Loxo Oncology Receives Breakthrough Therapy Designation from U.S. Food and Drug Administration for LOXO-101

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STAMFORD, Conn., July 13, 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 U.S. Food and Drug Administration (FDA) has granted Breakthrough Therapy Designation to LOXO-101, a selective inhibitor of tropomyosin receptor kinase (TRK), “for the treatment of unresectable or metastatic solid tumors with NTRK-fusion proteins in adult and pediatric patients who require systemic therapy and who have either progressed following prior treatment or who have no acceptable alternative treatments.”

“We’re pleased to have been granted Breakthrough Therapy Designation for LOXO-101 and look forward to working more closely with the FDA to bring this therapy to patients with TRK fusion cancers,” said Josh Bilenker, M.D., chief executive officer at Loxo Oncology. “Data presented to date from the ongoing adult and pediatric studies of LOXO-101 have demonstrated durable anti-tumor activity across TRK fusion cancers, further validating LOXO-101’s potential to address the unmet medical need among patients with these genetically defined cancers. We remain on track to provide an enrollment update regarding the LOXO-101 Phase 2 trial in the second half of 2016.”

The FDA's Breakthrough Therapy Designation is intended to expedite the development and review of a drug candidate that is planned for use to treat a serious or life-threatening disease or condition when preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

The LOXO-101 Breakthrough Therapy Designation application included data from the ongoing Phase 1 dose-escalation study of LOXO-101 in adult patients with advanced solid tumors, the ongoing Phase 1 pediatric study of LOXO-101 in patients with advanced solid tumors or primary CNS tumors, and the ongoing Phase 2 basket trial of LOXO-101 in adult cancer patients whose tumors harbor TRK 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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