Loxo Oncology TRK Inhibitor
Larotrectinib (LOXO-101) Shows Durable Anti-Tumor Activity Across TRK Fusion Cancers in ESMO Asia Phase 1 Update

December 18, 2016

– Six of Seven TRK Fusion Patients Achieve Confirmed RECIST Partial Responses and All Remain in Response –
– All TRK Fusion Patients Remain on Study With Median Follow-Up of 15 Cycles –
– Company to Host Investor Conference Call and Webcast on Monday, December 19, 2016 at 8:00 a.m. EST –

STAMFORD, Conn., Dec. 18, 2016 (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 updated results from its adult Phase 1 open-label, dose-escalation trial of larotrectinib (LOXO-101), a selective inhibitor of tropomyosin receptor kinase (TRK). The data were presented today at the 2016 European Society for Medical Oncology (ESMO) Asia Congress in Singapore. Data from this ongoing Phase 1 trial were last reported at the American Association for Cancer Research (AACR) Annual Meeting in April 2016.

As of a November 10, 2016 data cutoff, 59 patients with refractory solid tumors had been enrolled and treated with single agent larotrectinib, including eight patients with cancers harboring TRK fusions. Seven patients with TRK fusion cancers were on study sufficiently long for an efficacy assessment, while an eighth TRK fusion patient had been recently enrolled and was not yet evaluated for response. Six of the seven efficacy evaluable patients achieved a confirmed partial response, as defined by standard RECIST criteria. The seventh patient, as previously reported, demonstrated clear radiographic tumor regressions, including in the central nervous system, and remains on study, but had not met the threshold required for a RECIST response. All responders remained in response, with one patient in cycle 22, one patient in cycle 19, one patient in cycle 18, two patients in cycle 15 and one patient in cycle 11. Each cycle is 28 days, or approximately one month.

Larotrectinib has been well tolerated at doses that include and exceed the recommended Phase 2 dose of 100 mg BID. A maximum tolerated dose (MTD) has not been defined. The majority of adverse events reported by the investigators have been mild to moderate.

“The depth of responses and durability data with larotrectinib in patients with TRK fusion cancers are among the most promising that we see in oncology Phase 1 clinical trials,” said Todd Bauer, M.D., associate director, drug development and principal investigator, Sarah Cannon Research Institute and presenter of the larotrectinib oral presentation. “We believe our patients would benefit from the addition of larotrectinib to the armamentarium of matched targeted therapies for our patients, as our continued utilization of molecular testing in clinical practice will naturally lead to the identification of patients with TRK fusions.”

“We continue to be very pleased with the efficacy and safety data we are seeing across the larotrectinib program,” said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. “We look forward to further evaluating larotrectinib in adults with TRK fusion cancers in our Phase 2 NAVIGATE study and in pediatric patients in the SCOUT Phase 1/2 study, and sharing those data publicly over time.”

Larotrectinib (LOXO-101) Phase 1 Results
Larotrectinib is currently being evaluated in an ongoing dose-escalation Phase 1 trial in patients with solid tumors refractory to standard therapy. As of November 10, 2016, 59 patients with advanced cancer had been treated at six dose levels: 50 mg QD, 100 mg QD, 100 mg BID, 150 mg BID, 200 mg QD and 200 mg BID. The median age of these patients is 59 (ranging from 19-82) and the median number of prior treatments is three (ranging from 0-24).

Safety Analysis
Larotrectinib has been well tolerated in the 59 patients treated, including 34 patients at a dose of 100mg BID. Adverse events reported regardless of attribution to study drug are generally consistent with those previously presented. The most common adverse events, largely Grade 1 and 2, include fatigue (37 percent), dizziness (29 percent), anemia (25 percent) and dyspnea (25 percent). No individual Grade 3 or 4 adverse events occurred in more than three patients treated at 100mg BID or more than five patients in the entire study population. The frequency of toxicities did not correlate with dose level. The MTD has not yet been defined.

Efficacy Analysis
As of November 10, 2016, eight patients with cancers harboring TRK fusions had been enrolled, representing a broad range of tumor types, namely mammary analogue secretory cancer of the salivary glands (MASC, n=3), gastrointestinal stromal tumor (n=2), soft tissue sarcoma, thyroid carcinoma and non-small cell lung cancer. Seven patients with TRK fusion cancers were on study sufficiently long for an efficacy assessment, while an eighth TRK fusion patient had been recently enrolled and was not yet evaluated for response. Six of the seven efficacy evaluable patients achieved a confirmed partial response, as defined by standard RECIST criteria. A seventh patient, as previously reported, demonstrated clear radiographic tumor regressions, including in the central nervous system, and remains on study, but had not met the threshold required for a RECIST response. All responders remained in response, with one patient in cycle 22, one patient in cycle 19, one patient in cycle 18, two patients in cycle 15 and one patient in cycle 11. Each cycle is 28 days, or approximately one month.

On Monday, December 19, 2016, Loxo Oncology plans to file a Form 8-K with the U.S. Securities and Exchange Commission (SEC) containing the larotrectinib materials presented at the ESMO Asia meeting. These materials will also be posted to the Loxo Oncology website.

Conference Call and Webcast Information
Loxo Oncology will host a conference call and live webcast with slides and Q&A on Monday, December 19, 2016 at 8:00 a.m. ET to discuss the larotrectinib data and provide a comprehensive program and pipeline update. The company will issue a press release prior to the start of the call. The company anticipates that the conference call and webcast will last 60-90 minutes. To participate in the conference call, please dial (877) 930-8065 (domestic) or (253) 336-8041 (international) and refer to conference ID 16640119. A live webcast of the presentation will be available at 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 Larotrectinib (LOXO-101)
Larotrectinib (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, larotrectinib has demonstrated encouraging preliminary efficacy. Larotrectinib is also being evaluated in the NAVIGATE global Phase 2 multi-center basket trial in patients with solid tumors that harbor TRK gene fusions, and the SCOUT Phase 1/2 trial in pediatric patients, including patients with advanced cancer, TRK gene fusions and infantile fibrosarcoma. Larotrectinib has been granted Breakthrough Therapy Designation by the U.S. FDA. For additional information about the larotrectinib clinical trials, please refer to www.clinicaltrials.gov. Interested patients and physicians can contact the Loxo Oncology Physician and Patient Clinical Trial Hotline at 1-855-NTRK-123 or visit www.loxooncologytrials.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:
"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 the timing and success of our clinical trials, the potential therapeutic benefits
and economic value of our lead product candidate or other product candidates, and timing of future filings. 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.

Contacts for Loxo Oncology, Inc.

Company:
Jacob S. Van Naarden
Chief Business Officer
jake@loxooncology.com

Investors:
Peter Rahmer
The Trout Group, LLC
646-378-2973
prahmer@troutgroup.com

Media:
Dan Budwick
Pure Communications, Inc.
973-271-6085
dan@purecommunicationsinc.com

Loxo Oncology, Inc.