Loxo Oncology Accepts Invitation to Present LOXO-101 to the FDA’s Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee

June 15, 2016

STAMFORD, Conn., June 15, 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 that the company has accepted an invitation from the U.S. Food and Drug Administration (FDA) to participate in a meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee on June 29, 2016. The purpose of the meeting is to improve and encourage the development of oncology and hematology drugs for pediatric use. These meetings are held regularly by the FDA, with various invited sponsors. At the meeting, Loxo Oncology plans to present an overview of LOXO-101, with an emphasis on opportunities for pediatric development.

Background material for this meeting will be available on the FDA website approximately 2 days prior to the meeting.

Clinical Development of LOXO-101 in Pediatric Cancers

Loxo Oncology is conducting an ongoing Phase 1 multicenter, open-label clinical trial in pediatric patients with advanced solid or primary CNS tumors. In order to meet the criteria for enrollment, patients must be between one year of age and 21 years of age with a locally advanced or metastatic solid tumor or primary CNS tumor that has progressed, or was nonresponsive to available therapies, and for which no standard or available curative therapy exists. Patients at least one month old are eligible for enrollment if they have a diagnosis of infantile/congenital fibrosarcoma or congenital mesoblastic nephroma, with a documented NTRK fusion that has progressed, or was nonresponsive to available therapies, and for whom no standard or available curative therapy exists. The primary endpoint of the trial is to explore the safety of LOXO-101. Secondary endpoints include the characterization of pharmacokinetic properties, the identification of the maximum tolerated dose and/or the Phase 2 dose, a description of antitumor activity and a description of pain and health related quality of life impact.

In April 2016, Loxo Oncology announced the publication of a case report in the online edition of Pediatric Blood and Cancer, co-authored with Nemours Children’s Hospital, Northwestern University and St. Jude Children’s Research Hospital, describing a partial response in the first patient with a TRK fusion cancer enrolled in the pediatric Phase 1 dose-escalation trial of LOXO-101. The 16-month old female patient with advanced infantile fibrosarcoma (IFS), a rare pediatric cancer, experienced a 90 percent tumor regression, and repeat scans showed continued decrease in tumor volume. As of the preparation of the manuscript, the patient was in study cycle 5 with a RECIST confirmed partial response, and was beginning to achieve normal developmental milestones.

LOXO-101 has shown objective partial responses in adult patients with tumors harboring TRK gene fusions in a Phase 1 trial. LOXO-101 is also being evaluated in a global Phase 2 multi-center basket trial in adult patients with solid tumors that harbor TRK gene fusions.

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 and a Phase 1 trial in pediatric patients. For additional information about the LOXO-101 clinical trials, please refer to www.clinicaltrials.gov or www.loxooncologytrials.com. 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, the timing and success of our clinical trials, success in our collaborations and the potential therapeutic benefits of our lead product candidate or other 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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