



Loxo Oncology Announces Receipt of Breakthrough Therapy Designation from U.S. Food and Drug Administration for LOXO-292

September 5, 2018

STAMFORD, Conn., Sept. 05, 2018 (GLOBE NEWSWIRE) -- Loxo Oncology, Inc. (Nasdaq:LOXO), a biopharmaceutical company developing highly selective medicines for patients with genomically defined cancers, today announced that the U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to LOXO-292, a selective RET inhibitor, for:

- the treatment of patients with metastatic RET-fusion-positive non-small cell lung cancer who require systemic therapy and have progressed following platinum-based chemotherapy and an anti-PD-1 or anti-PD-L1 therapy; and for
- the treatment of patients with RET-mutant medullary thyroid cancer who require systemic therapy, have progressed following prior treatment and have no acceptable alternative treatment options.

"We look forward to working with FDA to streamline the development of LOXO-292 in the two patient populations that have comprised the bulk of our initial clinical trial enrollment," said Josh Bilenker, M.D., chief executive officer at Loxo Oncology. "Given the many available therapies for non-small cell lung cancer and medullary thyroid cancer, we are pleased that LOXO-292 has shown encouraging data in refractory patients, and hope to demonstrate the full potential of this treatment in additional populations over time."

The LOXO-292 Breakthrough Therapy Designation was based on data from the ongoing global Phase 1/2 LIBRETTO-001 clinical trial. In 2019, the company plans to provide an update on the overall long-term LOXO-292 clinical development plan, based on feedback from global regulators.

The FDA's Breakthrough Therapy Designation is intended to expedite the development and review of a drug candidate that is planned for use to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

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.

LOXO-292 is currently being studied in the global [LIBRETTO-001 Phase 1/2 trial](#). For additional information about the LOXO-292 clinical trial, please refer to www.clinicaltrials.gov. Interested patients and physicians can contact the Loxo Oncology Physician and Patient RET Clinical Trial Hotline at 1-855-RET-4-292 or email clinicaltrials@loxooncology.com.

About RET-Altered Cancers

Genomic alterations in the RET kinase, which include fusions and activating point mutations, lead to overactive RET signaling and uncontrolled cell growth. RET fusions have been identified in approximately 2% of non-small cell lung cancer, 10-20% of papillary and other thyroid cancers, and a subset of other cancers. Activating RET point mutations



account for approximately 60% of medullary thyroid cancer (MTC). Both RET fusion cancers and RET-mutant MTC are primarily dependent on this single activated kinase for their proliferation and survival. This dependency, often referred to as "oncogene addiction," renders such tumors highly susceptible to small molecule inhibitors targeting RET.

About Loxo Oncology

Loxo Oncology is a biopharmaceutical company developing 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 www.loxooncology.com.

Forward Looking Statements

This press release contains "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from what we expect. Examples of forward-looking statements include, among others, the reporting, timing and success of the LIBRETTO-001 trial and LOXO-292, and the timing or success of regulatory approvals. Further information on potential risk factors that could affect our business and its financial results are detailed in our most recent Annual Report on Form 10-K, and other reports as filed from time to time with the Securities and Exchange Commission. We undertake no obligation to publicly update any forward-looking statement, whether written or oral, that may be made from time to time, whether as a result of new information, future developments or otherwise.

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