Loxo Oncology Announces Clinical Proof of Concept Publication for Next-Generation TRK Inhibitor LOXO-195

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STAMFORD, Conn., June 03, 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 the online publication of a new research brief in Cancer Discovery outlining the preclinical rationale for LOXO-195 and clinical proof-of-concept data from the first two patients treated. LOXO-195 was developed to treat patients with TRK fusion cancers who become resistant while receiving another TRK inhibitor, such as Loxo Oncology’s larotrectinib.

“This publication highlights the potential for LOXO-195 to extend the period of durable disease control for patients with TRK fusion cancers,” said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. “We believe that today’s ASCO presentation establishes larotrectinib as the clear first choice for patients with TRK fusion cancers. However, over time, patients will require new treatment options, since oncogene-addicted metastatic cancers ultimately evade targeted therapies. We have been relentless in the development of LOXO-195 so that it could be ready in time for the current larotrectinib clinical trial participants and future patients who depend upon us to realize the full potential of TRK inhibition in the management of advanced cancer.”

LOXO-195 was designed to address anticipated mechanisms of acquired resistance in cancers exposed to a prior TRK inhibitor, including “solvent front” mutations (e.g. NTRK1 G595R, NTRK3 G623R), which are not well-addressed by existing investigational agents. LOXO-195 will be developed as a sequential treatment, to follow larotrectinib or another TRK inhibitor, to extend the total time of benefit from TRK inhibition.

The Cancer Discovery research brief provides early but encouraging evidence that the sequential use of larotrectinib followed by LOXO-195 could extend the total duration of disease control for patients with TRK fusion cancers. An analogous paradigm has already been established for other oncogene-addicted tumors, such as those driven by androgen and estrogen signaling, EGFR mutations and ABL gene fusions. The brief describes the first two patients with TRK fusion cancers who responded to larotrectinib but later relapsed. An adult with colorectal cancer and a child with infantile fibrosarcoma were biopsied at the time of tumor progression and found to have a solvent front TRK mutation in the existing TRK fusion, which explained the diminished activity of larotrectinib. As no other treatment options exist to address TRK fusion solvent front mutations, Loxo Oncology, in collaboration with the U.S. FDA, enabled these patients to access LOXO-195 through emergency use Investigational New Drug applications (INDs). Both patients responded to LOXO-195, with minimal adverse events reported.

A formal LOXO-195 IND was recently cleared by the U.S. FDA, and a Phase 1/2 trial is opening globally.
About LOXO-195
LOXO-195 is a potent, oral and selective investigational new drug in clinical development for the treatment of patients with cancers that have acquired resistance to initial TRK therapy such as larotrectinib. 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. Though drugs such as larotrectinib can induce durable responses in these patients, the cancer may eventually begin to grow again. This phenomenon is called “acquired resistance,” in that the cancer has acquired features conferring resistance to the initial therapy that was once effective. Emerging data in the field of TRK inhibition suggest that acquired resistance may emerge due to TRK kinase point mutations, such as those in the solvent front domain, xDFG domain, or gatekeeper region. LOXO-195 was designed to address these new point mutations and induce a new response in the patient’s cancer. Interested patients and physicians can contact the Loxo Oncology Physician and Patient Clinical Trial Hotline at 1-855-NTRK-123 or email clinicaltrials@loxooncology.com.

About TRK Fusion Cancer
TRK fusions are chromosomal abnormalities that occur when one of the NTRK genes (NTRK1, NTRK2, NTRK3) becomes abnormally connected to another, unrelated gene (e.g. ETV6, LMNA, TPM3). This abnormality results in uncontrolled TRK signaling that can lead to cancer. TRK fusions occur rarely but broadly in various adult and pediatric solid tumors, including appendiceal cancer, breast cancer, cholangiocarcinoma, colorectal cancer, GIST, infantile fibrosarcoma, lung cancer, mammary analogue secretory carcinoma of the salivary gland, melanoma, pancreatic cancer, thyroid cancer, and various sarcomas. TRK fusions can be identified through various diagnostic tests, including targeted next-generation sequencing (NGS), immunohistochemistry (IHC), polymerase chain reaction (PCR), and fluorescent in situ hybridization (FISH). For more information, please visit www.TRKtesting.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 and the potential therapeutic benefits of our 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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