



# Loxo Oncology Announces Submission of European Marketing Authorization Application for Larotrectinib

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STAMFORD, Conn., Aug. 27, 2018 (GLOBE NEWSWIRE) -- Loxo Oncology, Inc. (Nasdaq:LOXO), a biopharmaceutical company developing highly selective medicines for patients with genomically defined cancers, today announced that its collaboration partner, Bayer, has submitted a marketing authorization application (MAA) for larotrectinib to the European Medicines Agency (EMA). Larotrectinib is being investigated to potentially treat adult and pediatric patients with locally advanced or metastatic solid tumors with a neurotrophic tyrosine receptor kinase (NTRK) gene fusion.

"Larotrectinib has demonstrated exciting clinical responses in patients with TRK fusion cancer across various tumor types in both children and adults," said Ulrik Lassen, M.D., Ph.D., Department of Oncology, Rigshospitalet, Copenhagen. "The regulatory submission of larotrectinib in Europe moves us closer to being able to provide a targeted treatment option to these patients for which there is currently no approved therapy."

Loxo Oncology and Bayer are engaged in a collaboration for the development and commercialization of larotrectinib. In May 2018, larotrectinib was granted Priority Review by the U.S. Food and Drug Administration (FDA) 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).

## 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 regulatory filings 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](http://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](http://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](http://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, 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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