

# Eli Lilly and Company

## Acquisition of Loxo Oncology

January 7, 2019

*Lilly*

# Agenda

## **Transaction Highlights and Strategic Rationale**

Dave Ricks, Chairman and Chief Executive Officer

## **Combination with Lilly Oncology**

Anne White, President, Lilly Oncology

## **Loxo Oncology Portfolio Overview**

Dan Skovronsky, M.D., Ph.D., Chief Scientific Officer  
and President, Lilly Research Labs

## **Financial Implications**

Josh Smiley, Chief Financial Officer

## **Question and Answer Session**

# SAFE HARBOR PROVISION

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During this conference call, we anticipate making projections and forward-looking statements that are based on management's current expectations, but actual results may differ materially due to various factors. For example, our results – alone or following the completion of this acquisition – may be affected by competitive developments; the timing and success of new product launches; regulatory and legal matters; patent disputes; government investigations; governmental actions regarding pricing, importation and reimbursement; changes in tax law; acquisitions; business development transactions; the state of the financial markets; and the impact of exchange rates.

Also, the proposed acquisition is subject to customary closing conditions, including a successful tender offer and antitrust clearance. For additional information about relevant risk factors, please refer to both Lilly's and Loxo Oncology's Forms 10-K and 10-Q.

Finally, the information we provide about our products and pipeline is for the benefit of the investment community. It is not intended to be promotional and is not sufficient for prescribing decisions.

The company undertakes no duty to update forward-looking statements.

# ADDITIONAL INFORMATION ABOUT THE ACQUISITION AND WHERE TO FIND IT

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The tender offer for the outstanding shares of Loxo Oncology referenced in this communication has not yet commenced. This communication is for informational purposes only and is neither an offer to purchase nor a solicitation of an offer to sell shares of Loxo Oncology, nor is it a substitute for the tender offer materials that Lilly and its acquisition subsidiary will file with the SEC upon commencement of the tender offer. At the time the tender offer is commenced, Lilly and its acquisition subsidiary will file tender offer materials on Schedule TO, and Loxo Oncology will file a Solicitation/Recommendation Statement on Schedule 14D-9 with the SEC with respect to the tender offer. **THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND CERTAIN OTHER TENDER OFFER DOCUMENTS) AND THE SOLICITATION/RECOMMENDATION STATEMENT WILL CONTAIN IMPORTANT INFORMATION. HOLDERS OF SHARES OF LOXO ONCOLOGY ARE URGED TO READ THESE DOCUMENTS CAREFULLY WHEN THEY BECOME AVAILABLE (AS EACH MAY BE AMENDED OR SUPPLEMENTED FROM TIME TO TIME) BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION THAT HOLDERS OF LOXO ONCOLOGY SECURITIES SHOULD CONSIDER BEFORE MAKING ANY DECISION REGARDING TENDERING THEIR SECURITIES.** The Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement, will be made available to all holders of shares of Loxo Oncology at no expense to them. The tender offer materials and the Solicitation/Recommendation Statement will be made available for free at the SEC's web site at [www.sec.gov](http://www.sec.gov).

In addition to the Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement, Lilly and Loxo Oncology file annual, quarterly and current reports and other information with the SEC. Lilly's and Loxo Oncology's filings with the SEC are available for free to the public from commercial document-retrieval services and at the website maintained by the SEC at [www.sec.gov](http://www.sec.gov).

# STRATEGIC RATIONALE

Loxo Oncology acquisition consistent with Lilly strategy



## Grow Revenue



- Brings opportunity for multiple near-term launches, bolstering oncology franchise
- Enhances growth prospects post-Alimta patent expiration
- Contributes revenue in 2019

## Improve Productivity



- No changes to 2020 operating margin goal
- Targeted oncology is an efficient operating model
- Deal accretive to operating margins over time

## Create Long-Term Value



- Consistent with strategy to upgrade pipeline and enhance future growth through business development
- Potential for meaningful value contribution well into 2030s

## Speed Life-Changing Medicines



- Therapies with significant effect size in targeted populations
- Potential to launch multiple first-and/or best-in-class medicines
- Multiple assets de-risked clinically

# LILLY ONCOLOGY PORTFOLIO ENHANCED

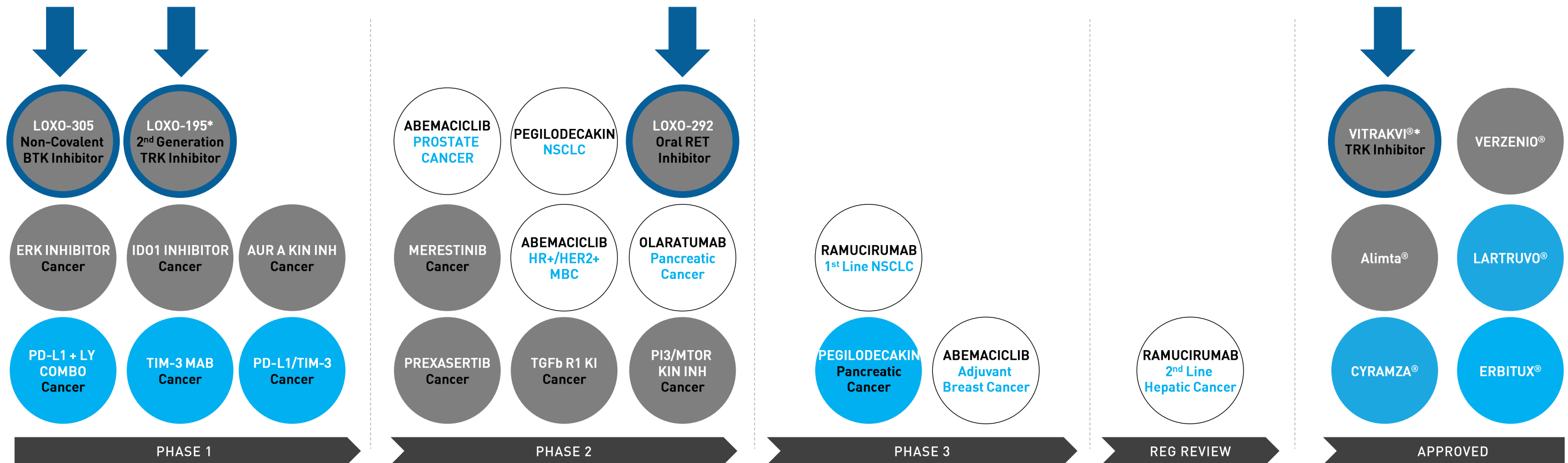
Existing Lilly Oncology Pipeline as of January 4, 2019



## LEGEND

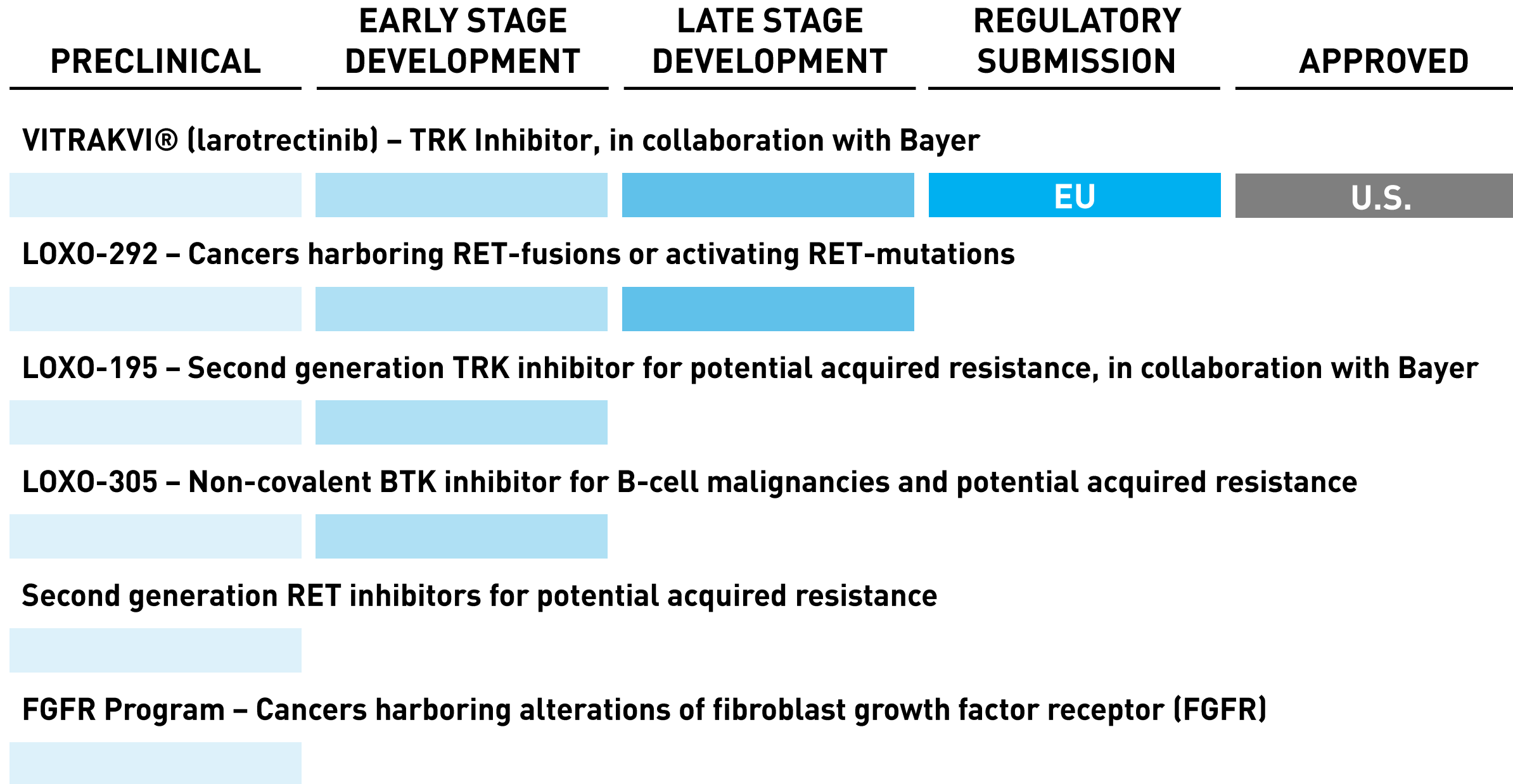
- CHEMICAL ENTITY
- BIOTECH ENTITY
- NILEX
- LOXO Additions

\* Commercial Collaboration



# LOXO ONCOLOGY PORTFOLIO

Highly selective, targeted cancer therapies for specific tumor mutations





# VITRAKVI (LAROTRECTINIB)

SELECTIVE ORAL TRK INHIBITOR IN COLLABORATION WITH BAYER<sup>(1)</sup>



## KEY ATTRIBUTES

### First in class

- FDA accelerated approval November 2018
- Submitted to EMA in August 2018

### Best in class

- 75% overall response rate (ORR) across various solid tumors in adults and children<sup>(2)</sup>
  - 53% partial response<sup>(2)</sup>
  - 22% complete response<sup>(2)</sup>
- First treatment with tumor-agnostic indication at time of initial FDA approval

### Observed adverse events mostly grade 1/2

## DATA PRESENTATIONS

### NEJM publication February 2018

- Clinical data in 55 patients with TRK fusion cancer

### ITPCC September 2018

- Poster with clinical data in children and adolescents with TRK fusion metastatic thyroid carcinoma

### IASLC World Lung September 2018

- Presentation of clinical data in TRK fusion NSCLC

### American Thyroid Association October 2018

- Poster of clinical data in TRK fusion thyroid cancer

### ESMO October 2018

- Presentation of one year follow-up data for 55 patients in NEJM, and additional 67 enrolled subsequently

Abbreviations: NEJM=New England Journal of Medicine; ITPCC=Integrative Therapies Program for Children with Cancer; IASLC=International Association for the Study of Lung Cancer; ESMO=European Society for Medical Oncology

(1) Loxo Oncology leads global development activities and U.S. regulatory activities. Bayer leads ex-U.S. regulatory activities and worldwide commercial activities. Globally, Bayer and Loxo Oncology share development costs 50/50. In the U.S., there is co-promotion agreement. Globally, Bayer books sales. Loxo Oncology receives 50% of U.S. operating profit and a royalty outside the U.S.

(2) Per U.S. Prescribing Information.

Not for promotional use



# LOXO-195

NEXT GENERATION TRK INHIBITOR IN COLLABORATION WITH BAYER<sup>(1)</sup>



## KEY ATTRIBUTES

### Continuation of TRK franchise

- Designed to address acquired resistance in patients treated with TRK inhibitors

### Currently being evaluated in Phase 1 / 2 study

- Study initiated in July 2017
- Granted Orphan Drug Designation by FDA
- Phase 1 data expected 1H 2019

### Projected submission in 2021, potential regulatory action in 2022

## DATA PRESENTATIONS

### AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics 2016

- Data presented on potency, specificity and favorable in-vivo properties in animals

### Cancer Discovery June 2017

- Research brief outlining preclinical rationale

Abbreviations: AACR=American Association for Cancer Research; NCI=National Cancer Institute; EORTC=European Organization for Research and Treatment of Cancer

(1) Loxo Oncology leads global development activities and U.S. regulatory activities. Bayer leads ex-U.S. regulatory activities and worldwide commercial activities. Globally, Bayer and Loxo Oncology share development costs 50/50. In the U.S., there is co-promotion agreement. Globally, Bayer books sales. Loxo Oncology receives 50% of U.S. operating profit and a royalty outside the U.S.

### KEY ATTRIBUTES

#### Potentially first-in-class, launching in 2020

- Breakthrough Therapy designation for three indications:
  - RET-fusion positive NSCLC, RET-fusion positive thyroid cancer and RET-mutant medullary thyroid cancer
- Currently in Phase 2 portion of LIBRETTO-001 study
- Pending regulatory discussions, potential for U.S. submission in late 2019

#### Potentially best in class

- ORR rates: RET-fusion positive NSCLC (68%)<sup>(1)</sup>, RET-fusion positive thyroid cancer (78%)<sup>(2)</sup> and RET-mutant medullary thyroid cancer (59%)<sup>(2)</sup>
- Presentation of registrational Phase 2 data 2H 2019

#### Adverse events mostly grade 1/2

### DATA PRESENTATIONS

#### ASCO June 2018

- 82 patients with RET-altered cancers

#### IASLC World Lung September 2018

- Update from ASCO in 38 patients with RET fusion positive NSCLC

#### American Thyroid Association October 2018

- Update from ASCO in 38 patients with RET-mutant medullary thyroid cancer and RET fusion-positive thyroid cancer

# LOXO-305

HIGHLY SELECTIVE NON-COVALENT BTK INHIBITOR, FULLY OWNED BY LOXO ONCOLOGY



## KEY ATTRIBUTES

- **Designed to address resistance and intolerance in patients treated with approved BTK inhibitors**
  - BTK is a validated therapeutic target in numerous B-cell malignancies
  - LOXO-305 is highly active against wild-type BTK and cysteine-481 mutated BTK, which frequently drives resistance to covalent BTK inhibitors
- **Phase 1 / 2 trial initiated December 2018**
  - Patients with various B-cell leukemias and lymphomas

## DATA PRESENTATIONS

- **Society of Hematologic Oncology Annual Meeting September 2018**
  - Preclinical characterization data

# FINANCIAL IMPLICATIONS

## OFFER SUMMARY AND SOURCES OF VALUE



### OFFER SUMMARY

All-cash tender at \$235.00 per share

Premium of approximately 68% to the closing share price on January 4, 2019

Aggregate purchase price of approximately \$8.0 billion

Net of Loxo Oncology cash and investments, purchase price of approximately \$7.2B



### SOURCES OF VALUE

Several sources of value across Loxo Oncology pipeline, with multiple assets de-risked clinically

LOXO-292 most substantial single component

Significant value from TRK franchise

LOXO-305 ascribed modest value given early stage of development

Potential upside from pre-clinical pipeline



# FINANCIAL IMPLICATIONS

## FINANCING SUMMARY AND FINANCIAL IMPACT



### FINANCING SUMMARY

Combination of cash and debt to fund acquisition

Maintain flexibility to pursue licensing and M&A within current credit rating

No change to dividend policy

Likely limit share repurchases to \$3.5 billion during 1H 2019



### FINANCIAL IMPACT

No changes to 2020 financial expectations

Impact to 2019 Financial Guidance to be updated in Q4 2018 earnings announcement in February 2019

Potentially accretive on cash basis in 2022

Potential to drive significant revenue and margin expansion over time



# Summary

Loxo Oncology is an exciting acquisition for Lilly, continuing our strategy of utilizing external innovation to augment internal research and development efforts

Targeted therapies and genetic-based diagnostics offer significant potential to improve the lives of people with advanced cancer

Loxo Oncology's portfolio has potential to contribute multiple first-in-class and/or best-in-class therapies

Transaction bolsters Lilly's oncology franchise and has potential to drive significant growth in the mid-term

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**Grow Revenue**

**Improve Productivity**

**Speed Life-Changing  
Medicines**

**Create Long-Term Value**

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# Question and Answer Session