Loxo Oncology Announces Broad Pipeline Update at AACR-NCI-EORTC, Including New LOXO-101 Phase 1 Data
October 26, 2015

– LOXO-101 Phase 1 Update Selected for Press Program –
– Two Poster Presentations Highlight First Preclinical Data from RET and FGFR Programs –
– Company to Host Investor Conference Call and Webcast on Monday, November 9, 2015 –

STAMFORD, Conn., Oct. 26, 2015 (GLOBE NEWSWIRE) -- Loxo Oncology, Inc. (Nasdaq:LOXO), a biopharmaceutical company innovating the development of highly selective medicines for patients with genetically defined cancers, today announced that it will present clinical and preclinical data from its pipeline of targeted, investigational oncology medicines at the 27th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics taking place in Boston on November 5-9, 2015. New results from the Phase 1 study of Loxo Oncology’s tropomyosin receptor kinase (TRK) inhibitor, LOXO-101, will be reported in a late-breaking oral presentation. This presentation was selected for inclusion in the press program, and as a result, only the abstract title will appear in the October 26, 2015 online data release. The study data will remain embargoed until November 8, 2015 at 10:30 a.m. Eastern Time.

Loxo Oncology will also present two preclinical posters containing the first publicly disclosed data for its Rearranged during Transfection (RET) and Fibroblast Growth Factor Receptor (FGFR) programs. The posters will include in vitro and in vivo data on chemistry series showing potential best-in-class selectivity and target coverage profiles for these exciting emerging targets. Like TRK, RET and FGFR are known to participate in gene fusion events, and thus, activate cancers as single-gene alterations. In addition, RET and FGFR are also known to harbor activating gene mutations which are also likely to confer drug sensitivity. Loxo Oncology plans to use genetically driven patient enrollment strategies to demonstrate proof of efficacy early in clinical development for the RET and FGFR programs.

Loxo Oncology recently announced enrollment of the first patient in its Phase 2 basket trial of LOXO-101. A basket trial is a new clinical trial design that enrolls patients based on a common, defining genetic feature of their cancer rather than based on an anatomic definition. General information about basket trial designs will be discussed in a plenary presentation on November 8, 2015 at 8:50 a.m. Eastern Time in the Veterans Memorial Auditorium by David Hyman, M.D. of Memorial Sloan Kettering Cancer Center, LOXO-101 global principal investigator.

The details of the LOXO-101 oral presentation is as follows:

Press Program Date & Time: November 8, 2015, 10:30 a.m. Eastern Time
Oral Presentation Date & Time: November 8, 2015, 3:45 p.m. to 4:25 p.m. Eastern Time
Title: Clinical Safety and Activity from a Phase 1 Study of LOXO-101, a Selective TRKA/B/C Inhibitor, in Solid Tumor Patients with NTRK Gene Fusions
Session: Spotlight on Proffered Papers Session 3
Presenter: David Hong, M.D., deputy chair, Department of Investigational Cancer Therapeutics, Division of Cancer Medicine, The University of Texas MD Anderson Cancer Center
Location: Veteran’s Memorial Auditorium
The details of the Loxo Oncology poster presentations are as follows:

**Poster Session Data & Time:** November 7, 2015, 12:30 p.m. to 3:30 p.m. Eastern Time  
**Title:** Identification and Characterization of Highly Potent and Selective Kinase Inhibitors for the Treatment of RET-Driven Cancers  
**Session:** Poster Session B, Therapeutic Agents: Small Molecule Kinase Inhibitors  
**Abstract Number:** B192  
**Location:** Exhibit Hall C-D

**Poster Session Date & Time:** November 8, 2015, 12:30 p.m. to 3:30 p.m. Eastern Time  
**Title:** Identification of First-in-Class, Highly Potent FGFR Kinase Inhibitors that Spare FGFR1  
**Session:** Poster Session C, Therapeutic Agents: Small Molecule Kinase Inhibitors  
**Abstract Number:** C196  
**Location:** Exhibit Hall C-D

**Conference Call and Webcast Information**

Loxo Oncology will host a conference call, live webcast with slides and Q&A on Monday, November 9, 2015 at 8:00 a.m. Eastern Time to discuss the LOXO-101 data and pipeline program updates. To participate in the conference call, please dial (877) 930-8065 (domestic) or (253) 336-8041 (international) and refer to conference ID 66690460. A live webcast of the presentation will be available at [http://ir.loxooncology.com/](http://ir.loxooncology.com/). A replay of the webcast will be available shortly after the conclusion of the call and archived on the company's website for 30 days following the call.

**About LOXO-101**

LOXO-101 is a potent, oral and selective investigational new drug in clinical development for the treatment of patients with cancers that harbor abnormalities involving the tropomyosin receptor kinases (TRKs). Growing research suggests that the NTRK genes, which encode for TRKs, can become abnormally fused to other genes, resulting in growth signals that can lead to cancer in many sites of the body. In an ongoing Phase 1 clinical trial, LOXO-101 has demonstrated encouraging preliminary efficacy. LOXO-101 is also being evaluated in a global Phase 2 multi-center basket trial in patients with solid tumors that harbor TRK gene fusions. For additional information about both the LOXO-101 clinical trials, please refer to [www.clinicaltrials.gov](http://www.clinicaltrials.gov). Interested patients and physicians can contact the Loxo Oncology Physician and Patient Clinical Trial Hotline at 1-855-NTRK-123.

**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](http://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, statements we make regarding our partnerships, timing and success of our clinical trials, the potential therapeutic benefits and economic value of our lead product candidate, potential growth opportunities and potential market opportunities. 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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