

Exploring the path to selective TRK inhibition

At Loxo Oncology, our mission is to translate scientific knowledge about the drivers of cancer into selective drugs that deliver rapid benefits to patients

Larotrectinib (LOXO-101) is an investigational cancer medicine that exclusively targets a protein known as tropomyosin receptor kinase (TRK). Research suggests that some patients develop cancer because of a gene abnormality involving this protein. Early clinical trial results suggest that larotrectinib (LOXO-101) can have profound effects when tumor genetic profiling reveals a TRK or NTRK gene fusion in the cancer.

Larotrectinib (LOXO-101) has been studied in an adult Phase 1 study and a pediatric Phase 1 study. Across these two studies, 8 evaluable patients with TRK fusions were treated, including patients with sarcoma, thyroid cancer, lung cancer, GIST, salivary gland cancer, and infantile fibrosarcoma. In these two trials, which provided initial safety and efficacy data, **7 out of 8 patients (88%) have had confirmed RECIST partial responses with larotrectinib (LOXO-101).**^{1,2}

Larotrectinib (LOXO-101) was developed in partnership with Array BioPharma. FDA has granted larotrectinib (LOXO-101) breakthrough therapy designation.

Loxo Oncology works with a patient concierge service to help ensure that travel and logistics for patients and caregivers are not a barrier to trial entry.

Physicians and patients interested in participating in a clinical trial can contact the Loxo Oncology Physician and Patient Clinical Trial Hotline at 1-855-NTRK-123 (1-855-687-5123) or send an email to info@loxooncology.com for more information.

The following larotrectinib (LOXO-101) clinical trials are actively recruiting:

NAVIGATE

NCT02576431 | Study of larotrectinib (LOXO-101) in Subjects With NTRK Fusion Positive Solid Tumors

Global, multicenter, single-arm, open-label, Phase 2 basket trial in patients with solid tumors with a fusion of NTRK1, NTRK2, or NTRK3. Loxo Oncology collaborates with the clinical, laboratory, and molecular pathology communities in both academia and industry to help ensure that patients with TRK fusions and their treating physicians are notified about the larotrectinib (LOXO-101) Phase 2 clinical trial to help integrate a trial recruitment mechanism for appropriate patients into routine clinical practice.

SCOUT

NCT02637687 | Oral TRK Inhibitor LOXO-101 for Treatment of Advanced Pediatric Solid or Primary Central Nervous System Tumors

This Phase 1/2 clinical trial is a multicenter, open-label trial in pediatric patients with advanced solid or primary central nervous system tumors. The trial uses a liquid formulation of larotrectinib (LOXO-101), with dose adjusted by body surface area.

NCT02122913 | Oral TRK Inhibitor LOXO-101 for Treatment of Advanced Adult Solid Tumors

Larotrectinib (LOXO-101) is currently being evaluated in an ongoing multicenter, open-label, Phase 1 study in adult subjects with advanced solid tumors that have progressed or are nonresponsive to available therapies and for which no standard or available curative therapy exists.

The information provided on LoxoOncologyTrials.com is intended only for healthcare professionals. If you are a patient, please consult with your physician.

For additional information about larotrectinib (LOXO-101) clinical trials, and to view trial site locations, visit clinicaltrials.gov.

Loxo Oncology is committed to helping patients who have not responded to available therapies and may benefit from its investigational therapies. Loxo Oncology's Policy for Access to Investigational Agents describes the principles and government regulations that the company will follow when considering a request. A copy of this policy can be found by visiting loxooncology.com/patients-caregivers.

References

1. Hong DS, Farago AS, Brose MS, et al. Clinical safety and activity from a phase 1 study of larotrectinib (LOXO-101), a selective TRKA/B/C inhibitor, in solid-tumor patients with NTRK gene fusions. In: Proceedings from the ESMO Asia 2016 Congress; December 18, 2016; Singapore. 2. Nagasubramanian R, Wei J, Gordon P, Rastatter JC, Cox MC, Pappo A. Infantile fibrosarcoma with *NTRK3-ETV6* fusion successfully treated with the tropomyosin-related kinase inhibitor LOXO-101. *Pediatr Blood Cancer*. 2016;63(8):1468-1470.