

## Protocol Plain Language Summary

### A clinical study of belzutifan for treatment of kidney cancer (MK-6482-013)

**Protocol Title:** Phase 2 Study of MK-6482 in Participants With Advanced Renal Cell Carcinoma

#### Why is this study needed?

Researchers are looking for new ways to treat a type of kidney cancer called advanced **renal cell carcinoma (RCC)**. Advanced means cancer has spread to other parts of the body or cannot be removed with surgery. **Belzutifan**, also called MK-6482, is a study medicine designed to block a protein that helps tumors grow and survive.

In this study, researchers want to learn if more people who take a higher daily dose of belzutifan have RCC shrink or go away than those people who take a standard daily dose of belzutifan.

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

About 150 people with advanced RCC will take part in this study. They will be ages 18 and older and:

- Have the most common type of RCC called clear cell RCC
- Had cancer get worse during or after previous treatment for RCC
- Do not need to be treated with oxygen

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

People will take belzutifan once a day by mouth as tablets.

#### How is this study designed?

A person may be in this study for up to about 4 years. Each person will have an equal chance of being assigned to either:

- Belzutifan at a higher dose
- Belzutifan at a standard dose

People will take belzutifan until the cancer gets worse, they don't tolerate it, or they decide to stop taking part in the study.

Both the people in the study and the researcher will know which study treatment a person is getting (**open-label study**). During the study, people will give urine and blood samples, have tumor and imaging tests, and physical examinations.

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

| Main goal   | How it will be measured   |
|---|---|
| To learn if more people who receive a higher dose of belzutifan have an <b>objective response</b> than those people who receive a standard dose of belzutifan | <b>Objective response rate</b> is the number of people whose cancer responds to treatment (gets smaller or goes away)   |
| Other goals   | How they will be measured   |
| To learn the <b>cancer response</b> to belzutifan   | Researchers will measure: <ul style="list-style-type: none"> <li>• <b>Progression free survival:</b> the length of time from the start of treatment until the cancer grows or spreads, or death from any cause</li> <li>• <b>Duration of response:</b> the length of time from when the cancer first responds to treatment until the cancer grows, spreads, or death from any cause</li> <li>• <b>Overall survival:</b> the length of time that people live from the start of treatment until death from any cause</li> <li>• <b>Clinical benefit rate:</b> the number of people whose cancer stays the same for at least 6 months or the cancer gets smaller or goes away</li> </ul> |
| To learn about the <b>safety</b> of belzutifan and how well people <b>tolerate</b> it   | During the study, the number of people who: <ul style="list-style-type: none"> <li>• Had an <b>adverse event (AE)</b> – an AE is a health problem that happens or worsens during a study</li> <li>• Stopped treatment due to an AE</li> </ul>   |
| To learn about the amount of belzutifan in a person’s body over time  | Researchers will measure the amount of belzutifan in a person’s blood samples at certain times during the study   |

## What are the possible benefits and risks?

People in this study may or may not benefit from the treatment received during the study. More information about the benefits and risks for a person may be found in the Investigator’s Brochure, Protocol, and Informed Consent documents.