



Loxo Oncology Announces Accepted Abstracts at the 88th Annual Meeting of the American Thyroid Association

September 18, 2018

STAMFORD, Conn., Sept. 18, 2018 (GLOBE NEWSWIRE) -- Loxo Oncology, Inc. (Nasdaq:LOXO), a biopharmaceutical company developing highly selective medicines for patients with genomically defined cancers, today announced that abstracts from its LOXO-292 and larotrectinib programs have been accepted for oral presentations at the 88th Annual Meeting of the American Thyroid Association to be held October 3-7, 2018, in Washington, DC.

The LOXO-292 oral presentation will provide an updated analysis of patients with RET mutant medullary thyroid cancer and RET fusion thyroid cancers enrolled in the dose escalation cohorts of the ongoing LIBRETTO-001 Phase 1/2 clinical trial. The larotrectinib oral presentation will provide an analysis of patients with TRK fusion thyroid cancer enrolled to the larotrectinib clinical program.

The schedule for the presentations is as follows:

LOXO-292 Oral Presentation Session Date & Time: October 6, 2018, 9:05 a.m.-9:20 a.m. ET

Title: Clinical Activity of LOXO-292, a Highly Selective RET Inhibitor, in Patients with RET-Altered Thyroid Cancers

Session Title: Clinical Short Call Oral

Presenter: Lori J. Wirth, M.D.

Larotrectinib Oral Presentation Session Date & Time: October 4, 2018, 1:50 p.m.-2:05 p.m. ET

Title: Activity of Larotrectinib in Patients with Advanced TRK Fusion Thyroid Cancer

Session Title: Thursday Clinical Oral Abstracts

Presenter: Marcia S. Brose, M.D., Ph.D.

About LOXO-292

LOXO-292 is an 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 and mutations occur across multiple tumor types with varying frequency. 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 has been granted Breakthrough Therapy Designation by the U.S. FDA.

LOXO-292 is currently being studied in the global [LIBRETTO-001 Phase 1/2 trial](#). For additional information about the LOXO-292 clinical trial, please refer to www.clinicaltrials.gov. 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 RET-Altered Cancers

Genomic alterations in the RET kinase, which include fusions and activating point mutations, lead to overactive RET signaling and uncontrolled cell growth. RET fusions have been identified in approximately 2% of non-small cell lung cancer, 10-20% of papillary and other thyroid cancers, and a subset of other cancers. Activating RET point mutations account for approximately 60% of medullary thyroid cancer (MTC). Both RET fusion cancers and RET-mutant MTC 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.

About Larotrectinib

Larotrectinib is an oral and selective investigational tropomyosin receptor kinase (TRK) inhibitor in clinical development for



the treatment of patients with cancers that harbor a neurotrophic tyrosine receptor kinase (NTRK) gene fusion. 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 clinical trials, larotrectinib demonstrated anti-tumor activity in patients with tumors harboring NTRK gene fusions, regardless of patient age or tumor type. In an analysis of 55 RECIST-evaluable adult and pediatric patients with NTRK gene fusions, using a July 17, 2017 data cutoff, larotrectinib demonstrated a 75 percent centrally-assessed confirmed overall response rate (ORR) and an 80 percent investigator-assessed confirmed ORR, across many different types of solid tumors. The majority (93 percent) of all adverse events were grade 1 or 2.

Larotrectinib has been granted Priority Review, Breakthrough Therapy Designation, Rare Pediatric Disease Designation and Orphan Drug Designation by the U.S. FDA.

In November 2017, Loxo Oncology and Bayer entered into an exclusive global collaboration for the development and commercialization of larotrectinib and LOXO-195, a next-generation TRK inhibitor. Bayer and Loxo Oncology are jointly developing the two products with Loxo Oncology leading the ongoing clinical studies as well as the filing in the U.S., and Bayer leading ex-U.S. regulatory activities and worldwide commercial activities. In the U.S., Loxo Oncology and Bayer will co-promote the products.

For additional information about the larotrectinib 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 or visit www.loxooncologytrials.com/trk-trials.

About TRK Fusion Cancer

TRK fusion cancer occurs when a neurotrophic tyrosine receptor kinase (*NTRK*) gene fuses with another unrelated gene, producing an altered tropomyosin receptor kinase (TRK) protein. The altered protein, or TRK fusion protein, is constantly active, triggering a permanent signal cascade. These proteins become the primary driver of the spread and growth of tumors in patients with TRK fusion cancer. TRK fusion cancer is not limited to certain types of cells or tissues and can occur in any part of the body. NTRK gene fusions occur in various adult and pediatric solid tumors with varying prevalence, 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. Only sensitive and specific tests can reliably detect TRK fusion cancer. Next-generation sequencing (NGS) can provide a comprehensive view of genomic alterations across a large number of genes. Fluorescence in situ hybridization (FISH) can also be used to test for TRK fusion cancer, and immunohistochemistry (IHC) can be used to detect the presence of TRK protein.

About Loxo Oncology

Loxo Oncology is a biopharmaceutical company developing highly selective medicines for patients with genomically 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, with the intention of 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 or regulatory approvals related to larotrectinib, LOXO-195 or LOXO-292, the success of our collaboration with Bayer and our commercial activities. Further information on potential risk factors that could affect our business and its financial results are detailed in our most recent Annual Report on Form 10-K, 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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