Loxo Oncology Announces Larotrectinib Pan-TRK IHC Companion Diagnostic Collaboration with Ventana Medical Systems, Inc., a member of the Roche Group

March 20, 2017

STAMFORD, Conn., March 20, 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 Company has entered into a collaboration agreement with Ventana Medical Systems, Inc., a member of the Roche Group (Roche), to develop and commercialize a pan-TRK immunohistochemistry (IHC) test as a companion diagnostic to identify patients across tumor types suitable for treatment with larotrectinib.

“We are excited to partner with Roche, the global leader in developing and commercializing IHC assays for cancer diagnostics. Our initial technology assessment suggests that an IHC pan-TRK assay is feasible, which is exciting since Roche has thousands of VENTANA BenchMark instruments installed worldwide,” said Josh Bilenker, M.D., Chief Executive Officer of Loxo Oncology. “IHC remains a mainstay of the cancer pathology workup, due in part to its speed, limited tissue requirements, low cost, and established reimbursement paradigms. Diagnostics are a crucial part of our commercial strategy, and we believe IHC will be an important tool, alongside next-generation sequencing, that pathologists can employ in screening for patients who may benefit from larotrectinib.”

Loxo Oncology and Roche will utilize an investigational assay piloted by Loxo Oncology that will be further developed by Roche using its flagship OptiView DAB detection technology. Initially, the parties will optimize and validate the assay to ensure it is sufficiently robust to withstand clinical and regulatory scrutiny. The parties plan to first globally commercialize an analytical assay and then develop a Class III assay for pre-market approval (PMA) from the U.S. Food and Drug Administration (FDA). FDA approval will be based on analyses of patient samples collected from ongoing larotrectinib clinical trials to support clinical claims referencing larotrectinib. Roche is responsible for developing, obtaining and maintaining regulatory approvals for the companion diagnostic test in the United States, specified countries in the European Union and other countries that recognize the CE/ in vitro diagnostic registration process, as mutually agreed.

About Larotrectinib (LOXO-101)
Larotrectinib (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, larotrectinib has demonstrated encouraging preliminary efficacy. Larotrectinib is also being evaluated in the NAVIGATE global Phase 2 multi-center basket trial in patients with solid tumors that harbor TRK gene fusions, and the SCOUT Phase 1/2 trial in pediatric patients, including patients with advanced cancer, TRK gene fusions and infantile fibrosarcoma. Larotrectinib has been granted Breakthrough Therapy Designation and Rare Pediatric Disease Designation by the U.S. FDA. 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.

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, statements we make regarding the timing and success of our clinical trials or regulatory approvals, the potential therapeutic benefits and economic value of our lead product candidate or other product candidates, and timing of future filings. 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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