**2019 Business Results** 

JANUARY 30, 2020

# **AGENDA**



### INTRODUCTION AND KEY RECENT EVENTS

Dave Ricks, Chairman and Chief Executive Officer

### Q4 AND FY 2019 FINANCIAL RESULTS AND 2020 FINANCIAL GUIDANCE

Josh Smiley, Senior Vice President, Finance and 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; litigation and investigations; business development transactions, including the pending acquisition of Dermira, Inc.; 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**



- 8% revenue growth in Q4; 9% in constant currency
- Revenue growth driven by:
  - 10% volume growth
  - Key growth products accounted for 46% of total revenue

### **Improve Productivity**



- Non-GAAP:
  - Gross margin was 79.9% (79.6% excluding FX impact on international inventories sold)
  - Operating margin was 26.3%

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



- Announced the acquisition of Dermira, Inc.
- Completed \$0.3 billion in share repurchases
- Distributed \$0.6 billion via dividends

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



- Positive results from the BREEZE-AD4 and BREEZE-AD5 trials studying baricitinib in atopic dermatitis
- Submitted:
  - Selpercatinib in the U.S. and Europe
  - Tanezumab osteoarthritis pain in the U.S.
  - Dulaglutide alternate doses in the U.S. and Europe
  - Baricitinib atopic dermatitis in Europe and Japan

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



#### COMMERCIAL

• Announced plans to make available two additional lower-priced versions of **Humalog® Mix75/25<sup>TM</sup> KwikPen®** and **Humalog Junior KwikPen**, both at a list price 50 percent lower than the branded versions.

#### **REGULATORY**

- Along with Boehringer Ingelheim, received U.S. FDA approval for Trijardy™ XR
   (empagliflozin + linagliptin + metformin XR) for the treatment of type 2 diabetes;
- Received European Commission approval of Cyramza® to expand the label to include the results from the RELAY study in patients with metastatic EGFRmutated non-small cell lung cancer (NSCLC);
- Received European Commission approval of **Baqsimi<sup>TM</sup>**, the first and only nasally administered glucagon to treat severe hypoglycemia in adults and children with diabetes ages four years and older;
- Submitted **selpercatinib** for the treatment of *RET* fusion-positive NSCLC, *RET*-mutant medullary thyroid cancer (MTC) and *RET* fusion-positive thyroid cancer in the U.S. and European Union;
- Granted a Priority Review from the U.S. FDA for selpercatinib for the treatment of RET fusion-positive NSCLC, RET-mutant MTC and RET fusion-positive thyroid cancer;
- Submitted **Trulicity** ® alternate doses for the treatment of type 2 diabetes in the U.S. and European Union;
- Submitted **Olumiant**® for the treatment of atopic dermatitis to the European Union and Japan; and
- In collaboration with Pfizer, submitted **tanezumab** for the treatment of moderate to severe osteoarthritis pain in the U.S.

#### **CLINICAL**

- Announced the **baricitinib** BREEZE-AD4 and BREEZE-AD5 studies in moderate to severe atopic dermatitis both achieved their primary endpoint of proportion of patients achieving EASI75 at Week 16;
- Along with Innovent Biologics, Inc., announced Tyvyt® in combination with Alimta® and platinum met the primary endpoint of progression-free survival in 1L advanced or recurrent nonsquamous NSCLC; and
- Announced, in collaboration with Boehringer Ingelheim, that the Phase 3
   EMPERIAL trials of **empagliflozin** demonstrated no significant change versus placebo from baseline to week 12 in exercise ability, as measured by the sixminute walk test.

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

- Announced a definitive agreement to acquire **Dermira, Inc.**, a biopharmaceutical company dedicated to developing new therapies for chronic skin conditions;
- Announced modernization of the Boehringer Ingelheim alliance to focus combined expertise on the development and commercialization of Jardiance®;
- Announced global commercialization agreement to integrate **DexCom, Inc.**products into Lilly's personalized diabetes management system;
- The U.S. District Court for the Southern District of Indiana ruled in Lilly's favor regarding the **Alimta** vitamin regimen patent;
- Distributed nearly \$0.6 billion to shareholders via the dividend and announced a 15% dividend increase; and
- Returned \$0.3 billion to shareholders via share repurchase.

# **COMPARISON MEASURES**



### "REPORTED" RESULTS

Include all financial results as reported in accordance with Generally Accepted Accounting Principles (GAAP)

### "NON-GAAP" MEASURES

Start with "REPORTED" RESULTS

Reflect adjustments for items such as:

$\bigcirc$	Discontinued operations of Elanco Animal Health
	Acquired in-process R&D charges and other income and expenses from business development activities
$\Diamond$	Amortization of intangible assets
	Asset impairment, restructuring and other special charges
$\Diamond$	Charges related to the suspension of promotion of Lartruvo
$\Diamond$	Gain on sale of China antibiotics business
$\Diamond$	Charge related to the repurchase of debt
	Certain income tax items

# 2019 INCOME STATEMENT - REPORTED



Millions; except per share data

	Q4 2019	<b>Change</b>	YTD 2019	<b>Change</b>
TOTAL REVENUE	\$6,114	8%	\$22,319	4%
GROSS MARGIN	79.0%	(1.0pp)	78.8%	0.6pp
TOTAL OPERATING EXPENSE*	3,431	(5)%	12,624	(5)%
OPERATING INCOME	1,400	56%	4,974	41%
OPERATING MARGIN	22.9%	6.9pp	22.3%	5.8pp
OTHER INCOME (EXPENSE)	263	NM	292	NM
EFFECTIVE TAX RATE	10.1%	NM	11.9%	(2.5pp)
NET INCOME - CONTINUING OPERATIONS	\$1,496	33%	\$4,638	47%
<b>EPS - CONTINUING OPERATIONS</b>	\$1.64	<b>49</b> %	\$4.96	63%
EPS - DISCONTINUED OPERATIONS	-	NM	\$3.93	NM
EPS - TOTAL	\$1.64	<b>49</b> %	\$8.89	NM

<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

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

Lilly

Millions; except per share data

Q4 2019

	GAAP Reported	Adjustments	Non-GAAP Adjusted	Non-GAAP Adjusted Change
TOTAL REVENUE	\$6,114	-	\$6,114	8%
GROSS MARGIN	79.0%	0.9%	79.9%	(0.7pp)
TOTAL OPERATING EXPENSE	3,431	(151)	3,280	6%
OPERATING INCOME	1,400	205	1,605	10%
OPERATING MARGIN	22.9%	3.4%	26.3%	0.4pp
OTHER INCOME (EXPENSE)	263	(57)	206	NM
EFFECTIVE TAX RATE	10.1%	2.5%	12.6%	(3.0pp)
NET INCOME - CONTINUING OPERATIONS	\$1,496	87	\$1,583	26%
<b>EPS - CONTINUING OPERATIONS</b>	\$1.64	0.09	\$1.73	31%
<b>EPS - DISCONTINUED OPERATIONS</b>	_	_	-	NM
EPS - TOTAL	\$1.64	0.09	\$1.73	31%

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)

Lilly

Millions; except per share data

### **YTD 2019**

	GAAP Reported	Adjustments	Non-GAAP Adjusted	Non-GAAP Adjusted Change
TOTAL REVENUE	\$22,319	_	\$22,319	4%
GROSS MARGIN	78.8%	1.3%	80.1%	0.3pp
TOTAL OPERATING EXPENSE	12,624	(815)	11,809	7%
OPERATING INCOME	4,974	1,105	6,079	(1)%
OPERATING MARGIN	22.3%	4.9%	<b>27.2</b> %	(1.3pp)
OTHER INCOME (EXPENSE)	292	(58)	234	96%
EFFECTIVE TAX RATE	11.9%	(0.1)%	11.8%	(3.9pp)
<b>NET INCOME - CONTINUING OPERATIONS</b>	\$4,638	930	\$5,568	6%
<b>EPS - CONTINUING OPERATIONS</b>	\$4.96	1.08	\$6.04	11%
<b>EPS - DISCONTINUED OPERATIONS</b>	\$3.93	(3.93)	<del>-</del>	NM
EPS - TOTAL	\$8.89	(2.85)	\$6.04	11%

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

# **EPS RECONCILIATION**



	Q4 2019	Q4 2018	Change	YTD 2019	YTD 2018	Change
EPS (REPORTED)	\$1.64	\$1.10	<b>49</b> %	\$8.89	\$3.13	NM
CHARGE RELATED TO REPURCHASE OF DEBT	0.22			0.22		
ASSET IMPAIRMENT, RESTRUCTURING, AND OTHER SPECIAL CHARGES	0.14	0.18		0.58	0.24	
AMORTIZATION OF INTANGIBLE ASSETS	0.05	0.03		0.18	0.28	
2017 U.S. TAX REFORM AND OTHER TAX ITEMS	(0.05)	(0.33)		(0.05)	(0.27)	
GAIN ON SALE OF CHINA ANTIBIOTICS BUSINESS	(0.26)			(0.26)		
ACQUIRED IN-PROCESS RESEARCH AND DEVELOPMENT		0.27		0.21	1.96	
LARTRUVO CHARGES				0.14		
REDUCED SHARES OUTSTANDING		0.07		0.07	0.20	
DISCONTINUED OPERATIONS				(3.93)	(0.08)	
OTHER, NET					(0.02)	
EPS (NON-GAAP)	\$1.73	\$1.32	31%	\$6.04	\$5.44	11%

Note: Numbers may not add due to rounding; see slides 26 and 27 for more details on these significant adjustments.

# EFFECT OF PRICE/RATE/VOLUME ON REVENUE



Millions Q4 2019

	Amount	Price	FX Rate	Volume	Total	CER
U.S.	\$3,519	(1)%	<b>-</b> %	8%	7%	7%
EUROPE	1,013	(3)%	(4)%	15%	8%	12%
JAPAN	709	(1)%	4%	8%	11%	7%
REST OF WORLD	873	3%	(2)%	11%	13%	14%
<b>TOTAL REVENUE</b>	\$6,114	(1)%	<b>-</b> %	10%	8%	9%

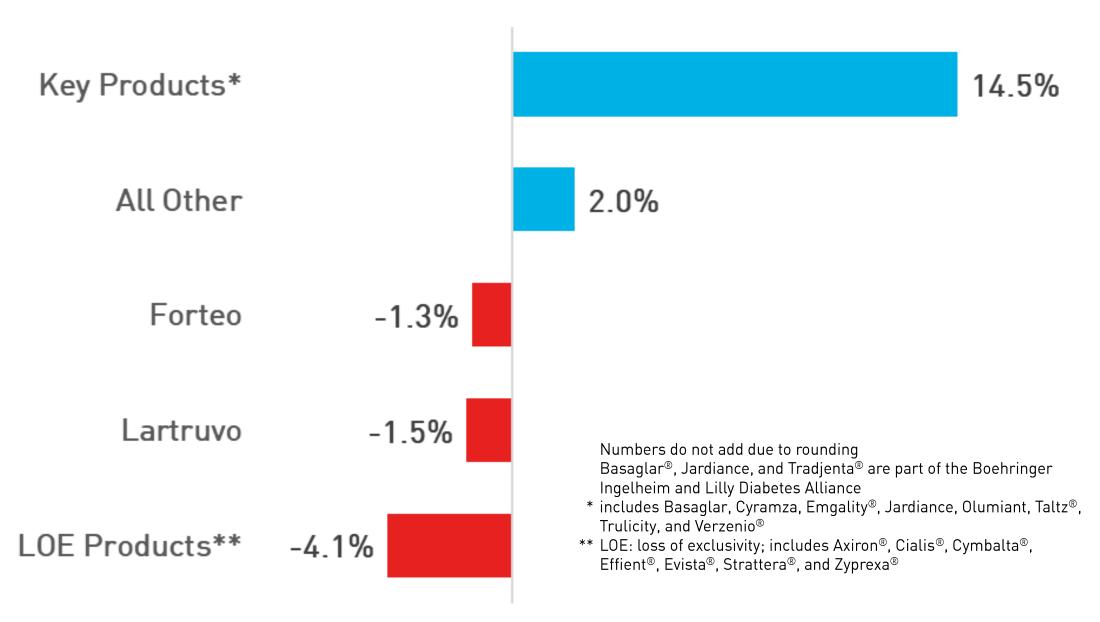
### **YTD 2019**

	Amount	Price	FX Rate	Volume	Total	CER
U.S.	\$12,723	(3)%	<b>-</b> %	6%	3%	3%
EUROPE	3,765	(2)%	(6)%	10%	3%	8%
JAPAN	2,548	(2)%	1%	7%	6%	5%
REST OF WORLD	3,284	<b>-</b> %	(4)%	13%	8%	13%
<b>TOTAL REVENUE</b>	\$22,319	(3)%	(1)%	8%	4%	5%

# **KEY PRODUCTS DRIVING WW VOLUME GROWTH**

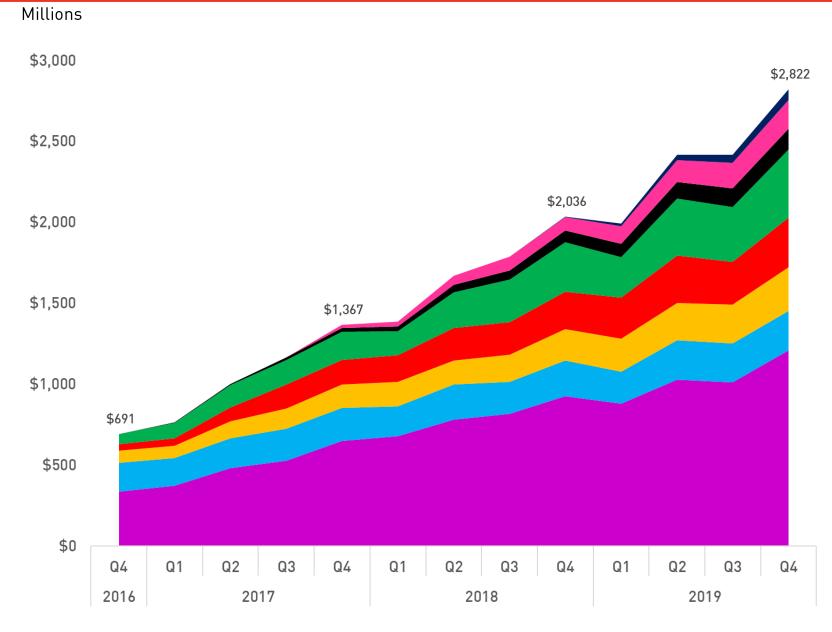


### Contribution to 10% Q4 WW Volume Growth



# **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.

#### **EMGALITY**

- Approved in cluster headache in U.S. in Q2 2019
- U.S. NBRx SOM 47% at the end of Q4 2019

#### VERZENIO

- Announced positive OS data in HR+, HER2- mBC in Q3 2019
- U.S. TRx grew over 46% vs. Q4 2018

#### OLUMIANT

- RA U.S. launch July 2018
- Significant driver of volume growth in Europe

#### TALTZ

- Approved Q3 2019 in radiographic axSpA in U.S.
- Total molecule U.S. TRx grew nearly 40% vs. Q4 2018

#### BASAGLAR

- U.S. TRx 21% SOM at end of Q4 2019
- TRx grew over 18% since Q4 2018

#### JARDIANCE

- Market leader in U.S. TRx SOM 55% and NTS SOM over 61%
- Class growth accelerating: U.S. TRx +19% and NTS +47% vs. Q4 2018

#### CYRAMZA

- Approved in EGFR+ 1L NSCLC in the E.U. in Q1 2020
- U.S. SOM in 2L NSCLC YoY has nearly doubled from Q4 2018

#### TRULICITY

- U.S. TRx leader with over 45% SOM
- U.S. GLP-1 class growth +29% vs. Q4 2018

# **EFFECT OF FOREIGN EXCHANGE ON 2019 RESULTS**



Year-on-Year Growth Q4 2019 YTD 2019

REPORTED	With FX	w/o FX	With FX	w/o FX
TOTAL REVENUE	8%	9%	4%	5%
COST OF SALES	14%	13%	1%	9%
GROSS MARGIN	7%	8%	5%	4%
OPERATING EXPENSE	(5)%	(5)%	(5)%	(4)%
OPERATING INCOME	56%	59%	41%	34%
<b>EPS – CONTINUING OPERATIONS</b>	49%	50%	63%	56%

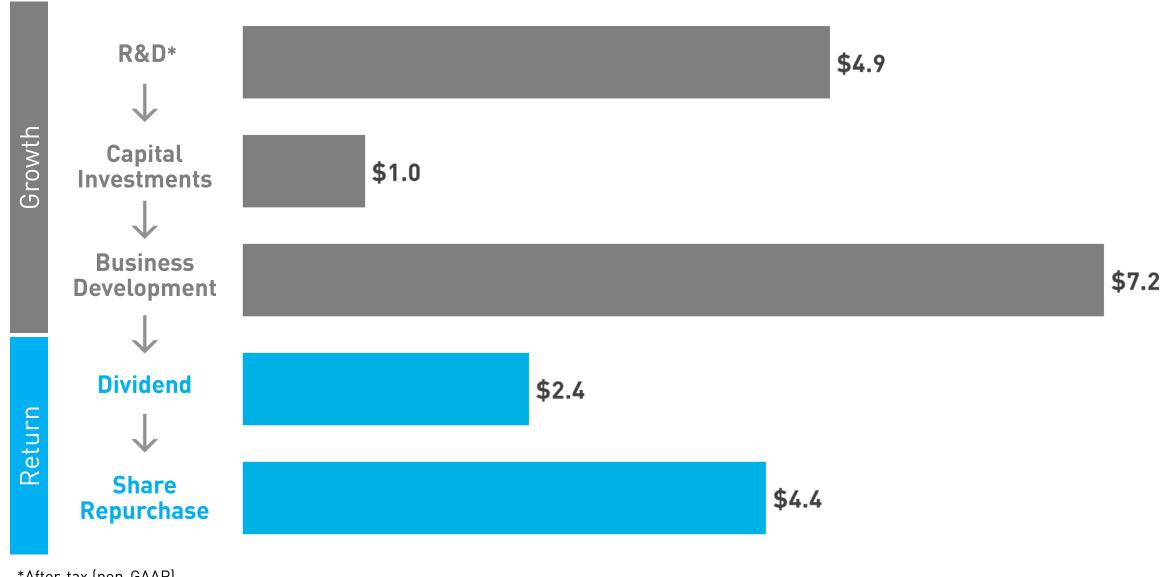
NON-GAAP	With FX	w/o FX	With FX	w/o FX
TOTAL REVENUE	8%	9%	4%	5%
COST OF SALES	13%	12%	2%	11%
GROSS MARGIN	7%	8%	4%	4%
OPERATING EXPENSE	6%	7%	7%	8%
OPERATING INCOME	10%	11%	(1)%	(3)%
<b>EPS - CONTINUING OPERATIONS</b>	31%	33%	11%	8%

# **CAPITAL ALLOCATION**



Billions

### **2019 Capital Allocation**



\*After-tax (non-GAAP)

# **2020 GUIDANCE**



	Prior	Updated	Comments
TOTAL REVENUE	\$23.6 – \$24.1 billion	\$23.7 - \$24.2 billion	Updated to include QBREXZA and positive trends in our core business performance
GROSS MARGIN % (GAAP)	approx. 79%	unchanged	
GROSS MARGIN % (NON-GAAP)	approx. 81%	unchanged	
MKTG, SELLING & ADMIN.	\$6.1 – \$6.3 billion	\$6.2 - \$6.4 billion	Updated to include commercial expenses to support QBREXZA
RESEARCH & DEVELOPMENT	\$5.6 - \$5.9 billion	unchanged	
OTHER INCOME/(EXPENSE)	\$(250) – \$(100) million	unchanged	
TAX RATE	approx. 15%	unchanged	
EARNINGS PER SHARE (GAAP)	\$6.38 - \$6.48	\$6.18 – \$6.28	Updated to reflect charges related to the pending acquisition of Dermira
EARNINGS PER SHARE (NON-GAAP)	\$6.70 – \$6.80	unchanged	
OPERATING INCOME % (GAAP)	29%	28%	Updated to reflect impact of pending acquisition of Dermira
OPERATING INCOME % (NON-GAAP)	31%	unchanged	

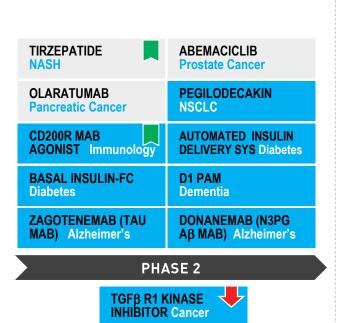
<sup>\*</sup>Assumes GAAP and non-GAAP shares outstanding 910 million Not for promotional use

# LILLY SELECT NME AND NILEX PIPELINE

**JANUARY 27, 2020** 







	NME	MOVEMENT SINCE October 22, 2019
	NILEX	ACHIEVED MILESTONE
*	Commercial Collaboration	REMOVAL

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





Not for promotional use

2019 **Q4 EARNINGS** 

# **RECAP OF KEY EVENTS 2019**

New since last update



#### **Phase 3 Initiations**

- Tirzepatide for obesity
- Baricitinib for alopecia areata
- Mirikizumab for Crohn's disease
- Baricitinib for psoriatic arthritis

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

- Oulaglutide alternate doses for type 2 diabetes
- **Empagliflozin** CHF exercise ability studies<sup>1</sup>
- Linagliptin CAROLINA CV outcomes study<sup>1,3</sup>
- → Baricitinib for atopic dermatitis³ (first three of five studies)
- 🐼 lxekizumab non-radiographic axial spondyloarthritis
- 🐼 lxekizumab psoriasis head-to-head vs. guselkumab
- ✓ Tanezumab for osteoarthritis pain² and chronic low back pain²
- **▼ Tanezumab** for osteoarthritis pain long-term safety study<sup>2</sup>
- Olaratumab for soft tissue sarcoma (OS readout) 3
- Selpercatinib for NSCLC and thyroid cancer (registrational Phase 2)3
- ✓ Ramucirumab for 1L EGFR NSCLC cancer (PFS readout)³
- Pegilodecakin for 2L pancreatic cancer

### **Medical Meeting Presentations**

- **⊘ Dulaglutide** REWIND CV outcomes study
- ✓ Ultra rapid lispro for type 1 and type 2 diabetes
- ✓ Selpercatinib for NSCLC and thyroid cancer

### **Regulatory Submissions**

- Gonnected Pen for type 1 and type 2 diabetes (US)
- ✓ Dulaglutide alternate doses for type 2 diabetes (US
  ✓ /EU
  ✓)
- **✓ Dulaglutide** REWIND CV outcomes study (US/EU)
- ✓ Empagliflozin for type 1 diabetes¹ (US)
- ✓ Ultra rapid lispro for type 1 and type 2 diabetes (US
- Galcanezumab for episodic cluster headache (EU)
- ✓ **Ixekizumab** for non-radiographic axial spondyloarthritis (US 🍪 /EU 🤡 /J 🐼 )
- 🐼 Ixekizumab for radiographic axial spondyloarthritis (EU🤡/J🤡)
- Selpercatinib for NSCLC and thyroid cancer (US)
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#### **Regulatory Actions**

- ✓ Nasal glucagon for hypoglycemia (US ✓ /EU✓ )
- Lasmiditan for acute migraine (US)
- Galcanezumab for episodic cluster headache (US)
- 🍑 lxekizumab for radiographic axial spondyloarthritis (US 🤡 /J 🤡 )
- Ramucirumab for 2L high AFP hepatocellular cancer (US < √EU < √J < √S)
  </p>
- ✓ Dulaglutide REWIND CV outcomes study (EU)

#### Other

- Alimta US settlement agreement
- Full separation of Elanco Animal Health
- Closing of **Loxo Oncology** acquisition
- <sup>1</sup> In collaboration with Boehringer Ingelheim
- <sup>2</sup> In collaboration with Pfizer
- 3 Data presented at medical meeting

# **POTENTIAL KEY EVENTS 2020**





#### **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 HFrEF<sup>1</sup> **Tirzepatide** for type 2 diabetes (first of five)

Mirikizumab in psoriasis

Mirikizumab in ulcerative colitis (induction data)

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

#### **Regulatory Submissions**

- ✓ Tanezumab osteoarthritis pain (US)²

#### **Regulatory Actions**

**2019 Q4 EARNINGS** 

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

**Dulaglutide REWIND CV outcomes study (US)** 

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)

**Ixekizumab** for radiographic axial spondyloarthritis (EU)

**⊘ Ramucirumab** for 1L EGFR NSCLC cancer (US/EU **⊘**/J)

Selpercatinib for NSCLC and thyroid cancers (US)

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

<sup>&</sup>lt;sup>2</sup> in collaboration with Pfizer, occurred in Q4 2019

# TIRZEPATIDE PROGRAM UPDATE



### SURPASS-CVOT TRIAL DESIGN

Approximately 12,500 patients with Type 2
Diabetes and confirmed atherosclerotic CV disease



**Primary Endpoint:** Time to first occurrence of the composite endpoint of CV Death, MI or Stroke

### **Key Secondary Endpoints**

- Time to all-cause mortality
- Time to first occurrence of individual components of primary endpoint (CV Death, MI and Stroke)

### CLINICAL UPDATE

- Type 2 Diabetes Phase 3 SURPASS program
- o Strong investigator interest
- Four of eight trials fully enrolled
- o Top-line results from first study expected late 2020
- Obesity Phase 3 SURMOUNT program now ongoing
- NASH Phase 2 SYNERGY-NASH program now ongoing

# BARICITINIB ATOPIC DERMATITIS PROGRAM



### **Data Package**

- Five studies in patients with moderate-to-severe atopic dermatitis
- Includes three monotherapy studies and two studies in combination with topical corticosteroids

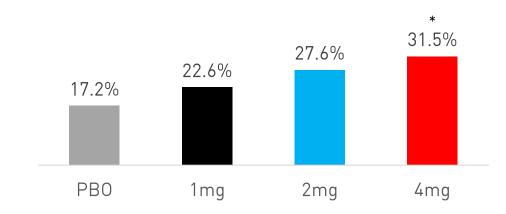
### Safety

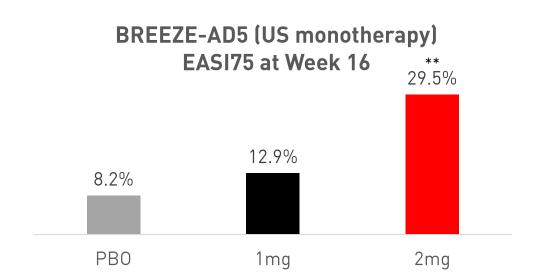
- BREEZE-AD4 and BREEZE-AD5 consistent with known safety findings of baricitinib in atopic dermatitis
- Well characterized safety database with over 10,000 patient years of safety data across indications

### **Submission Timing**

- Submitted in Europe and Japan
- U.S. submission planned in 2020

# BREEZE-AD4 (OUS TCS combo, cyclosporine failures) EASI75 at Week 16





# **SUMMARY**



- Q4 2019 volume-driven revenue growth of 8% (9% in constant currency)
- Operating income as a % of revenue improved nearly 40 bps vs. Q4 2018
- Progress on our innovation-based strategy, including three Phase 3 initiations and several
  positive data readouts and regulatory submissions
- Deployed nearly \$0.6 billion to shareholders via the dividend and completed \$0.3 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**

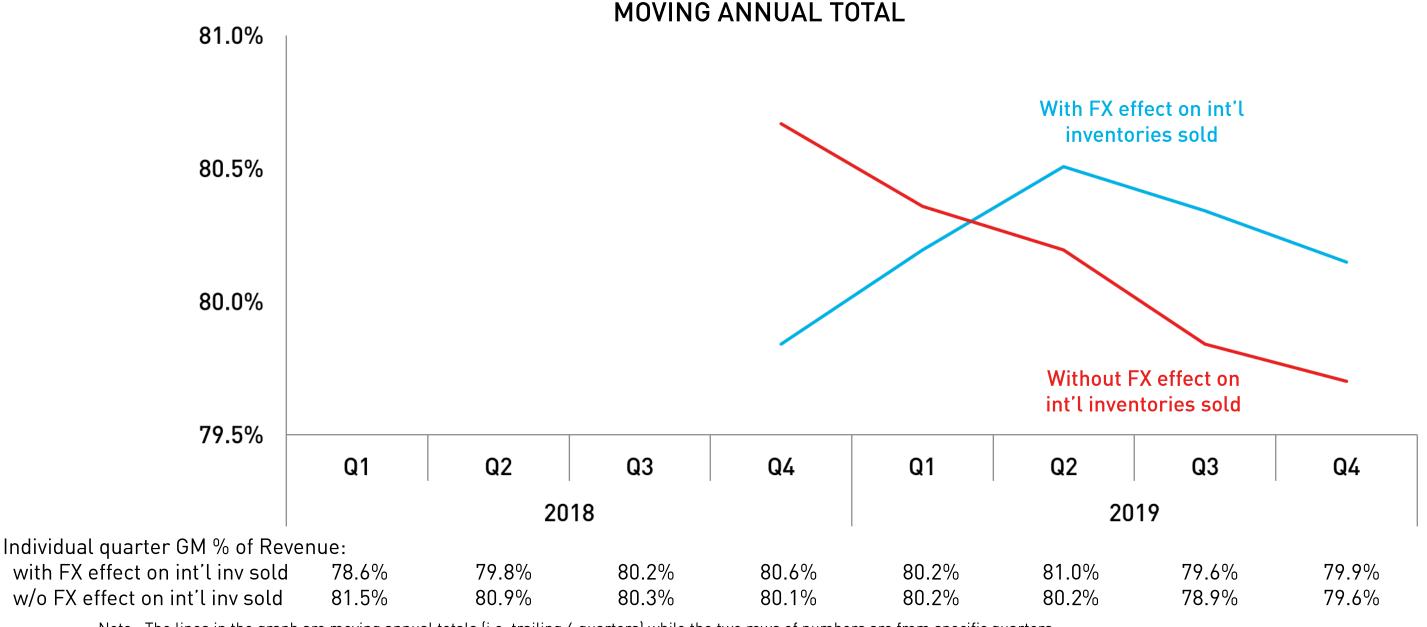


- Fund existing marketed and pipeline products
- Bolster growth prospects via business development
- Annual dividend increases

# Supplementary Slides

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



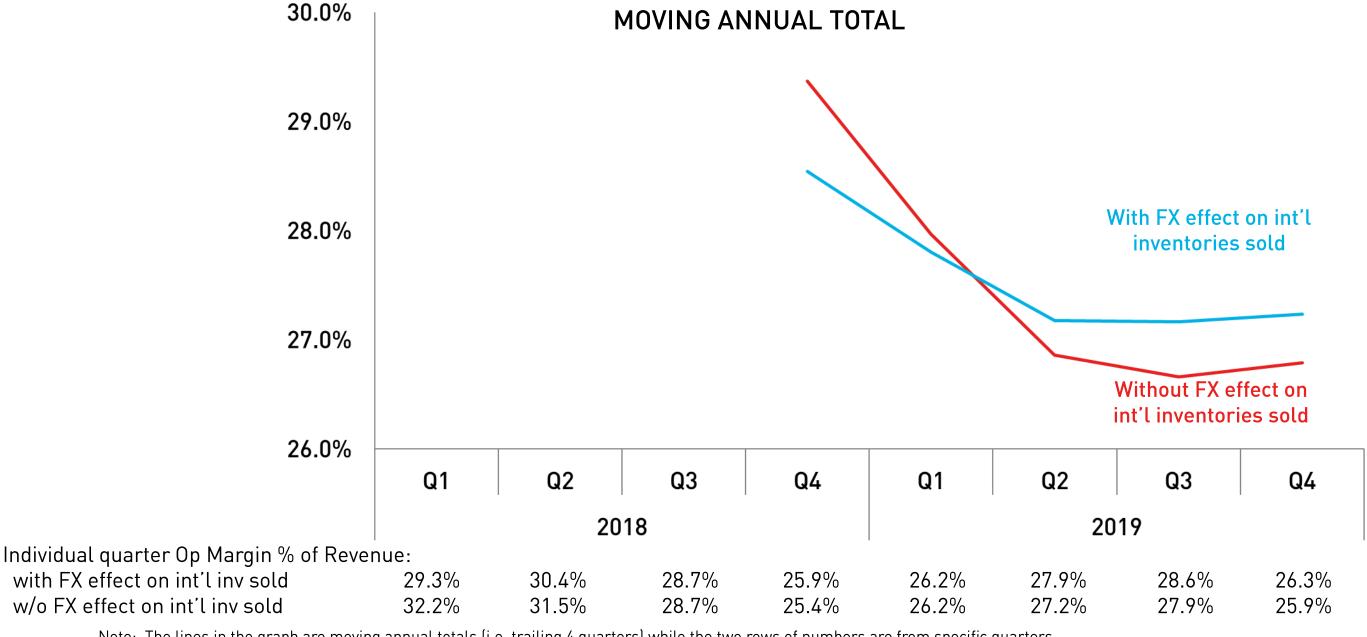


Note: The lines in the graph are moving annual totals (i.e. trailing 4 quarters) while the two rows of numbers are from specific quarters.

<sup>\* 2018</sup> 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.

# **Q4 2019 INCOME STATEMENT NOTES**



#### 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).

#### Q4 2018 NON-GAAP INFORMATION HAS BEEN ADJUSTED TO ELIMINATE:

- acquired in-process R&D charges totaling \$329.4 million (pretax), or \$0.27 per share (after-tax), related to business development
  activity with Dicerna Pharmaceuticals, SIGA Technologies, Chugai Pharmaceutical Co., LTD, NextCure, Inc. and Hydra Biosciences;
- amortization of intangible assets primarily associated with costs of marketed products acquired or licensed from third parties totaling \$37.2 million (pretax), or \$0.03 per share (after-tax);
- asset impairment, restructuring and other special charges of \$192.7 million (pretax), or \$0.18 per share (after-tax), primarily associated with severance costs incurred as a result of actions taken to reduce the company's cost structure;
- 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 (after-tax); and
- adjustments to tax expenses associated with U.S. tax reform and the separation of the Elanco animal health business totaling (\$318.4) million, or (\$0.33) per share (after-tax).

# YTD 2019 INCOME STATEMENT NOTES



#### 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 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 SA, 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 as part of the closing of the acquisition of Loxo Oncology and charges associated with the decision to close and sell a research and development facility located in the United Kingdom, totaling \$563.5 million (pretax), or \$0.58 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);
- 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 (after-tax);
- 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, or (\$0.05) per share (after-tax); and
- discontinued operations of the Elanco Animal Health business, reduction totaling \$3.681 billion, or (\$3.93) per share (after-tax).

#### YTD 2018 NON-GAAP INFORMATION HAS BEEN ADJUSTED TO ELIMINATE:

- acquired in-process R&D charges acquired in a transaction other than a business combination totaling \$1,984 billion (pretax), or \$1.96 per share (after-tax), primarily driven by the acquisitions of ARMO Biosciences and Dicerna Pharmaceuticals;
- amortization of intangible assets primarily associated with costs of marketed products acquired or licensed from third parties totaling \$348.6 million (pretax), or \$0.28 per share (after-tax);
- asset impairment, restructuring and other special charges, totaling \$292.7 million (pretax), or \$0.22 per share (after-tax);
- adjustments to the 2017 Toll Tax for U.S. tax reform proposed regulations and tax expenses associated with the separation of the Elanco animal health business totaling (\$262.9) million, or (\$0.27) 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 \$0.20 per share (after-tax); and
- discontinued operations of the Elanco Animal Health business, reduction totaling (\$81.4) million, or (\$0.08) per share (after-tax).

# **COMPARATIVE EPS SUMMARY 2018/2019**



	1Q18	2Q18	3Q18	4Q18	2018	1Q19	2Q19	3Q19	4Q19	2019
Reported	1.16	(0.25)	1.12	1.10	3.13	4.31	1.44	1.37	1.64	8.89
Non-GAAP	1.31	1.48	1.34	1.32	5.44	1.33	1.50	1.48	1.73	6.04

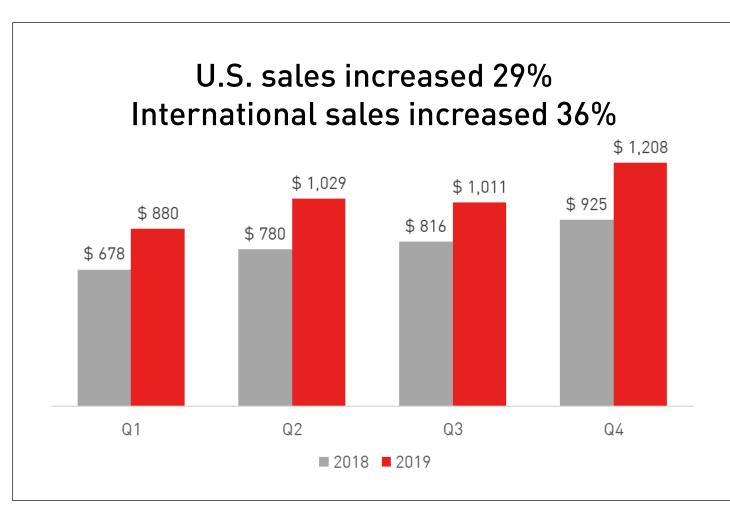
Note: Numbers may not add due to rounding.

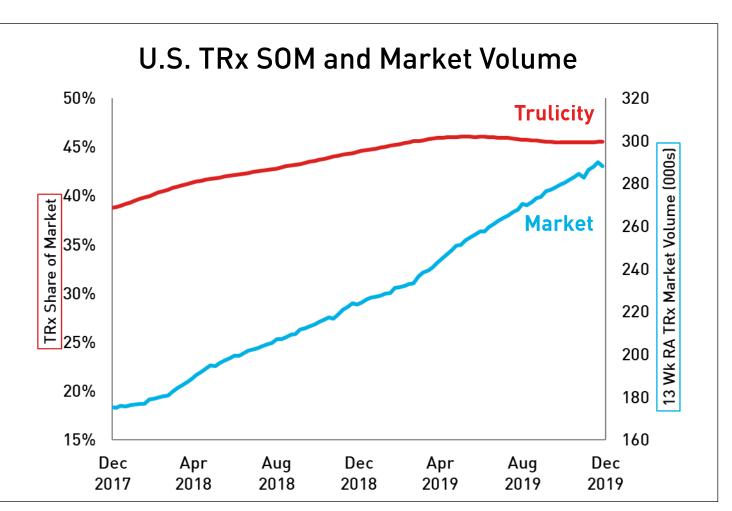
For a complete reconciliation to reported earnings, see slides 26 and 27 and our earnings press release dated January 30, 2020.

# **Q4 2019 TRULICITY SALES INCREASED 31%**



### Millions





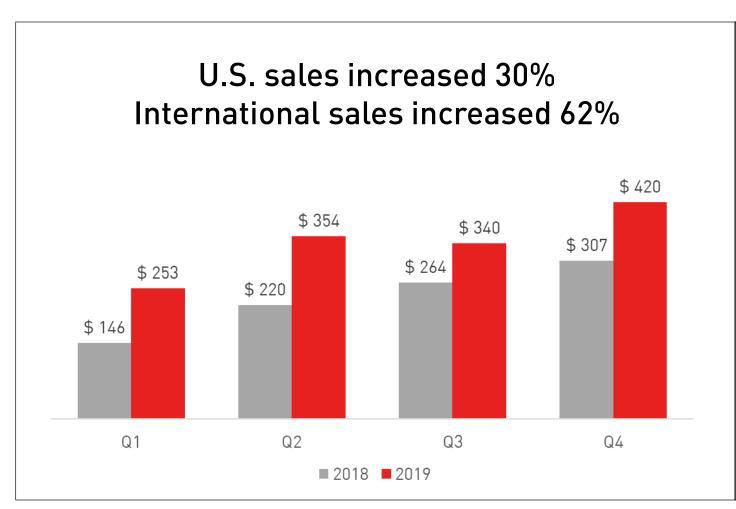
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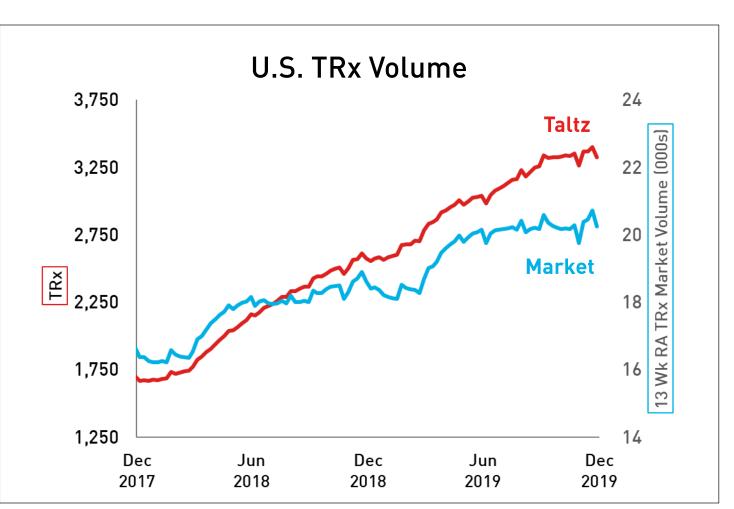
Source: IQVIA NPA TRx 3MMA, weekly data December 27, 2019

# **Q4 2019 TALTZ SALES INCREASED 37%**



### Millions





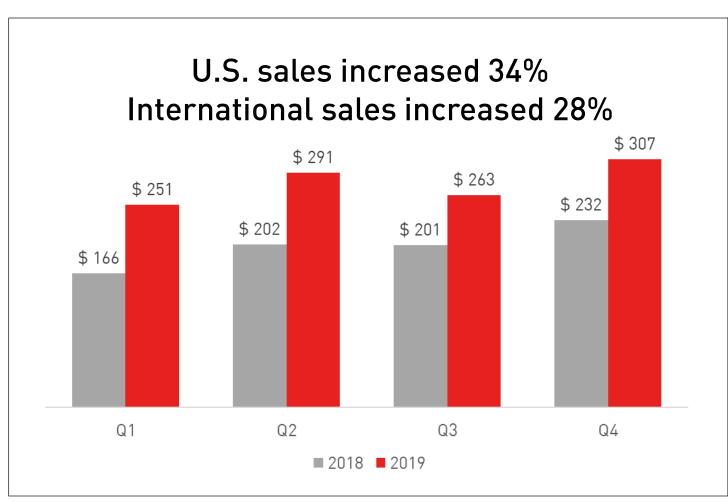
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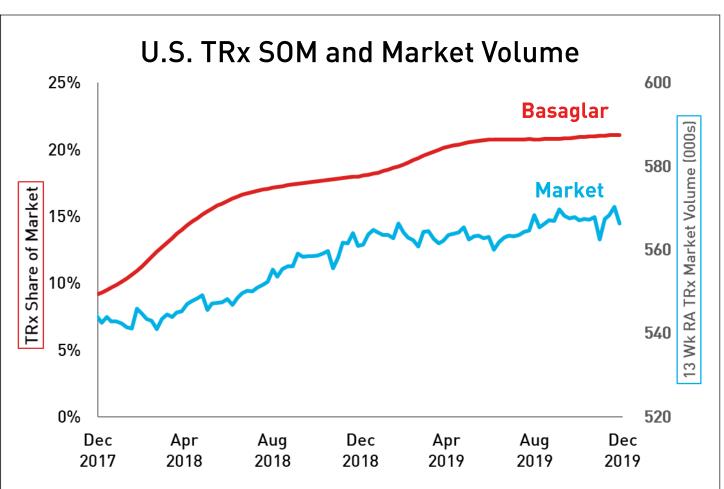
Source: IQVIA NPA TRx 3MMA, weekly data December 27, 2019

# **Q4 2019 BASAGLAR SALES INCREASED 32%**



### Millions





Note: Numbers may not add due to rounding.

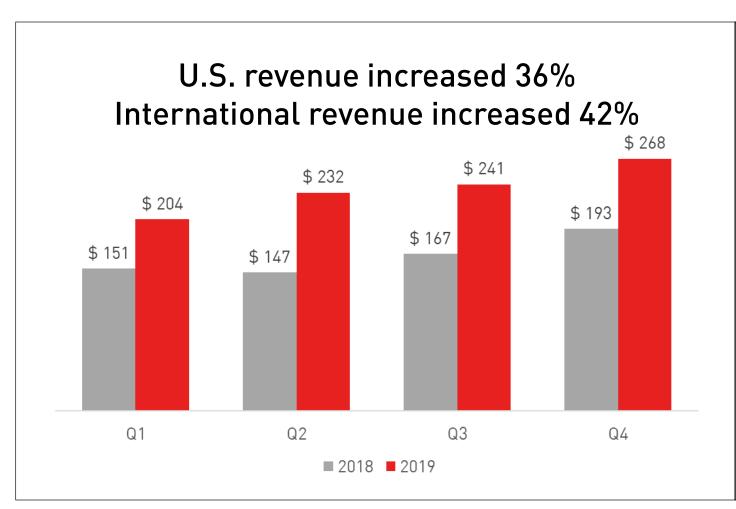
Source: IQVIA NPA TRx 3MMA, weekly data December 27, 2019

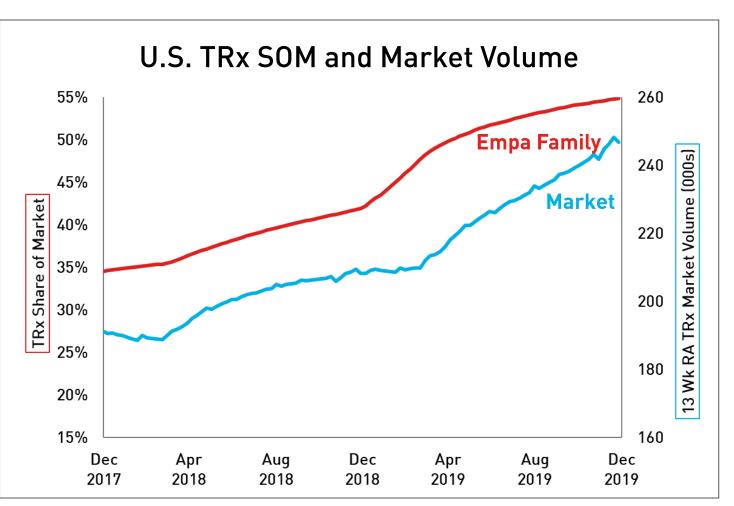
Note: Basaglar is part of the Boehringer Ingelheim and Lilly Diabetes Alliance

# **Q4 2019 JARDIANCE REVENUE INCREASED 39%**



### Millions





Note: Numbers may not add due to rounding.

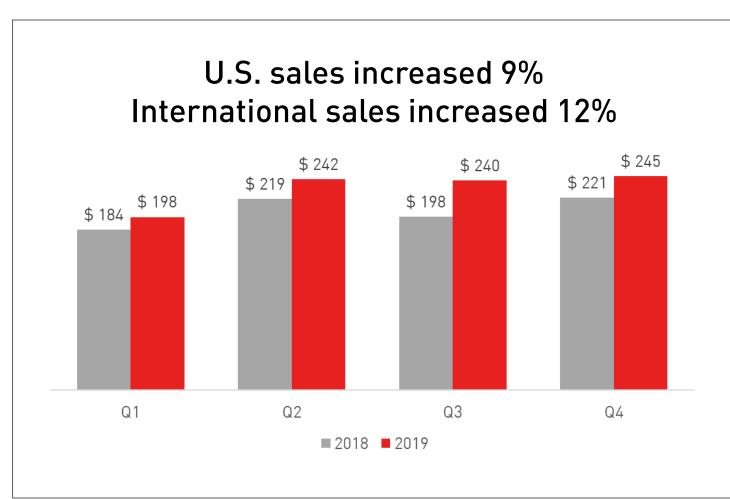
Source: IQVIA NPA TRx 3MMA, weekly data December 27, 2019

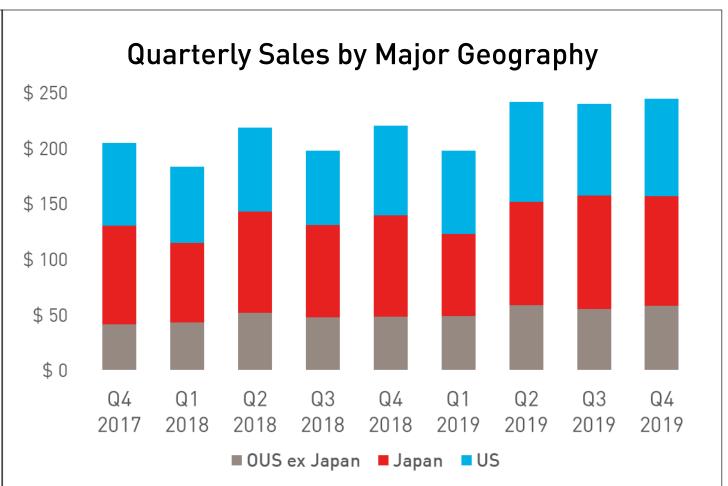
Note: Jardiance is part of the Boehringer Ingelheim and Lilly Diabetes Alliance

# **Q4 2019 CYRAMZA SALES INCREASED 11%**



### Millions



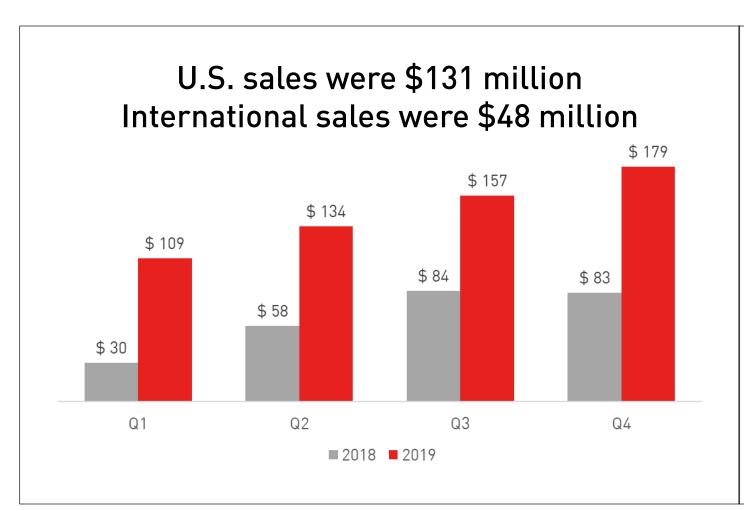


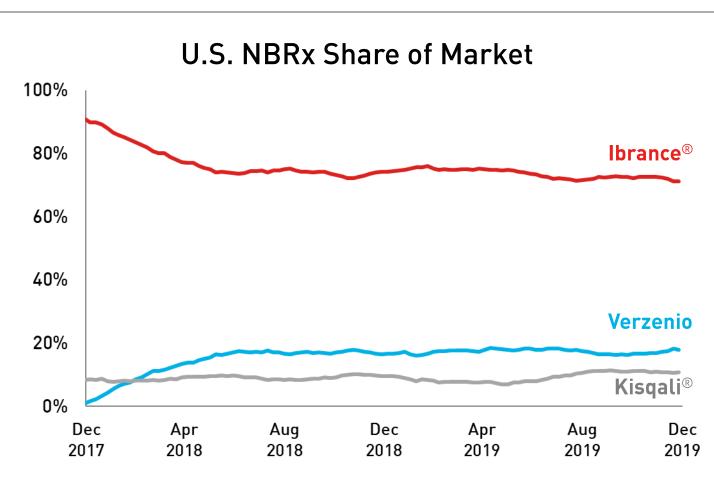
Note: Numbers may not add due to rounding.

# Q4 2019 VERZENIO SALES WERE \$179 MILLION



### Millions





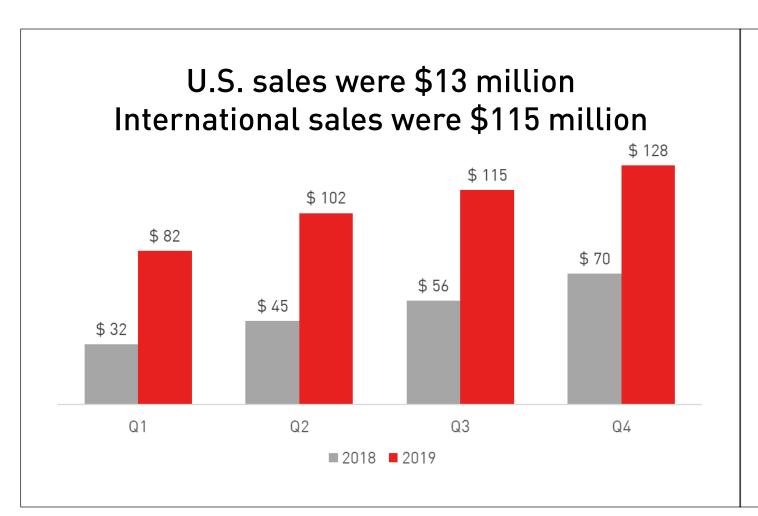
Note: Numbers may not add due to rounding.

Source: IQVIA NPA NBRx 3MMA, weekly data December 27, 2019

# **Q4 2019 OLUMIANT SALES WERE \$128 MILLION**



### Millions



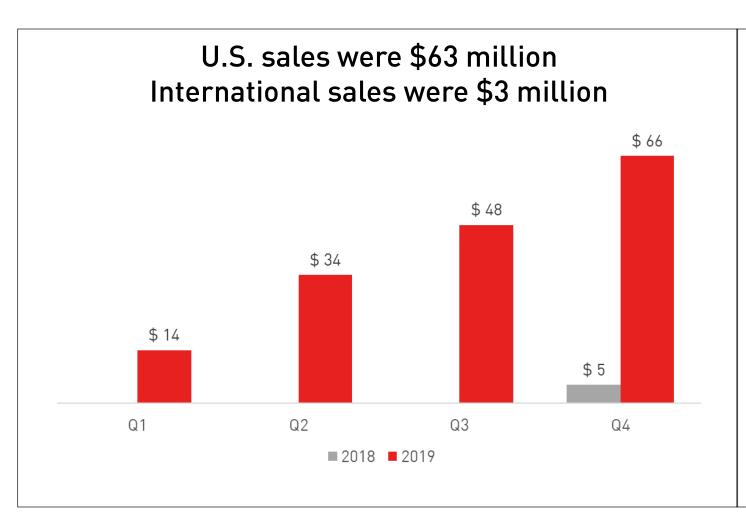
- Launched in the U.S. in July 2018
- Q4 sales driven by Europe, led by Germany
- Key driver of volume growth in Europe and Japan

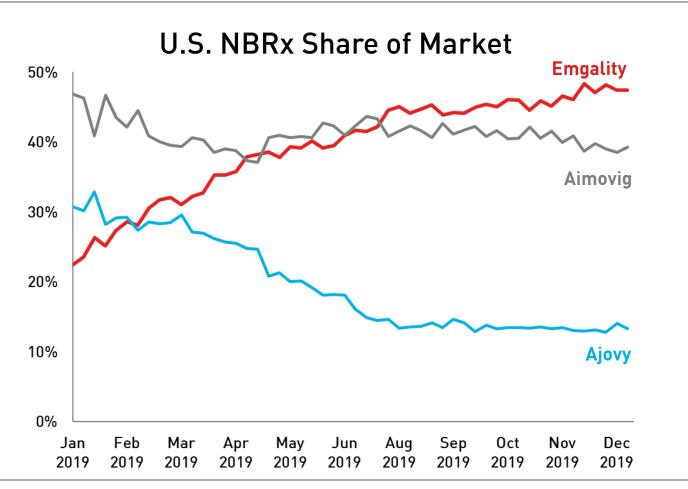
Note: Numbers may not add due to rounding.

# **Q4 2019 EMGALITY SALES WERE \$66 MILLION**



### Millions





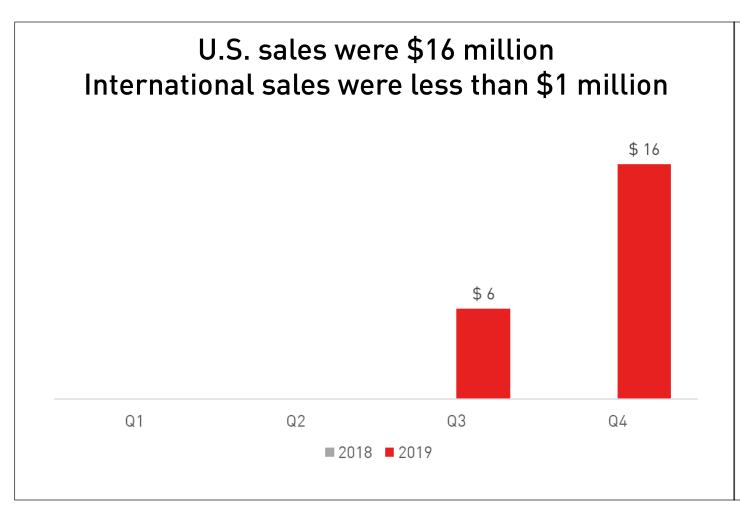
Note: Numbers may not add due to rounding.

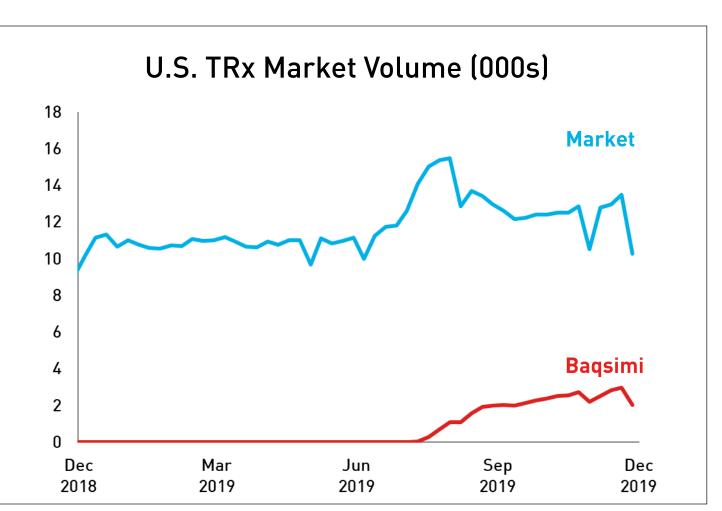
Source: IQVIA NPA NBRx 3MMA, weekly data December 27, 2019

# Q4 2019 BAQSIMI SALES WERE \$16 MILLION



#### Millions





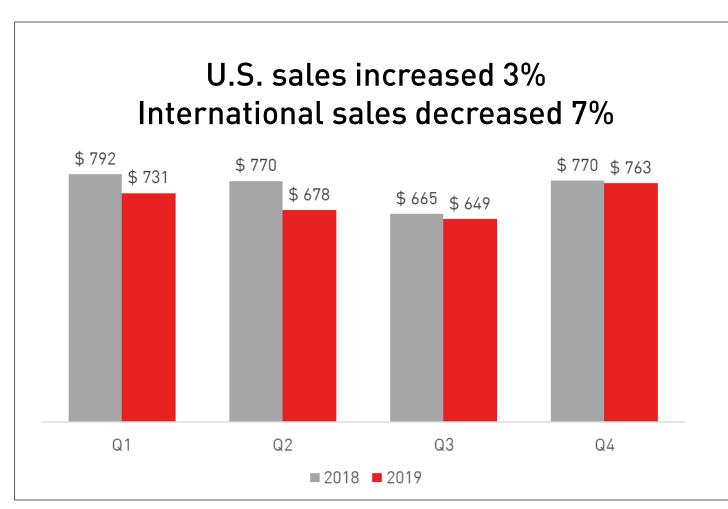
Note: Numbers may not add due to rounding.

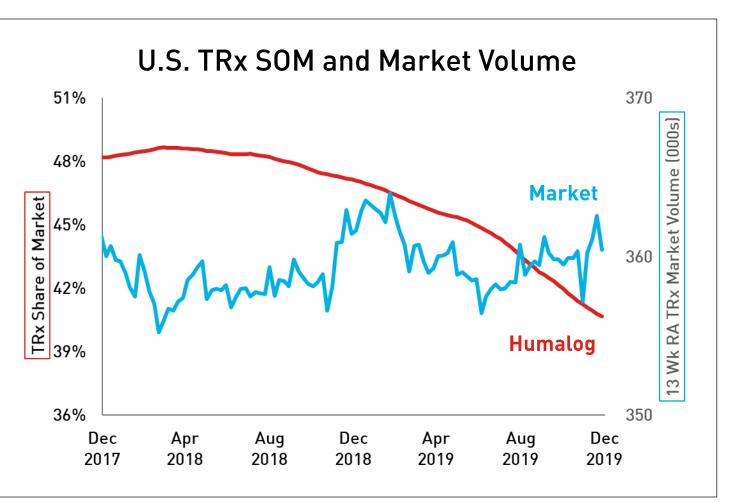
Source: IQVIA NPA TRx, weekly data December 27, 2019

#### Q4 2019 HUMALOG® SALES DECREASED 1%



#### Millions





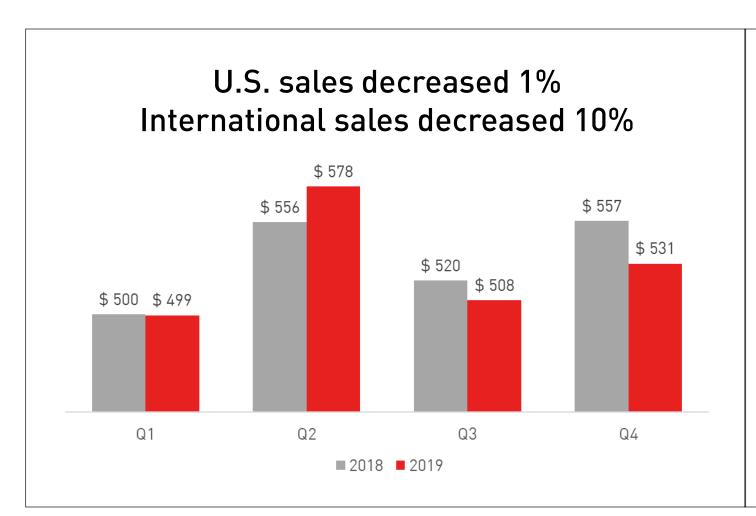
Note: Numbers may not add due to rounding.

Source: IQVIA NPA TRx 3MMA, weekly data December 27, 2019

#### **Q4 2019 ALIMTA SALES DECREASED 5%**



#### Millions



	Q4 Sales	Change	Performance	Rate
U.S. Alimta	\$313.7	(1%)	(1%)	-
OUS Alimta	\$217.0	(10%)	(9%)	(1%)
WW Alimta	\$530.7	(5%)	(4%)	(0%)

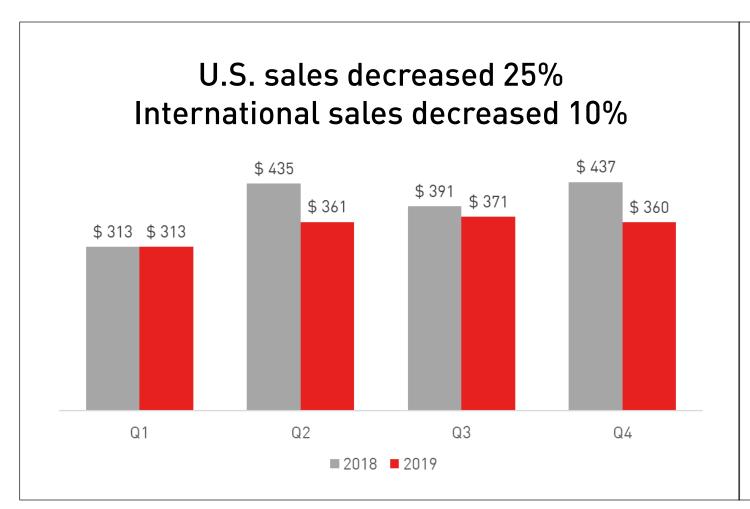
- U.S. sales decrease primarily driven by lower realized prices, partially offset by increased volume
- OUS sales decrease driven primarily by lower realized prices and, to a lesser extent, the unfavorable impact of FX, partially offset by increased demand

Note: Numbers may not add due to rounding.

#### Q4 2019 FORTEO® SALES DECREASED 18%



#### Millions



	Q4 Sales	Change	Performance	Rate
U.S. Forteo	\$171.7	(25%)	(25%)	-
OUS Forteo	\$188.5	(10%)	(10%)	(0%)
WW Forteo	\$360.2	(18%)	(18%)	(0%)

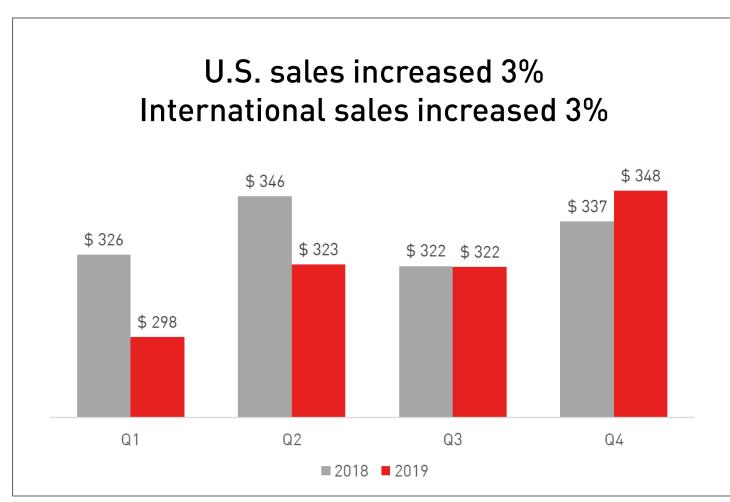
- U.S. sales decrease primarily driven by decreased demand
- OUS sales decrease driven by decreased volume and, to a lesser extent, lower realized prices

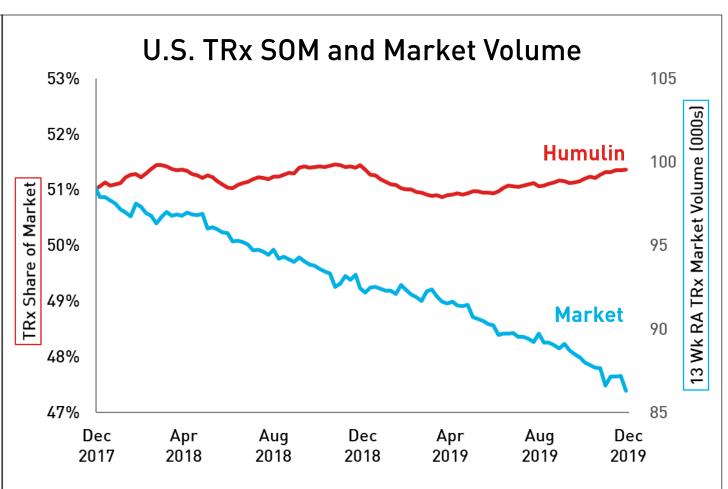
Note: Numbers may not add due to rounding.

#### Q4 2019 HUMULIN® SALES INCREASED 3%



#### Millions





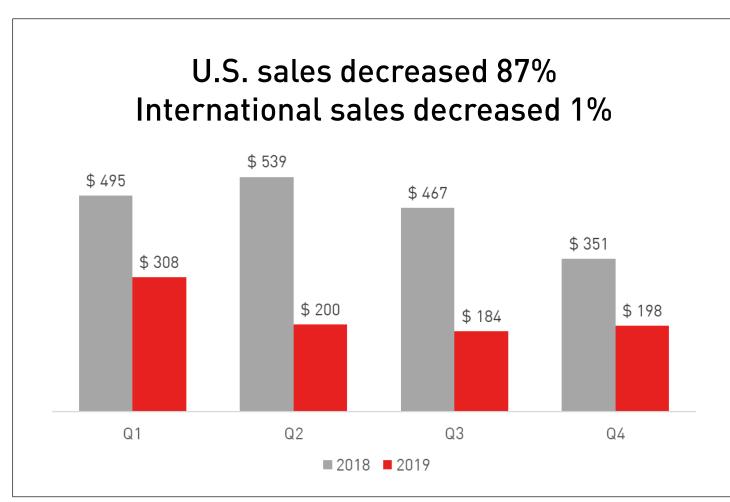
Note: Numbers may not add due to rounding.

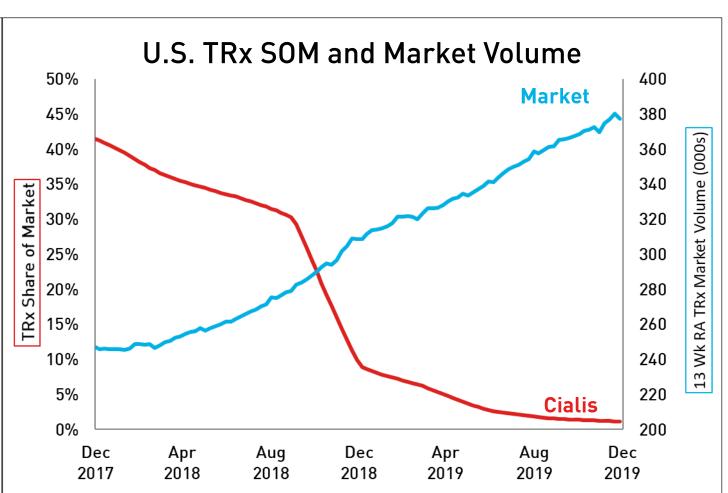
Source: IQVIA NPA TRx 3MMA, weekly data December 27, 2019

#### Q4 2019 CIALIS SALES DECREASED 44%



#### Millions





Note: Numbers may not add due to rounding.

Source: IQVIA NPA TRx 3MMA, weekly data December 27, 2019

# **SELECT TRIALS – CYRAMZA**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04145349	Desmo- plastic Small Round Cell Tumor	CAMPFIRE: A Study of Ramucirumab (LY3009806) in Children and Young Adults With Desmoplastic Small Round Cell Tumor	1/2	34	Progression Free Survival (PFS)	Jul 2023	Jul 2023
NCT02898077	Gastro- esophageal Junction Adeno- carcinoma	A Study of Paclitaxel With or Without Ramucirumab (LY3009806) in Participants With Gastric or Gastroesophageal Cancer	3	450	Overall Survival (OS)	Jul 2020	Dec 2020
NCT02564198^	Pediatric Solid Tumor	A Study of Ramucirumab (LY3009806) in Children With Refractory Solid Tumors	1	36	Maximum Tolerated Dose of Ramucirumab	Mar 2020	Mar 2020
NCT04145700	Synovial Sarcoma	CAMPFIRE: A Study of Ramucirumab (LY3009806) in Children and Young Adults With Synovial Sarcoma	1/2	33	Progression Free Survival (PFS)	Jul 2023	Jul 2023

<sup>^</sup>Children's Oncology Group listed as additional sponsor

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

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

# **SELECT TRIALS – JARDIANCE**



							<b>4</b>
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)	3	6200	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 $\geq$ 40% in eGFR from randomization) or (ii) Cardiovascular death	Jun 2022	Jun 2022
NCT03332212	Heart Failure	A Study That Looks at the Function of the Heart in Patients With Heart Failure Who Take Empagliflozin	3	86	Change from baseline to week 12 in PCr/ATP ratio in the resting state measured by 31P MRS.	Apr 2020	Apr 2020
NCT03057977	Heart Failure	EMPagliflozin outcomE tRial in Patients With chrOnic heaRt Failure With Reduced Ejection Fraction (EMPEROR-Reduced)	3	3600	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 reduced Ejection Fraction (HFrEF)	Jun 2020	Jul 2020
NCT03057951	Heart Failure	EMPagliflozin outcomE tRial in Patients With chrOnic heaRt Failure With Preserved Ejection Fraction (EMPEROR-Preserved)	3	5750	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 net clinical benefit, hierarchical composite endpoint composed of time to death, number of heart failure events (HFEs), time to first HFE, change in KCCQ-CSS from baseline after 90 days of treatment	Apr 2021	Jul 2021
				<del></del>			
NCT03429543	Diabetes Mellitus, Type 2	Diabetes Study of Linagliptin and Empagliflozin in Children and Adolescents (DINAMO)TM	3	186	DINAMO TM: Change from baseline in HbA1c (%)	Jul 2021	Jan 2022

In collaboration with Boehringer Ingelheim

<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
NCT03570749	Alopecia Areata	A Study of Baricitinib (LY3009104) in Participants With Severe or Very Severe Alopecia Areata	2/3	725	Percentage of Participants Achieving Alopecia Areata Investigator Global Assessment (AA-IGA <sup>TM</sup> 0 or 1 with a <u>&gt;</u> 2 Point Improvement	Nov 2020	Mar 2022
NCT03899259	Alopecia Areata	A Study of Baricitinib (LY3009104) in Adults With Severe or Very Severe Alopecia Areata	3	476	Percentage of Participants Achieving Alopecia Areata Investigator Global Assessment (AA-IGA™) 0 or 1 with a ≥Point Improvement	Dec 2020	Mar 2022
NCT03428100	Atopic Dermatitis	A Long-term Study of Baricitinib (LY3009104) With Topical Corticosteroids in Adults With Moderate to Severe Atopic Dermatitis That Are Not Controlled With Cyclosporine or for Those Who Cannot Take Oral Cyclosporine Because it is Not Medically Advisable	e 3	500	Proportion of Participants Achieving Eczema Area and Severity Index 75 (EASI75) (High or Mid Dose)	Nov 2019	Jun 2023
NCT03435081	Atopic Dermatitis	A Study of Baricitinib (LY3009104) in Adult Participants With Moderate to Severe Atopic Dermatitis	3	450	Proportion of Participants Achieving Eczema Area and Severity Index 75 (EASI75) (High Dose)	Dec 2019	Sep 2021
NCT03952559	Atopic Dermatitis	A Study of Baricitinib (LY3009104) in Children and Adolescents With Atopic Dermatitis	3	465	Percentage of Participants Achieving Investigator's Global Assessment (IGA) of 0 or 1 with a <a>2 Point Improvement</a>	Apr 2021	Jan 2024
NCT03334435	Atopic Dermatitis	A Study of Long-term Baricitinib (LY3009104) Therapy in Atopic Dermatitis	3	1760	Proportion of Participants with a Response of Investigator's Global Assessment (IGA) 0 or 1 at 16 Weeks	Sep 2021	Sep 2023
NCT03559270	Atopic Dermatitis	A Study of Baricitinib (LY3009104) in Participants With Moderate to Severe Atopic Dermatitis	3	300	Proportion of Participants Achieving Eczema Area and Severity Index (EASI75)	Nov 2021	Dec 2021
NCT03773978	Juvenile Idiopathic Arthritis	A Study of Baricitinib in Participants From 2 Years to Less Than 18 Years Old With Juvenile Idiopathic Arthritis	3	197	Time to Disease Flare	Aug 2021	Aug 2021
NCT03773965	Juvenile Idiopathic Arthritis	A Study of Baricitinib in Participants From 1 Year to Less Than 18 Years Old With Juvenile Idiopathic Arthritis	3	190	Number of Participants with One or More Serious Adverse Event(s) (SAEs)	Dec 2027	Dec 2027

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

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

# **SELECT TRIALS – OLUMIANT (CONT.)**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT01885078	Rheumatoid Arthritis	An Extension Study in Participants With Moderate to Severe Rheumatoid Arthritis	3	2944	Number of Participants (pts) with One or More Drug Related Adverse Events (AEs) or any Serious AEs	Feb 2024	Mar 2024
NCT04086745	Rheumatoid Arthritis	A Study of Baricitinib in Participants With Rheumatoid Arthritis	4	1300	Time from First Dose of Study Treatment to First Event of Venous Thromboembolism (VTE)	Dec 2024	Dec 2024
NCT03915964	Rheumatoid Arthritis	A Study of Baricitinib (LY3009104) in Participants With Rheumatoid Arthritis	4	2600	Time from First Dose of Study Treatment to First Event of Venous Thromboembolism (VTE)	Feb 2026	Feb 2026
NCT04088396	Systemic Juvenile Idiopathic Arthritis	A Study of Baricitinib (LY3009104) in Participants From 1 Year to Less Than 18 Years Old With sJIA	3	103	Time to Disease Flare	Apr 2023	Apr 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)	May 2021	Jun 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)	May 2021	Jun 2021
NCT03843125	Systemic Lupus Erythematosus	A Study of Baricitinib in Participants With Systemic Lupus Erythematosus (SLE)	3	1100	Percentage of Participants with Treatment-Emergent Adverse Events (TEAEs)	May 2024	Jun 2024
NCT04088409	Uveitis	A Study of Baricitinib (LY3009104) in Participants From 2 Years to Less Than 18 Years Old With Active JIA-Associated Uveitis or Chronic Anterior Antinuclear Antibody-Positive Uveitis	3	40	Percentage of Responders	Jul 2022	Jan 2028

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

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

### **SELECT TRIALS – SELPERCATINIB**



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
	Γ		Ι				1
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	400	Progression Free Survival (PFS) by Blinded Independent Central Review (BICR) (with or without Pembrolizumab)	Dec 2023	Apr 2026

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

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

# **SELECT TRIALS – TALTZ**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03129100	AxSpA	A Long Term Extension Study of Ixekizumab (LY2439821) in Participants With Axial Spondyloarthritis	3	750	Proportion of Participants who do not Experience a Flare (Combined Ixekizumab Treatment)	May 2020	Mar 2021

<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	I WITH LANCER PAIN LILIE TO KONE METASTASIS WHO ARE TAKING	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

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

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

# **SELECT TRIALS – TRULICITY**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT02963766	Type 2 Diabetes	A Study of Dulaglutide (LY2189265) in Children and Adolescents With Type 2 Diabetes	3	150	Change from Baseline in Hemoglobin A1c (HbA1c)	Jun 2021	Jan 2022

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

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

### **SELECT TRIALS – ULTRA-RAPID LISPRO**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03830281	Type 1 Diabetes Mellitus	A Study Comparing LY900014 to Insulin Lispro (Humalog) in Adults With Type 1 Diabetes Using Insulin Pump Therapy	3	526	Change from Baseline in Hemoglobin A1c (HbA1c)	Jan 2020	Jan 2020
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)	Jan 2021	Jan 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)	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)	Nov 2020	Nov 2020

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

# **SELECT TRIALS – MIRIKIZUMAB**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT03482011	Psoriasis	A Study to Evaluate the Efficacy and Safety of Mirikizumab (LY3074828) in Participants With Moderate-to-Severe Plaque Psoriasis	3	689	Percentage of Participants with a Static Physician's Global Assessment of (sPGA) (0,1) with at Least a 2-point Improvement from Baseline	Mar 2019	Feb 2020
NCT03535194	Psoriasis	A Study to Assess if Mirikizumab is Effective and Safe Compared to Secukinumab and Placebo in Moderate to Severe Plaque Psoriasis (OASIS-2)	3	1443	Percentage of Participants with a Static Physician's Global Assessment (sPGA) of (0,1) with at Least a 2-point Improvement from Baseline	Mar 2020	Dec 2020
NCT03556202	Psoriasis	A Long-term Study to Evaluate Safety and Maintenance of Treatment Effect of LY3074828 in Participants With Moderate-to-Severe Plaque Psoriasis (OASIS-3)	3	1816	Percentage of Participants with a Static Physician's Global Assessment Among Those who Entered the Study with a sPGA of 0,1(sPGA) of (0,1)	May 2024	May 2024
NCT03926130	Crohn's Disease	A Study of Mirikizumab (LY3074828) in Participants With Crohn's Disease	3	1100	Percentage of Participants Achieving Endoscopic Response	Feb 2022	Jul 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	Jun 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

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

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

#### **SELECT TRIALS – SOLANEZUMAB**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT01760005^	Alzheimers Disease	Dominantly Inherited Alzheimer Network Trial: An Opportunity to Prevent Dementia. A Study of Potential Disease Modifying Treatments in Individuals at Risk for or With a Type of Early Onset Alzheimer's Disease Caused by a Genetic Mutation.		490#	Assess cognitive efficacy in individuals with mutations causing dominantly inherited AD as measured by change in the DIAN-TU cognitive composite score.	Dec 2020##	Mar 2021##
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

<sup>^</sup>Washington University in St. Louis School of Medicine listed as primary sponsor

<sup>^^</sup>Alzheimer's Therapeutic Research Institute listed as additional sponsor

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

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

<sup>#</sup>Includes all participants in multi-drug platform study

<sup>##</sup>For ongoing study arms in multi-drug platform study. Dates for solanezumab are primary completion: Nov 2019, completion: Nov 2019

### **SELECT TRIALS – TIRZEPATIDE**



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
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)	Sep 2020	Oct 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		472	Change from Baseline in Hemoglobin A1c (HbA1c) (10 mg and 15 mg)	Jan 2021	Jan 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	Mar 2021	Mar 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	1872	Change from Baseline in Hemoglobin A1c (HbA1c) (10 mg and 15 mg)	Mar 2021	Apr 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)	Apr 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	Feb 2022

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

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

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



Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
NCT04166773	Non-alcoholic Steatohepatitis	· · · · · · · · · · · · · · · · · · ·		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

### **SELECT TRIALS - VERZENIO**



Study	Indication*			Patients	Primary Outcome**	Primary Completion	Completion
NCT04071262	Advanced Cancer	A Study of Abemaciclib (LY2835219) in Combination With Other Anti-Cancer Therapies in Japanese Participants With Advanced Cancer	1	9	Number of Participants with Dose Limiting Toxicities (DLTs)	May 2020	Jul 2021
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
NCT02057133	Breast Neoplasms	A Study of LY2835219 (Abemaciclib) in Combination With Therapies for Breast Cancer That Has Spread	1	198	Number of Participants with One or More Drug-Related Adverse Events	Apr 2021	Oct 2022
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
NCT03706365	Prostate Cancer	A Study of Abiraterone Acetate Plus Prednisone With or Without Abemaciclib (LY2835219) in Participants With Prostate Cancer	2	180	Radiographic Progression Free Survival (rPFS)	Sep 2021	Feb 2024

<sup>^</sup>NSABP Foundation Inc listed as additional sponsor

<sup>^^</sup>Merck Sharp & Dohme Corp. listed as additional sponsor

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

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

#### **SELECT TRIALS - EARLY PHASE DIABETES**



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Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completio
Basal Insulin - FC	NCT03736785	Type 2 Diabetes Mellitus	A Study of LY3209590 in Participants With Type 2 Diabetes Mellitus	2	375	Change from Baseline in Hemoglobin A1c (HbA1c)	Feb 2020	Feb 2020
GLP-1R NPA	NCT03929744	Healthy	A Study of LY3502970 in Healthy Participants	1	160	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug	Apr 2020	Apr 2020
GIP/GLP	NCT04178733	Healthy	A Safety Study of LY3493269 Given as a Single Injection in Healthy Participants	1	54	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
ANGPTL3/8 MAB	NCT04052594	Dyslipidemias	A Study of LY3475766 in Healthy Participants	1	97	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Jul 2020	Jul 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	Aug 2020	Aug 2020
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	Sep 2020	Sep 2020
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	Sep 2020	Sep 2020

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

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

# **SELECT TRIALS – EARLY PHASE IMMUNOLOGY**



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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
CD200R MAB Agonist	NCT03750643	Dermatitis, Atopic	A Study of LY3454738 in Healthy Participants and Participants With Atopic Dermatitis	1	128	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
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	May 2020	May 2020
IL-2 CONJUGATE	NCT04133116^	Healthy	A Study of LY3471851 in Healthy Participants	1	36	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Mar 2020	Mar 2020
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	Jan 2021	Jan 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	Jan 2021	Jan 2021
PD-1 Antibody 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	Jun 2021	Sep 2021

<sup>^</sup>Nektar Therapeutics listed as additional sponsor

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

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

### **SELECT TRIALS – EARLY PHASE NEURODEGENERATION**

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Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
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)	Jun 2020	Jun 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
O-GlcNAcase Inh.	NCT03944031	Healthy	A Study of the Effects of LY3372689 on the Brain in Healthy Participants	1	28	Percent O-GlcNAcase (OGA) Enzyme Occupancy (EO)	Feb 2020	Feb 2020
O-GlcNAcase Inh.	NCT04106206	Healthy	A Safety Study of LY3372689 in Healthy Participants	1	54	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Observed by the Investigator During Study Drug Administration	Mar 2020	Mar 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	Oct 2020	Oct 2020

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

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

# **SELECT TRIALS - EARLY PHASE ONCOLOGY**



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
Pegilodecakin	NCT03382912	Non Small Cell Lung Cancer	Study of Pegilodecakin (LY3500518) With Nivolumab Compared to Nivolumab Alone Second-line Tx in Participants With Metastatic Non-Small Cell Lung Cancer	2	50	Objective Response Rate	Aug 2019	Aug 2022
Pegilodecakin	NCT03382899	Non Small Cell Lung Cancer	Study of Pegilodecakin (LY3500518) With Pembrolizumab Compared to Pembrolizumab Alone First-line Tx in Participants With Metastatic Non-Small Cell Lung Cancer	2	100	Objective Response Rate	Dec 2019	Nov 2022
Olaratumab	NCT03086369	Metastatic Pancreatic Cancer	A Study of Nab-Paclitaxel and Gemcitabine With or Without Olaratumab (LY3012207) in Participants With Metastatic Pancreatic Cancer	1/2	186	Number of Participants with Dose Limiting Toxicities (DLTs) Phase 1b	Apr 2020	Nov 2021
BTK Inhibitor	NCT03740529	Chronic Lymphocytic Leukemia	A Study of Oral LOXO-305 in Patients With Previously Treated CLL/SLL or NHL	1/2	190	Maximum Tolerated Dose (MTD)	Oct 2020	Apr 2020
Olaratumab	NCT02659020	Soft Tissue Sarcoma	A Study of Olaratumab (LY3012207) in Participants With Advanced Soft Tissue Sarcoma	1/2	310	Phase 1b: Recommended Phase 2 Dose of Olaratumab: Number of Participants with Dose Limiting Toxicity (DLT)	Dec 2020	Dec 2020
Aur A Kinase Inhibitor	NCT03898791	Small Cell Lung Cancer	A Study of LY3295668 Erbumine in Participants With Extensive-stage Small-Cell Lung Cancer	1/2	64	Number of Participants with Dose Reductions	Feb 2021	Feb 2021
KRAS G12C Inhibitor	NCT04165031	Advanced Solid Tumor	A Study of LY3499446 in Participants With Advanced Solid Tumors With KRAS G12C Mutation	1/2	230	Phase 1: Number or Participants with Dose Limiting Toxicities (DLTs)	Dec 2021	Dec 2021

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

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

# **SELECT TRIALS – EARLY PHASE ONCOLOGY (CONT.)**



Molecule	Study	Indication*	Title	Phase	Patients	Primary Outcome**	Primary Completion	Completion
PD-1/PD-L1 Bispecific	NCT03936959	Advanced Cancer	A Study of LY3434172, a PD-1 and PD-L1 Bispecific Antibody, in Advanced Cancer	1	40	Number of Participants with Dose Limiting Toxicities (DLTs)	Jun 2020	Nov 2020
Olaratumab	NCT03126591^	Soft Tissue Sarcoma	A Study of Olaratumab (LY3012207) Plus Pembrolizumab in Participants With Advanced or Metastatic Soft Tissue Sarcoma	1	41	Number of Participants with Olaratumab Dose Limiting Toxicities (DLTs)	Jul 2020	Oct 2020
Aur A Kinase Inhibitor	NCT03955939	Metastatic Breast Cancer	A Study of LY3295668 Erbumine in Participants With Breast Cancer That Has Spread to Other Parts of the Body	1	100	Number of Participants with Dose Reductions	Mar 2021	Mar 2021
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
SERD	NCT04188548	Breast Cancer	A Study of LY3484356 in Participants With Advanced or Metastatic Breast Cancer	1	215	Number of Participants with Dose Limiting Toxicities (DLTs)	Oct 2022	Apr 2023
CD226 Agonist Antibody	NCT04099277	Solid Tumor	A Study of LY3435151 in Participants With Solid Tumors	1	230	Number of Participants with LY3435151 Dose-Limiting Toxicities (DLTs)	Jan 2023	Jan 2023
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>Merck Sharp & Dohme Corp. listed as additional sponsor

<sup>^^</sup>New Approaches to Neuroblastoma Therapy Consortium (NANT) listed as additional sponsor

<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
PACAP38 MAB	NCT03692949	Healthy	A Study of LY3451838 in Healthy Participants	1	80	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	18	Change from Baseline in Cinnamaldehyde (CA)-Induced Dermal Blood Flow (DBF) Measured by Laser Doppler Imaging (LDI)	Feb 2020	Feb 2020
TRPA1 Antagonist	NCT03977974	Healthy	A Study of LY3526318 in Healthy Participants	1	80	Number of Participants with One or More Serious Adverse Event(s) (SAEs) Considered by the Investigator to be Related to Study Drug Administration	Feb 2020	Feb 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	Apr 2020	Apr 2020

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