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# CLINICAL TRIAL ANNOUNCEMENT

## Post-Authorization Safety Study Trial to Evaluate Larotrectinib in patients with **Locally Advanced or Metastatic TRK fusion Cancer**

Official Title: ON-TRK: PrOpective Non-interventional study in patients  
with locally advanced or metastatic TRK fusion cancer treated with larotrectinib

The purpose of this study is to assess the safety and tolerability of of larotrectinib  
in patients with locally advanced or metastatic solid tumor harboring *NTRK* gene  
fusion for whom a decision to treat with larotrectinib has been made before enroll-  
ment.

TRK fusion cancer is rare but presents as a variety of solid tumors. Larotrectinib is a  
highly selective TRK inhibitor that, in a pooled analysis of patients in phase 1/2  
clinical trials, demonstrated an effective and sustained response in the majority of  
patients with TRK fusion cancer.

**Larotrectinib** is approved with a relatively small number of patients enrolled to one  
of three early phase trials. The results indicated clinical effectiveness for larotrec-  
tinib in patients with TRK fusion cancer; but the available safety data are relatively  
limited. This post-approval study will generate additional safety data in a larger  
population.

**Key Inclusion Criteria:**

- Patients with locally advanced or metastatic solid tumor harboring an *NTRK* gene fusion
- Decision to treat with larotrectinib made by treating physician prior to study enrollment

**Key Exclusion Criteria:**

- Any contraindications as listed in the local approved product information
- Prior treatment with larotrectinib or other kinase inhibitor with TRK inhibition
- Patients with *NTRK* gene amplification or *NTRK* point mutation