



# Lilly Announces Agreement To Acquire Loxo Oncology

January 7, 2019

- Acquisition will broaden the scope of Lilly's oncology portfolio into precision medicines through the addition of a marketed therapy and a pipeline of highly selective potential medicines for patients with genomically defined cancers.
- Loxo Oncology's pipeline includes LOXO-292, an oral RET inhibitor being studied across multiple tumor types, which recently was granted Breakthrough Therapy designation by the FDA and could launch in 2020.
- Loxo Oncology's Vitrakvi<sup>®</sup> (larotrectinib) is an oral TRK inhibitor developed and commercialized in collaboration with Bayer that was recently approved by the FDA.
- Lilly will commence a tender offer to acquire all outstanding shares of Loxo Oncology for a purchase price of \$235.00 per share in cash, or approximately \$8.0 billion.
- Lilly will conduct a conference call with the investment community and media today at 8:45 a.m. EST.

INDIANAPOLIS and STAMFORD, Conn., Jan. 07, 2019 (GLOBE NEWSWIRE) -- Eli Lilly and Company (NYSE: LLY) and Loxo Oncology, Inc. (NASDAQ: LOXO) today announced a definitive agreement for Lilly to acquire Loxo Oncology for \$235.00 per share in cash, or approximately \$8.0 billion. Loxo Oncology is a biopharmaceutical company focused on the development and commercialization of highly selective medicines for patients with genomically defined cancers.

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The acquisition would be the largest and latest in a series of transactions Lilly has conducted to broaden its cancer treatment efforts with externally sourced opportunities for first-in-class and best-in-class therapies. Loxo Oncology is developing a pipeline of targeted medicines focused on cancers that are uniquely dependent on single gene abnormalities that can be detected by genomic testing. For patients with cancers that harbor these genomic alterations, a targeted medicine could have the potential to treat the cancer with dramatic effect.

Loxo Oncology has a promising portfolio of approved and investigational medicines, including:

- LOXO-292, a first-in-class oral RET inhibitor that has been granted Breakthrough Therapy designation by the FDA for three indications, with an initial potential launch in 2020. LOXO-292 targets cancers with alterations to the rearranged during transfection (RET) kinase. RET fusions and mutations occur across multiple tumor types, including certain lung and thyroid cancers as well as a subset of other cancers.
- LOXO-305, an oral BTK inhibitor currently in Phase 1/2. LOXO-305 targets cancers with alterations to the Bruton's tyrosine kinase (BTK), and is designed to address acquired resistance to currently available BTK inhibitors. BTK is a validated molecular target found across numerous B-cell leukemias and lymphomas.
- Vitrakvi, a first-in-class oral TRK inhibitor developed and commercialized in collaboration with Bayer that was recently approved by the U.S. Food and Drug Administration (FDA). Vitrakvi is the first treatment that targets a specific genetic abnormality to receive a tumor-agnostic indication at the time of initial FDA approval.
- LOXO-195, a follow-on TRK inhibitor also being studied by Loxo Oncology and Bayer for acquired resistance to TRK inhibition, with a potential launch in 2022.

"Using tailored medicines to target key tumor dependencies offers an increasingly robust approach to cancer treatment," said Daniel Skovronsky, M.D., Ph.D., Lilly's chief scientific officer and president of Lilly Research Laboratories. "Loxo



Oncology's portfolio of RET, BTK and TRK inhibitors targeted specifically to patients with mutations or fusions in these genes, in combination with advanced diagnostics that allow us to know exactly which patients may benefit, creates new opportunities to improve the lives of people with advanced cancer."

"We are gratified that Lilly has recognized our contributions to the field of precision medicine and are excited to see our pipeline benefit from the resources and global reach of the Lilly organization," said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. "Tumor genomic profiling is becoming standard-of-care, and it will be critical to continue innovating against new targets, while anticipating mechanisms of resistance to available therapies, so that patients with advanced cancer have the chance to live longer and better lives."

"Lilly Oncology is committed to developing innovative, breakthrough medicines that will make a meaningful difference for people with cancer and help them live longer, healthier lives," said Anne White, president of Lilly Oncology. "The acquisition of Loxo Oncology represents an exciting and immediate opportunity to expand the breadth of our portfolio into precision medicines and target cancers that are caused by specific gene abnormalities. The ability to target tumor dependencies in these populations is a key part of our Lilly Oncology strategy. We look forward to continuing to advance the pioneering scientific innovation begun by Loxo Oncology."

"We are excited to have reached this agreement with a team that shares our commitment to ensuring that emerging translational science reaches patients in need," said Jacob Van Naarden, chief operating officer of Loxo Oncology. "We are confident that the work we have started, which includes an FDA approved drug, and a pipeline spanning from Phase 2 to discovery, will continue to thrive in Lilly's hands."

Under the terms of the agreement, Lilly will commence a tender offer to acquire all outstanding shares of Loxo Oncology for a purchase price of \$235.00 per share in cash, or approximately \$8.0 billion. The transaction is not subject to any financing condition and is expected to close by the end of the first quarter of 2019, subject to customary closing conditions, including receipt of required regulatory approvals and the tender of a majority of the outstanding shares of Loxo Oncology's common stock. Following the successful closing of the tender offer, Lilly will acquire any shares of Loxo Oncology that are not tendered into the tender offer through a second-step merger at the tender offer price.

The tender offer represents a premium of approximately 68 percent to Loxo Oncology's closing stock price on January 4, 2019, the last trading day before the announcement of the transaction. Loxo Oncology's board recommends that Loxo Oncology's shareholders tender their shares in the tender offer. Additionally, a Loxo Oncology shareholder, beneficially owning approximately 6.6 percent of Loxo Oncology's outstanding common stock, has agreed to tender its shares in the tender offer.

This transaction will be reflected in Lilly's financial results and financial guidance according to Generally Accepted Accounting Principles (GAAP). Lilly will provide an update to its 2019 financial guidance, including the expected impact from the acquisition of Loxo Oncology, as part of its fourth-quarter and full-year 2018 financial results announcement on February 13, 2019.

For Lilly, Deutsche Bank is acting as the exclusive financial advisor and Weil, Gotshal & Manges LLP is acting as legal advisor in this transaction. For Loxo Oncology, Goldman Sachs & Co. LLC is acting as exclusive financial advisor and Fenwick & West LLP is acting as legal advisor.

#### **Conference Call and Webcast**

Lilly will conduct a conference call with the investment community and media today at 8:45 a.m. EST to discuss the acquisition of Loxo Oncology. Investors, media and the general public can access a live webcast of the conference call through the Webcasts & Presentations link that will be posted on Lilly's website at [www.lilly.com](http://www.lilly.com). The webcast of the conference call will be available for replay through February 7, 2019.

#### **About LOXO-292**

LOXO-292 is an oral and selective investigational new drug in clinical development for the treatment of patients with cancers that harbor abnormalities in the rearranged during transfection (RET) kinase. RET fusions and mutations occur across multiple tumor types with varying frequency. LOXO-292 was designed to inhibit native RET signaling as well as anticipated acquired resistance mechanisms that could otherwise limit the activity of this therapeutic approach. LOXO-292



has been granted Breakthrough Therapy Designation by the U.S. FDA for three indications, and could launch as early as 2020.

#### **About LOXO-305**

LOXO-305 is an investigational, highly selective non-covalent Bruton's tyrosine kinase (BTK) inhibitor. BTK plays a key role in the B-cell antigen receptor signaling pathway, which is required for the development, activation and survival of normal white blood cells, known as B-cells, and malignant B-cells. BTK is a validated molecular target found across numerous B-cell leukemias and lymphomas including chronic lymphocytic leukemia, Waldenstrom's macroglobulinemia, mantle cell lymphoma and marginal zone lymphoma.

#### **About Vitrakvi<sup>®</sup> (larotrectinib)**

Vitrakvi is an oral TRK inhibitor for the treatment of adult and pediatric patients with solid tumors with a neurotrophic receptor tyrosine kinase (NTRK) gene fusion without a known acquired resistance mutation that are either metastatic or where surgical resection will likely result in severe morbidity, and have no satisfactory alternative treatments or have progressed following treatment. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

#### **About LOXO-195**

LOXO-195 is a selective TRK inhibitor that is being investigated to address potential mechanisms of acquired resistance that may emerge in patients receiving Vitrakvi<sup>®</sup> (larotrectinib) or other multikinase inhibitors with anti-TRK activity.

#### **About Eli Lilly and Company**

Lilly is a global healthcare leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at [www.lilly.com](http://www.lilly.com) and [www.lilly.com/newsroom/social-channels](http://www.lilly.com/newsroom/social-channels). C-LLY

#### **About Loxo Oncology**

Loxo Oncology is a biopharmaceutical company focused on the development and commercialization of highly selective medicines for patients with genomically defined cancers. Our pipeline focuses on cancers that are uniquely dependent on single gene abnormalities, such that a single drug has the potential to treat the cancer with dramatic effect. We believe that the most selective, purpose-built medicines have the highest probability of maximally inhibiting the intended target, with the intention of delivering best-in-class disease control and safety. Our management team seeks out experienced industry partners, world-class scientific advisors and innovative clinical-regulatory approaches to deliver new cancer therapies to patients as quickly and efficiently as possible. For more information, please visit the company's website at <http://www.loxooncology.com>.

#### **Lilly Cautionary Statement Regarding Forward-Looking Statements**

*This press release contains forward-looking statements about the benefits of Lilly's acquisition of Loxo Oncology, Inc. ("Loxo Oncology"). It reflects Lilly's current beliefs; however, as with any such undertaking, there are substantial risks and uncertainties in implementing the transaction and in drug development. Among other things, there can be no guarantee that the transaction will be completed in the anticipated timeframe, or at all, or that the conditions required to complete the transaction will be met, that Lilly will realize the expected benefits of the transaction, that the molecules will be approved on the anticipated timeline or at all, or that the potential products will be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission ("the SEC"). Lilly will provide an update to certain elements of its 2019 financial guidance as part of its fourth quarter and full-year 2018 financial results announcement. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.*

#### **Loxo Oncology Cautionary Statement Regarding Forward-Looking Statements**

*This press release contains "forward-looking statements" relating to the acquisition of Loxo Oncology by Lilly. Such forward-looking statements include the ability of Loxo Oncology and Lilly to complete the transactions contemplated by the merger*



agreement, including the parties' ability to satisfy the conditions to the consummation of the offer and the other conditions set forth in the merger agreement and the possibility of any termination of the merger agreement, as well as the role of targeted genomics and diagnostics in oncology treatment and acceleration of our work in developing medicines. Such forward-looking statements are based upon current expectations that involve risks, changes in circumstances, assumptions and uncertainties. Actual results may differ materially from current expectations because of risks associated with uncertainties as to the timing of the offer and the subsequent merger; uncertainties as to how many of Loxo Oncology's stockholders will tender their shares in the offer; the risk that competing offers or acquisition proposals will be made; the possibility that various conditions to the consummation of the offer or the merger may not be satisfied or waived; the effects of disruption from the transactions contemplated by the merger agreement on Loxo Oncology's business and the fact that the announcement and pendency of the transactions may make it more difficult to establish or maintain relationships with employees, suppliers and other business partners; the risk that stockholder litigation in connection with the offer or the merger may result in significant costs of defense, indemnification and liability; other uncertainties pertaining to the business of Loxo Oncology, including those set forth in the "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" sections of Loxo Oncology's Annual Report on Form 10-K for the year ended December 31, 2017, which is on file with the SEC and available on the SEC's website at [www.sec.gov](http://www.sec.gov). Additional factors may be set forth in those sections of Loxo Oncology's Quarterly Report on Form 10-Q for the quarter ended September 30, 2018, filed with the SEC in the fourth quarter of 2018. In addition to the risks described above and in Loxo Oncology's other filings with the SEC, other unknown or unpredictable factors could also affect Loxo Oncology's results. No forward-looking statements can be guaranteed and actual results may differ materially from such statements. The information contained in this press release is provided only as of the date of this report, and Loxo Oncology undertakes no obligation to update any forward-looking statements either contained in or incorporated by reference into this report on account of new information, future events, or otherwise, except as required by law.

#### **Additional Information about the Acquisition and Where to Find It**

The tender offer for the outstanding shares of Loxo Oncology referenced in this communication has not yet commenced. This announcement 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 special reports and other information with the SEC. You may read and copy any reports or other information filed by Lilly or Loxo Oncology at the SEC public reference room at 100 F Street, N.E., Washington, D.C. 20549. Please call the Commission at 1-800-SEC-0330 for further information on the public reference room. Lilly's and Loxo Oncology's filings with the SEC are also available to the public from commercial document-retrieval services and at the website maintained by the SEC at [www.sec.gov](http://www.sec.gov).

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