Loxo Oncology Announces Enrollment of First Patient in Phase 1 Clinical Trial for Highly Selective RET Inhibitor, LOXO-292

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STAMFORD, Conn., May 10, 2017 (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 first patient has been enrolled in the Phase 1 clinical trial of LOXO-292, an investigational, highly potent and selective RET inhibitor. RET gene alterations are thought to play a key role in the development of certain cases of lung, thyroid, colon and other cancers.

"We are excited to put a second, purpose-built precision medicine into clinical development," said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. "We believe that patients with RET-altered lung, thyroid and other cancers have highly actionable genetic events that are not well addressed by existing therapies. LOXO-292 was designed to deliver potent RET inhibition, while avoiding off-target activities that can compromise dose intensity and contribute to toxicity. If our hypothesis is correct, LOXO-292 could have meaningful single agent anti-tumor activity in RET-altered cancers, and the ability to address key resistance mutations that could otherwise limit the clinical potential of RET inhibition in affected patients. In advancing our larotrectinib program, we have worked closely and creatively with patients and their doctors to deliver on the promise of precision medicine. We hope that LOXO-292 opens a new and exciting chapter in this story."

This first-in-human, global, multi-center Phase 1 trial will evaluate LOXO-292 as a single agent in patients with advanced solid tumors. The primary objective of the trial is to determine the maximum tolerated dose or recommended dose for further study. Key secondary objectives include measures of safety, pharmacokinetics, and anti-tumor activity (i.e. Objective Response Rate and Duration of Response, as determined by RECIST v1.1). The trial includes a dose escalation phase and dose expansion phase. During the dose escalation phase, up to 30 patients with advanced solid tumors may be enrolled to inform the selection of a dose and schedule for the expansion phase. In the expansion phase, five cohorts are planned to allow for the characterization of preliminary activity of LOXO-292 in the following genetically-defined populations: 1) RET-fusion lung cancer patients with prior RET inhibitor experience; 2) RET-fusion lung cancer patients with no prior RET inhibitor experience; 3) RET-mutant medullary thyroid cancer patients with prior RET inhibitor experience; 4) RET-mutant medullary thyroid cancer patients with no prior RET inhibitor experience; and 5) other RET-altered solid tumors. Loxo Oncology anticipates that approximately 15 patients will be enrolled to each of the expansion cohorts.

About LOXO-292

LOXO-292 is a potent, oral and selective investigational new drug in clinical development for the treatment of patients with cancers that harbor abnormalities in the rearranged during transfection (RET) kinase. RET fusions have been identified in approximately 2% of non-small cell lung cancer, 10-20% of papillary thyroid cancer, and a subset of colon and other cancers. RET point mutations account for approximately 60% of medullary thyroid cancer. Both RET fusion and select RET mutated cancers are primarily dependent on this single activated kinase for their proliferation and survival. This dependency, often referred to as "oncogene addiction," renders such tumors highly susceptible to small molecule inhibitors targeting RET. LOXO-292 was designed to inhibit native RET signaling as well as anticipated acquired resistance mechanisms that could otherwise limit the activity of this therapeutic approach. LOXO-292 is currently being studied in a Phase 1 trial. Interested patients and physicians can contact the Loxo Oncology Physician and Patient RET Clinical Trial Hotline at 1-855-RET-4-292 or email clinicaltrials@loxooncology.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: “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 availability of funding, 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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