Loxo Oncology Announces FDA Clearance of Investigational New Drug (IND) Application for Next-Generation TRK Inhibitor, LOXO-195

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The United States Food and Drug Administration cleared the Investigational New Drug (IND) application for LOXO-195, Loxo Oncology’s next-generation TRK inhibitor. LOXO-195 was developed to treat patients with TRK fusion cancers who become resistant while receiving another TRK inhibitor, such as larotrectinib.

“We hope that LOXO-195 can extend the period of durable disease control for patients with TRK fusion cancers,” said Josh Bilenker, M.D., chief executive officer of Loxo Oncology. “Today, there are patients receiving larotrectinib in ongoing clinical trials who have ongoing clinical responses. We have an obligation to these patients, and all patients with TRK fusion cancers, to be ready when they need a new treatment option.”

Informed by internal research and the medical literature, LOXO-195 was designed to address anticipated mechanisms of acquired resistance in cancers exposed to a prior TRK inhibitor, including “solvent front” mutations (e.g. NTRK1 G595R, NTRK3 G623R), which are not well-addressed by existing investigational agents. LOXO-195 will be developed as a sequential treatment, to follow larotrectinib or another TRK inhibitor, to extend the total time of benefit from TRK inhibition.

LOXO-195 will initially be studied in a multi-center Phase 1/2 trial. The primary objective of the trial is to determine the maximum tolerated dose or recommended dose for further study. Key secondary objectives include measures of safety, pharmacokinetics, and anti-tumor activity (i.e. Objective Response Rate and Duration of Response, as determined by RECIST v1.1). The trial will include a dose escalation phase and dose expansion phase.

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. 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. 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.

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, the availability of funding, timing and success of our clinical trials, success in our collaborations and the potential therapeutic benefits of our lead product candidate or other product candidates. 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.

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