

ACT015 (Inclusion Criteria)

Inclusion Criteria:

Patient must meet all of the following inclusion criteria:

1. Patients with a locally advanced or metastatic solid tumor with RET activation who:

-Are not eligible for an ongoing LOXO-292 clinical trial (e.g., for clinical, geographic or financial reasons), but are deemed appropriate candidates to receive LOXO-292 treatment by the Investigator and the Sponsor, or

-Have progressed on or are intolerant to standard therapy, or

-No standard therapy exists, or

-In the opinion of the Investigator, are not candidates for or who would be unlikely to derive significant clinical benefit from standard therapy

2. Evidence of an activating RET gene alteration in tumor tissue from a laboratory with Clinical Laboratory Improvement Act (CLIA), International Organization for Standardization (ISO)/independent ethics committee (IEC), College of American Pathologists (CAP), or other similar certification.

3. Eighteen years of age or older at the time of consent.

4. Ability to provide consent.

5. Provision of a signed informed consent prior to any protocol specific procedures. Patients already receiving LOXO-292 who enroll in this protocol must be re-consented and sign the consent form for this expanded access protocol.

6. Patients who are deemed eligible by the Sponsor's medical monitor.

7. Willingness of men and women of reproductive potential to observe conventional and effective birth control for the duration of treatment and for 3 months following the last dose of study treatment.

8. Adequate hematologic, renal and hepatic function as defined in Section 6.1. Patients with values outside of the specified limits may be enrolled if approved by the Loxo Oncology medical monitor. In such cases, a modified starting dose and safety guided monitoring plan will be discussed with the Investigator for safe LOXO-292 exposure.