

Q4

*Lilly*

2020 BUSINESS RESULTS JANUARY 29, 2021

# AGENDA



## INTRODUCTION AND KEY RECENT EVENTS

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

## Q4 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. 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



- 22% revenue growth in Q4; 7% excluding bamlanivimab
- 10% revenue growth YTD; 6% excluding bamlanivimab
- YTD revenue growth driven by:
  - 15% volume growth; 11% excluding bamlanivimab
  - Key growth products, which accounted for over half of total revenue

### Improve Productivity



- Non-GAAP:
  - Gross margin in Q4 was 78.6% and 79.3% YTD 2020 (79.9% in Q4 and 79.7% YTD 2020 excluding bamlanivimab)
  - Operating margin in Q4 was 33.0% and 29.6% YTD 2020 (32.7% in Q4 and 30.2% YTD 2020 excluding bamlanivimab revenue and COVID-19 therapy expense)

### Create Long-Term Value



- Acquired Prevail Therapeutics, entering clinical phase gene therapy
- Distributed nearly \$0.7 billion via dividends in Q4
- No shares repurchased in Q4

### Speed Life-Changing Medicines



- Positive results from BRUIN trial for LOXO-305 in mantle cell lymphoma (MCL), chronic lymphocytic leukemia (CLL) and small lymphocytic lymphoma (SLL)
- Positive results from SURPASS-1 trial of tirzepatide in type 2 diabetes
- Positive results from TRAILBLAZER-ALZ trial of donanemab in early symptomatic Alzheimer's disease
- FDA Emergency Use Authorization (EUA) for bamlanivimab and baricitinib for COVID-19

# KEY EVENTS SINCE THE LAST EARNINGS CALL



## REGULATORY

- The U.S. Food and Drug Administration (FDA) granted an EUA for investigational neutralizing antibody **bamlanivimab** (LY-CoV555) 700 mg for the treatment of mild to moderate COVID-19 patients;
- The FDA issued an EUA for **baricitinib** to be used in combination with remdesivir in hospitalized adult and pediatric patients two years of age or older with suspected or laboratory-confirmed COVID-19 who require supplemental oxygen, invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO);
- The FDA accepted the supplemental New Drug Application for **Jardiance**<sup>®</sup> (empagliflozin) for adults with heart failure with reduced ejection fraction; and
- Submitted **Verzenio**<sup>®</sup> for high-risk HR+, HER2- early breast cancer in the U.S. and are awaiting acceptance from the FDA.

## CLINICAL

- Presented updated data for **LOXO-305** from the Phase 1/2 BRUIN clinical trial at the American Society of Hematology (ASH):
  - A 52% overall response rate in mantle cell lymphoma patients previously treated with a covalent BTK inhibitor;
  - A 62% overall response rate in BTK pre-treated CLL/SLL patients, rising to 84% in patients followed for 10 or more months; consistent response rates regardless of reason for prior BTK discontinuation or BTK mutation status;

## CLINICAL (CONT.)

- **Tirzepatide** significantly reduced A1C and body weight in people with type 2 diabetes with more than half of participants taking the highest dose achieving normal A1C levels in SURPASS-1;
- Presented positive primary outcome data for **Verzenio** building on previous interim analysis of monarchE, which continued to show clinically significant improvement in invasive disease-free survival for people with HR+, HER2-high risk early breast cancer;
- **Donanemab** showed significant slowing of decline in patients with early symptomatic Alzheimer's disease, and met the primary endpoint of change from baseline to 76 weeks in the Integrated Alzheimer's disease Rating Scale, slowing decline by 32 percent relative to placebo;
- **Bamlanivimab** prevented COVID-19 at nursing homes in the BLAZE-2 trial, reducing risk by up to 80 percent for residents; and
- New data from BLAZE-1 showed treatment with neutralizing antibodies **bamlanivimab** and **etesevimab** together reduced risk of COVID-19 hospitalizations and death by 70 percent in high-risk patients.

# KEY EVENTS SINCE THE LAST EARNINGS CALL



## BUSINESS DEVELOPMENT

- Announced a non-exclusive, global agreement with **Ypsomed** to advance an automated insulin delivery system as part of Lilly's connected diabetes solutions;
- Entered into a research collaboration and exclusive license agreement with **Precision Biosciences** to utilize Precision's proprietary ARCUS® genome editing platform for the research and development of potential in vivo therapies for genetic disorders, with an initial focus on Duchenne muscular dystrophy and two other undisclosed gene targets;
- Completed the acquisition of **Prevail Therapeutics**, establishing a gene therapy program at Lilly, anchored by Prevail's portfolio of neuroscience assets, and broadening Lilly's commitment to use novel modalities to address otherwise fatal genetic forms of neurodegenerative disease;
- Announced a research collaboration and exclusive license agreement with **Merus NV** to discover novel T-cell re-directing bispecific antibodies;
- Announced a collaboration with **Vir Biotechnology** and **GlaxoSmithKline** to evaluate bamlanivimab (LY-CoV555) with VIR-7831 (GSK4182136) in low-risk patients with mild to moderate COVID-19; and
- Announced a license agreement with **Asahi Kasei Pharma** for a Phase 1 chronic pain drug candidate.

## OTHER

- Signed an agreement with the U.S. government to supply 950,000 vials of neutralizing antibody **bamlanivimab** (LY-CoV555) 700 mg for \$1.1875 billion expected to deliver by 1/31/21 as well as an additional agreement to supply 500,000 doses for \$625 million expected to deliver by 3/31/21;
- Announced a 15% dividend increase;
- Announced Chief Information and Digital Officer **Aarti Shah's** retirement expected in the first half of 2021, after 27 years of service;
- The Board of Directors elected **Gabrielle Sulzberger** as a new member, serving on both the Audit Committee and Ethics and Compliance Committee; and
- Announced \$30 million investment in **Unseen Capital Health Fund**, which will provide support for minority-owned, early-stage healthcare companies as part of Lilly's racial justice efforts.

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



Millions; except per share data

Q4 2020

	GAAP Reported	Adjustments	Non-GAAP Adjusted	Non-GAAP Adjusted Change
<b>TOTAL REVENUE</b>	\$7,440	-	<b>\$7,440</b>	22%
<b>GROSS MARGIN</b>	76.9%	1.7%	<b>78.6%</b>	(1.3pp)
<b>TOTAL OPERATING EXPENSE</b>	3,728	(336)	<b>3,392</b>	3%
<b>OPERATING INCOME</b>	1,992	464	<b>2,456</b>	53%
<b>OPERATING MARGIN</b>	26.8%	6.2%	<b>33.0%</b>	6.8pp
<b>OTHER INCOME (EXPENSE)</b>	477	-	<b>477</b>	NM
<b>EFFECTIVE TAX RATE</b>	14.3%	0.1%	<b>14.4%</b>	1.8pp
<b>NET INCOME</b>	\$2,117	392	<b>\$2,509</b>	58%
<b>EPS</b>	<b>\$2.32</b>	\$0.43	<b>\$2.75</b>	59%

Note: Numbers may not add due to rounding; see slide 26 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
<b>TOTAL REVENUE</b>	\$24,540	-	<b>\$24,540</b>	10%
<b>GROSS MARGIN</b>	77.7%	1.6%	<b>79.3%</b>	(0.8pp)
<b>TOTAL OPERATING EXPENSE</b>	12,999	(792)	<b>12,207</b>	3%
<b>OPERATING INCOME</b>	6,058	1,207	<b>7,265</b>	20%
<b>OPERATING MARGIN</b>	24.7%	4.9%	<b>29.6%</b>	2.4pp
<b>OTHER INCOME (EXPENSE)</b>	1,172	-	<b>1,172</b>	NM
<b>EFFECTIVE TAX RATE</b>	14.3%	(0.1)%	<b>14.2%</b>	2.4pp
<b>NET INCOME</b>	\$6,194	1,042	<b>\$7,236</b>	30%
<b>EPS</b>	<b>\$6.79</b>	\$1.14	<b>\$7.93</b>	31%

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



# PRICE/RATE/VOLUME EFFECT ON REVENUE



Millions

## Q4 2020

	<u>Amount</u>	<u>Price</u>	<u>FX Rate</u>	<u>Volume</u>	<u>Total</u>	<u>CER</u>
<b>U.S.</b>	\$4,598	(5)%	-%	36%	31%	31%
<b>EUROPE</b>	1,203	3%	7%	9%	19%	12%
<b>JAPAN</b>	664	(2)%	3%	(7)%	(6)%	(10)%
<b>CHINA</b>	321	(27)%	7%	57%	37%	31%
<b>REST OF WORLD</b>	654	(2)%	(4)%	8%	2%	6%
<b>TOTAL REVENUE</b>	\$7,440	(4)%	1%	24%	22%	20%

## YTD 2020

	<u>Amount</u>	<u>Price</u>	<u>FX Rate</u>	<u>Volume</u>	<u>Total</u>	<u>CER</u>
<b>U.S.</b>	\$14,229	(5)%	-%	17%	12%	12%
<b>EUROPE</b>	4,188	(1)%	2%	10%	11%	10%
<b>JAPAN</b>	2,583	(4)%	2%	3%	1%	(1)%
<b>CHINA</b>	1,117	(43)%	(0)%	62%	19%	19%
<b>REST OF WORLD</b>	2,423	(2)%	(4)%	10%	3%	7%
<b>TOTAL REVENUE</b>	\$24,540	(5)%	0%	15%	10%	10%

Note: Numbers may not add due to rounding.

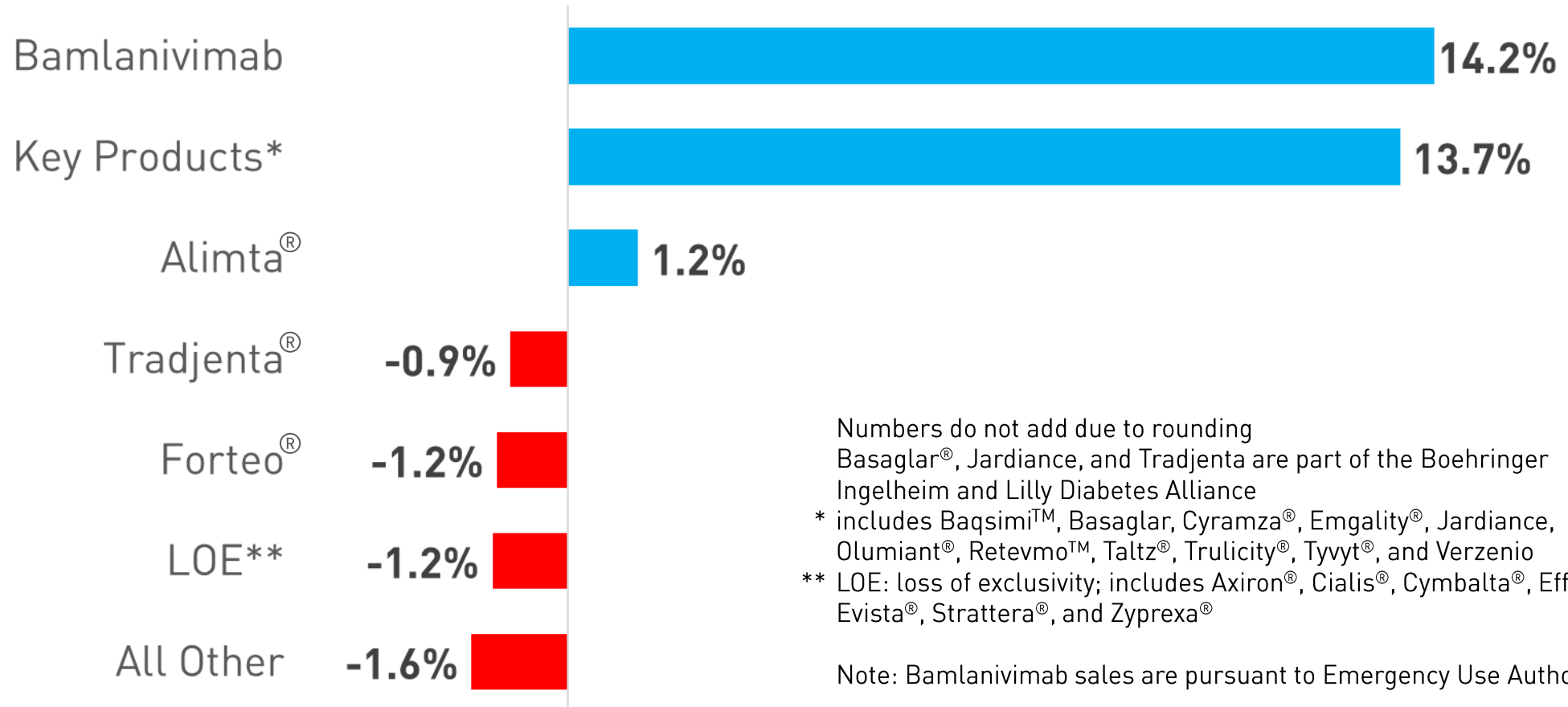
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CER = price change + volume change

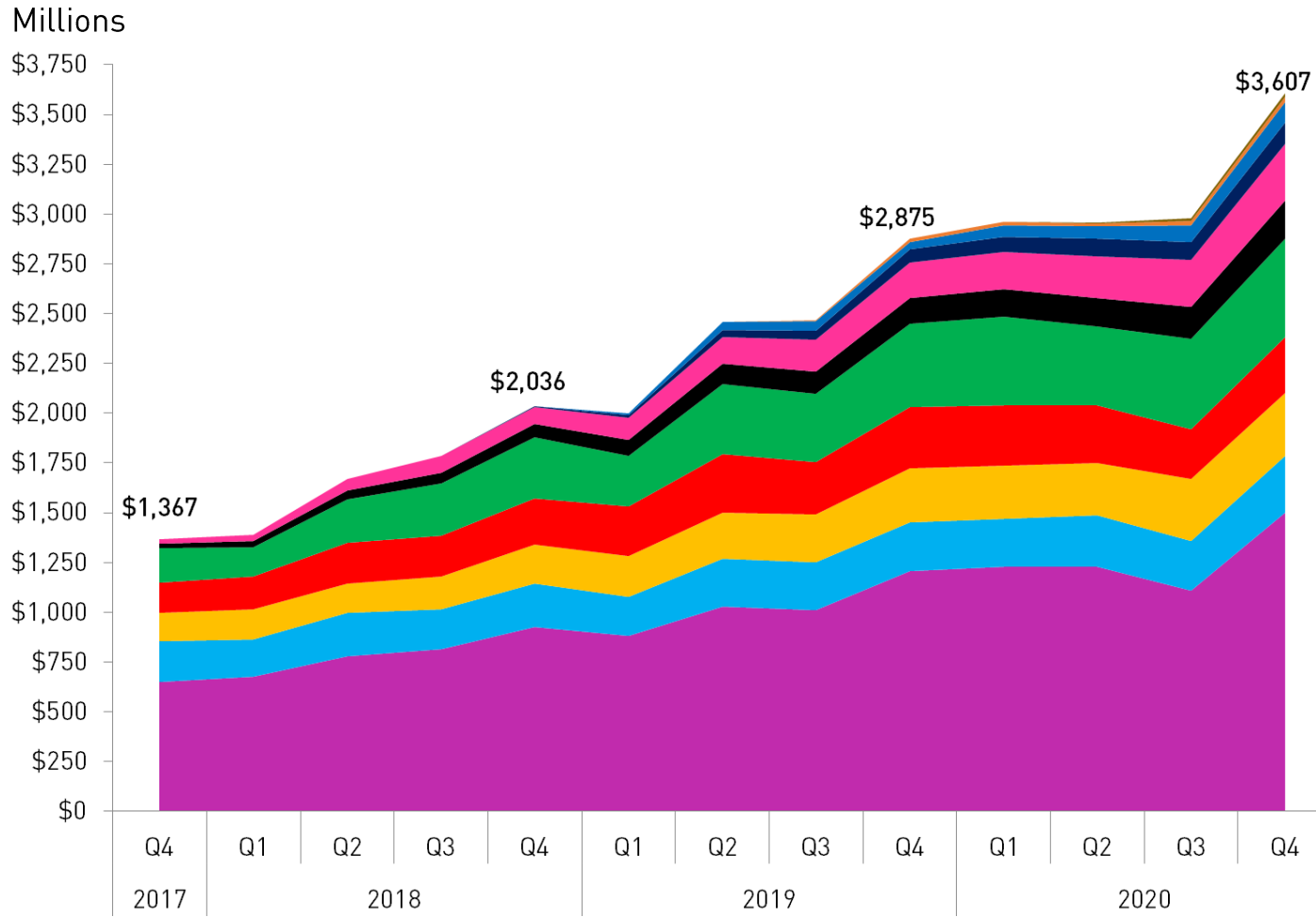
# KEY PRODUCTS DRIVING WW VOLUME GROWTH



## Contribution to 24% Q4 WW Volume Growth



# UPDATE ON KEY GROWTH PRODUCTS



- 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 Q4 2020
- TYVYT**
  - Added to China's National Drug Reimbursement List in 2020
- EMGALITY**
  - U.S. TRx SOM increased by 10pp YTD vs. 2019
  - U.S. NBRx SOM 38% at the end of Q4 2020
- VERZENIO**
  - U.S. NBRx SOM nearly 27% at end of Q4 2020
  - U.S. TRx grew nearly 66% vs. Q4 2019, outpacing market growth
- OLUMIANT**
  - OUS sales grew 46% vs. Q4 2019
- TALTZ**
  - IL-17 class grew nearly 10% vs. Q4 2019 for U.S. TRx in dermatology
  - Total molecule U.S. TRx grew nearly 23% vs. Q4 2019
- BASAGLAR**
  - U.S. TRx nearly 19% SOM at end of Q4 2020
- JARDIANCE**
  - Market leader in U.S. TRx SOM 59% and NTS SOM nearly 65%
  - U.S. SGLT2 class grew nearly 19% vs. Q4 2019
- CYRAMZA**
  - U.S. sales growth +19% vs. Q4 2019
- TRULICITY**
  - U.S. TRx leader with nearly 45% SOM
  - U.S. GLP-1 class grew 22% vs. Q4 2019

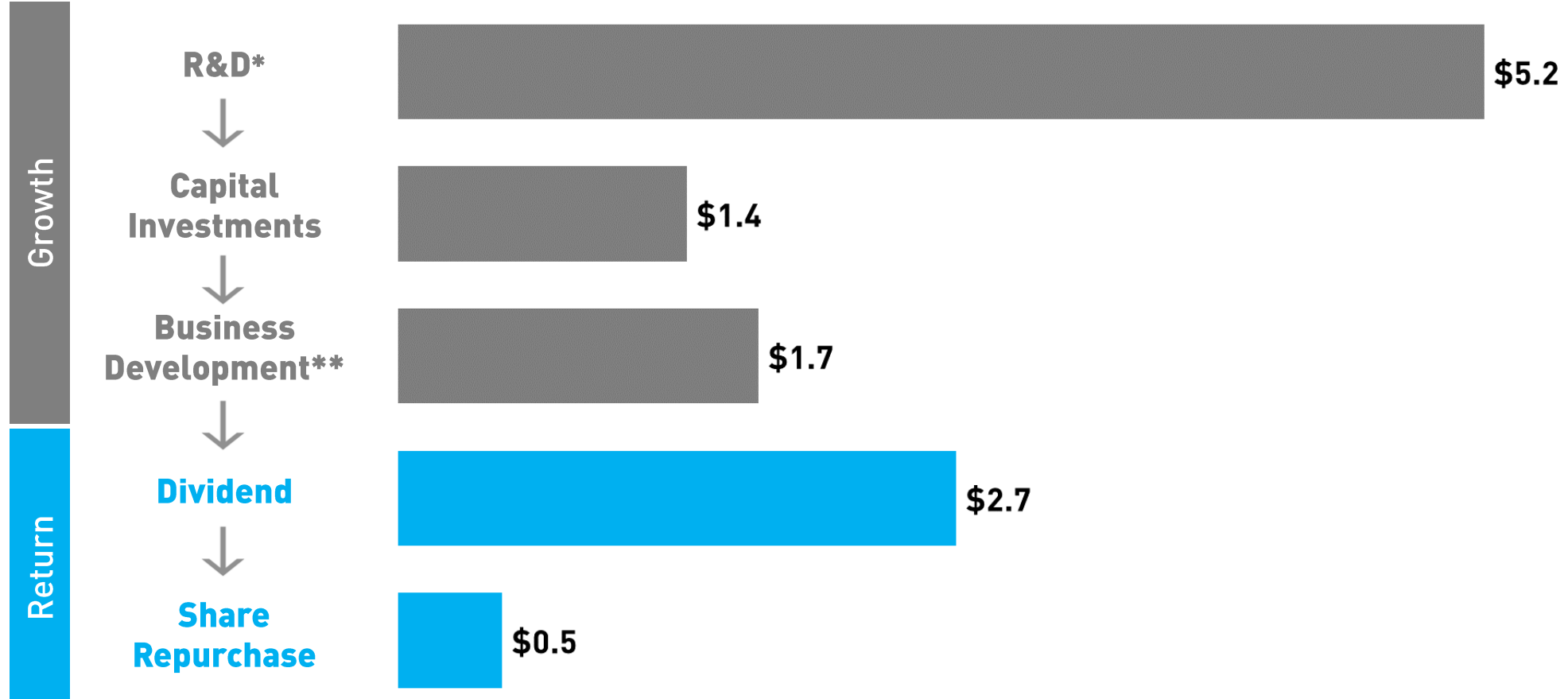
Note: Jardiance is sold by Boehringer Ingelheim; Lilly records as revenue its share of Jardiance gross margin. Jardiance and Basaglar are part of the Boehringer Ingelheim and Lilly Diabetes Alliance.

# CAPITAL ALLOCATION



Billions

## YTD 2020 Capital Allocation



\*After-tax (non-GAAP)

\*\*Includes equity investments, cash inflows from sale of product rights and debt repayment associated with business development

# 2021 GUIDANCE



	Prior	Updated	Comments
<b>TOTAL REVENUE</b>	\$26.5 – \$28.0 billion	unchanged	
<b>GROSS MARGIN % (GAAP)</b>	approx. 77%	unchanged	
<b>GROSS MARGIN % (NON-GAAP)</b>	approx. 79%	unchanged	
<b>MKTG, SELLING &amp; ADMIN.</b>	\$6.2 – \$6.4 billion	unchanged	
<b>RESEARCH &amp; DEVELOPMENT</b>	\$6.5 – \$6.7 billion	unchanged	Includes \$300-400M of investment in COVID-19 therapies
<b>OTHER INCOME/(EXPENSE)</b>	\$(300) – \$(200) million	unchanged	
<b>TAX RATE</b>	approx. 15%	unchanged	
<b>EARNINGS PER SHARE (GAAP)</b>	\$7.25 – \$7.90	\$7.10 – \$7.75	Reflects an increase in acquired IPR&D related to business development transactions
<b>EARNINGS PER SHARE (NON-GAAP)</b>	\$7.75 – \$8.40	unchanged	
<b>OPERATING INCOME % (GAAP)</b>	approx. 30%	unchanged	
<b>OPERATING INCOME % (NON-GAAP)</b>	approx. 32%	unchanged	

Assumes GAAP and non-GAAP shares outstanding 906 million

Updated FX assumptions of 1.17 (Euro), 106 (Yen) and 6.82 (Renminbi)

# DONANEMAB – TRAILBLAZER-ALZ

POSITIVE PHASE 2 RESULTS FOR A POTENTIAL TREATMENT FOR ALZHEIMER'S DISEASE



## KEY TAKEAWAYS

- Met the primary endpoint of change from baseline to 76 weeks in iADRS<sup>1</sup>, slowing decline by 32% relative to placebo
- Consistent improvements observed on all prespecified secondary endpoints for cognition and function
- Rapid and deep plaque clearance seen on patients treated with donanemab
- Safety profile was consistent with observations from Phase 1

<sup>1</sup>Integrated Alzheimer's Disease Rating Scale (iADRS) is a clinical composite tool combining the cognitive measure ADAS-Cog13 and functional measure ADCS-iADL, two commonly-used measures in Alzheimer's disease

<sup>2</sup>AD/PD = Alzheimer's & Parkinson's Diseases Conference

## NEXT STEPS

- Full results to be shared on March 13<sup>th</sup> at AD/PD<sup>2</sup>
- Plan to discuss study results and next steps with regulators
- TRAILBLAZER-ALZ 2 ongoing
  - 18-month study
  - Plan to enroll at least twice the number of patients as TRAILBLAZER-ALZ
  - Enrollment expected to complete by end of 2021
  - Readout projected for 2023

# COVID-19 ANTIBODY CLINICAL PROGRAM



## AMBULATORY (RECENTLY DIAGNOSED)

### BLAZE-1

- Bamlanivimab alone and together with etesevimab
- Phase 3 showed a 70% reduction in hospitalization or death in high-risk patients for bamlanivimab + etesevimab
- Bamlanivimab alone (700mg) authorized for emergency use
- Submitted request for EUA for bamlanivimab and etesevimab together (700/1400mg)
- 2,400+ patients enrolled

### BLAZE-4

- Evaluating lower doses of bamlanivimab alone and together with etesevimab
- Initial results show comparable effects on viral load and symptoms with lower doses
- Expanded to evaluate bamlanivimab together with VIR-7831
- 700+ patients enrolled



## POST-EXPOSURE PROPHYLAXIS

### BLAZE-2

- Bamlanivimab alone (4200mg)
- Prevented symptomatic COVID-19 infection, reduced risk by up to 80% for nursing home residents
- 1,250+ patients enrolled; residents and staff of long-term care facilities
- Plan to pursue expanded EUA

**Over 4,000 trial participants dosed with bamlanivimab (alone or together with another neutralizing antibody)**

# LILLY SELECT NME AND NILEX PIPELINE

JANUARY 26, 2021



KHK INHIBITOR II Diabetes / NASH	PYY ANALOG Diabetes
IL-17A SMALL MOL INHIBITOR Immunology	ANGPTL3 siRNA CVD
GIPR AGONIST LA Diabetes	GIP/GLP COAGONIST PEPTIDE II Diabetes
PR001 Gene Therapy Parkinson's Disease	PR006 Gene Therapy Frontotemporal Dementia
IDH1 INHIBITOR Cancer	LP(a) INHIBITOR CVD
ANGPTL3/8 MAB CVD	CD73 INHIBITOR Cancer
GLP-1R NPA Diabetes	NRG4 AGONIST Heart Failure
GGG TRI-AGONIST Diabetes	CD200R MAB AGONIST Immunology
O-GLCNACASE INH Alzheimer's	KHK INHIBITOR Diabetes / NASH
N3PG Aβ MAB Alzheimer's	TRPA1 ANTAGONIST Pain
PD-1 MAB AGONIST Immunology	GIP/GLP COAGONIST PEPTIDE Diabetes
BTLA MAB AGONIST Immunology	SERD Cancer
AUR A KINASE INHIBITOR Cancer	OXYNTOMODULIN Diabetes

**PHASE 1**

CDK7 INHIBITOR Cancer	TAU MORPHOMER Alzheimer's
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ABEMACICLIB Prostate Cancer	
TIRZEPATIDE NASH	SSTR4 AGONIST Pain
PACAP38 MAB Migraine	IL-2 CONJUGATE Systemic Lupus Erythematosus
EPIREG/TGFα MAB Chronic Pain	BTK INHIBITOR (LOXO-305) B-Cell Malignancies
CXCR1/2L MAB Hidradenitis Suppurativa	AUTOMATED INSULIN DELIVERY SYS Diabetes
BASAL INSULIN-FC Diabetes	MEVIDALEN (D1 PAM) Symptomatic LBD
ZAGOTENEMAB (TAU MAB) Alzheimer's	DONANEMAB (N3PG Aβ MAB) Alzheimer's

**PHASE 2**

EMPAGLIFLOZIN* Post MI	TANEZUMAB* Cancer Pain
SELPERCATINIB 1L Med Thyroid Cancer	SELPERCATINIB 1L NSCLC
TIRZEPATIDE Obesity	TIRZEPATIDE CV Outcomes
BARICITINIB Systemic Lupus Erythematosus	BARICITINIB Alopecia Areata
MIRIKIZUMAB Crohn's Disease	MIRIKIZUMAB Ulcerative Colitis
EMPAGLIFLOZIN* Heart Failure pEF	EMPAGLIFLOZIN* Chronic Kidney Disease
BAMLANIVIMAB^ (LY-CoV555) COVID-19	ETESEVIMAB^ (LY-CoV016) COVID-19
TIRZEPATIDE Diabetes	LEBRIKIZUMAB Atopic Dermatitis
SOLANEZUMAB Preclinical AD	MIRIKIZUMAB Psoriasis

**PHASE 3**

BARICITINIB^ COVID-19
ABEMACICLIB Adjuvant Breast Cancer
EMPAGLIFLOZIN* Heart Failure rEF
CONNECTED CARE PREFILLED INSULIN PEN Diabetes
TANEZUMAB* Osteoarthritis Pain

**LEGEND**

● NME	<b>MOVEMENT SINCE October 20, 2020</b>
● NILEX	
* Commercial Collaboration	📌 ACHIEVED MILESTONE
+ In combination with bamlanivimab	⬇️ REMOVAL
^ Emergency Use Authorization has been granted	

**REG REVIEW**

**APPROVED**



# RECAP OF KEY EVENTS 2020

  New since last update



## Phase 3 Initiations

- ✓+ **Tirzepatide** CV outcome study (H2H vs. dulaglutide)
- ✓+ **Lebrikizumab** for atopic dermatitis (Dermira acquisition)
- ✓+ **Selpercatinib** for 1L NSCLC<sup>3</sup>
- ✓+ **Selpercatinib** for 1L medullary thyroid cancer<sup>3</sup>
- ✓+ **Bamlanivimab** for post-exposure COVID-19 prophylaxis

## Phase 3 Top-Line Data Disclosures

- ✓+ **Empagliflozin** for HFrEF<sup>1</sup>
- ✓+ **Tirzepatide** for type 2 diabetes (first of five)
- ✓+ **Baricitinib** for atopic dermatitis (last two of five studies)
- ✓+ **Mirikizumab** for psoriasis (OASIS-1 & -2)
- ✓+ **Mirikizumab** for ulcerative colitis (induction data) – (now expected 2021)
- ✓- **Solanezumab** for dominantly inherited Alzheimer's
- ✓+ **Abemaciclib** for high-risk HR+, HER2- early breast cancer
- ✓+ **Baricitinib** for hospitalized COVID-19 patients

## 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** for HFrEF<sup>1</sup>

Not for promotional use

## Regulatory Submissions

- ✓+ **Baricitinib** for atopic dermatitis (US ✓+ /EU ✓+ /J ✓+)
- ✓+ **Tanezumab** osteoarthritis pain (US<sup>2</sup> ✓+ /EU ✓+)
- ✓+ **Selpercatinib** for NSCLC and thyroid cancers (EU ✓+ /J ✓+)<sup>3</sup>
- ✓+ **Abemaciclib** for high-risk HR+, HER2- early breast cancer (US ✓+ /EU ✓+)
- ✓+ **Empagliflozin** for HFrEF (US ✓+ /EU ✓+ /J ✓+)<sup>1</sup>

## 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)<sup>1</sup>
- ✓+ **Ultra rapid lispro** for type 1 and type 2 diabetes (US ✓+ /EU ✓+ /J ✓+)
- ✓+ **Flortaucipir** as a PET imaging agent (US)
- ✓- **Galcanzumab** for episodic cluster headache (EU)
- ✓+ **Ixekizumab** for non-radiographic axial spondyloarthritis (US ✓+ /EU ✓+ /J ✓+)
- ✓+ **Ixekizumab** for radiographic axial spondyloarthritis (EU)
- ✓+ **Ramucirumab** for 1L EGFR NSCLC cancer (US ✓+ /EU ✓+ /J ✓+)
- ✓+ **Selpercatinib** for NSCLC and thyroid cancers (US)
- ✓+ **Baricitinib** for atopic dermatitis (EU)
- ✓+ **Bamlanivimab** EUA for mild to moderate COVID-19 in high-risk patients
- ✓+ **Baricitinib** EUA for hospitalized COVID-19 in combination with remdesivir

2020 Q4 EARNINGS

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

<sup>2</sup> in collaboration with Pfizer

<sup>3</sup> US submission occurred in Q4 2019; Japan submission for NSCLC in Q4 2020

# POTENTIAL KEY EVENTS 2021

New since last update



## Phase 3 Initiations

**Abemaciclib** for HR+, HER2+ early breast cancer

**LOXO-305** for MCL monotherapy

**LOXO-305** for CLL monotherapy

**LOXO-305** for CLL combination therapy

**LOXO-305** for CLL first-line

**Tirzepatide** for obesity (3 additional studies)

**Tirzepatide** for HFpEF

## Phase 3 & Other Key Data Disclosures

**Baricitinib** for alopecia areata

**Baricitinib** for systemic lupus erythematosus

**Donanemab** for early Alzheimer's disease

**Empagliflozin** for HFpEF<sup>1</sup>

**Lebrikizumab** for atopic dermatitis

**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

Not for promotional use

## 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)

**Bamlanivimab + Etesevimab** for COVID-19 (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/J)

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

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

<sup>2</sup> in collaboration with Pfizer

<sup>3</sup> Japan approval occurred in Q4 2020

# 2020 SUMMARY



- **Volume-driven revenue growth** of 10%, with key growth products launched since 2014 comprising the majority of annual revenue for the first time
- Operating income as a % of revenue **improved ~300 bps** vs. YTD 2019 on a non-GAAP basis, excluding COVID-19 therapies
- Progress on our **innovation-based strategy**, including positive data readouts for LOXO-305, tirzepatide and Verzenio monarchE, as well as EUA authorizations for bamlanivimab and baricitinib for COVID-19
- Deployed \$2.7 billion to shareholders via the dividend and completed \$0.5 billion of share repurchases

## Grow Revenue



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

## Improve Productivity



Non-GAAP operating margin % of revenue goal of ~31% in 2020 achieved excluding impact of COVID-19

## 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

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# 2020 INCOME STATEMENT – REPORTED



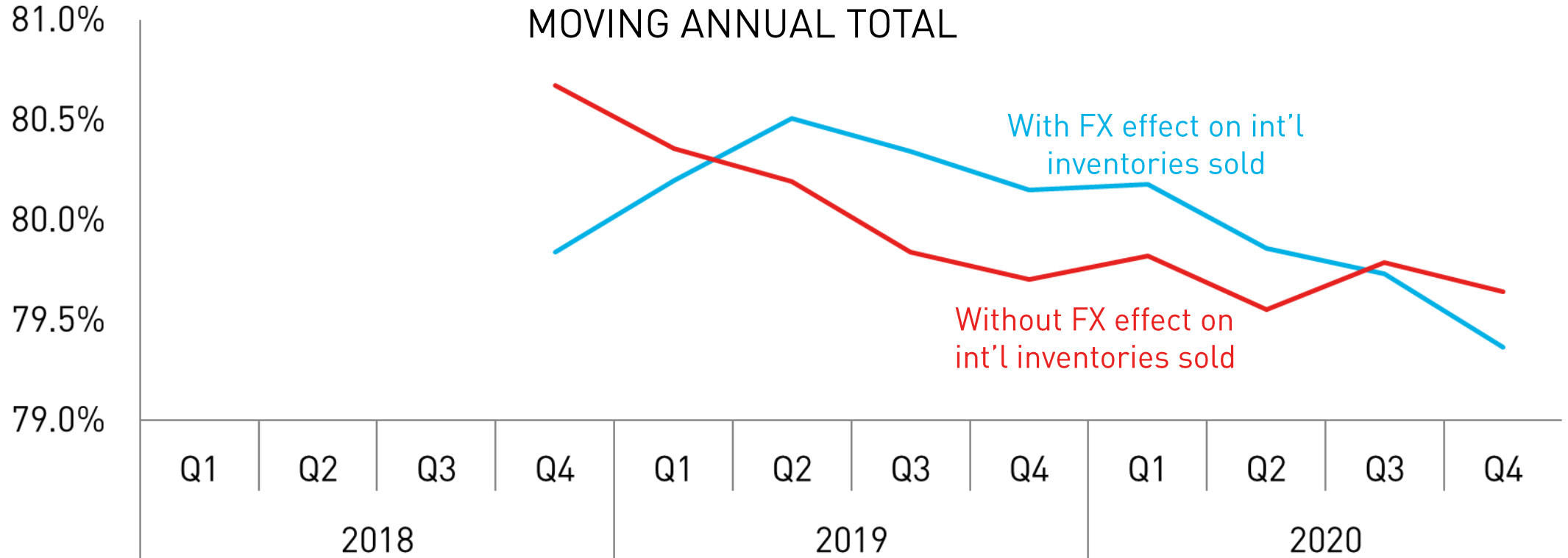
Millions; except per share data

	<b>Q4 2020</b>	<b>Change</b>	<b>YTD 2020</b>	<b>Change</b>
<b>TOTAL REVENUE</b>	\$7,440	22%	\$24,540	10%
<b>GROSS MARGIN</b>	76.9%	(2.1pp)	77.7%	(1.1pp)
<b>TOTAL OPERATING EXPENSE*</b>	3,728	9%	12,999	3%
<b>OPERATING INCOME</b>	1,992	42%	6,058	22%
<b>OPERATING MARGIN</b>	26.8%	3.9pp	24.7%	2.4pp
<b>OTHER INCOME (EXPENSE)</b>	477	81%	1,172	NM
<b>EFFECTIVE TAX RATE</b>	14.3%	4.2pp	14.3%	2.4pp
<b>NET INCOME - CONTINUING OPERATIONS</b>	\$2,117	42%	\$6,194	34%
<b>EARNINGS PER SHARE</b>	<b>\$2.32</b>	<b>41%</b>	<b>\$6.79</b>	<b>37%</b>

\* 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

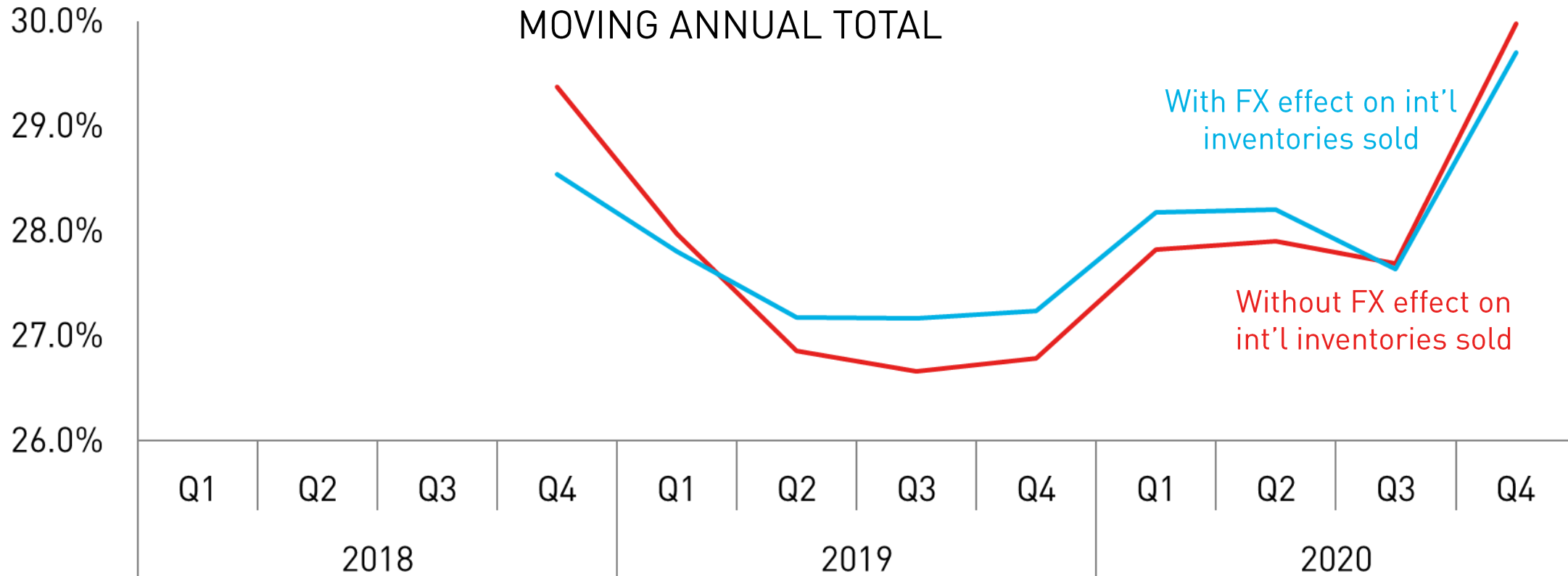


**Individual quarter GM % of Revenue:**

	2018 Q4	2019 Q1	2019 Q2	2019 Q3	2019 Q4	2020 Q1	2020 Q2	2020 Q3	2020 Q4
with FX effect on int'l inv sold	78.6%	80.2%	81.0%	79.6%	79.9%	80.3%	79.6%	79.1%	78.6%
w/o FX effect on int'l inv sold	81.5%	80.2%	80.2%	78.9%	79.6%	80.6%	79.1%	79.9%	79.1%

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



**Individual quarter Op. Margin % of Revenue:**

with FX effect on int'l inv sold	29.3%	30.4%	28.7%	25.9%	26.2%	27.9%	28.6%	26.3%	30.1%	28.0%	26.2%	33.0%
w/o FX effect on int'l inv sold	32.2%	31.5%	28.7%	25.4%	26.2%	27.2%	27.9%	25.9%	30.4%	27.5%	27.0%	33.5%

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

REPORTED	Q4 2020		YTD 2020	
	With FX	w/o FX	With FX	w/o FX
<b>TOTAL REVENUE</b>	22%	20%	10%	10%
<b>COST OF SALES</b>	34%	28%	16%	13%
<b>GROSS MARGIN</b>	18%	18%	8%	9%
<b>OPERATING EXPENSE</b>	9%	8%	3%	3%
<b>OPERATING INCOME</b>	42%	44%	22%	24%
<b>EARNINGS PER SHARE</b>	41%	43%	37%	40%
<b>NON-GAAP</b>	<b>With FX</b>	<b>w/o FX</b>	<b>With FX</b>	<b>w/o FX</b>
<b>TOTAL REVENUE</b>	22%	20%	10%	10%
<b>COST OF SALES</b>	30%	23%	14%	11%
<b>GROSS MARGIN</b>	20%	20%	9%	10%
<b>OPERATING EXPENSE</b>	3%	3%	3%	3%
<b>OPERATING INCOME</b>	53%	54%	20%	22%
<b>EARNINGS PER SHARE</b>	59%	60%	31%	34%



# EPS RECONCILIATION



	<b>Q4 2020</b>	<b>Q4 2019</b>	<b>Change</b>	<b>YTD 2020</b>	<b>YTD 2019</b>	<b>Change</b>
<b>EPS (REPORTED)</b>	<b>\$2.32</b>	<b>\$1.64</b>	<b>41%</b>	<b>\$6.79</b>	<b>\$8.89</b>	<b>(24)%</b>
<b>DISCONTINUED OPERATIONS</b>					(3.93)	
<b>ACQUIRED IN-PROCESS RESEARCH AND DEVELOPMENT</b>	0.35			0.64	0.21	
<b>AMORTIZATION OF INTANGIBLE ASSETS</b>	0.11	0.05		0.36	0.18	
<b>ASSET IMPAIRMENT, RESTRUCTURING, AND OTHER SPECIAL CHARGES</b>	(0.03)	0.14		0.14	0.58	
<b>LARTRUVO CHARGES</b>					0.14	
<b>REDUCED SHARES OUTSTANDING</b>					0.07	
<b>TAX</b>		(0.05)			(0.05)	
<b>GAIN ON SALE OF CHINA ANTIBIOTICS BUSINESS</b>		(0.26)			(0.26)	
<b>CHARGE RELATED TO REPURCHASE OF DEBT</b>		0.22			0.22	
<b>EPS (NON-GAAP)</b>	<b>\$2.75</b>	<b>\$1.73</b>	<b>59%</b>	<b>\$7.93</b>	<b>\$6.04</b>	<b>31%</b>

Note: Numbers may not add due to rounding.

Not for promotional use

# Q4 2020 INCOME STATEMENT NOTES



## Q4 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 \$127.3 million (pretax), or \$0.11 per share (after-tax);
- acquired in-process R&D charges totaling \$366.3 million (pretax), or \$0.35 per share (after-tax), related to business development transactions with Innovent Biologics, Inc., Disarm Therapeutics, and Fochon Pharmaceuticals, Ltd.; and
- other specified items, primarily adjustments to prior period estimates for asset impairment and severance costs, totaling \$30.1 million (pre-tax), or \$0.03 per share (after-tax).

## Q4 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 \$53.2 million (pretax), or \$0.05 per share (after-tax);
- asset impairment, restructuring and other special charges related to our decision to close and sell a research and development facility located in the United Kingdom, as well as severance costs incurred as a result of actions taken to reduce the company's cost structure, totaling \$151.7 million (pretax), or \$0.14 per share (after-tax);
- other income (expense) exclude the gain on sale of the company's antibiotics business in China as well as net charges related to the repurchase of debt, totaling \$57.3 million (pretax), or \$0.04 per share (after-tax); and
- adjustments to tax expenses associated with the tax benefit from a capital loss on the disposition of subsidiary stock totaling \$42.0 million, or \$0.05 per share (after-tax).

# 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 \$411.0 million (pretax), or \$0.36 per share (after-tax);
- acquired in-process R&D charges totaling \$660.4 million (pretax), or \$0.64 per share (after-tax), related to both a business development transaction with a pre-clinical stage company as well as business development transactions with Sitryx, AbCellera Biologics Inc., Evox Therapeutics, Junshi Biosciences, Innovent Biologics, Inc., Disarm Therapeutics, and Fochon Pharmaceuticals, Ltd.; and
- asset impairment, restructuring and other special charges, primarily severance costs incurred as a result of actions taken worldwide to reduce the company's cost structure, as well as acquisition and integration costs incurred as part of the closing of the acquisition of Dermira, totaling \$131.2 million (pretax), or \$0.14 per share (after-tax).

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

- amortization of intangibles primarily associated with costs of marketed products acquired or licensed from third parties totaling \$205.0 million (pretax), or \$0.18 per share (after-tax);
- costs associated with upfront payments for acquired in-process research and development projects acquired in a transaction other than a business combination, primarily related to business development activity with AC Immune, ImmuNext, Inc., Avidity Biosciences, Inc., and Centrexion Therapeutics Corporation, totaling \$239.6 million (pretax), or \$0.21 per share (after-tax);
- charges primarily associated with the accelerated vesting of Loxo Oncology employee equity awards following the acquisition of Loxo Oncology, totaling \$563.5 million (pretax), or \$0.58 per share (after-tax);
- other income (expense) exclude the gain on the sale of the company's antibiotics business in China as well as net charges related to the repurchase of debt, totaling \$57.3 million (pretax), or \$0.04 per share (after-tax);
- the assumption that the disposition of Elanco occurred at the beginning of all periods presented and therefore includes the benefit from the reduction in shares of common stock outstanding totaling \$0.07 per share;
- charges related to the suspension of promotion of Lartruvo totaling \$96.7 million (pretax), or \$0.14 per share (after-tax);
- adjustments to tax expenses associated with the tax benefit from a capital loss on the disposition of subsidiary stock totaling \$42.0 million (pretax), or \$0.05 per share (after-tax); and
- discontinued operations of the Elanco Animal Health business totaling \$3.681 billion (pretax), or \$3.93 per share (after-tax).

# COMPARATIVE EPS SUMMARY 2019/2020



	<b>1Q19</b>	<b>2Q19</b>	<b>3Q19</b>	<b>4Q19</b>	<b>2019</b>	<b>1Q20</b>	<b>2Q20</b>	<b>3Q20</b>	<b>4Q20</b>	<b>2020</b>
Reported	4.31	1.44	1.37	1.64	8.89	1.60	1.55	1.33	2.32	6.79
Non-GAAP	1.33	1.50	1.48	1.73	6.04	1.75	1.89	1.54	2.75	7.93

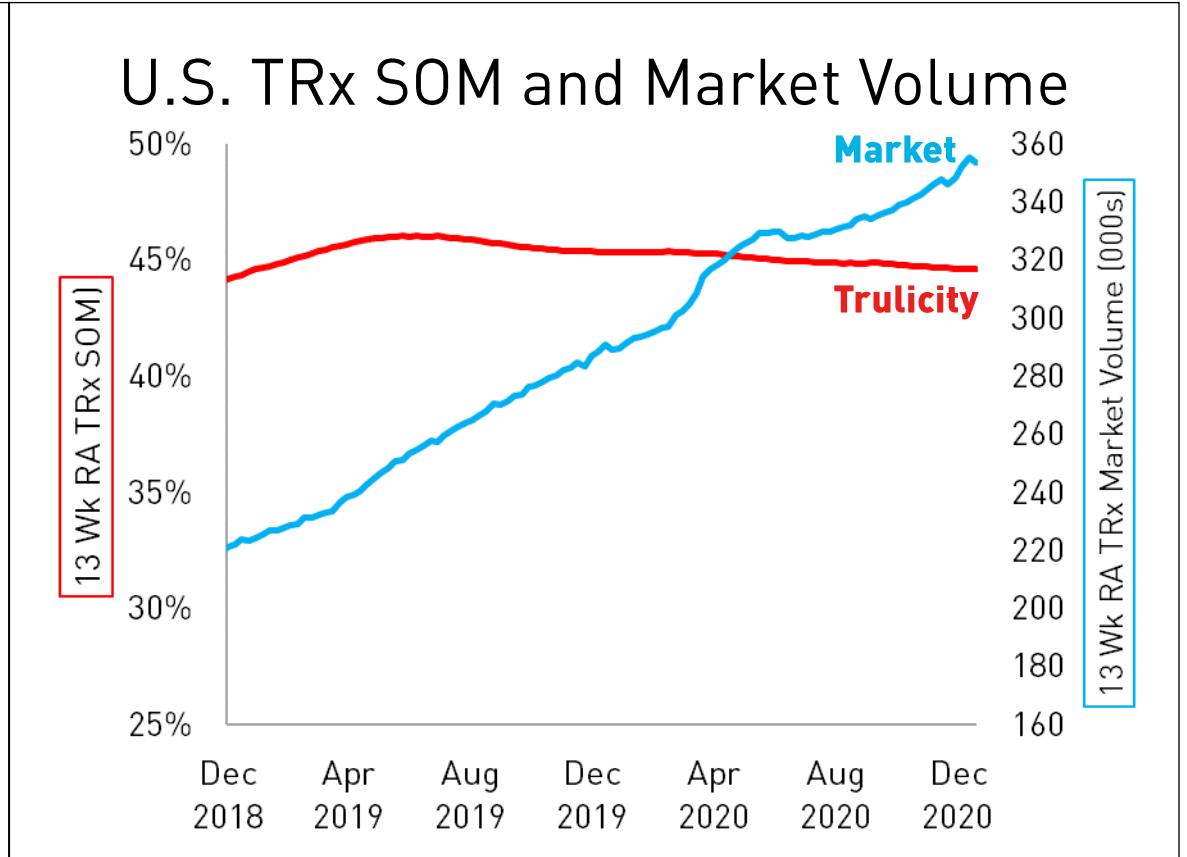
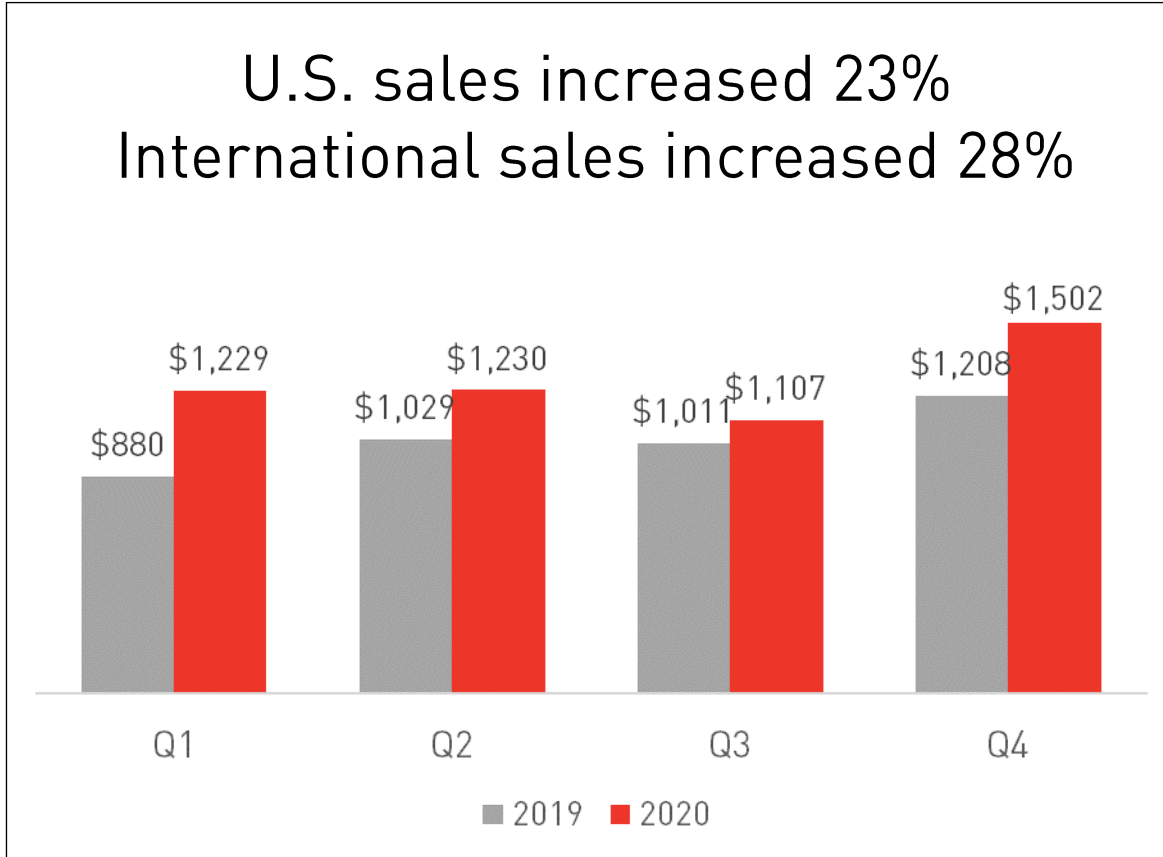
Note: Numbers may not add due to rounding.

For a complete reconciliation to reported earnings, see slide 25 and our earnings press release dated January 29, 2021

# Q4 2020 TRULICITY SALES INCREASED 24%



Millions



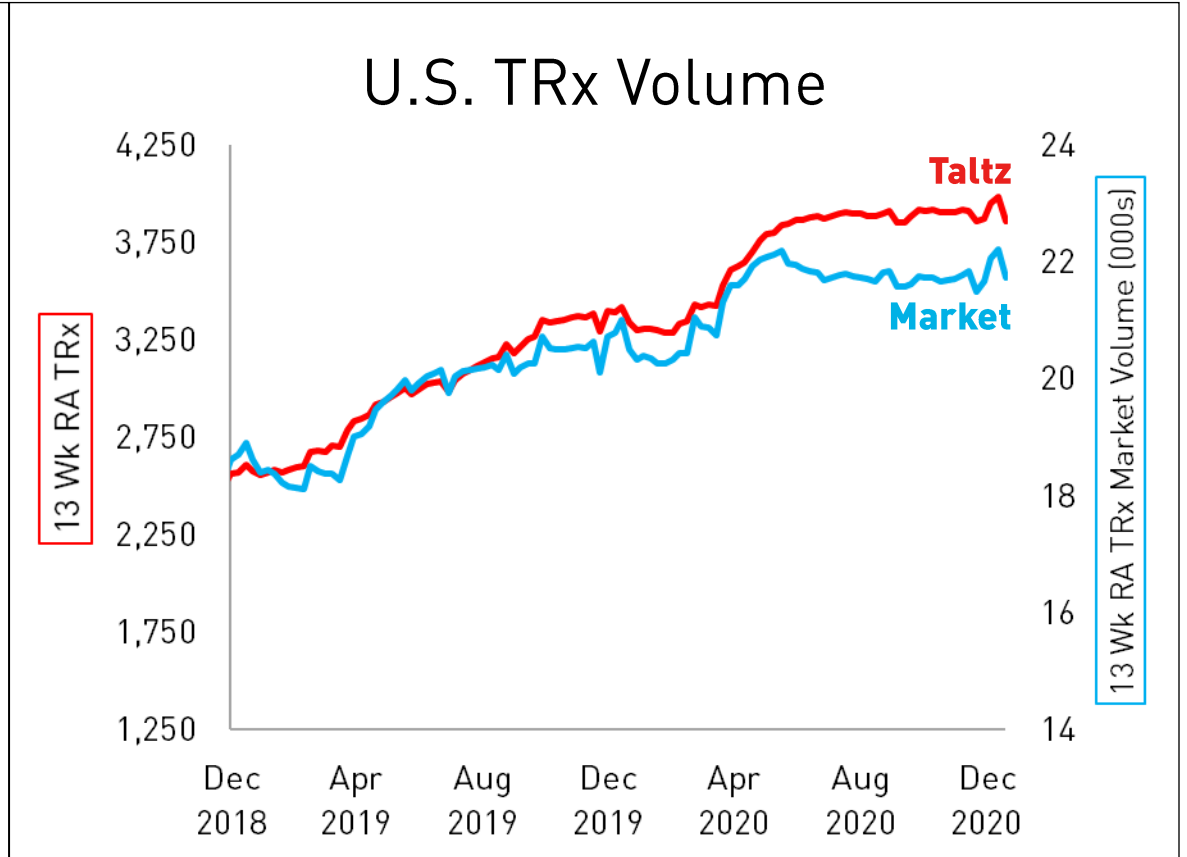
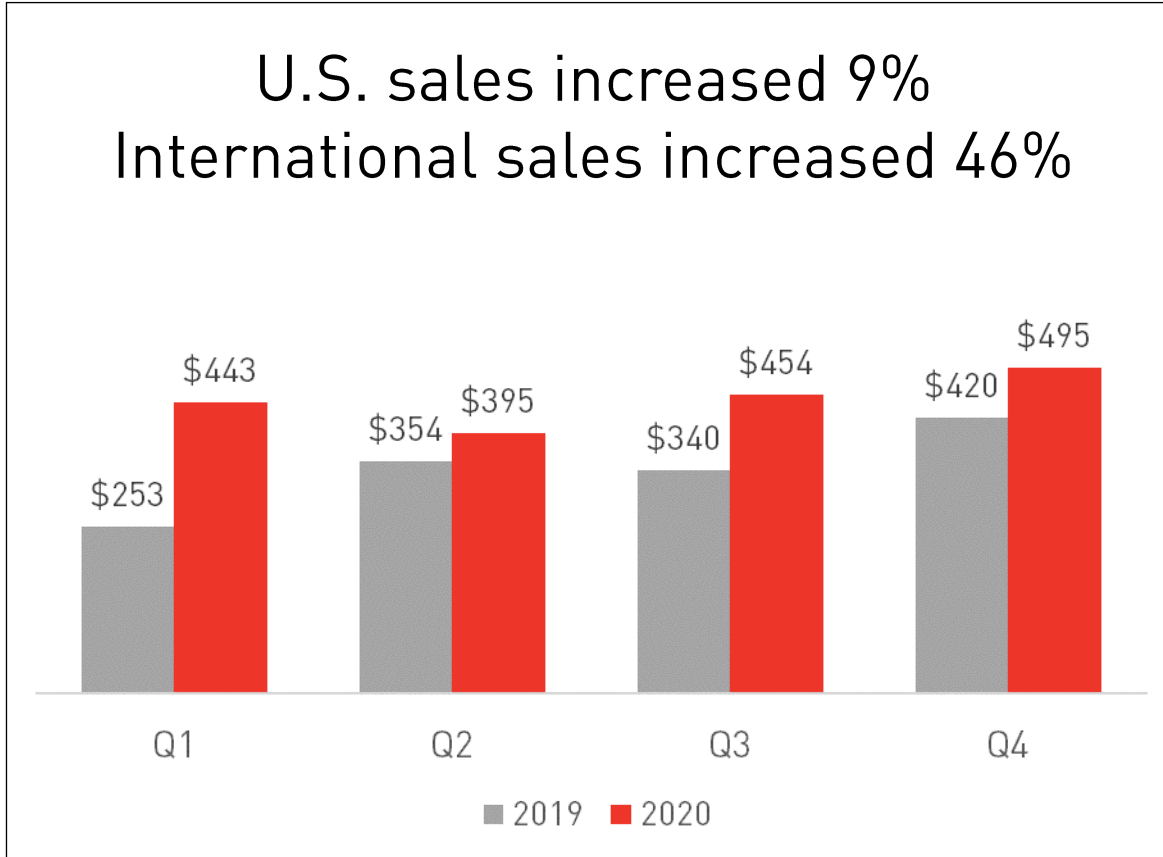
Note: Numbers may not add due to rounding.

Source: IQVIA NPA TRx 3MMA, weekly data December 25, 2020

# Q4 2020 TALTZ SALES INCREASED 18%



Millions



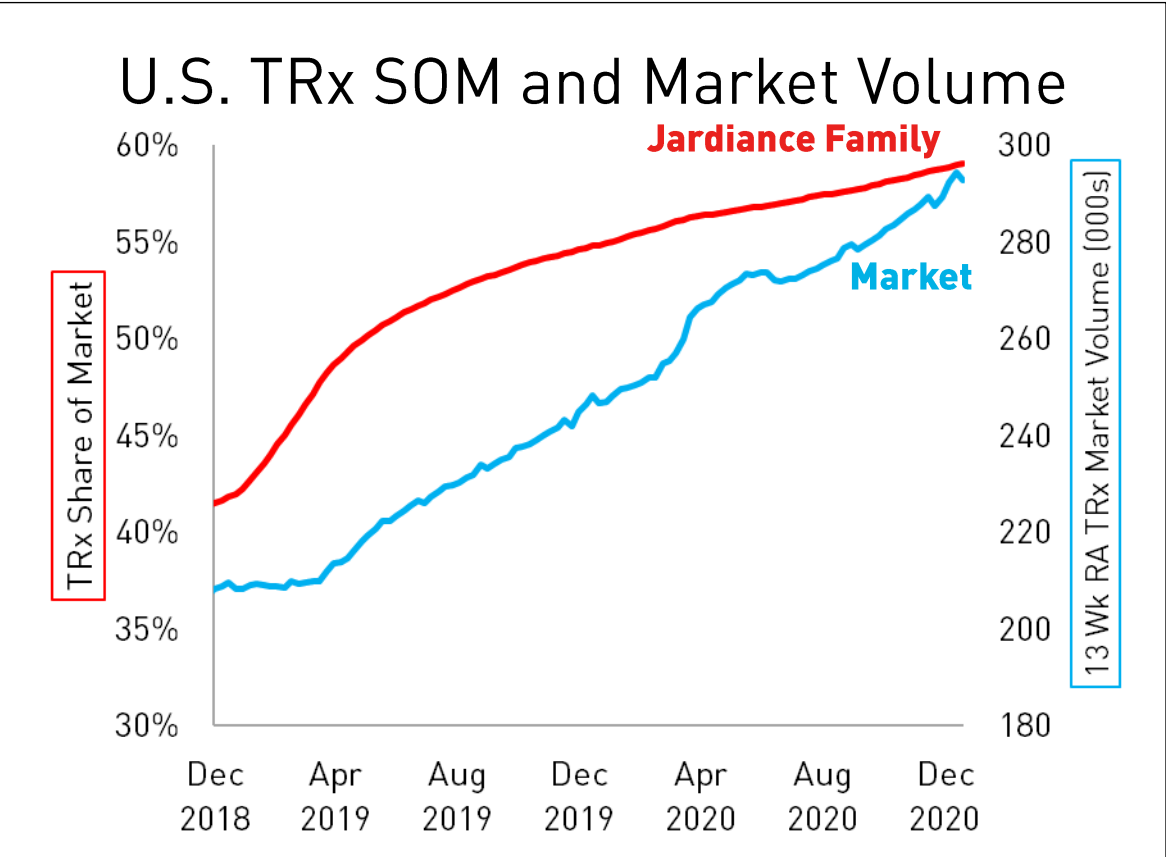
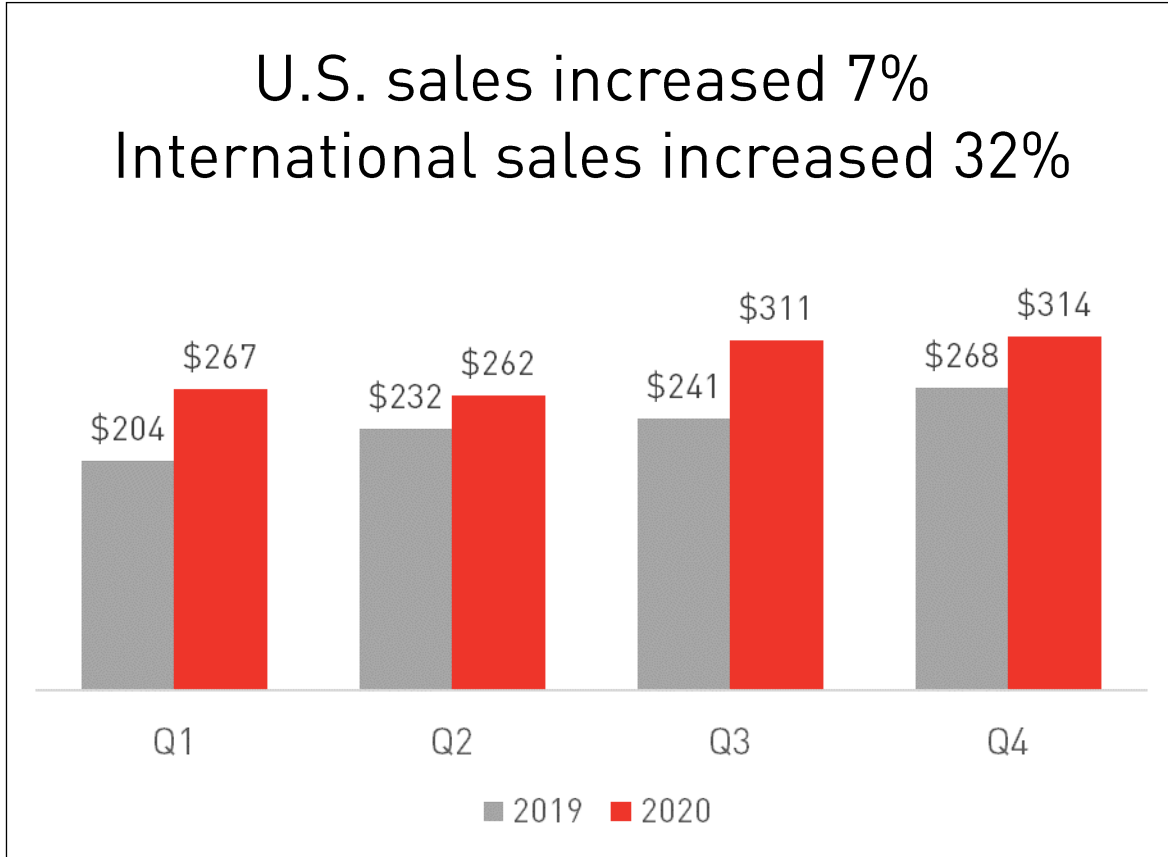
Note: Numbers may not add due to rounding.

Source: IQVIA NPA TRx 3MMA, weekly data December 25, 2020  
Note: TRx data is representative of the dermatology market

# Q4 2020 JARDIANCE SALES INCREASED 17%



Millions



Note: Numbers may not add due to rounding.

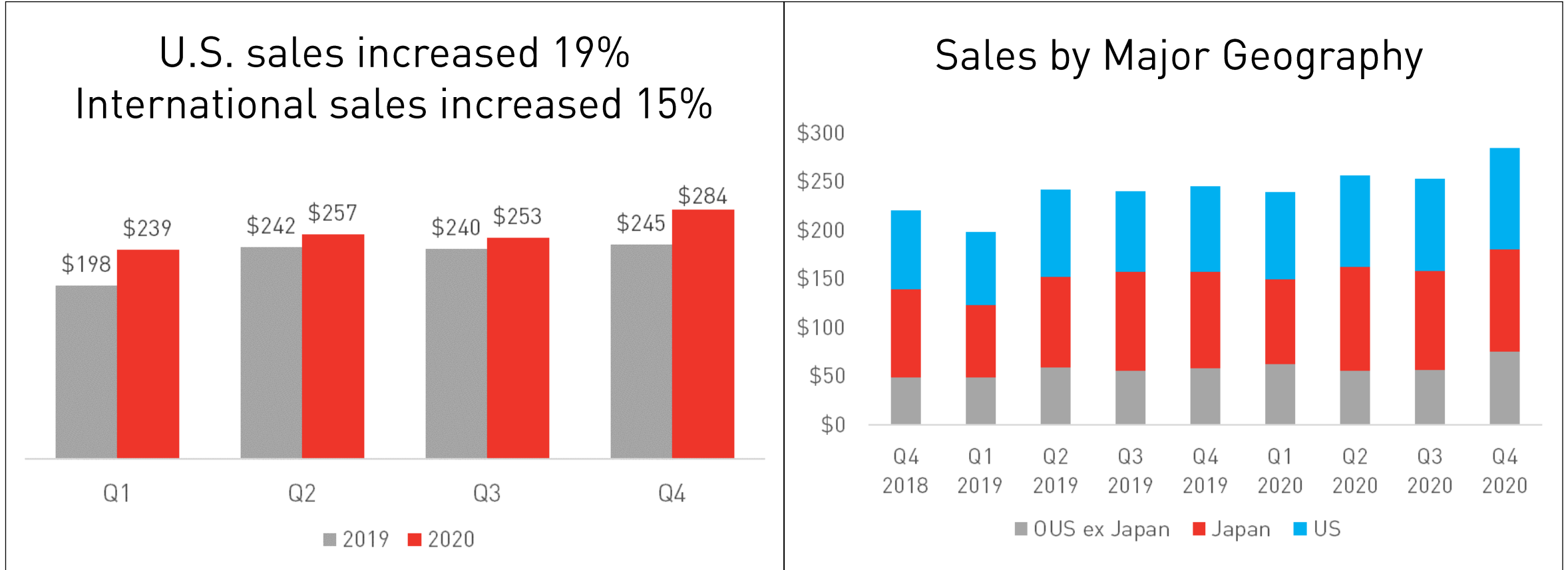
Source: IQVIA NPA TRx 3MMA, weekly data December 25, 2020

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

# Q4 2020 CYRAMZA SALES INCREASED 16%



Millions



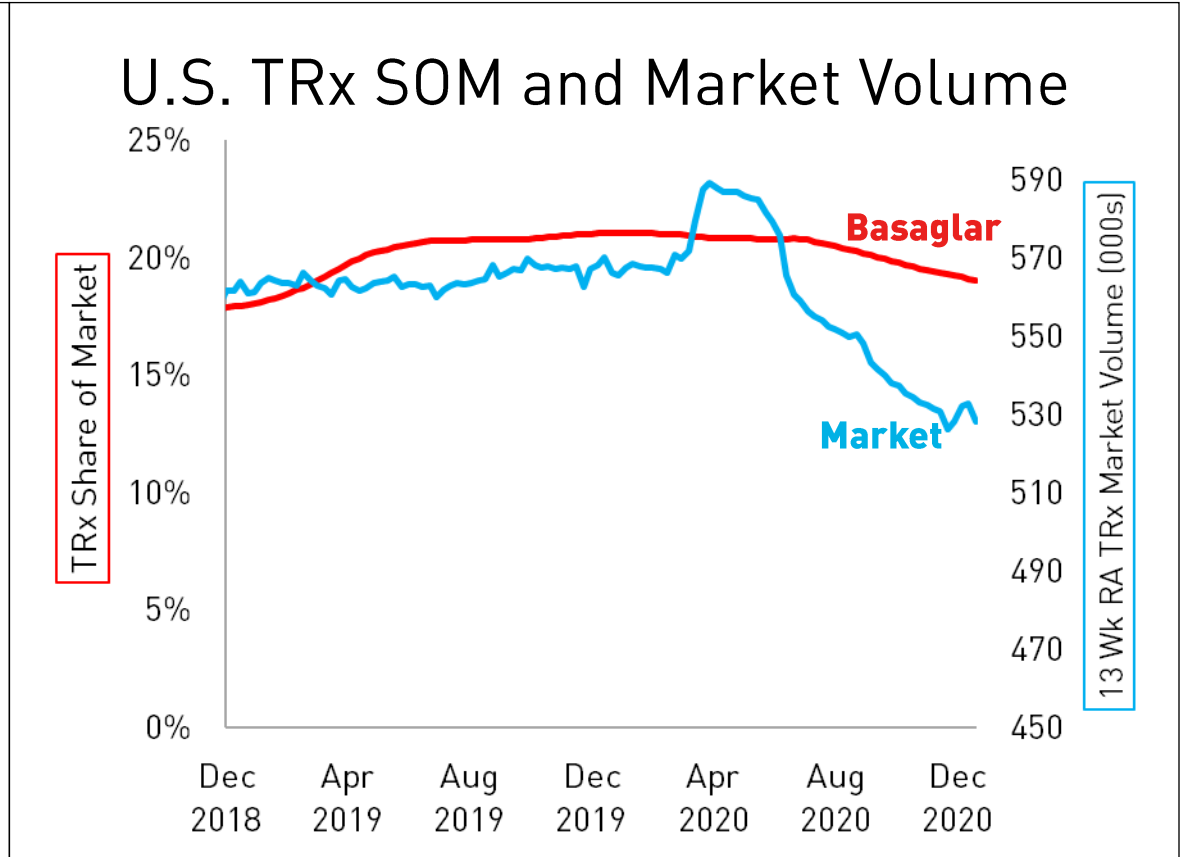
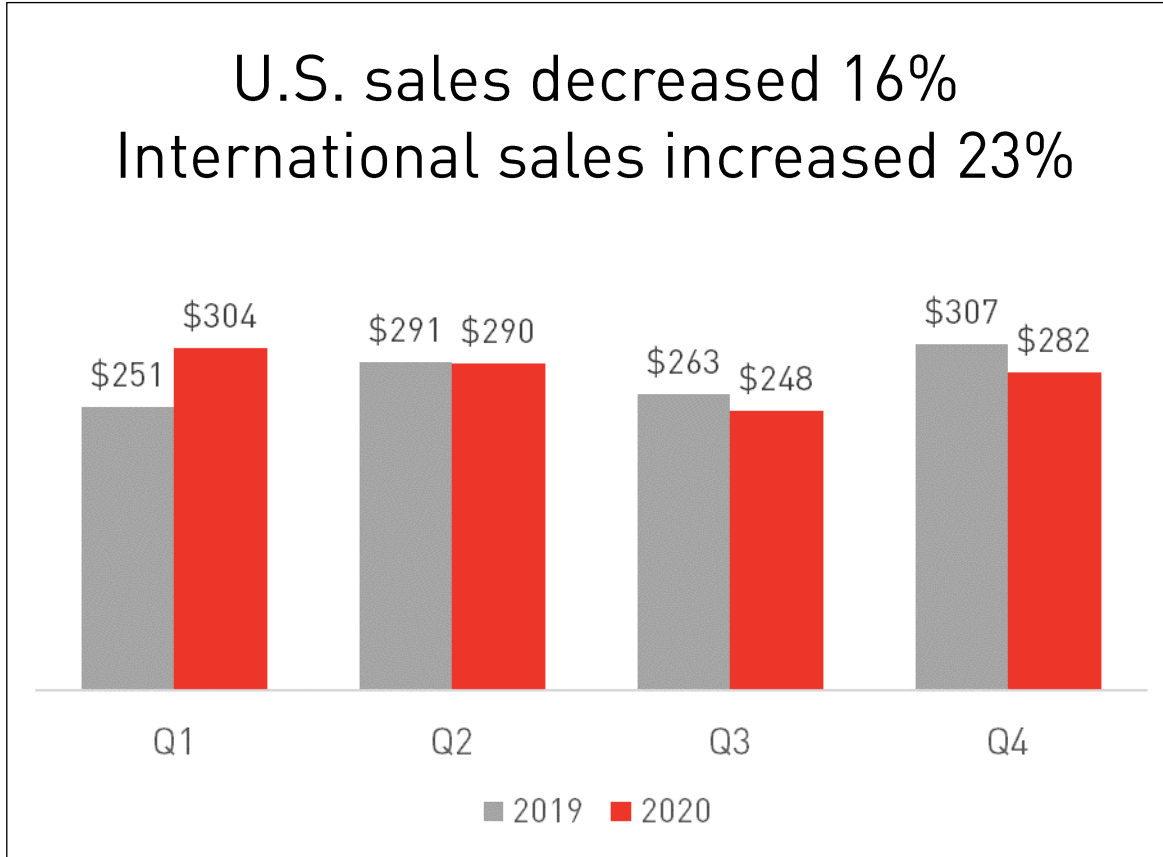
Note: Numbers may not add due to rounding.



# Q4 2020 BASAGLAR SALES DECREASED 8%



Millions



Note: Numbers may not add due to rounding.

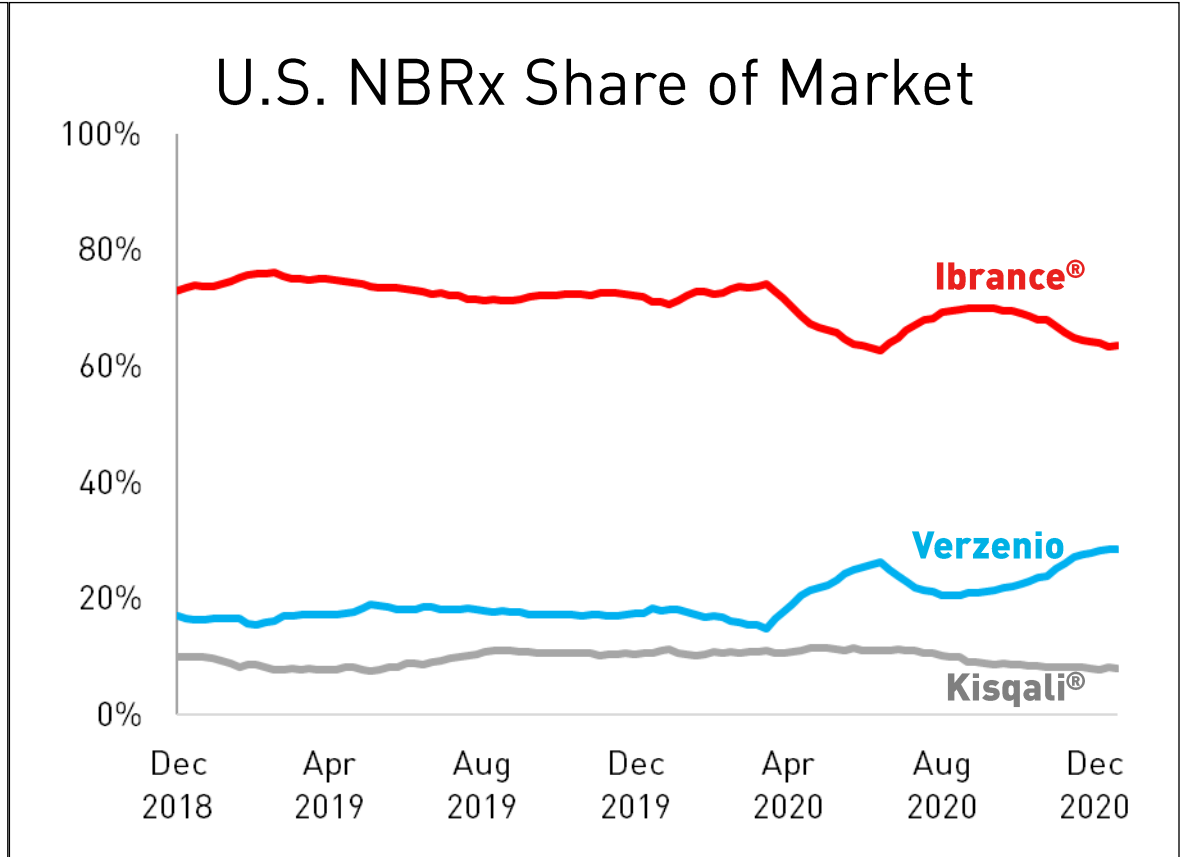
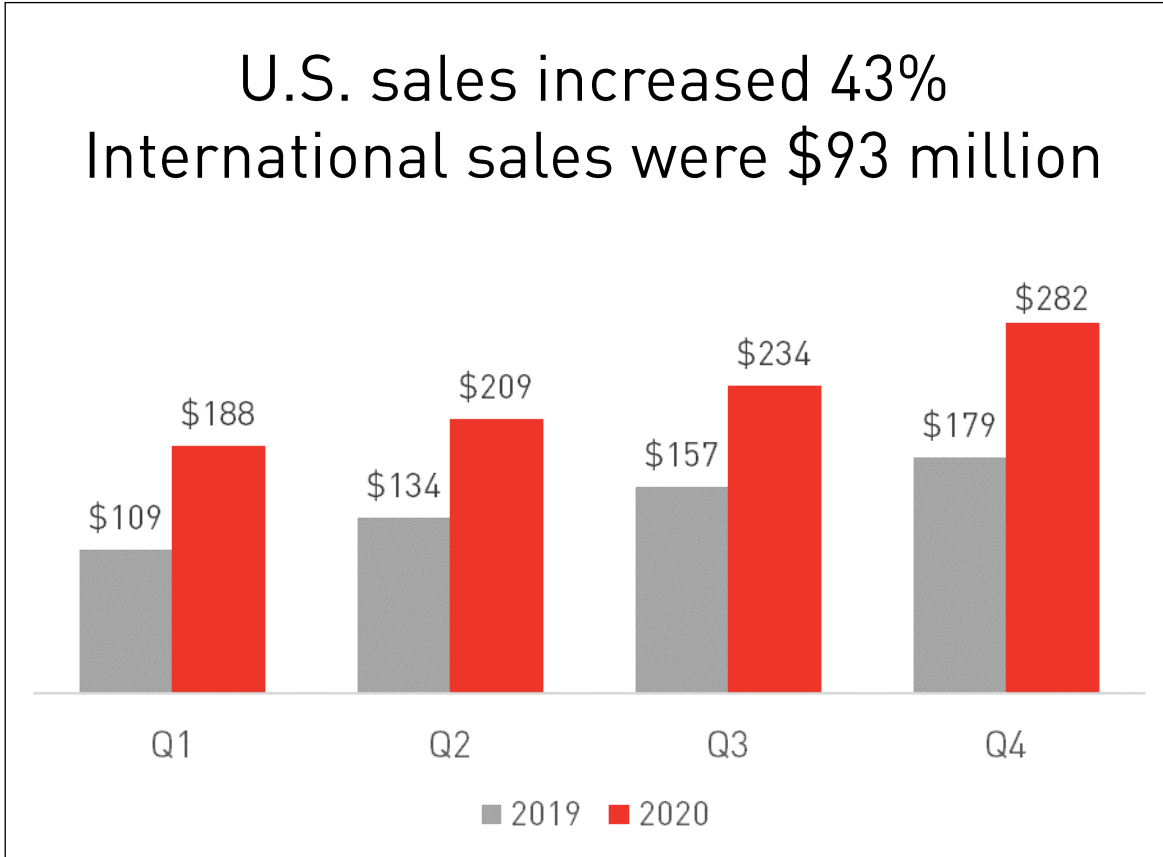
Source: IQVIA NPA TRx 3MMA, weekly data December 25, 2020

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

# Q4 2020 VERZENIO SALES INCREASED 57%



Millions



Note: Numbers may not add due to rounding.

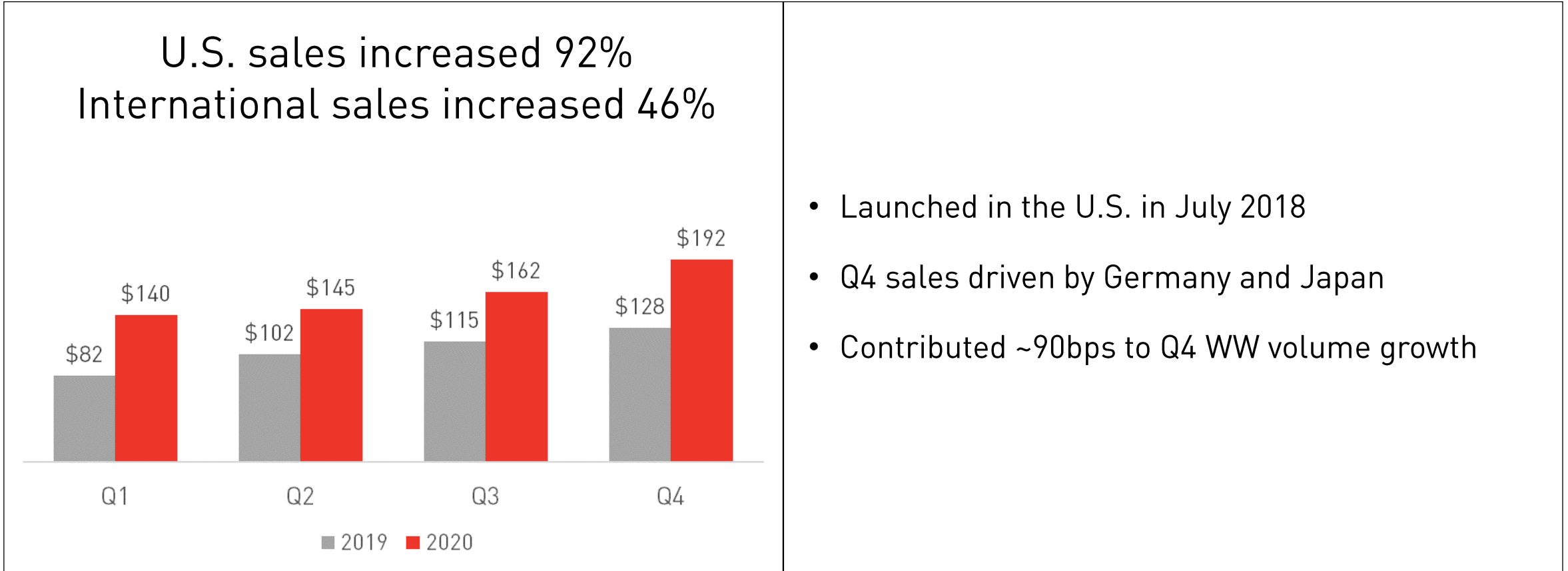
Source: IQVIA NPA NBRx 3MMA, weekly data December 25, 2020

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

# Q4 2020 OLUMIANT SALES INCREASED 50%



Millions



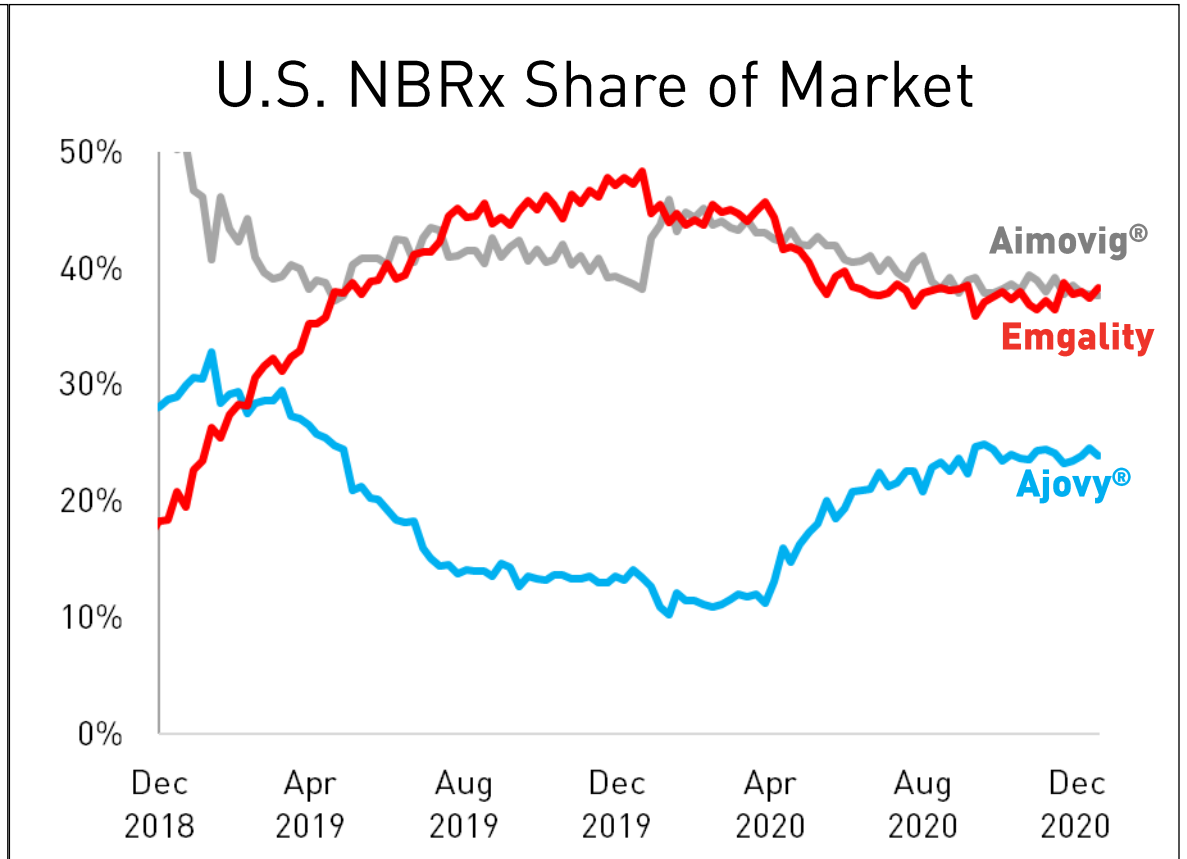
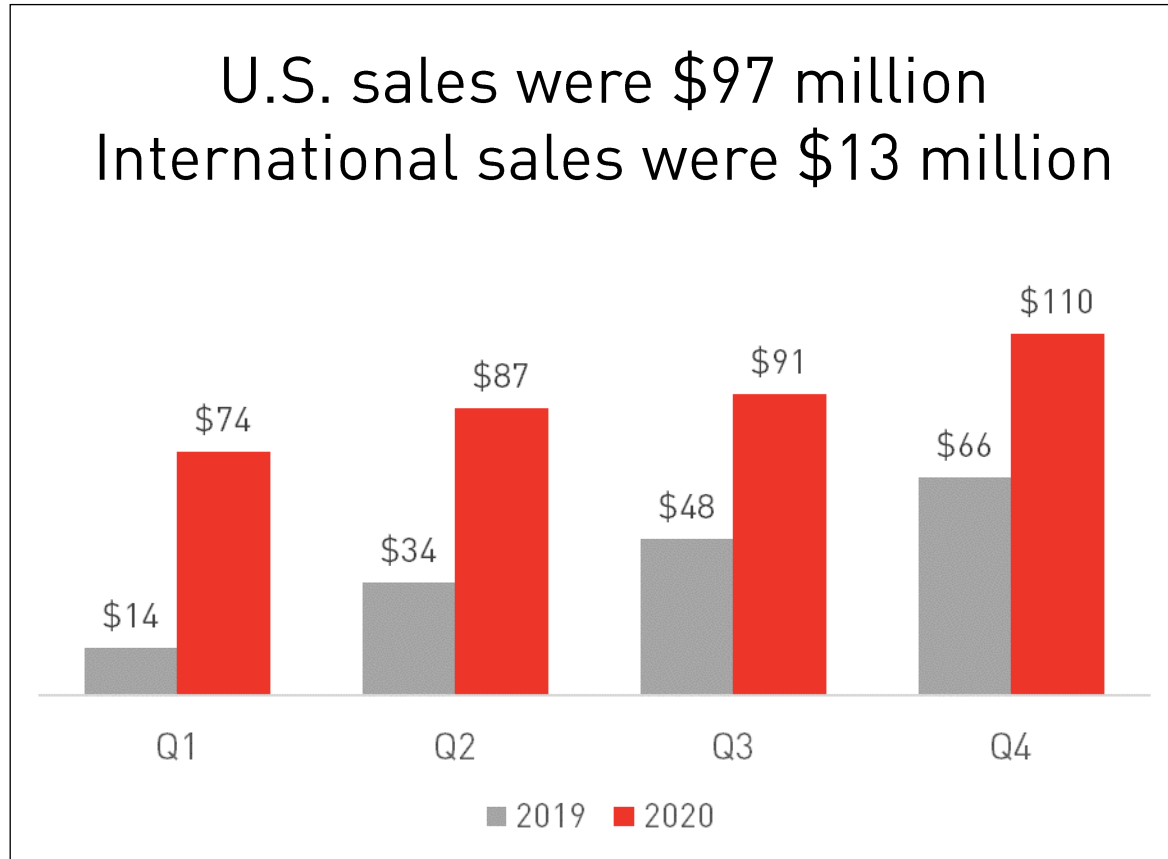
- Launched in the U.S. in July 2018
- Q4 sales driven by Germany and Japan
- Contributed ~90bps to Q4 WW volume growth

Note: Numbers may not add due to rounding.

# Q4 2020 EMGALITY SALES WERE \$110 MILLION



Millions



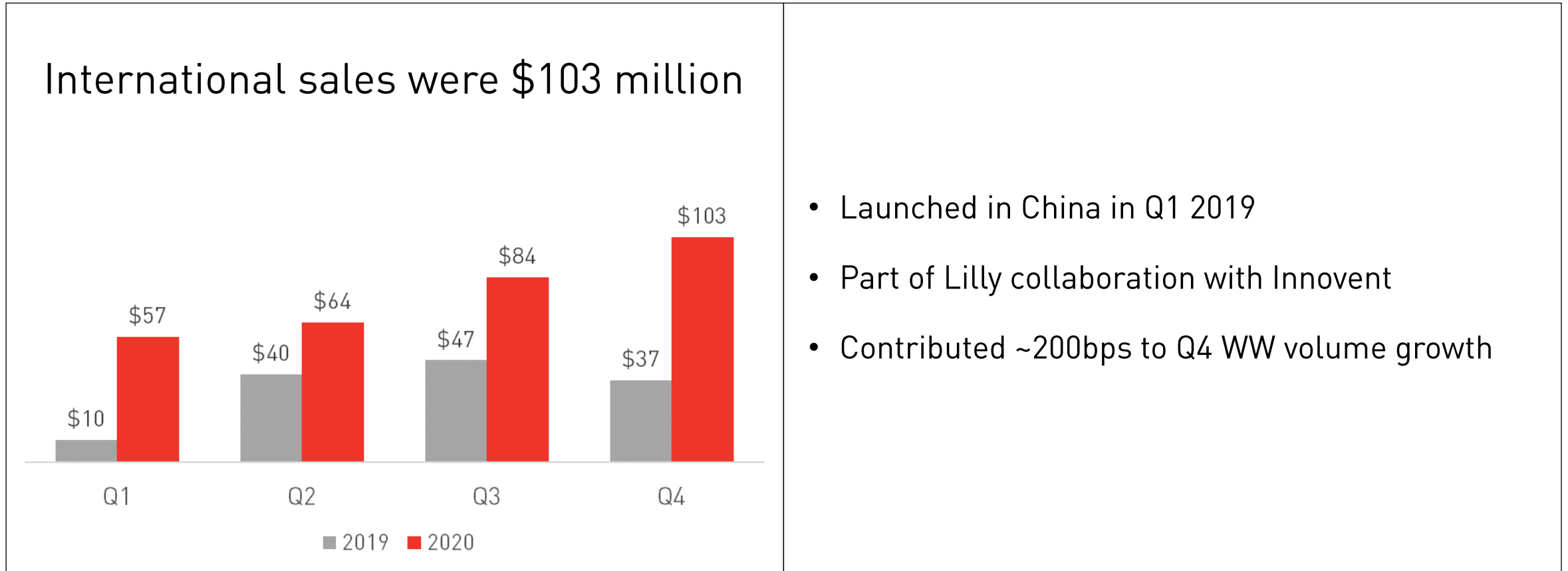
Note: Numbers may not add due to rounding.

Source: IQVIA NPA NBRx, weekly data December 25, 2020

# Q4 2020 TYVYT SALES WERE \$103 MILLION



Millions

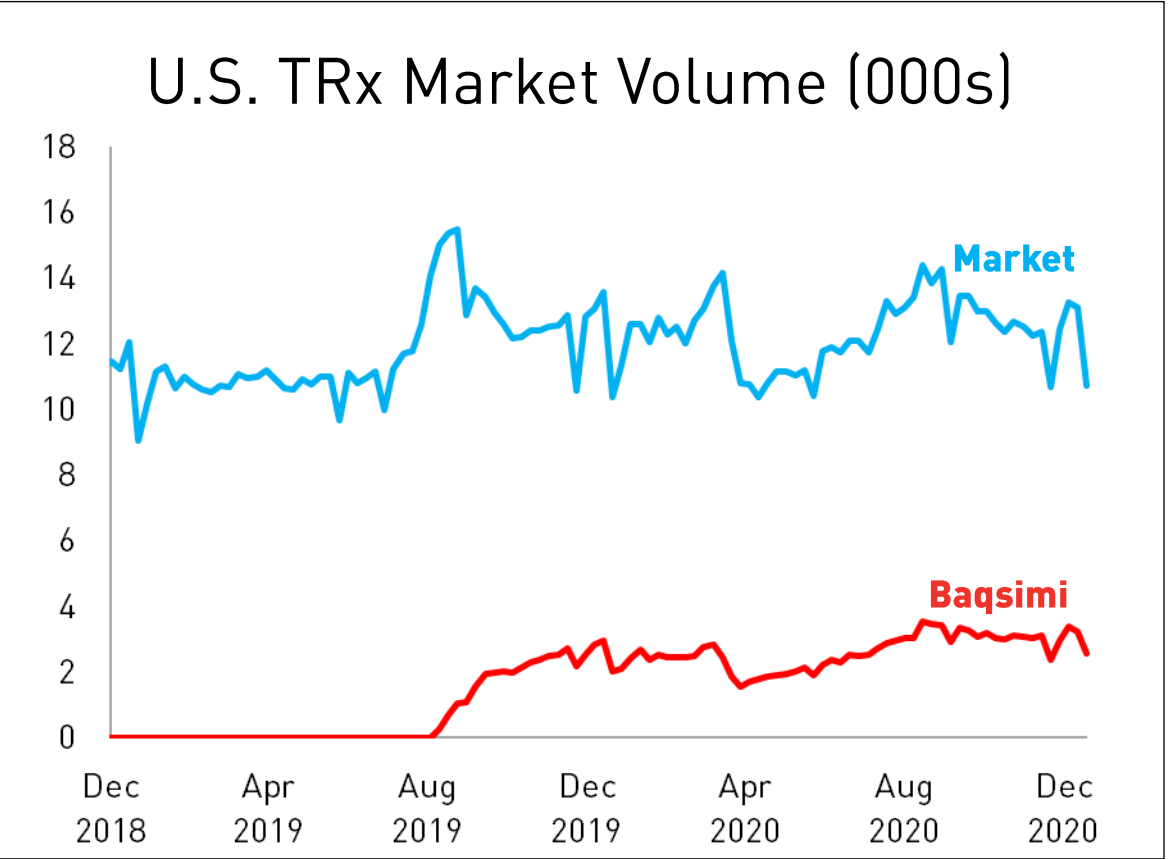
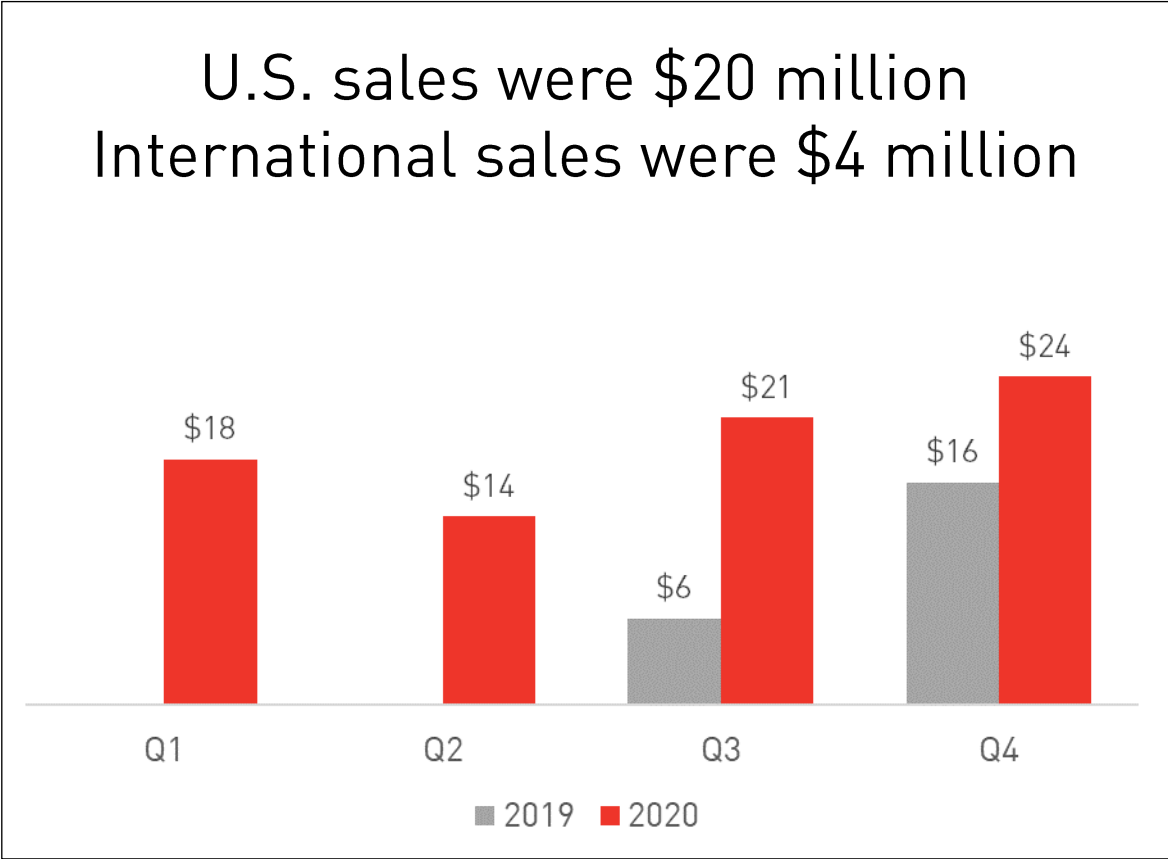


Note: Numbers may not add due to rounding.

# Q4 2020 BAQSIMI SALES WERE \$24 MILLION



Millions



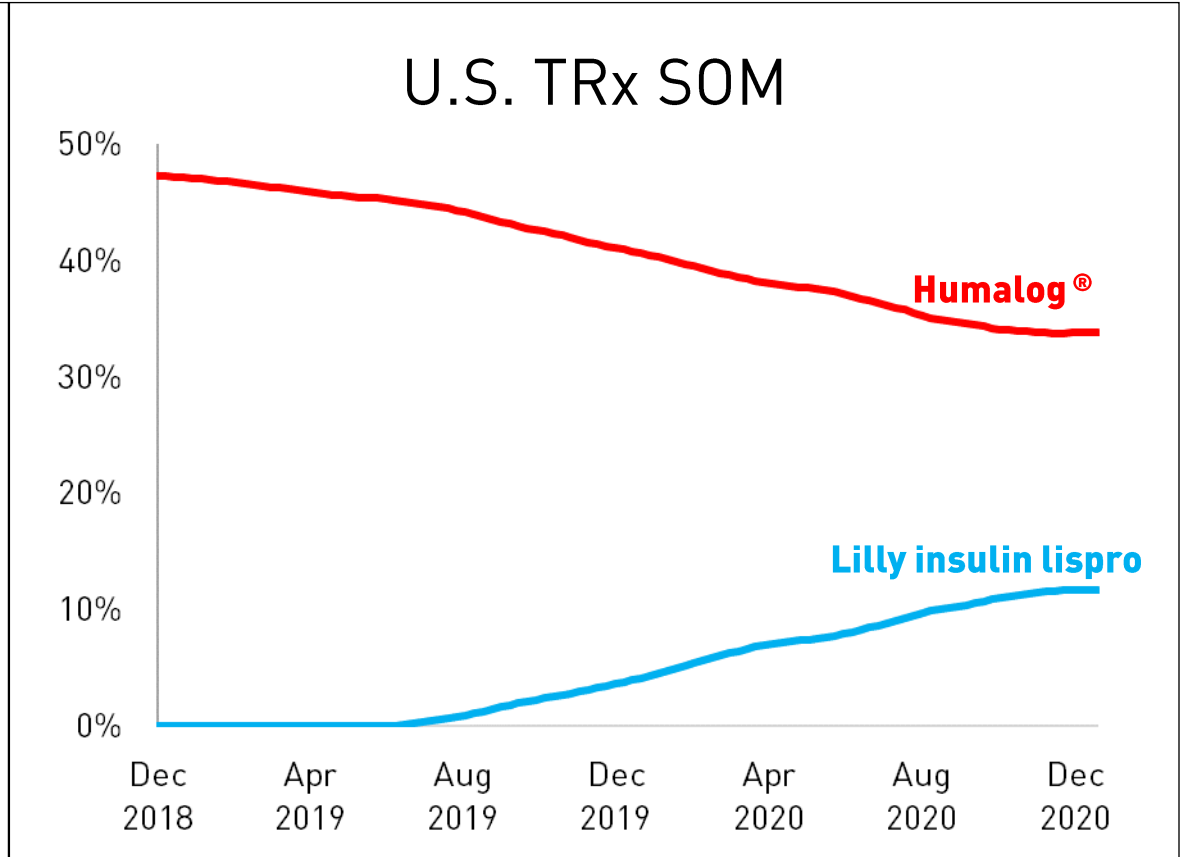
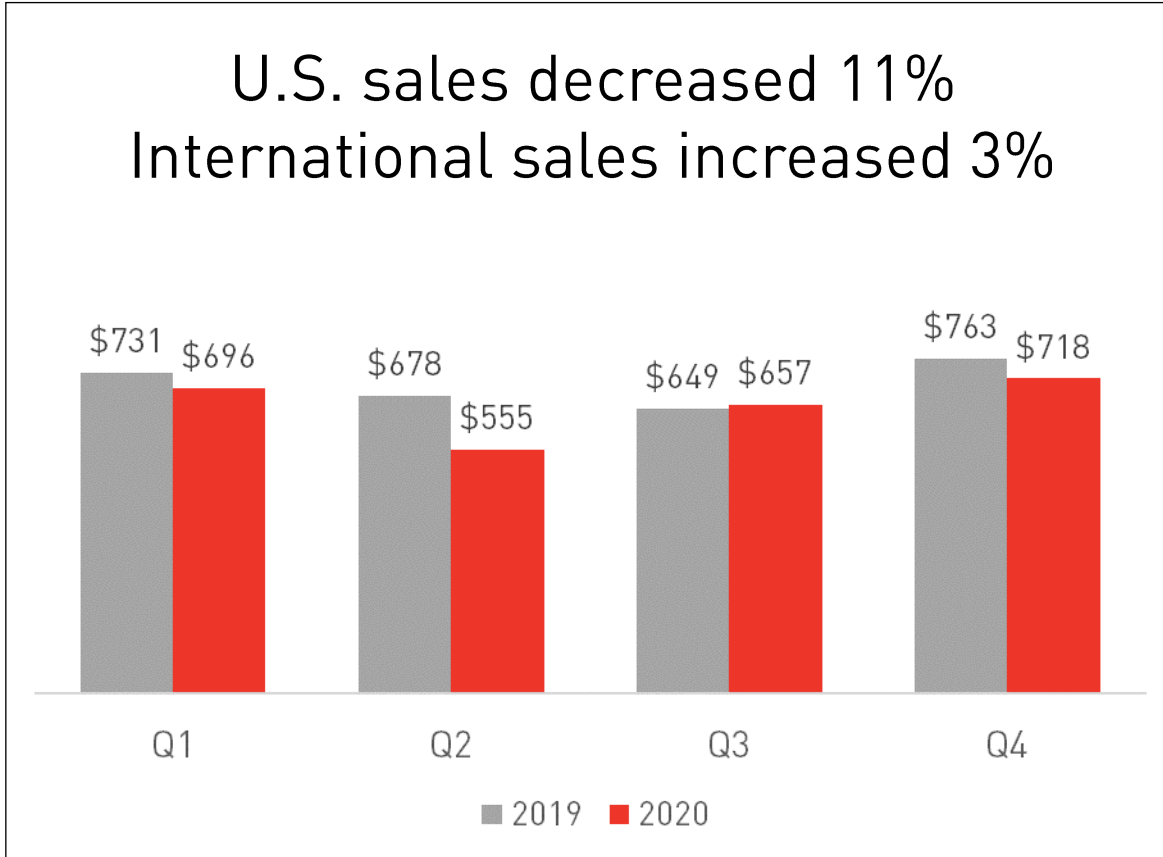
Note: Numbers may not add due to rounding.

Source: IQVIA NPA TRx weekly data December 25, 2020

# Q4 2020 HUMALOG SALES DECREASED 6%



Millions



Note: Numbers may not add due to rounding.

Source: IQVIA NPA TRx 3MMA, weekly data December 25, 2020

# SELECT TRIALS – BAMLANIVIMAB (LY-CoV555)



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	3300	Percentage of Participants Who Experience COVID-Related Hospitalization or Death from Any Cause [ Time Frame: Baseline through Day 29 ]	Sep 2020	May 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	Jan 2021	Apr 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	Mar 2021	Jun 2021
NCT04656691 <sup>3</sup>	COVID-19	At-Home Infusion Using Bamlanivimab in Participants With Mild to Moderate COVID-19	4	7500	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
NCT04518410 <sup>5</sup>	Coronavirus	ACTIV-2: A Study for Outpatients With COVID-19	2 3	2000	Duration of COVID-19 symptoms (Phase 2)	Dec 2021	Dec 2021

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

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

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

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

<sup>5</sup> Sponsored by NIAID, and also lists AIDS Clinical Trials Group

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 27, 2021



# SELECT TRIALS – BAMLANIVIMAB (LY-CoV555)



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04501978 <sup>6</sup>	Covid19	ACTIV-3: Therapeutics for Inpatients With COVID-19	3	10000	Pulmonary ordinal outcome (disease severity stratum 1)	Jul 2022	Jul 2022

<sup>6</sup> Sponsored by NIAID, also lists INSIGHT, University of Copenhagen, Medical Research Council and more

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 20, 2021

# SELECT TRIALS – JARDIANCE



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 $\leq 10$ mL/min/1.73m <sup>2</sup> , renal death, or a sustained decline of $\geq 40\%$ 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)	Mar 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.	Jun 2021	Jul 2021
NCT04509674	Myocardial Infarction	EMPACT-MI: A Study to Test Whether Empagliflozin Can Lower the Risk of Heart Failure and Death in People Who Had a Heart Attack (Myocardial Infarction)	3	3312	Composite of time to first heart failure hospitalisation or 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)

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 14, 2021

# 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 $\geq 2$ 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 $\geq 2$ 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 $\geq 2$ 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	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 2024	May 2024

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 22, 2021

# 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	3	350	Change from Baseline in Hemoglobin A1c (HbA1c)	Feb 2022	Feb 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
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

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 20, 2021

# SELECT TRIALS – MIRIKIZUMAB



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 (VIVID-1)	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 (VIVID-2)	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	Jan 2021	Dec 2021
NCT03524092	Ulcerative Colitis	A Maintenance Study of Mirikizumab in Participants With Moderately to Severely Active Ulcerative Colitis (LUCENT 2)	3	1044	Percentage of Participants in Clinical Remission	Nov 2021	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	Jul 2025
NCT04469062	Ulcerative Colitis	A Study of Mirikizumab (LY3074828) in Participants With Ulcerative Colitis (LUCENT-ACT)	3	1100	Percentage of Participants in Histologic Remission	Mar 2024	Jun 2024

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 20, 2021

# 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) $\leq 20$	Jan 2021	Jun 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) $\leq 20$	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]) [ Time Frame: Day 1 to Day 28 ]	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	Nov 2021

In collaboration with Incyte

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 22, 2021

# 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)	May 2024	Nov 2026
NCT03157128	Non-Small 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	250	Progression Free Survival (PFS) by Blinded Independent Central Review (BICR) (with Pembrolizumab)	Jan 2023	Aug 2025
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

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 20, 2021

# 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)	Jan 2023	Jan 2023

^ Also lists Alzheimer's Therapeutic Research Institute

\*Trial may have additional primary and other secondary outcomes

Source: clinicaltrials.gov, August 19, 2020



# 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

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

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

Source: clinicaltrials.gov, November 24, 2020

# SELECT TRIALS – TIRZEPATIDE



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04166773	Nonalcoholic Steatohepatitis	A Study of Tirzepatide (LY3298176) in Participants With Nonalcoholic Steatohepatitis (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
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
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	Feb 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	3	1881	Change from Baseline in Hemoglobin A1c (HbA1c) (10 mg and 15 mg)	Jan 2021	Feb 2021

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 20, 2021

# SELECT TRIALS – TIRZEPATIDE (CONTINUED)



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
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
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)	Nov 2021	Dec 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)	Jul 2022	Aug 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

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 22, 2021

# SELECT TRIALS – VERZENIO



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03155997^	Breast Cancer	Endocrine Therapy With or Without Abemaciclib (LY2835219) Following Surgery in Participants With Breast Cancer	3	4580	Invasive Disease Free Survival (IDFS)	Mar 2020	Jun 2029

^ Also lists NSABP Foundation Inc

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, November 20, 2020

# 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
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
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	Jan 2021	Jan 2021
GIP/GLP Coagonist Peptide	NCT04515576	Diabetes Mellitus, Type 2	A Study of LY3493269 in Participants With Type 2 Diabetes	1	56	Number of Participants with One or More Treatment-Emergent Adverse Event(s) (TEAEs) and Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Mar 2021	Mar 2021
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	Mar 2021	Mar 2021

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 20, 2021

# SELECT TRIALS – EARLY PHASE DIABETES (CONTINUED)



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
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	Apr 2021	Apr 2021
ANGPTL3/8 MAB	NCT04052594	Dyslipidemias	A Study of LY3475766 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	Apr 2021	Apr 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
Oxyntomodulin	NCT03928379	Diabetes Mellitus, Type 2	A Study of LY3305677 in Participants With Type 2 Diabetes	1	45	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug	Jun 2021	Jul 2021
KHK Inhibitor II	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

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 20, 2021

# SELECT TRIALS – EARLY PHASE DIABETES (CONTINUED)



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
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	Aug 2021	Aug 2021
PYY Analog	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
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

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 27, 2021

# 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	Sep 2021
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)	Dec 2021	Aug 2022
CXCR1/2L MAB	NCT04493502	Hidradenitis Suppurativa	A Study of LY3041658 in Adults With Hidradenitis Suppurativa	2	52	Percentage of Participants Achieving Hidradenitis Suppurativa Clinical Response (HiSCR)	Dec 2021	Jul 2022
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 $\geq 4$ 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
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

^ Also lists Nektar Therapeutics

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 20, 2021



# SELECT TRIALS – EARLY PHASE IMMUNOLOGY (CONTINUED)



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
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	Jun 2021	Jun 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	Aug 2021	Aug 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	Aug 2022	Aug 2022
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	Nov 2022	Nov 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

^ Also lists Nektar Therapeutics

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 20, 2021

# SELECT TRIALS – EARLY PHASE NEURODEGENERATION



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
Donanemab (N3PG AB 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 AB MAB)	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
Donanemab (N3PG AB 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	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

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 20, 2021

# SELECT TRIALS – EARLY PHASE NEURODEGENERATION (CONTINUED)



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
N3PG AB 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	Feb 2022	Feb 2022
PR001	NCT04127578	Parkinson Disease	Phase 1/2a Clinical Trial of PR001A in Patients With Parkinson's Disease With at Least One GBA1 Mutation (PROPEL)	1 2	12	Number of Treatment-Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)	Jun 2027	Jun 2027
PR006	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
PR001	NCT04411654	Gaucher Disease, Type 2	Phase 1/2 Clinical Trial of PR001 in Infants With Type 2 Gaucher Disease (PROVIDE)	1 2	15	Number of Adverse Events (AEs), Serious Adverse Events (SAEs), and Adverse Events leading to discontinuation	Apr 2028	Apr 2028

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 20, 2021

# SELECT TRIALS – EARLY PHASE ONCOLOGY



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
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	Feb 2021	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	150	Number of Participants with Dose Limiting Toxicity (DLT)	Jun 2021	Dec 2022
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
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	860	Maximum Tolerated Dose (MTD)	Feb 2023	May 2023

^ Also lists Merck Sharp & Dohme Corp.

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 20, 2021

# SELECT TRIALS – EARLY PHASE ONCOLOGY (CONTINUED)



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
BTK Inhibitor (LOXO-305)	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
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
BTK Inhibitor (LOXO-305)	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)	Aug 2024	Feb 2025

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

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 20, 2021

# 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
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)	May 2021	May 2022
SSTR4 Agonist	NCT04627038	Osteoarthritis	Chronic Pain Master Protocol (CPMP): A Study of LY3556050 in Participants With Osteoarthritis	2	150	Change from Baseline in Average Pain Intensity as Measured by the Numeric Rating Scale (NRS)	Jul 2021	Jul 2021
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	NCT04707157	Diabetic Peripheral Neuropathic Pain	Chronic Pain Master Protocol (CPMP): A Study of LY3556050 in Participants With Diabetic Peripheral Neuropathic Pain	2	150	Change from Baseline in Average Pain Intensity as Measured by the Numeric Rating Scale (NRS)	Jan 2022	Jan 2022

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 20, 2021

# SELECT TRIALS – EARLY PHASE PAIN (CONTINUED)



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

\*Molecule may have multiple indications

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

Source: clinicaltrials.gov, January 22, 2021

*Lilly*