



# Loxo Oncology Announces Global Development and Commercialization Partnership with Bayer for Larotrectinib and LOXO-195

November 14, 2017

*– Up to \$1.55B in Upfront, Regulatory, and Commercial Milestones –*

*– Loxo Oncology and Bayer to Co-Promote in U.S. with a 50/50 Profit Share; Bayer to Commercialize ROW –*

*– Loxo Oncology to Lead Global Development Activities –*

*– Conference Call Today at 8:00 a.m. ET –*

STAMFORD, Conn., Nov. 14, 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 it has entered into a global collaboration with Bayer to develop and commercialize larotrectinib and LOXO-195, Loxo Oncology's franchise of highly selective TRK inhibitors for patients with TRK fusion cancers.

Under the terms of the agreement, Loxo Oncology will receive a \$400M upfront payment. Loxo Oncology is eligible for \$450M in milestone payments upon larotrectinib regulatory approvals and first commercial sale events in certain major markets and an additional \$200M in milestone payments upon LOXO-195 regulatory approvals and first commercial sale events in certain major markets.

"This is a transformational collaboration for the company as we prepare for commercialization," said Jacob Van Naarden, chief business officer of Loxo Oncology. "Bayer has a history of successful co-promotion efforts with emerging biopharmaceutical companies and we are confident that their oncology team has the global reach and expertise, including an existing field force dedicated to cancer, to complement our existing commercial plans. We look forward to working with Bayer and believe that together we can bring our TRK inhibitors to more patients more quickly."

"We see great potential in larotrectinib and moreover the follow-on compound LOXO-195 which may provide additional benefit for patients who might progress on an initial TRK inhibition therapy. These agents have the potential to fulfill the promise of precision medicine, where tumor genetics rather than tumor site of origin define the treatment approach for patients," said Robert LaCaze, executive vice president and head of the Oncology Strategic Business Unit at Bayer.

Loxo Oncology will lead global development activities and United States (U.S.) regulatory activities. Bayer will lead ex-U.S. regulatory activities, and worldwide commercial activities. Globally, Loxo Oncology and Bayer will share development costs on a 50/50 basis. In the U.S., where Loxo Oncology and Bayer will co-promote the products, the parties will share commercial costs and profits on a 50/50 basis. Bayer will pay Loxo Oncology a \$25M milestone upon achieving a certain U.S. net sales threshold. Outside of the U.S., where Bayer will commercialize, Bayer will pay Loxo Oncology tiered, double-digit royalties on net sales, and sales milestones totaling \$475M. Bayer will book revenues worldwide.

Loxo Oncology was advised by Fenwick and West in the transaction.

## **Conference Call Information**

Loxo Oncology will host a conference call today at 8:00 a.m. ET to discuss this collaboration announcement. To participate in the conference call, please dial (877) 930-8065 (domestic) or (253) 336-8041 (international) and refer to conference ID 8077486. A replay will be available shortly after the conclusion of the call and archived on the company's website for 30



days following the call.

### **About Larotrectinib (LOXO-101)**

Larotrectinib 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 analysis of 55 RECIST-evaluable TRK fusion adult and pediatric patients, larotrectinib demonstrated a 75 percent independently-reviewed confirmed overall response rate (ORR) and an 80 percent investigator-assessed confirmed ORR, across many different types of solid tumors. Larotrectinib has been granted Breakthrough Therapy Designation, Rare Pediatric Disease Designation and Orphan Drug Designation by the U.S. FDA. 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](http://www.loxooncologytrials.com).

### **About LOXO-195**

LOXO-195 is a potent, oral and selective investigational new drug in clinical development for the treatment of patients with cancers that have acquired resistance to initial TRK therapy such as larotrectinib. Though drugs such as larotrectinib can induce durable responses in these patients, the cancer may eventually begin to grow again. This phenomenon is called "acquired resistance," in that the cancer has acquired features conferring resistance to the initial therapy that was once effective. Emerging data in the field of TRK inhibition suggest that acquired resistance may emerge due to TRK kinase point mutations, such as those in the solvent front domain, xDFG domain, or gatekeeper region. LOXO-195 was designed to address these new point mutations and induce a new response in the patient's cancer. Interested patients and physicians can contact the Loxo Oncology Physician and Patient Clinical Trial Hotline at 1-855-NTRK-123 or email [clinicaltrials@loxooncology.com](mailto:clinicaltrials@loxooncology.com).

### **About TRK Fusion Cancer**

TRK 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 TRK signaling that can lead to cancer. TRK 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. TRK fusions can be identified through various diagnostic tests, including targeted next-generation sequencing (NGS), immunohistochemistry (IHC), polymerase chain reaction (PCR), and fluorescent in situ hybridization (FISH). For more information, please visit [www.TRKtesting.com](http://www.TRKtesting.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](http://www.loxooncology.com).

### **Bayer: Science For A Better Life**

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their quality of life. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2016, the Group employed around 115,200 people and had sales of EUR 46.8 billion. Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.7 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to [www.bayer.com](http://www.bayer.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 its ability to co-develop and co-commercialize larotrectinib or any other product candidate; the receipt of the upfront payment from Bayer; and Loxo Oncology's expectations regarding its ability to realize substantial potential downstream value and profits from its alliance with Bayer. 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 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.

#### **Contacts for Loxo Oncology, Inc.**

**Company:**

Jacob S. Van Naarden  
Chief Business Officer  
[jake@loxooncology.com](mailto:jake@loxooncology.com)

**Investors:**

Peter Rahmer  
The Trout Group, LLC  
646-378-2973  
[prahmer@troutgroup.com](mailto:prahmer@troutgroup.com)

**Media:**

Dan Budwick  
1AB Media  
973-271-6085  
[dan@1abmedia.com](mailto:dan@1abmedia.com)

Loxo Oncology, Inc.