FDA Accepts Larotrectinib New Drug Application and Grants Priority Review

May 29, 2018

– PDUFA date set for November 26, 2018 –

STAMFORD, Conn., May 29, 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 U.S. Food and Drug Administration (FDA) has accepted the company's New Drug Application (NDA) and granted Priority Review for larotrectinib for the treatment of adult and pediatric patients with locally advanced or metastatic solid tumors harboring an *NTRK* gene fusion. The FDA has set a target action date of November 26, 2018, under the Prescription Drug User Fee Act (PDUFA).

"We are excited the larotrectinib NDA has been accepted by FDA and granted Priority Review status," said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. "Larotrectinib marks an important shift towards treating cancer based on the tumor's genetics rather than its site of origin in the body."

The FDA grants Priority Review for the applications of medicines that, if approved, would provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to standard applications. Larotrectinib has also been granted Breakthrough Therapy Designation, Rare Pediatric Disease Designation and Orphan Drug Designation by the FDA.

Loxo Oncology and Bayer are engaged in a collaboration for the development and commercialization of larotrectinib. Bayer plans to submit a Marketing Authorization Application (MAA) in the European Union in 2018.

About Larotrectinib (LOXO-101)
Larotrectinib is an oral and highly 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, 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 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 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/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. It may affect greater than 60 percent of both adult and pediatric patients with certain rare tumor types, such as secretory breast, secretory salivary gland and infantile fibrosarcoma. 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 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, 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, including Loxo Oncology's expectations regarding the timing regulatory approval for larotrectinib and the timing and success of any commercial activities related to larotrectinib. 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.

Contacts for Loxo Oncology, Inc.

Company:
Lauren Cohen
Director, Corporate Communications
lcohen@loxooncology.com

Investors:
Peter Rahmer
Endurance Advisors, LLC
415-515-9763
prahmer@enduranceadvisors.com

Media:
Dan Budwick
1AB Media
973-271-6085
dan@1abmedia.com

Primary Logo

Image not found or type unknown

Loxo Oncology, Inc.