Loxo Oncology Announces Selection of LOXO-101 for NCI-MATCH Precision Medicine Clinical Trial

October 28, 2015

STAMFORD, Conn., Oct. 28, 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 the independent committee of the National Cancer Institute-Molecular Analysis for Therapy Choice (NCI-MATCH) clinical trial has chosen LOXO-101 as the sole, dedicated treatment arm for patients with tropomyosin receptor kinase, or TRK, gene fusions. The NCI-MATCH trial will initially enroll 3,000 patients with tumor biopsies available for comprehensive genomic profiling and assign these patients to an appropriate targeted therapy arm based on the molecular abnormalities of each tumor. NCI-MATCH, which began enrolling patients in August 2015, currently has 10 open treatment arms employing drugs from multiple sponsors, and plans to open as many as 25 additional arms over the next year. Each arm of the study pairs specific genetic alterations to a specific targeted treatment.

“We are honored that an independent committee of the NCI-MATCH trial has selected LOXO-101 for the TRK fusion arm of the NCI-MATCH trial,” said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. “NCI-MATCH captures the true spirit of precision medicine, and should answer many important questions for patients with advanced cancer. We look forward to working closely with NCI and its national network of investigators.”

About NCI-MATCH

NCI-MATCH is supported by NCI and coordinated by the ECOG-ACRIN Cancer Research Group, part of the NCI’s National Clinical Trials Network (NCTN). The NCTN has national reach and NCI-MATCH is opening at NCTN clinical sites across the United States. The trial opened for enrollment in August 2015 at more than 700 clinical trial sites in 48 states with the initial goal of analyzing tumor biopsies from 3,000 patients. Each arm utilizes only one targeted therapy and enrolls adults with advanced of genetically defined solid tumors and lymphomas that are no longer responding (or never responded) to standard therapy and have begun to grow. Additional arms will be added to NCI-MATCH through 2016. The primary endpoint for NCI-MATCH is the objective response rate, or ORR, defined as the percentage of patients whose tumors have a complete or partial response to treatment.

Biopsy specimens removed from patients' tumors are sent to a central pathology core site at the MD Anderson Cancer Center. Nucleic acids are isolated and assayed for more than 4,000 different variants across 143 genes at one of four clinical genetic testing labs. To efficiently investigate the effectiveness of molecularly targeted therapies for patients with the corresponding driver mutations, a broad-based genomic pre-screening effort such as this is necessary to find and assign patients whose tumors harbor these mutations, regardless of tumor origin. The trial covers the cost of the biopsy and molecular tests, and patients will receive the drugs without charge if they are eligible to enroll for an NCI-MATCH treatment. Neither the patients nor a health plan/insurance company will have to pay for any study-related biopsies or the assigned study drug(s) that were matched to a patient’s cancer.

For more information, see the NCI’s website here. Patients, families, and clinicians can also call NCI’s Cancer Information Service at 1-800-4-CANCER (1-800-422-6237) for assistance in English and Spanish or contact NCI's LiveHelp service.

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. 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.

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.

Contacts for Loxo Oncology, Inc.

Company:
Jacob S. Van Naarden
Vice President, Corporate Development and Strategy
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.