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CLINICAL TRIAL ANNOUNCEMENT

IRB Approved at the Study Level
Apr 18, 2021

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

Official Title (Protocol: Bayer 20324 ON-TRK) - PrOspective 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 enrollment.

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 larotrectinib 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

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