

## Protocol Plain Language Summary

### A clinical study of lenvatinib in children and young adults with solid tumors (MK-7902-013)

**Protocol Title:** An Open-Label, Multicenter Phase 2 Basket Study to Evaluate the Antitumor Activity and Safety of Lenvatinib in Children, Adolescents, and Young Adults with Relapsed or Refractory Solid Malignancies

#### Why is this study needed?

Researchers are looking for new ways to treat children and young adults with relapsed or refractory solid tumors. **Relapsed** means the cancer has come back after treatment. **Refractory** means the current treatment has stopped working to slow or stop cancer growth. **Solid tumors** are cancers mostly in body organs and tissues, not in the blood or other body liquids.

Researchers want to learn if **lenvatinib, the study medicine**, can treat children and young adults with relapsed or refractory solid tumors. Lenvatinib is a **targeted therapy**, which works to control how specific types of cancer cells grow and spread. The goal of this study is to learn if the cancer responds to treatment (the cancer gets smaller or goes away).

#### Who will take part in this study?

Up to about 150 children and young adults with relapsed or refractory solid tumors may be in the study. They will:

- Be between 2 and 21 years old
- Not have had major surgery within 3 weeks before starting the study medicine

#### What treatments are being given during the study?

Everyone will take **lenvatinib** once a day as a capsule or liquid.

They will take lenvatinib until the cancer gets worse, they start another cancer treatment, or they don't tolerate the study medicine.

#### How is this study designed?

Researchers will put children and young adults into groups based on the type of solid tumor. Researchers will watch how the different types of solid tumors respond to the study medicine. They may stop enrolling children and young adults with certain types of solid tumors if those cancers are not responding to the study medicine.

The children and young adults, their caregivers, and the researchers will know which study medicine a child or young adult is getting (**open-label study**). During the study, children and young adults will give urine and blood samples, have tumor and imaging tests, have physical and dental examinations, and answer questions.

A child or young adult may be in this study for up to 3 and a half years.

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## What are the goals of this study and how will they be measured?

Main goal	How it will be measured
To learn the <b>objective response (OR)</b> of children and young adults who take lenvatinib	<b>OR</b> is the number of children and young adults whose cancer responds to treatment (the cancer gets smaller or goes away) after 4 months of treatment. Researchers will measure OR for each type of solid tumor.
Other goals	How they will be measured
To learn more about the <b>cancer response</b> of children and young adults who receive lenvatinib	For each type of solid tumor, researchers will measure: <ul style="list-style-type: none"> <li>• <b>OR</b> during the study</li> <li>• <b>Progression-free survival (PFS)</b>: the length of time from when the person starts in the study until the cancer grows or spreads, or death from any cause</li> <li>• <b>Best overall response (BOR)</b>: the number of children and young adults whose cancer gets smaller or goes away during treatment</li> <li>• <b>Duration of response (DOR)</b>: the length of time from when the cancer first responds to treatment until the cancer grows or spreads, or death from any cause</li> <li>• <b>Disease control rate (DCR)</b>: the number of children and young adults who have the cancer stop growing for more than about 2 months or get smaller, or show no signs of cancer during the study</li> <li>• <b>Clinical benefit rate (CBR)</b>: the number of children and young adults whose cancer gets smaller, goes away, or stops growing for at least 5 months</li> </ul>
To learn about the <b>safety</b> of lenvatinib and how well children and young adults <b>tolerate</b> it	The number of children and young adults who: <ul style="list-style-type: none"> <li>• Have an <b>adverse event (AE)</b> – an AE is a health problem that happens or worsens during a study</li> <li>• Have a <b>serious adverse event (SAE)</b> – an SAE is a serious medical problem that happens or worsens during a study</li> <li>• Stop treatment due to an AE</li> </ul>
To learn how much children and young adults <b>like the taste</b> of liquid lenvatinib	Children and young adults who took lenvatinib as a liquid by mouth (or their caregivers) will answer questions to measure how much they like the taste
To learn <b>what happens to lenvatinib</b> in children's and young adults' bodies <b>over time</b>	Researchers will measure the amount of lenvatinib in blood samples at different time points

## What are the possible benefits and risks?

Clinical studies may have benefits and risks. Children and young adults may benefit because the study medicine may treat cancer or stop it from getting worse. There may be risks because the study medicine may not work or may cause health problems.

This study has a group of experts, separate from the researchers, who oversee the benefits and risks. If they decide that the study medicine is not safe or doesn't show benefit, the study can be stopped. More information about the benefits and risks is in the protocol.