



Loxo Oncology Announces Positive Top-Line Results from Independent Review Committee Assessment of Larotrectinib Dataset

October 18, 2017

– 75% Overall Response Rate by Independent Review; 80% Overall Response Rate by Investigator Assessment –

STAMFORD, Conn., Oct. 18, 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 top-line overall response rate (ORR) results from the independent review committee assessment of the larotrectinib dataset. The full dataset is being reserved for a future publication. Consistent with prior guidance, Loxo Oncology expects to submit a New Drug Application (NDA) for evaluation by the U.S. Food and Drug Administration (FDA) in late 2017 or early 2018, and a Marketing Authorisation Application (MAA) for evaluation by the European Medicines Agency (EMA) in 2018.

“Today’s results have exceeded our expectations, and confirm the depth and breadth of response larotrectinib delivers to patients with TRK fusion cancers,” said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. “We are indebted to our investigators and team members, whose care and sophistication in the execution of the larotrectinib clinical development program have now been validated by independent review.”

The following table compares response determinations between the independent review committee and investigators, using a July 17, 2017 data cut-off date:

	Independent Review Committee Assessed Response (n=55)		Investigator Assessed Response (n=55)	
Overall Response Rate (ORR = PR+CR)	75%	(95% CI: 61% – 85%)	80%*	(95% CI: 67% – 90%)
Partial Response (PR)	62	%	64%*	
Complete Response (CR)	13	%	16	%
Stable Disease	13	%	9	%
Progressive Disease	9	%	11	%
Not Evaluable	4	%	0	%

* Includes one unconfirmed partial response, as of July 17, 2017, which was subsequently confirmed.

Consistent with global written regulatory correspondence, the NDA/MAA dataset includes adult and pediatric tropomyosin receptor kinase (TRK) fusion patients enrolled in Loxo Oncology’s Phase 1 adult trial, Phase 2 trial (NAVIGATE), and Phase 1/2 pediatric trial (SCOUT). The dataset is based on the intent to treat (ITT) principle, using the first 55 TRK fusion patients with RECIST-evaluable disease enrolled to the three clinical trials, regardless of prior therapy or tumor tissue diagnostic method. The primary endpoint for the integrated analysis of efficacy is overall response rate (ORR) according to the independent review committee assessment, as measured by RECIST v1.1. A key secondary endpoint is ORR according to local investigator assessment, as measured by RECIST v1.1.



The larotrectinib adverse event profile is consistent with data previously presented publicly.

The larotrectinib program has continued to enroll and treat newly identified patients with TRK fusion cancers, beyond the 55 patients described above. The anti-tumor activity and safety of larotrectinib in these additional patients are consistent with data reported today and previously. Notably, no new patients with CNS metastases have been identified or treated in any setting.

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. 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

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.

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, statements we make regarding the timing and success of our clinical trials, the potential therapeutic benefits and economic value of our lead product candidate or other product candidates, and timing of future filings. 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

Investors:
Peter Rahmer
The Trout Group, LLC
646-378-2973
prahmer@troutgroup.com

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

[Primary Logo](#)

Image not found or type unknown

Loxo Oncology, Inc.