Loxo Oncology Announces Details of LOXO-292 Abstract to be Presented as Late-Breaking Presentation at the IASLC 18th World Conference on Lung Cancer

September 27, 2017

STAMFORD, Conn., Sept. 27, 2017 (GLOBE NEWSWIRE) -- Loxo Oncology, Inc. (Nasdaq:LOXO), a biopharmaceutical company innovating the development of highly selective medicines for patients with genetically defined cancers, announced details of the LOXO-292 abstract that will be presented as a late-breaking oral presentation at the International Association for the Study of Lung Cancer (IASLC) 18th World Conference on Lung Cancer being held from October 15-18, 2017, in Yokohama, Japan. LOXO-292 is Loxo Oncology’s highly selective RET inhibitor.

The abstract describes the first two patients with RET-fusion lung cancer with and without brain metastases treated with LOXO-292. Both patients had disease progression while receiving prior multi-kinase inhibitors (MKIs). On LOXO-292, both patients achieved partial responses. The first patient was previously treated with RXDX-105, enrolled on the first dose cohort of the Phase 1 trial, received LOXO-292 20 mg daily, and demonstrated a RECIST confirmed partial response. The second patient was previously treated with alectinib (starting at 600 mg twice daily and increased to 900 mg twice daily) and experienced disease progression systemically and in the brain. Due to the rapidly progressive nature of the brain metastases, the patient was ineligible for the Phase 1 trial and received LOXO-292 in doses ranging from 20-100 mg twice daily under an intra-patient dose escalation single patient protocol. The patient demonstrated a RECIST unconfirmed partial response, including a response in the brain, with a confirmatory response assessment pending as of the abstract’s writing. Both patients remained on LOXO-292 as of the abstract’s writing; additional patient follow-up for these two cases will be discussed in the oral presentation. In this early, two patient data set, LOXO-292 has been well-tolerated, with no adverse events attributed to LOXO-292.

“We are excited to present LOXO-292 proof-of-concept clinical data to the clinical community,” said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. “Just four months after initiating a Phase 1 trial, LOXO-292 is already achieving clinically meaningful levels of RET target coverage in patients, as evidenced by anti-tumor activity in pretreated patients. With our Phase 1 trial continuing to dose escalate, we look forward to providing a more comprehensive trial update in 2018.”

The schedule for the late-breaking oral presentation is as follows:

**Presentation Date:** October 18, 2017  
**Title:** LOXO-292, a potent, highly selective RET inhibitor, in MKI-resistant RET fusion-positive lung cancer patients with and without brain metastases  
**Session Title:** Emerging Genomic Targets  
**Presenter:** Vamsidhar Velcheti, M.D.

The full text of the abstract can be found here.

**About LOXO-292**
LOXO-292 is a potent, 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 have been identified in
approximately 2% of non-small cell lung cancer, 10-20% of papillary thyroid cancer, and a subset of colon and other cancers. RET point mutations account for approximately 60% of medullary thyroid cancer. Both RET fusion and select RET mutated cancers 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. 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 is currently being studied in a Phase 1 trial. 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 Loxo Oncology
Loxo Oncology is a biopharmaceutical company innovating the development of highly selective medicines for patients with genetically 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, thereby 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 availability of funding, timing and success of our clinical trials, the likelihood that early results will be replicated in later trial results and the potential therapeutic benefits of our product candidates. Further information on potential risk factors that could affect our business and its financial results are detailed in our most recent Quarterly Report on Form 10-Q, 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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