Loxo Oncology Announces Acceptance of Larotrectinib Oral Presentations at the American Society of Clinical Oncology (ASCO) Annual Meeting

April 5, 2017

STAMFORD, Conn., April 05, 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 larotrectinib (LOXO-101) interim clinical data across the RECIST-evaluable TRK fusion clinical trial database from all three ongoing clinical trials will be presented in a late-breaking oral presentation at the American Society of Clinical Oncology (ASCO) Annual Meeting held June 2 - 6, 2017 in Chicago, Illinois. The presentation is entitled, “The efficacy of larotrectinib (LOXO-101), a selective tropomyosin receptor kinase (TRK) inhibitor, in adult and pediatric TRK fusion cancers.” Additionally, interim pediatric Phase 1 clinical trial data, included in the aforementioned data set, will also be presented in a separate oral presentation at the ASCO Annual Meeting, entitled, “A pediatric phase 1 study of larotrectinib, a highly selective inhibitor of the tropomyosin receptor kinase (TRK) family.”

“Completing enrollment more quickly than anticipated created an opportunity to present data from our registrational program at ASCO this year,” said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. “We hope that the oral presentations help build awareness in the oncology community around TRK fusions as therapeutic targets across solid tumor diagnoses and the importance of comprehensive testing in patients with advanced cancer. Due to the late-breaking nature of the data, the presentations will be based on interim follow-up and local radiology assessments of patients in the registrational program, while the NDA/MAA submissions will rely on independent central radiology review and longer follow-up of these patients. In the second half of 2017, consistent with previous guidance, we plan to announce top-line registrational data for the program, including longer follow-up and results of the central radiology review.”

The Company will be hosting a conference call and webcast to discuss the data after they are presented at ASCO. Details regarding date and time will be announced closer to the ASCO conference.

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, the reporting, timing and success of our clinical trials. 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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