Loxo Oncology Completes Rolling Submission of New Drug Application to U.S. Food and Drug Administration for Larotrectinib for the Treatment of TRK Fusion Cancer

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STAMFORD, Conn., March 26, 2018 (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 completed the rolling submission of a New Drug Application (NDA) to the U.S. Food and Drug Administration (FDA) for larotrectinib for the treatment of adult and pediatric patients with locally advanced or metastatic solid tumors harboring an NTRK gene fusion.

“We are grateful to the many patients who participated in our clinical trials in the spirit of helping others with advanced cancer,” said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. “We hope that the larotrectinib development program inspires others to develop drugs for both adult and pediatric patients on the basis of tumor genetics rather than tumor site of origin.”

Loxo Oncology and Bayer are engaged in a collaboration for the development and commercialization of larotrectinib. A Marketing Authorisation Application (MAA) submission by Bayer in the European Union is expected in 2018.

About Larotrectinib (LOXO-101)

Larotrectinib is a potent, oral and highly selective tropomyosin receptor kinase (TRK) inhibitor. The investigational new drug is 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 marked and durable anti-tumor activity in TRK fusion cancer regardless of patient age or tumor type. In an analysis of 55 RECIST-evaluable adult and pediatric patients with NTRK gene fusions, larotrectinib demonstrated an 80 percent investigator-assessed confirmed overall response rate (ORR) and a 75 percent centrally-assessed confirmed ORR, across many different types of solid tumors. Larotrectinib was well tolerated; the majority of all adverse events were grade 1 or 2. There were no treatment-related grade 4 or 5 events, and no treatment-related grade 3 adverse events occurred in more than 5% of patients.

Larotrectinib has been granted 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 will jointly develop 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.

About TRK Fusion Cancer
Neurotrophic tyrosine receptor kinase (NTRK) gene 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 tropomyosin receptor kinase (TRK) signaling that can lead to cancer. NTRK 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. NTRK gene fusions can be identified through various diagnostic tests, including targeted next-generation sequencing (NGS), polymerase chain reaction (PCR), fluorescent in situ hybridization (FISH) or immunohistochemistry (IHC), to detect TRK protein. For more information, please visit www.trkcancer.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, including Loxo Oncology's expectations regarding the timing and success of our clinical trials and timing, if any, of regulatory approval. 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. 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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