>29.1%</b>	2.0pp
OTHER INCOME (EXPENSE)	536	-	536	NM
EFFECTIVE TAX RATE	13.7%	(0.2)%	13.5%	2.1pp
NET INCOME	\$2,869	451	\$3,320	26%
EPS	\$3.15	0.49	\$3.64	29%

Note: Numbers may not add due to rounding; see slide 28 for a complete list of significant adjustments.

## PRICE/RATE/VOLUME EFFECT ON REVENUE



Millions		Q2 2020				
	Amount	Price	FX Rate	Volume	Total	CER
U.S.	\$3,145	(8)%	-%	4%	(3)%	(3)%
EUROPE	873	(2)%	(2)%	(2)%	(6)%	(4)%
JAPAN	667	(5)%	3%	4%	2%	(1)%
CHINA	240	(41)%	(4)%	50%	4%	8%
REST OF WORLD	575	(2)%	(7)%	9%	1%	7%
TOTAL REVENUE	\$5,499	(7)%	(1)%	6%	(2)%	(2)%

#### **YTD 2020**

	_Amount_	Price	FX Rate	Volume	Total	CER
U.S.	\$6,474	(6)%	-%	11%	5%	5%
EUROPE	1,934	(2)%	(2)%	11%	6%	8%
JAPAN	1,259	(4)%	2%	7%	5%	3%
CHINA	507	(52)%	(4)%	71%	15%	18%
<b>REST OF WORLD</b>	1,185	(2)%	(4)%	12%	6%	10%
TOTAL REVENUE	\$11,359	(7)%	(1)%	13%	6%	7%

Note: Numbers may not add due to rounding.

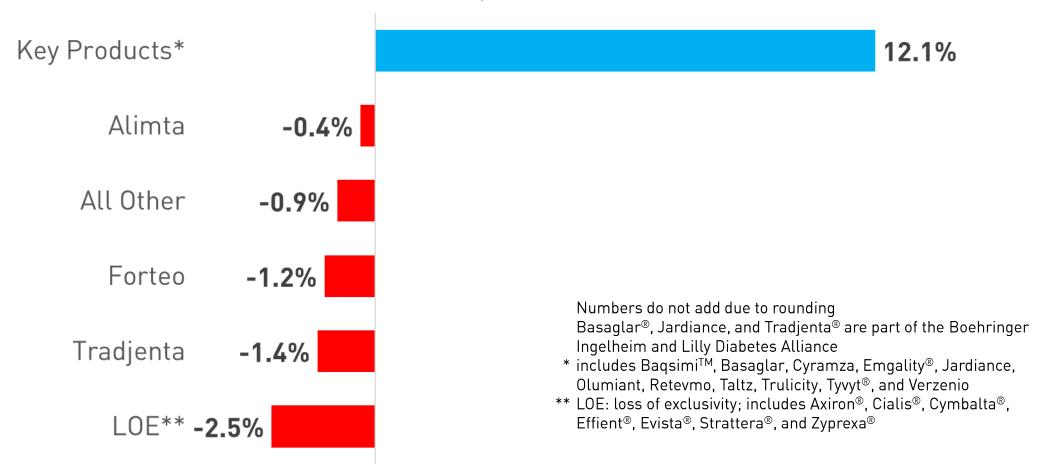
**2020 Q2 EARNINGS** 

CER = price change + volume change

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

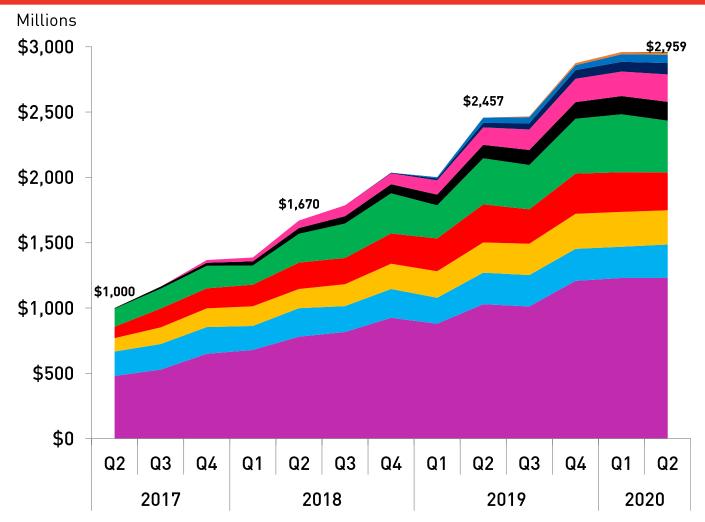


#### Contribution to 6% Q2 WW Volume Growth



## **UPDATE ON KEY GROWTH PRODUCTS**





Note: Jardiance is sold by Boehringer Ingelheim; Lilly records as revenue its share of Jardiance gross margin. Jardiance and Basaglar are part of the Boehringer Ingelheim and Lilly Diabetes Alliance.

RETEVMO

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

BAQSIMI

• Approved July 2019 in U.S., NBRx SOM 33% at end of Q2 2020

TYVYT

Added to China's National Drug Reimbursement List in 2020

**EMGALITY** 

• U.S. TRx SOM increased by 17pp vs. H1 2019

• U.S. NBRx SOM nearly 38% at the end of Q2 2020

VERZENIO

• Announced positive data in adjuvant setting (monarchE) in Q2 2020

• U.S. TRx grew over 57% vs. Q2 2019

**OLUMIANT** 

• OUS Sales grew nearly 44% vs. Q2 2019

**TALTZ** 

• IL-17 class grew nearly 18% vs. Q2 2019 for U.S. TRx in dermatology

• Total molecule U.S. TRx grew 35% vs. Q2 2019

BASAGLAR

• U.S. TRx nearly 21% SOM at end of Q2 2020

JARDIANCE

• Market leader in U.S. TRx SOM 57% and NTS SOM nearly 63%

• Class growth strong in U.S. TRx +20% vs. Q2 2019

CYRAMZA

• WW sales growth +6% vs. Q2 2019

TRULICITY

• U.S. TRx leader with nearly 45% SOM

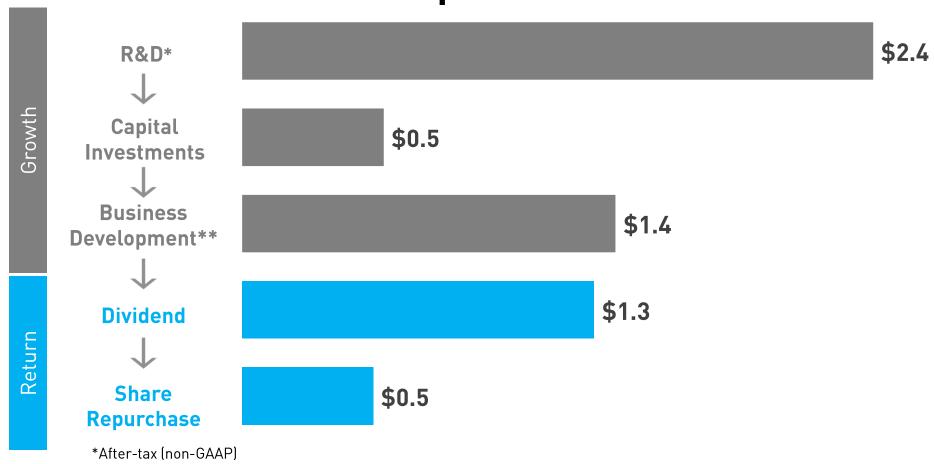
• U.S. GLP-1 class grew 27% vs. Q2 2019

## CAPITAL ALLOCATION





## YTD 2020 Capital Allocation



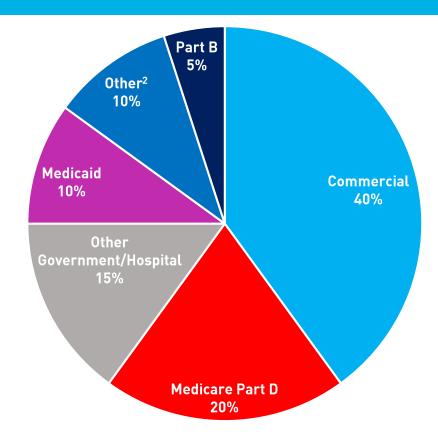
<sup>\*\*</sup>Includes equity investments and debt repayment associated with Business Development 2020 Q2 EARNINGS

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## **SEGMENT MIX DYNAMICS**



#### 1H 2020 U.S. GROSS SALES MIX<sup>1</sup>



<sup>1</sup>Numbers are rounded to nearest 5% and exclude alliance products <sup>2</sup>Other consists of non-contracted business, uninsured, and cash paying patients

## KEY CONSIDERATIONS

- Segment mix from commercial to Medicaid is expected to shift modestly in 2020 and is incorporated in our guidance
  - Commercial plan benefit designs differ significantly, impacting both net pricing and patient out-of-pocket costs in varying ways
  - Net pricing diverges across segments, across products within segments, and tends to be less significant for newer products
- Government relief packages may reduce the shift of patients into Medicaid
- Headwind of roughly \$200M expected in 2021

## **2020 GUIDANCE**



	Prior	Updated	Comments
TOTAL REVENUE	\$23.7 - \$24.2 billion	unchanged	
GROSS MARGIN % (GAAP)	approx. 79%	approx. 78%	
GROSS MARGIN % (NON-GAAP)	approx. 81%	approx. 80%	Reflects unfavorable impact of geographic mix and lower realized prices on revenue
MKTG, SELLING & ADMIN.	\$6.2 - \$6.4 billion	\$6.0 - \$6.2 billion	Reflects savings from reduced travel, meetings, and in-person promotional activities which are only partially offset by investments in digital capabilities
RESEARCH & DEVELOPMENT	\$5.6 - \$5.9 billion	unchanged	Reflects savings from pause in clinical trial activities offset by investment in potential COVID-19 treatments
OTHER INCOME/(EXPENSE)	\$(150) – \$0 million	\$350 – \$500 million	Updated to reflect Q2 equity portfolio gains
TAX RATE	approx. 15%	approx. 14%	Reflects net discrete tax benefits in first half of year
EARNINGS PER SHARE (GAAP)	\$6.20 - \$6.40	\$6.48 – \$6.68	Reflects net discrete tax benefits and improved OID partially offset by increase in Acquired IPR&D
EARNINGS PER SHARE (NON-GAAP)	\$6.70 – \$6.90	\$7.20 – \$7.40	Reflects net discrete tax benefit and improved OID expectations
OPERATING INCOME % (GAAP)	28%	unchanged	
OPERATING INCOME % (NON-GAAP)	31%	unchanged	

Assumes GAAP and non-GAAP shares outstanding 912 million

Updated FX assumptions of 1.11 (Euro), 108 (Yen) and 7.07 (Renminbi)

## POTENTIAL COVID-19 TREATMENTS



# **Baricitinib**JAK1 / JAK2 inhibitor

- Anti-inflammatory activity hypothesized to be beneficial in treating COVID-19<sup>1</sup>
- Part of National Institute of Allergy and Infectious Diseases' (NIAID)
   Phase 3 Adaptive COVID-19
   Treatment Trial
- Also initiated a Phase 3
   monotherapy study for hospitalized
   patients with COVID-19

# LY3127804 Angiopoietin 2 (Ang2) mAb

- Ang2 observed to be elevated in patients with acute respiratory distress syndrome
- Phase 2 trial enrolling patients with pneumonia who are hospitalized due to COVID-19

## Antibody Therapies

- Collaborations with AbCellera and Junshi Biosciences
- Assessing multiple fully-human antibodies identified from early COVID-19 survivors
- LY-CoV555<sup>2</sup> and LY-CoV016<sup>3</sup> have completed dosing in Phase 1 studies that support advancing the molecules

<sup>&</sup>lt;sup>1</sup>The approved rheumatoid arthritis indication includes warnings about risk for developing serious infection <sup>2</sup>In collaboration with AbCellera Biologics Inc.

<sup>&</sup>lt;sup>3</sup>In collaboration with Junshi Biosciences

## **COVID-19 ANTIBODY DEVELOPMENT PROGRAM**





- LY-CoV555 in hospitalized patients, completed dosing in June
- LY-CoV016 in healthy patients in the U.S, completed dosing in July
- Safety and pharmacokinetic data support advancing each molecule in development



- Initiated a Phase 2 study of LY-CoV555 in recently diagnosed mild-tomoderate COVID-19 patients (BLAZE-1)
- Preliminary efficacy data from BLAZE-1 in Q4 2020
- Registrational study of LY-CoV555 in recently diagnosed COVID-19 patients is expected to begin in the coming weeks



 Registrational study of LY-CoV555 in patients in longterm care facilities with high risk of exposure is expected to begin in the coming weeks

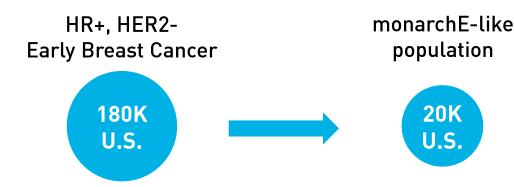


 Registrational study of LY-CoV555 in hospitalized patients is expected to begin in the coming weeks

## **VERZENIO** monarchE RESULTS



#### ANNUAL PATIENT POPULATION



Based on monarchE clinical pathological criteria, approximately 20K additional patients are added to the addressable market

The monarchE-like patient population represents a roughly 50% increase over the current metastatic opportunity, and the duration of therapy in the adjuvant setting is anticipated to be longer

#### **KEY TAKEAWAYS**

Significantly reduced the risk of cancer returning in people with high risk HR+, HER2- early breast cancer

The only CDK4&6 inhibitor to demonstrate statistically significant improvement in invasive disease-free survival

Detailed data will be presented at a medical meeting later this year

Initial submissions to be completed later this year

## TRULICITY ADA HIGHLIGHTS



### PHASE 3 DATA<sup>1</sup> (36 WEEKS)

# Change in HbA1C 1.5mg 3.0mg 4.5mg 1.5mg 3.0mg 4.5mg -6.8 lbs -8.8 lbs

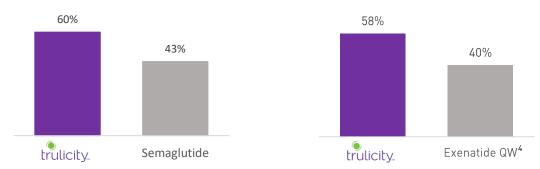
Compared to Trulicity 1.5 mg, both the 3.0mg and 4.5mg doses led to significant HbA1C reductions and weight loss

Results were maintained at 52 weeks

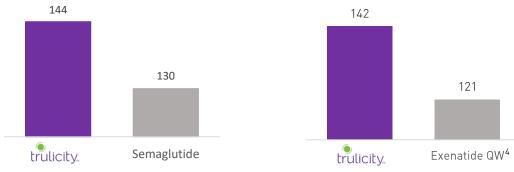
-1.9%

#### REAL-WORLD DATA<sup>2</sup>

#### Adherence measured by proportion of days covered<sup>3</sup>



#### Persistence measured by length of continuous therapy (days)<sup>5</sup>



Baseline: HbA1c (8.6%), body weight (211.4 lbs.); data presented are least squares mean ± standard error, efficacy estimand (on-treatment without rescue medication)

-10.4 lbs

Not for promotional use 2020 Q2 EARNINGS

 $<sup>^2</sup>$ Real world data represents Trulicity 0.75mg and 1.5mg, semaglutide 0.25, 0.5mg and 1.0mg, and exenatide QW 2mg doses

³Proportion of days covered (PDC) is defined as defined as the number of days with drug on-hand divided by the number of days in the specified time interval (6-month follow-up period for this study). Adherent patients were those with PDC ≥ 80% 4Exenatide QW indicated exenatide once weekly administered in the BCise pen device

<sup>&</sup>lt;sup>5</sup>Persistence measured by continuous therapy from the point of initiation until the end of the follow-up period, allowing for a maximum gap of 45 or 60 days from the date the previous fill's supply ran out to the next fill

## LILLY SELECT NME AND NILEX PIPELINE

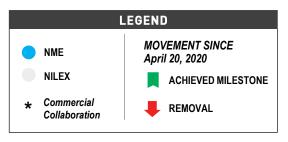
JULY 28, 2020



KHK INHIBITOR	SARS-COV-2 MAB
NASH / Diabetes	(LY-CoV016) COVID-19
CD73 INHIBITOR	NRG4 AGONIST
Cancer	Heart Failure
GIP/GLP COAGONIST	TAU MORPHOMER
PEPTIDE Diabetes	Alzheimer's
ANGPTL3/8 MAB	SSTR4 AGONIST
CVD	Pain
GLP-1R NPA	TRPA1 ANTAGONIST
Diabetes	Pain
GGG TRI-AGONIST	D1 PAM II
Diabetes	Dementia
O-GLCNACASE INH	CDK7 INHIBITOR
Alzheimer's	Cancer
N3PG Aβ MAB	ERK INHIBITOR
Alzheimer's	Cancer
PD-1 MAB AGONIST	SERD
Immunology	Cancer
PACAP38 MAB	IL-2 CONJUGATE
Pain	Immunology
BTLA MAB AGONIST	GDF 15 AGONIST
Immunology	Diabetes
AUR A KINASE	OXYNTOMODULIN
INHIBITOR Cancer	Diabetes
IL-33 MAB	CXCR1/2L MAB
Immunology	Immunology

OLARATUMAB Pancreatic Cancer	
TIRZEPATIDE NASH	ABEMACICLIB Prostate Cancer
EPIREG/TGFα MAB Chronic Pain	SARS-COV-2 MAB (LY-CoV555) COVID-19
ANGIOPOIETIN 2 MAB COVID-19	BTK INHIBITOR (LOXO-305) Cancer
CD200R MAB AGONIST Immunology	AUTOMATED INSULIN DELIVERY SYS Diabetes
BASAL INSULIN-FC Diabetes	MEVIDALEN (D1 PAM) Dementia
ZAGOTENEMAB (TAU MAB) Alzheimer's	DONANEMAB (N3PG Aβ MAB) Alzheimer's
PHA	ASE 2

TIRZEPATIDE Obesity	TIRZEPATIDE CV Outcomes			
ABEMACICLIB Adjuvant Breast Cancer	BARICITINIB COVID-19			
BARICITINIB Alopecia Areata	BARICITINIB Systemic Lupus Erythematosus			
MIRIKIZUMAB Crohn's Disease	MIRIKIZUMAB Ulcerative Colitis			
TANEZUMAB* Cancer Pain	EMPAGLIFLOZIN* Chronic Kidney Disease			
EMPAGLIFLOZIN* Heart Failure pEF	EMPAGLIFLOZIN* Heart Failure rEF			
SELPERCATINIB 1L Med Thyroid Cancer	SELPERCATINIB 1L NSCLC			
TIRZEPATIDE Diabetes	LEBRIKIZUMAB Atopic Dermatitis			
SOLANEZUMAB Preclinical AD	MIRIKIZUMAB Psoriasis			
PHASE 3				



DULAGLUTIDE
3.0 / 4.5 mg

BARICITINIB
Atopic Dermatitis

CONNECTED CARE
PREFILLED INSULIN PEN
Diabetes

TANEZUMAB\*
Osteoarthritis Pain

REG REVIEW



PHASE 1



## **POTENTIAL KEY EVENTS 2020**

New since last update



#### **Phase 3 Initiations**

- **▼Tirzepatide** CV outcome study (H2H vs. dulaglutide)
- **⊘Selpercatinib** for 1L NSCLC<sup>3</sup>
- Selpercatinib for 1L medullary thyroid cancer<sup>3</sup>

#### **Phase 3 Top-Line Data Disclosures**

- **⋘Empagliflozin** CHF outcomes study HFrEF¹
  - Tirzepatide for type 2 diabetes (first of five)
- Baricitinib for atopic dermatitis (last two of five studies)
- Mirikizumab in psoriasis (OASIS-1 & -2)
  - Mirikizumab in ulcerative colitis (induction data) (now expected 2021)
- Solanezumab for dominantly inherited Alzheimer's

#### **Medical Meeting Presentations**

- **☑ Dulaglutide** alternate doses for type 2 diabetes
  - **LOXO-305** additional data from Phase 1/2 study
  - **Abemaciclib** for high risk HR+,HER2- early breast cancer
  - Empagliflozin CHF outcomes study HFrEF

#### **Regulatory Submissions**

- ✓ Baricitinib for atopic dermatitis (US
  ✓ /EU
  ✓ /J
  ✓)
- $\bigcirc$  **Tanezumab** osteoarthritis pain (US<sup>2</sup>  $\bigcirc$ /EU $\bigcirc$ )
- ✓ Selpercatinib for NSCLC and thyroid cancers (EU
  ✓/J)³

**Abemaciclib** for high risk HR+,HER2- early breast cancer

**Empagliflozin** CHF outcomes study HFrEF

#### **Regulatory Actions**

**Dulaglutide** alternate doses for type 2 diabetes (US/EU)

- ✓ Dulaglutide REWIND CV outcomes study (US)
- ✓ Empagliflozin + linagliptin + metformin XR for type 2 diabetes (US)¹
- ✓ Ultra rapid lispro for type 1 and type 2 diabetes (US
  ✓ /EU
  ✓ /J
  ✓)
- ✓ Flortaucipir as a PET imaging agent (US)
- Galcanezumab for episodic cluster headache (EU)
- **⋘ Ixekizumab** for non-radiographic axial spondyloarthritis (US**⋘**/EU**⋘**/J)
- 🐼 lxekizumab for radiographic axial spondyloarthritis (EU)
- ✓ Ramucirumab for 1L EGFR NSCLC cancer (US ✓ /EU✓/J)
- Selpercatinib for NSCLC and thyroid cancers (US)

2020 **Q2 EARNINGS** 

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<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> occurred in Q4 2019

## YTD 2020 SUMMARY



- Volume-driven revenue growth of 6% (7% in constant currency)
- Operating income as a % of revenue improved 200 bps vs. H1 2019 on a non-GAAP basis
- Progress on our innovation-based strategy, including eight approvals and several key readouts
- Deployed nearly \$1.4 billion to shareholders via the dividend and completed \$0.5 billion of share repurchases

#### **Grow Revenue**



Minimum average annual revenue growth of 7% in constant currency from 2015 through 2020

#### **Improve Productivity**



Excluding FX on int'l inventories sold, minimum non-GAAP operating margin % of revenue of 31% in 2020

#### **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**



## **2020 INCOME STATEMENT - REPORTED**



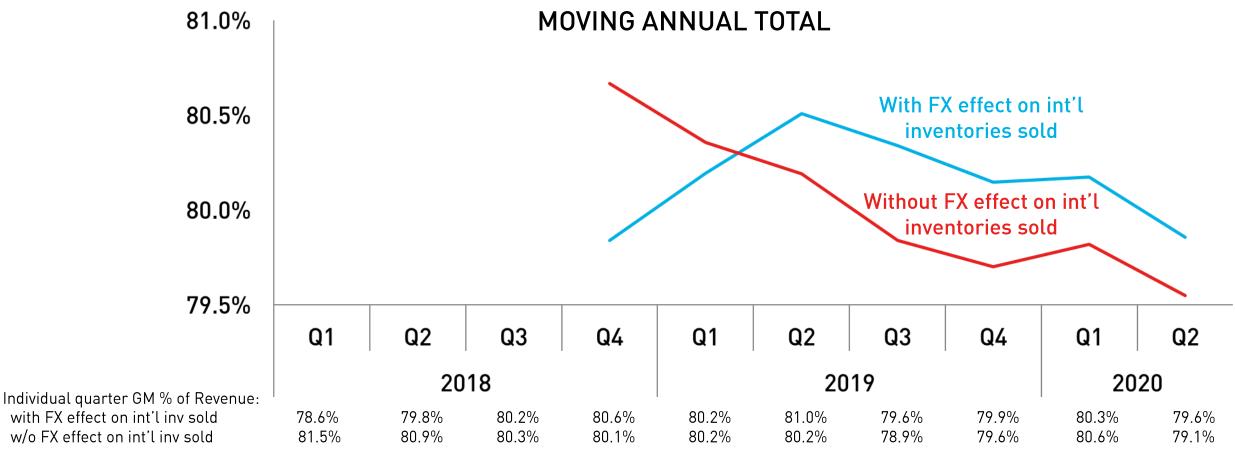
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TOTAL OPERATING EXPENSE*	3,081	2%	6,134	(3)%
OPERATING INCOME	1,197	(20)%	2,788	30%
OPERATING MARGIN	21.8%	(4.8pp)	24.5%	4.6pp
OTHER INCOME (EXPENSE)	447	NM	536	NM
EFFECTIVE TAX RATE	14.1%	4.6pp	13.7%	(0.3pp)
NET INCOME - CONTINUING OPERATIONS	\$1,412	6%	\$2,869	52%
EARNINGS PER SHARE	\$1.55	8%	\$3.15	(46)%

<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

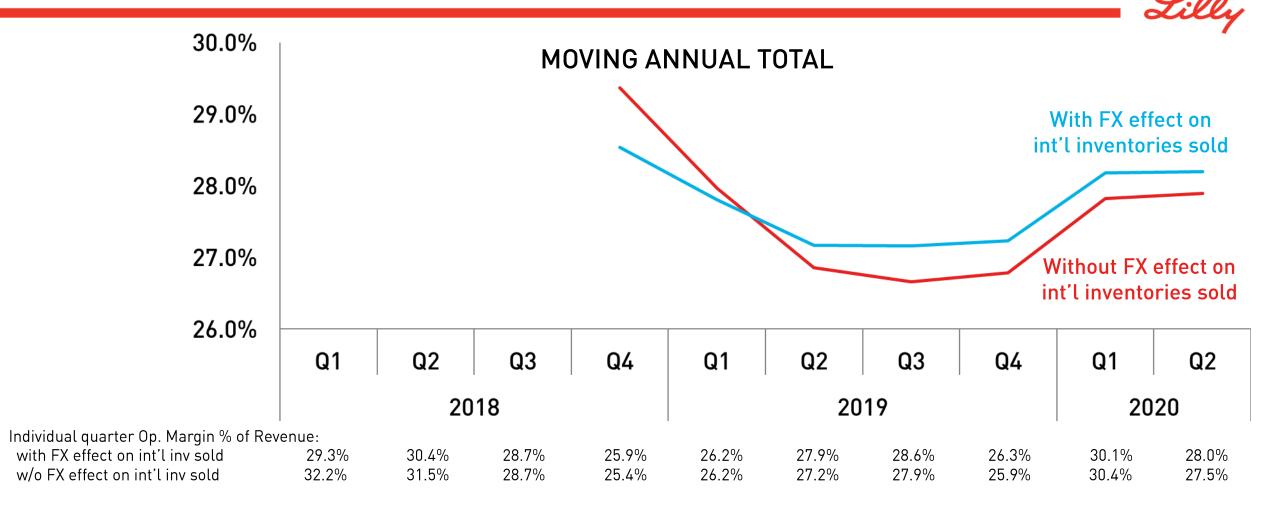
## **NON-GAAP GROSS MARGIN % OF REVENUE**





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. \* 2018 has been reclassified to reflect divestiture of Elanco Animal Health in 2019.

## **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.

\* 2018 has been reclassified to reflect divestiture of Elanco Animal Health in 2019.

## **EFFECT OF FX ON 2020 RESULTS**



Year-on-Year Growth	Q2 2020	YTD 2020

REPORTED	With FX	w/o FX	With FX	w/o FX
TOTAL REVENUE	(2)%	(2)%	6%	7%
COST OF SALES	9%	9%	8%	8%
<b>GROSS MARGIN</b>	(5)%	(4)%	5%	6%
OPERATING EXPENSE	2%	3%	(3)%	(2)%
<b>OPERATING INCOME</b>	(20%)	(19)%	30%	33%
<b>EARNINGS PER SHARE</b>	8%	9%	59%	62%

NON-GAAP	With FX	w/o FX	With FX	w/o FX
TOTAL REVENUE	(2)%	(2%)	6%	7%
COST OF SALES	4%	5%	9%	9%
<b>GROSS MARGIN</b>	(4)%	(3)%	5%	6%
OPERATING EXPENSE	(5)%	(4)%	1%	1%
<b>OPERATING INCOME</b>	(2)%	(1)%	14%	15%
EARNINGS PER SHARE	26%	28%	29%	31%

## **EPS RECONCILIATION**



	Q2 2020	Q2 2019	Change	YTD 2020	YTD 2019	Change
EPS (REPORTED)	\$1.55	\$1.44	8%	\$3.15	\$5.84	(46)%
DISCONTINUED OPERATIONS					(3.86)	
ACQUIRED IN-PROCESS RESEARCH AND DEVELOPMENT	0.25	0.02		0.30	0.14	
AMORTIZATION OF INTANGIBLE ASSETS	0.09	0.04		0.14	0.08	
ASSET IMPAIRMENT, RESTRUCTURING, AND OTHER SPECIAL CHARGES				0.06	0.44	
LARTRUVO CHARGES					0.14	
REDUCED SHARES OUTSTANDING					0.05	
EPS (NON-GAAP)	\$1.89	\$1.50	26%	\$3.64	\$2.83	29%

Note: Numbers may not add due to rounding; see slides 27 and 28 for more details on these significant adjustments.

## **Q2 2020 INCOME STATEMENT NOTES**



#### Q2 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 \$102.8 million (pretax), or \$0.09 per share (after-tax); and
- acquired in-process R&D charges totaling \$241.8 million (pretax), or \$0.25 per share (after-tax), related to business development activity other than a business combination, related to AbCellera Biologics Inc., Evox Therapeutics, Junshi Biosciences and a pre-clinical stage company.

#### Q2 2019 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 \$51.6 million (pretax), or \$0.04 per share (after-tax); and
- acquired in-process R&D charges totaling \$25.0 million (pretax), or \$0.02 per share (after-tax), related to business development activity other than a business combination, related to Avidity Biosciences Inc.

## YTD 2020 INCOME STATEMENT NOTES



#### YTD 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 \$157.2 million (pretax), or \$0.14 per share (after-tax);
- acquired in-process R&D charges totaling \$294.1 million (pretax), or \$0.30 per share (after-tax), related to business development activity other than a business combination, related to AbCellera Biologics Inc., Evox Therapeutics, Junshi Biosciences, Sitryx, a pre-clinical stage company; and
- asset impairment, restructuring and other special charges, primarily acquisition and integration costs as part of the closing of the acquisition of Dermira, totaling \$64.1 million (pretax), or \$0.06 per share (after-tax).

#### YTD 2019 NON-GAAP INFORMATION HAS BEEN ADJUSTED TO ELIMINATE:

- discontinued operations of the Elanco Animal Health business, reduction totaling \$3.681 billion, or \$3.86 per share (after-tax);
- assumption that the disposition of Elanco occurred at the beginning of the year and therefore include the benefit from the reduction in shares of common stock outstanding, totaling \$0.05 per share (after-tax);
- amortization of intangible assets primarily associated with costs of marketed products acquired or licensed from third parties totaling \$95.2 million (pretax), or \$0.08 per share (after-tax);
- acquired in-process R&D charges totaling \$161.9 million (pretax), or \$0.14 per share (after-tax), related to business development activity other than a business combination, related to AC Immune SA, Avidity Biosciences Inc. and ImmuNext, Inc.;
- Charges related to the suspension of promotion of Lartruvo, totaling \$96.7 million (pretax), or \$0.14 per share (after-tax); and
- Charges primarily associated with the accelerated vesting of Loxo employee equity awards as a result of the closing of the acquisition of Loxo Oncology, totaling \$411.8 million (pretax), or \$0.44 per share (after-tax).

## **COMPARATIVE EPS SUMMARY 2019/2020**



	1Q19	2Q19	3Q19	4Q19	2019	1Q20	2Q20	3Q20	4Q20	2020
Reported	4.31	1.44	1.37	1.64	8.89	1.60	1.55			
Non-GAAP	1.33	1.50	1.48	1.73	6.04	1.75	1.89			

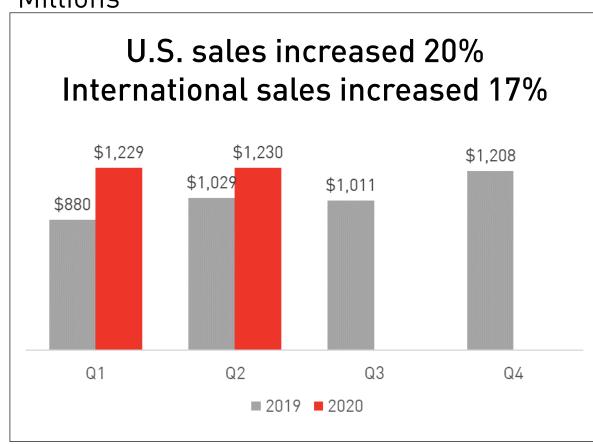
Note: Numbers may not add due to rounding.

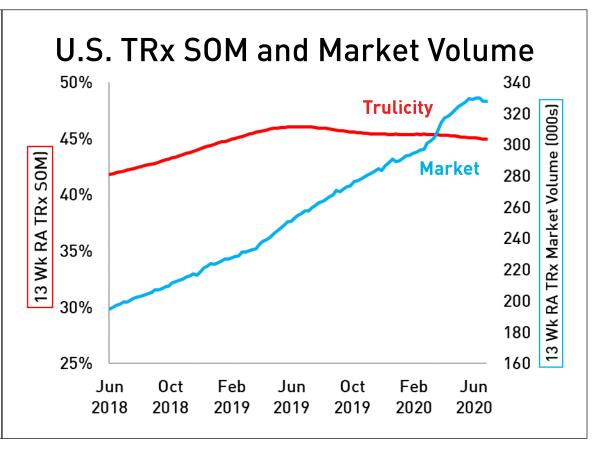
For a complete reconciliation to reported earnings, see slide 26 and our earnings press release dated July 30, 2020

## **Q2 2020 TRULICITY SALES INCREASED 20%**



#### Millions





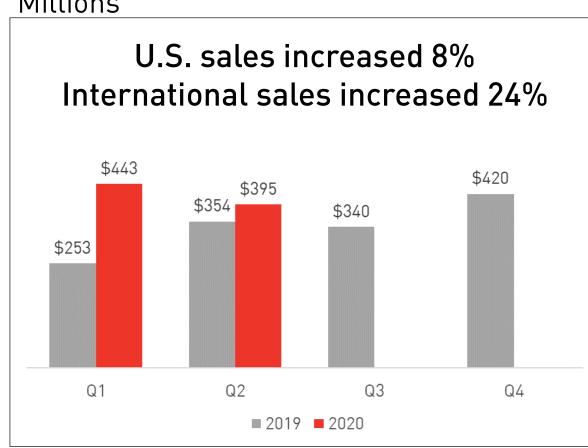
Note: Numbers may not add due to rounding.

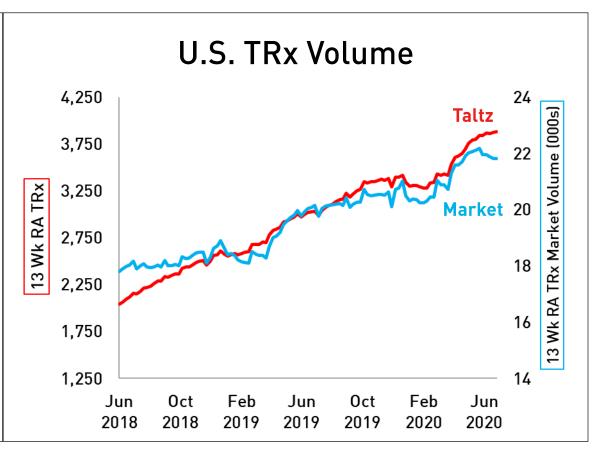
Source: IQVIA NPA TRx 3MMA, weekly data June 26, 2020

## **Q2 2020 TALTZ SALES INCREASED 12%**



#### Millions





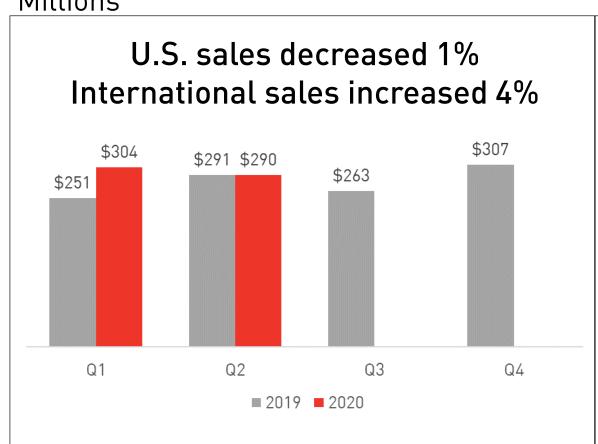
Note: Numbers may not add due to rounding.

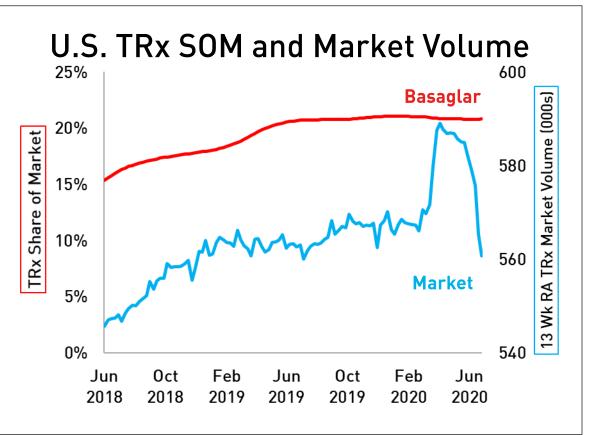
Source: IQVIA NPA TRx 3MMA, weekly data June 26, 2020 Note: TRx data is representative of the dermatology market

## Q2 2020 BASAGLAR SALES FLAT VS. Q2 2019



#### Millions





Note: Numbers may not add due to rounding.

Source: IQVIA NPA TRx 3MMA, weekly data June 26, 2020

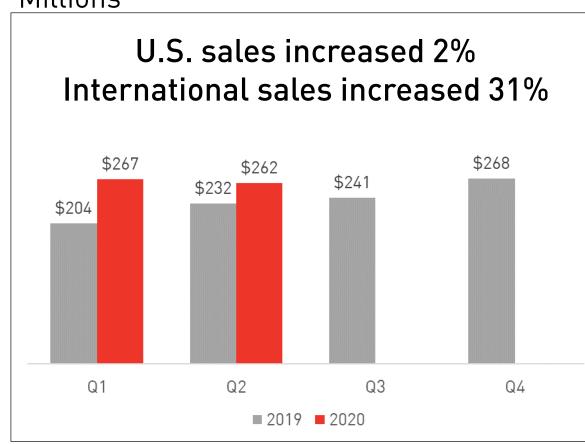
Note: Basaglar is part of the Boehringer Ingelheim and Lilly Diabetes Alliance

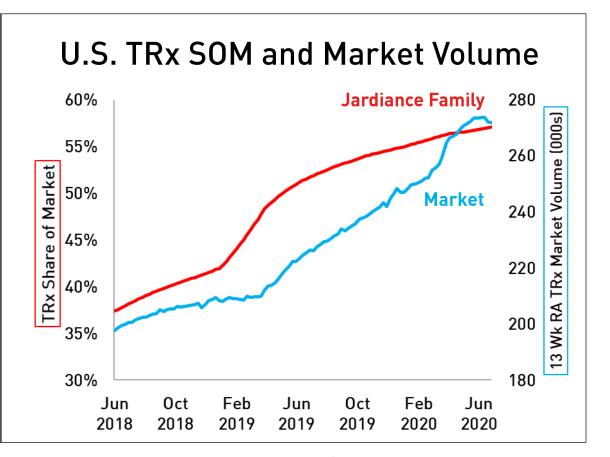
2020 **Q2 EARNINGS** 

## **Q2 2020 JARDIANCE SALES INCREASED 13%**



#### Millions





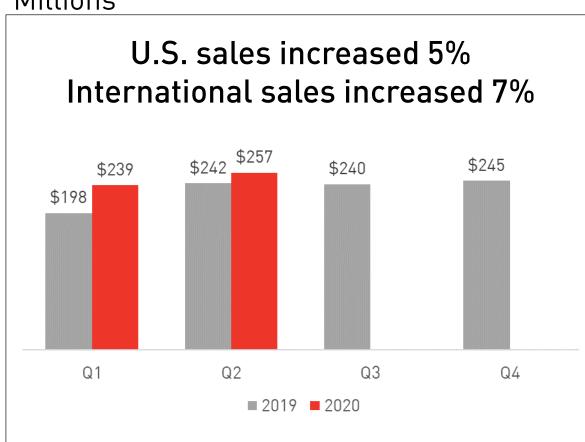
Note: Numbers may not add due to rounding.

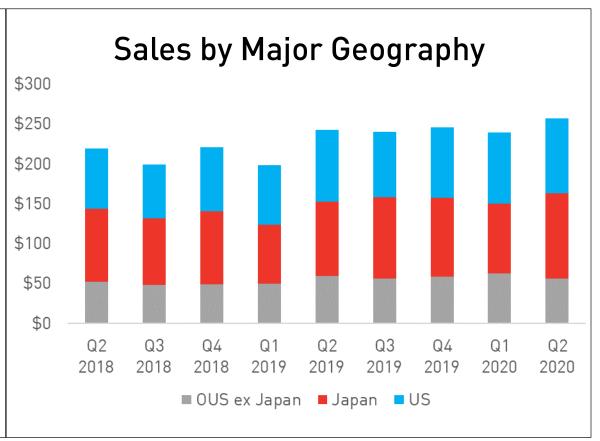
Source: IQVIA NPA TRx 3MMA, weekly data June 26, 2020 Note: Jardiance is part of the Boehringer Ingelheim and Lilly Diabetes Alliance

## **Q2 2020 CYRAMZA SALES INCREASED 6%**



#### Millions



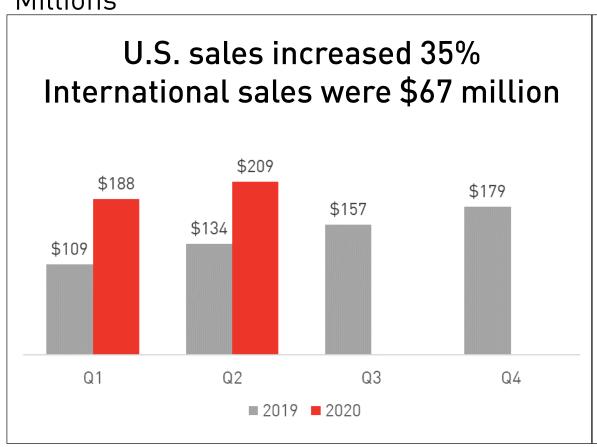


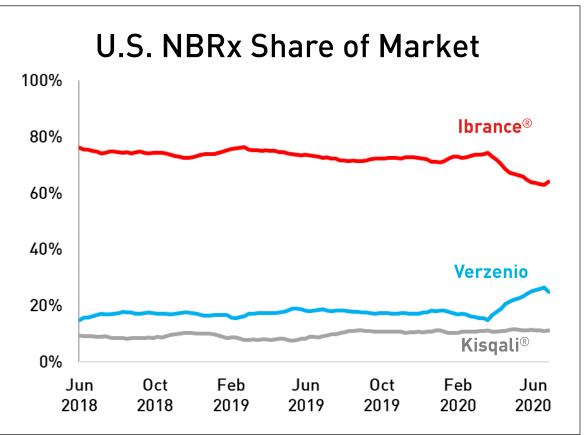
Note: Numbers may not add due to rounding.

## **Q2 2020 VERZENIO SALES INCREASED 56%**



#### Millions





Note: Numbers may not add due to rounding.

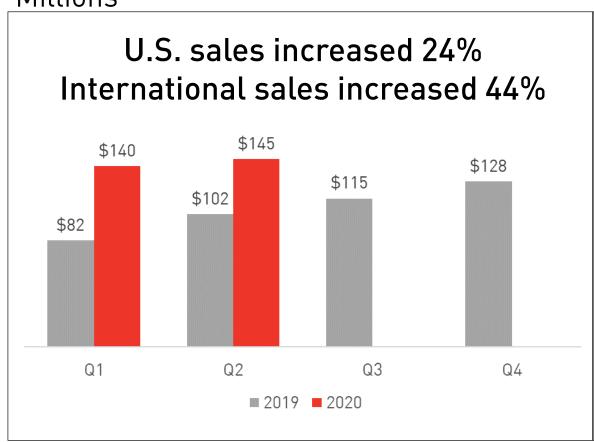
Source: IQVIA NPA NBRx 3MMA, weekly data June 26, 2020

\*Note: Q2 2020 IQVIA data was impacted by an addition of data for Verzenio

## **Q2 2020 OLUMIANT SALES INCREASED 42%**



#### Millions



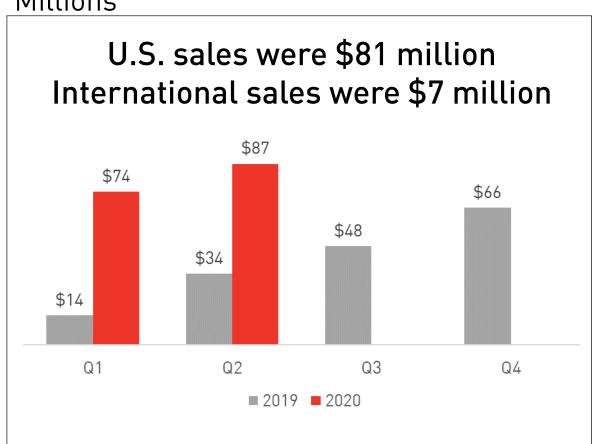
- Launched in the U.S. in July 2018
- Q2 sales driven by Germany and Japan
- Contributed 90bps to Q2 WW volume growth

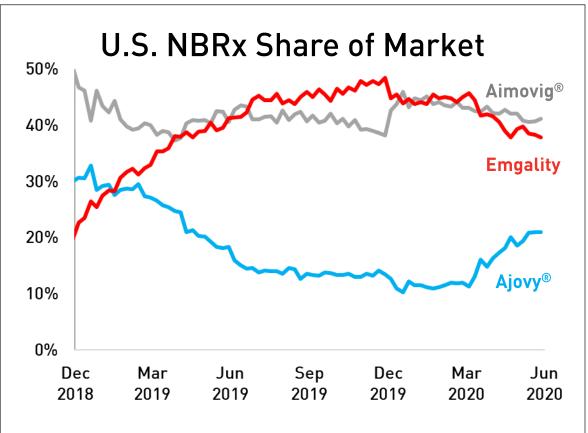
Note: Numbers may not add due to rounding.

## **Q2 2020 EMGALITY SALES WERE \$87 MILLION**



#### Millions





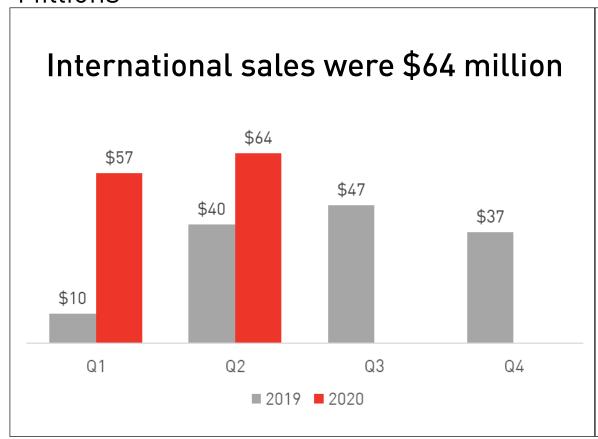
Note: Numbers may not add due to rounding.

Source: IQVIA NPA NBRx, weekly data June 26, 2020

#### **Q2 2020 TYVYT SALES INCREASED 60%**



#### Millions



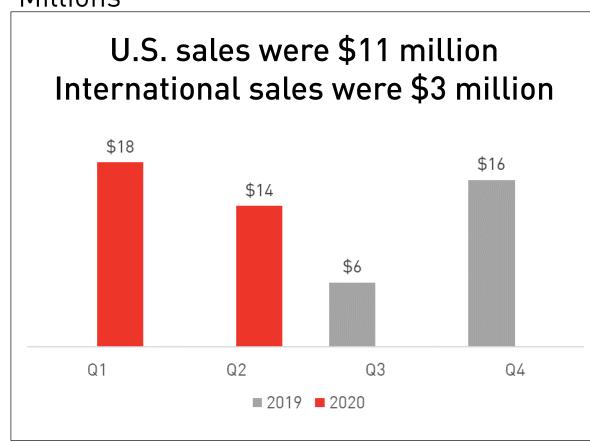
- Launched in China in Q1 2019
- Part of Lilly collaboration with Innovent
- Contributed 150bps to Q2 WW volume growth

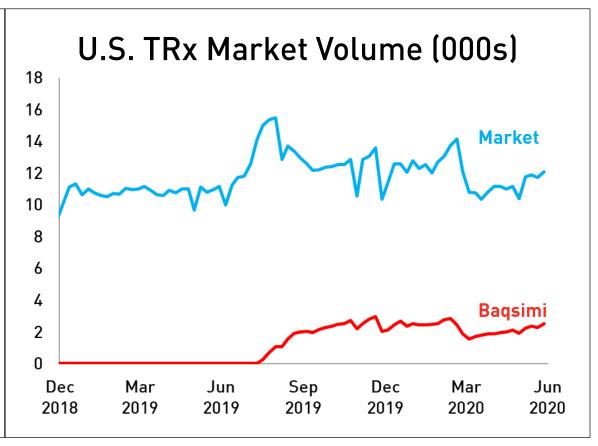
Note: Numbers may not add due to rounding.

## Q2 2020 BAQSIMI SALES WERE \$14 MILLION



#### Millions





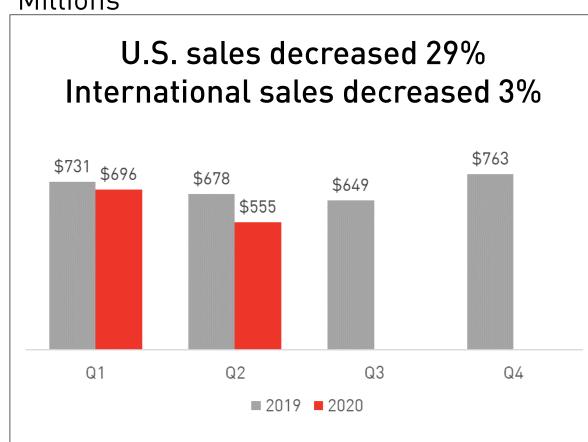
Note: Numbers may not add due to rounding.

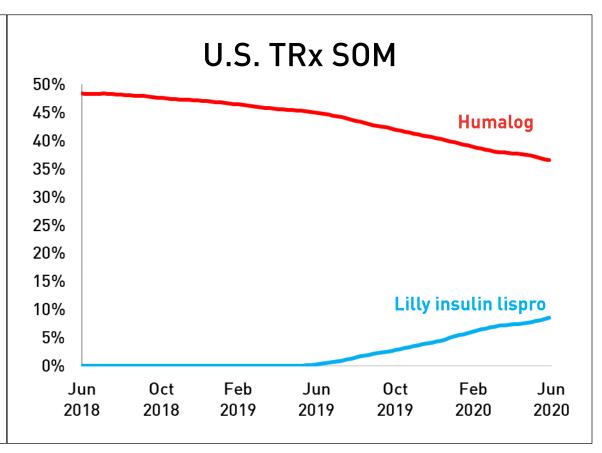
Source: IQVIA NPA TRx weekly data June 26, 2020

#### Q2 2020 HUMALOG SALES DECREASED 18%



#### Millions





Note: Numbers may not add due to rounding.

Source: IQVIA NPA TRx 3MMA, weekly data June 26, 2020

#### **SELECT TRIALS - JARDIANCE**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03594110^	Chronic Kidney Disease	EMPA-KIDNEY (The Study of Heart and Kidney Protection With Empagliflozin)		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 <u>&gt;</u> 40% in eGFR from randomization) or (ii) Cardiovascular death	Jun 2022	Jun 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)	Oct 2020	Nov 2020
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.	Jun 2021	Jul 2021

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 <u>&gt;</u> 2 points from Baseline to Week 16	Jun 2021	May 2022
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
NCT04250337	Atopic Dermatitis	Safety and Efficacy of Lebrikizumab (LY3650150) in Combination With Topical Corticosteroid in Moderate to Severe Atopic Dermatitis.	3	200	The primary efficacy endpoint is the percentage of patients with an IGA score of 0 or 1 and a reduction <a href="mailto:22">2</a> -points from Baseline to Week 16.	Aug 2021	Oct 2021
NCT04250350	Atopic Dermatitis	Study to Assess the Safety and Efficacy of Lebrikizumab (LY3650150) in Adolescent Patients With Moderate-to-Severe Atopic Dermatitis	3	200	Number of adverse events from Baseline to Week 52	Mar 2022	May 2022
NCT04392154	Atopic Dermatitis	Long-term Safety and Efficacy Study of Lebrikizumab (LY3650150) in Participants With Moderate-to-Severe Atopic Dermatitis	3	900	Proportion of participants discontinued from study treatment due to adverse events through the last treatment visit.	May 2023	May 2023

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

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

### **SELECT TRIALS – LYUMJEV**



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		350	Change from Baseline in Hemoglobin A1c (HbA1c)	May 2022	May 2022
NCT03952143	Type 2 Diabetes Mellitus	A Study of LY900014 Compared to Insulin Lispro (Humalog) in Adults With Type 2 Diabetes	3	564	Change from Baseline in Hemoglobin A1c (HbA1c)	Feb 2021	Feb 2021

<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	ients Primary Outcome**		Completio
NCT03556202	Psoriasis	A Long-term Study to Evaluate Safety and Maintenance of Psoriasis Treatment Effect of LY3074828 in Participants With Moderate-to-Severe Plaque Psoriasis (OASIS-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	926130 Crohn's Disease A Study of Mirikizumab (LY3074828) in Participants With Crohn's Disease		1150	Percentage of Participants Achieving Endoscopic Response	Feb 2022	Jul 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	Nov 2023	Nov 2023
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	Sep 2020	Dec 2021
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	Mar 2021	Jun 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	840	Percentage of Participants in Clinical Remission	Aug 2023	Aug 2023
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 - 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) <20	Feb 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	400	Percentage of Participants who Die or Require Non-Invasive Ventilation/High-Flow Oxygen or Invasive Mechanical Ventilation (including extracorporeal membrane oxygenation [ECMO])	Sep 2020	Sep 2020
NCT04401579^	COVID-19	Adaptive COVID-19 Treatment Trial 2 (ACTT-2)	3	1034	Time to recovery	Aug 2023	Aug 2023
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	750	Percentage of Participants Achieving a Systemic Lupus Erythematosus Responder Index 4 (SRI-4) Response (High Dose)	Oct 2021	Nov 2021

In collaboration with Incyte

<sup>^</sup> sponsored by NIAID

<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
NCT03899792	Medullary Thyroid Cancer	A Study of Oral LOXO-292 in Pediatric Patients With Advanced Solid or Primary Central Nervous System Tumors	1/2	100	To determine the safety of oral LOXO-292 in pediatric patients with advanced solid tumors: Dose limiting toxicities (DLTs)	Nov 2021	Oct 2022
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)	Feb 2023	Dec 2024
	N 6 11	DI 4/0 C: 1 (10)/0 000: D :: 1 N/:! A   1 C :: 1					
NCT03157128	Cell Lung Cancer	Phase 1/2 Study of LOXO-292 in Patients With Advanced Solid Tumors, RET Fusion-Positive Solid Tumors, and Medullary Thyroid Cancer	1/2	970	Phase 1: Maximum tolerated dose (MTD)	Mar 2022	May 2022
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	400	Progression Free Survival (PFS) by Blinded Independent Central Review (BICR) (with or without Pembrolizumab)	Dec 2023	Apr 2026
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	May 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
NCT02008357^	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)	Jul 2022	Jul 2022

Source: clinicaltrials.gov, January 18, 2020

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

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

<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	L Patients With Cancer Pain Due to Bone Metastasis Who Are	3	155	Change from baseline in daily average pain intensity in index bone metastasis cancer pain site	Aug 2020	May 2021

In collaboration with Pfizer

Source: clinicaltrials.gov, May 19, 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	Completion
NCT04166773	Non- alcoholic Steato- hepatitis	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	Mar 2022	Mar 2022
NCT04184622	Overweight	A Study of Tirzepatide (LY3298176) in Participants With Obesity or Overweight	3	2400	Percent Change from Baseline in Body Weight	Feb 2022	Apr 2024
NCT03954834	Type 2 Diabetes Mellitus	A Study of Tirzepatide (LY3298176) in Participants With Type 2 Diabetes Not Controlled With Diet and Exercise Alone	3	472	Change from Baseline in Hemoglobin A1c (HbA1c)	Oct 2020	Nov 2020
NCT03882970	Type 2 Diabetes Mellitus	A Study of Tirzepatide (LY3298176) Versus Insulin Degludec in Participants With Type 2 Diabetes	3	1420	Change from Baseline in Hemoglobin A1c (HbA1c) (10 mg and 15 mg)	Dec 2020	Jan 2021
NCT04039503	Type 2 Diabetes	A Study of Tirzepatide (LY3298176) Versus Placebo in Participants With Type 2 Diabetes Inadequately Controlled on Insulin Glargine With or Without Metformin	3	472	Change from Baseline in Hemoglobin A1c (HbA1c) (10 mg and 15 mg)	Dec 2020	Jan 2021
NCT03987919	Type 2 Diabetes	A Study of Tirzepatide (LY3298176) Versus Semaglutide Once Weekly as Add-on Therapy to Metformin in Participants With Type 2 Diabetes		1872	Change from Baseline in Hemoglobin A1c (HbA1c) (10 mg and 15 mg)	Jan 2021	Feb 2021
NCT03861039	Type 2 Diabetes Mellitus	A Long-term Safety Study of Tirzepatide (LY3298176) in Participants With Type 2 Diabetes	3	441	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Feb 2021	Mar 2021

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

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

### SELECT TRIALS - TIRZEPATIDE (CONTINUED)



Study	Indication*	* Title		Patients	Primary Outcome**	Primary Completion	Completion
NCT03861052	Type 2 Diabetes	A Study of Tirzepatide (LY3298176) Compared to Dulaglutide in Participants With Type 2 Diabetes	3	636	Change from Baseline in Hemoglobin A1c (HbA1c)	Mar 2021	Apr 2021
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)	May 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	956	Mean Change from Baseline in Hemoglobin A1c (HbA1c) (10 mg and 15 mg)	Feb 2022	Mar 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
NCT04031885	Metastatic Breast Cancer	A Study of Abemaciclib (LY2835219) in Combination With Fulvestrant Compared to Chemotherapy in Women With HR Positive, HER2 Negative Metastatic Breast Cancer	4	300	Objective Response Rate (ORR): Percentage of Participants Who Achieve Complete Response (CR) or Partial Response (PR)	Apr 2021	Dec 2022
NCT03155997^	Breast Cancer	Endocrine Therapy With or Without Abemaciclib (LY2835219) Following Surgery in Participants With Breast Cancer	3	4580	Invasive Disease Free Survival (IDFS)	Apr 2021	Jun 2027

Source: clinicaltrials.gov, May 5, 2020

<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 COVID-19**



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
SARS-COV-2 MAB (LY- CoV555)	NCT04427501^	COVID-19	A Study of LY3819253 (LY-CoV555) in Participants With Mild to Moderate COVID-19 Illness	2	400	Change from Baseline to Day 11 in Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) Viral Load	Aug 2020	Aug 2020
Angiopoietin 2 Mab	NCT04342897	COVID-19	A Study of LY3127804 in Participants With COVID-19	2	210	Number of Ventilator Free Days	Sep 2020	Sep 2020
SARS-COV-2 MAB (LY- CoV555)	NCT04411628^	COVID-19	A Study of LY3819253 (LY-CoV555) in Participants Hospitalized for COVID-19	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	Aug 2020	Aug 2020
SARS-COV-2 MAB (LY- CoV016)	NCT04441931	Healthy	A Study of LY3832479 in Healthy Participants	1	24	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug	Sep 2020	Sep 2020

<sup>^</sup> in collaboration with AbCellera Biologics 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	357	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	375	Change from Baseline in Hemoglobin A1c (HbA1c)	Sep 2021	Sep 2021
GIP/GLP Coagonist Peptide	NCT04178733	Healthy	A Safety Study of LY3493269 Given as a Single Injection in Healthy Participants	1	33	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	May 2020	May 2020
NRG4 Agonist I	NCT04352114	Healthy	A Study of LY3461767 in Healthy Participants	1	70	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Oct 2020	Oct 2020
Oxyntomodulin	NCT03928379	Diabetes Mellitus, Type 2	A Study of LY3305677 in Participants With Type 2 Diabetes	1	48	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug	Nov 2020	Nov 2020
GLP-1R NPA	NCT03929744	Healthy	A Study of LY3502970 in Healthy Participants	1	180	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug	Dec 2020	Dec 2020

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

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

# SELECT TRIALS - EARLY PHASE DIABETES (CONTINUED)



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
GGG Tri- Agonist	NCT04143802	Diabetes Mellitus, Type 2	A Study of LY3437943 in Participants With Type 2 Diabetes Mellitus (T2DM)	1	75	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Dec 2020	Dec 2020
Basal Insulin - FC	NCT04276428	Diabetes Mellitus, Type 2	A Study of LY3209590 in Japanese Participants With Type 2 Diabetes Mellitus	1	27	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Dec 2020	Dec 2020
ANGPTL3/8 MAB	NCT04052594	Dyslipidemias	A Study of LY3475766 in Healthy Participants	1	55	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Mar 2021	Mar 2021
GDF15 Agonist	NCT03764774	Healthy	A Study of LY3463251 in Healthy Participants	1	143	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Apr 2021	Apr 2021
GLP-1R NPA	NCT04426474	Diabetes Mellitus, Type 2	A Study of LY3502970 in Participants With Type 2 Diabetes	1	48	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug	Apr 2021	Apr 2021

<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
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	Aug 2021
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 ≥4 Point Reduction in Systemic Lupus Erythematosus Disease Activity Index (SLEDAI) 2000 (2K) Score	Jan 2023	Apr 2023
BTLA MAB Agonist	NCT03933943	Lupus Erythematosus, Systemic	A Study of LY3361237 in Participants With Systemic Lupus Erythematosus	1	24	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug	Jan 2021	Feb 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	Apr 2021	Apr 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	Apr 2021	Apr 2021

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

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

# SELECT TRIALS - EARLY PHASE IMMUNOLOGY (CONTINUED)



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
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	Jan 2022	Jan 2022
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	Dec 2022	Dec 2022

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

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

#### **SELECT TRIALS - EARLY PHASE NEURODEGENERATION**



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
Mevidalen (D1 PAM)	NCT03305809	Lewy Body Dementia	A Study of LY3154207 in Participants With Dementia Due to Lewy Body Dementia (LBD) Associated With Idiopathic Parkinson's Disease (PD) or Dementia With Lewy Bodies (DLB)	2	340	Change from Baseline in the Continuity of Attention (CoA) Composite Score of the Cognitive Drug Research Computerized Cognition Battery (CDR-CCB)	Jul 2020	Jul 2020
Donanemab (N3PG Aβ MAB)	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
Zagotenemab (Tau MAB)	NCT03518073	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
Donanemab (N3PG Aβ MAB)	NCT04437511	Alzheimer Disease	A Study of Donanemab (LY3002813) in Participants With Early Alzheimer's Disease (TRAILBLAZER-ALZ 2)	2	500	Change from Baseline on the Clinical Dementia Rating Scale–Sum of Boxes (CDR–SB)	Mar 2023	Apr 2024
O-GlcNAcase Inh.	NCT04392271	Healthy	A Study of the Effects of Multiple Doses of LY3372689 on the Brain in Healthy Participants	1	12	Percent O-GlcNAcase (OGA) Enzyme Occupancy (EO)	Oct 2020	Oct 2020
D1 PAM II	NCT04014361	Healthy	A Study of LY3154885 in Healthy Participants	1	102	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Jan 2021	Jan 2021

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

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

## SELECT TRIALS - EARLY PHASE NEURODEGENERATION (CONTINUED)



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
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	Sep 2021	Sep 2021
N3PG Aβ 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	Mar 2022	Mar 2022

<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
BTK Inhibitor (LOXO-305)	NCT03740529	Chronic Lymphocytic Leukemia	A Study of Oral LOXO-305 in Patients With Previously Treated CLL/SLL or NHL	1/2	403	Maximum Tolerated Dose (MTD)	Oct 2020	Apr 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	Oct 2020	Apr 2023
CD73 Inhibitor	NCT04148937^	Advanced Cancer	A Study of the CD73 Inhibitor LY3475070 Alone or in Combination With Pembrolizumab in Participants With Advanced Cancer	1	120	Number of Participants with Dose Limiting Toxicity (DLT)	Jun 2021	Dec 2022
ERK Inhibitor	NCT02857270	Advanced Cancer	A Study of LY3214996 Administered Alone or in Combination With Other Agents in Participants With Advanced/Metastatic Cancer	1	272	Number of Participants with LY3214996 Dose Limiting Toxicities (DLTs)	Dec 2021	Dec 2021
CDK7 Inhibitor	NCT03770494	Solid Tumor	A Study of LY3405105 in Participants With Advanced Cancer	1	215	Number of Participants with Dose Limiting Toxicities (DLTs)	May 2022	May 2022
Aur A Kinase Inhibitor	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 Merck Sharp & Dohme Corp.

<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**



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
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)	Mar 2021	Mar 2022
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)	Mar 2021	Mar 2022
PACAP38 MAB	NCT03692949	Healthy	A Study of LY3451838 in Healthy Participants	1	53	Number of Participants with any Treatment Emergent Adverse Event	Feb 2020	Feb 2020
TRPA1 Antagonist	NCT04183283	Healthy	A Study of LY3526318 in Healthy Women	1	16	Change from Baseline in Cinnamaldehyde (CA)- Induced Dermal Blood Flow (DBF) Measured by Laser Doppler Imaging (LDI)	Feb 2020	Mar 2020
SSTR4 Agonist	NCT04156750	Healthy	A Study of LY3556050 in Healthy Participants	1	51	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Aug 2020	Aug 2020

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

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