Protocol Plain Language Summary

A clinical study of MK-4830 and pembrolizumab to treat advanced solid tumors (MK-4830-001)

Protocol Title: A Phase 1 Open-Label, Multi-Arm, Multicenter Study of MK-4830 as Monotherapy and in Combination with Pembrolizumab for Participants with Advanced Solid Tumors

Why is this study needed?

Researchers are looking for ways to treat certain advanced solid tumors. **Advanced** means the cancer has spread to other parts of the body and cannot be removed with surgery. **Solid tumors** are cancers mostly in body organs and tissues, not in the blood or other body liquids. Some of the types of solid tumors in this study include cancers of the pancreas, brain, head and neck, lung, kidney, stomach, ovaries, breast, and tissues that line organs.

MK-4830 and **pembrolizumab**, the **study medicines**, are immunotherapies. **Immunotherapy** is a treatment that helps the immune system fight cancer. The goals of this study are to learn:

- About the safety of the study medicines and how well people tolerate them
- If the **cancer responds** (gets smaller or goes away) to the study medicines

Who will take part in this study?

About 442 people with certain advanced solid tumors will be in this study. They will be at least 18 years old and:

- Have not had certain treatments for the cancer within a certain time period before starting study treatment
- Have not had another type of cancer within the past 2 years

What treatments are being given during the study?

People will receive one or both of these every 3 weeks through a needle into a vein as an intravenous (IV) infusion for up to 2 years:

- **MK-4830,** at different dose levels (amounts)
- **MK-4830 and pembrolizumab**, pembrolizumab is at one dose level

Based on the type of cancer a person has, they may also receive **standard treatment,** which is chemotherapy or lenvatinib. **Chemotherapy** is medicine that destroys cancer cells or stops them from growing. **Lenvatinib** is a targeted therapy, which works to control how specific types of cancer cells grow and spread.

People will receive chemotherapy as an IV infusion and take lenvatinib by mouth once a day.

How is this study designed?

The study will have 2 parts:

Part 1: Researchers will give a small number of people with different types of cancer different dose levels of MK-4830. Researchers will then give people different dose levels of MK-4830 and pembrolizumab. Researchers will review the safety and how well people tolerate the study

medicines before giving them to more people. This will help choose the dose levels of MK-4830 for Part 2.

Part 2: A larger number of people with specific types of cancer will receive MK-4830 and pembrolizumab. MK-4830 will be at the dose levels chosen in Part 1. People may also receive standard treatment for their type of cancer.

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

A person will receive treatment for about 2 years, then researchers will follow up with people for the length of the study (up to 7 years total).

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

Main goals	How they will be measured
To learn about the **safety** of the study medicines and how well people **tolerate** them	The number of people who: • Have an **adverse event (AE)** – an AE is a health problem that happens or worsens during a study • Stop treatment due to an AE • Have a **dose-limiting toxicity (DLT)** during the first 3 weeks of treatment – a DLT is a medical problem related to the study medicine that may prevent researchers from giving the same or higher dose
To learn the **objective response (OR)** of people who receive MK-4830 and pembrolizumab with or without standard treatment	**OR** is the number of people whose cancer responds to treatment (gets smaller or goes away) during the study
Other goals	**How they will be measured**
To learn what happens to the study medicines in a person's body over time	Researchers will measure the amount of MK-4830 and pembrolizumab in people's blood samples at different times during the study
To learn if a person's immune system makes antibodies against the study medicines	The number of people who have antibodies against MK-4830 or pembrolizumab in blood samples during the study. **Antibodies** are proteins the immune system makes in response to foreign substances. This will only be measured in people who live in China.

What are the possible benefits and risks?

Clinical studies may have benefits and risks. People 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. More details about the possible benefits and risks are in the protocol.