Protocol Plain Language Summary

A clinical study of MK-4464 to treat people with advanced solid tumors (MK-4464-001)

Protocol Title: A Phase 1, Open-label, Multicenter Study of the Safety, Pharmacokinetics, and Pharmacodynamics of MK-4464 as Monotherapy and in Combination with Pembrolizumab in Participants with Advanced/Metastatic Solid Tumors

Why is this study needed?

Researchers are looking for new ways to treat people with advanced cancer caused by solid tumors. Advanced cancer is when it has spread to other parts of the body (**metastatic**) and cannot be removed with surgery.

MK-4464 is a study medicine designed to treat advanced solid tumors. The goal of this study is to learn about:

- The safety of MK-4464 and how well people tolerate it.
- The highest dose of MK-4464 that is well tolerated when given alone and with pembrolizumab. **Pembrolizumab** is an immunotherapy, which is a treatment that helps the immune system fight cancer.

Who will take part in this study?

About 260 people with advanced solid tumors will be in this study. They will be at least 18 years old and:

- Have a certain type of cancer, such as lung, colon, or stomach cancer
- Have not received certain transplants
- Have either:
  - Not responded to or tolerated standard treatment
  - Not qualify for or want to receive standard treatment

What treatments are being given?

During the study, people will be assigned to receive one or both treatments through a needle into a vein as an intravenous (IV) infusion:

- **MK-4464**, given at different dose levels (amounts)
- **Pembrolizumab**

All treatments will be given once every 3 weeks for up to 2 years.

How is this study designed?

This study has 2 parts:

Part 1: Researchers will assign people to 1 of 3 groups:

- **Group 1** will receive MK-4464 alone
- **Group 2** will receive MK-4464 with pembrolizumab
- **Group 3** will receive **radiolabelled** MK-4464 only on Day 1. Then they will receive MK-4464 with pembrolizumab. A radiolabel is added to detect the study medicine in the body.

Researchers will start by giving a few people in Group 1 a low dose of only MK-4464. Researchers will check for any safety concerns or medical problems before giving a higher dose. This may continue until they reach the highest dose level. Once a certain dose level is reached, researchers will assign the other people to Groups 1, 2, and 3.

People in Group 1 who stopped treatment due to the cancer growing or spreading may switch over to Group 2. Researchers will look at which dose levels of MK-4464 alone and with pembrolizumab were safe and well tolerated to give in Part 2 (**selected doses**).

Part 2: People will receive the selected dose of MK-4464 given alone or with pembrolizumab.

Researchers and all the people in the study will know which treatment the person takes (an open-label study). During the study, people may give tumor, blood, and urine samples, have imaging tests and physical examinations.

A person may be in this study for about 2 years and 2 months.

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

Main goals	How they will be measured
To learn the highest dose of MK-4464 that is well tolerated when given alone and with pembrolizumab	During the first 21 days of Part 1, the number of people who have a medical problem related to study medicine that prevents giving a higher dose (**dose-limiting toxicity**)
To learn about **safety** and how well people **tolerate** MK-4464	During the study, the number of people who: • Have an **adverse event (AE)**—an AE is a health problem that happens or worsens • Stop treatment due to an AE

Other goals	How they will be measured
To learn what happens to different doses of MK-4464 in a person's body over time	During the study, researchers will measure the amount of MK-4464 in people's blood samples many times
To learn the **objective response rate** (**ORR**) of people who receive MK-4464 alone and with pembrolizumab	**ORR** is the number of people whose cancer responds to treatment (gets smaller or goes away) during the study

What are the possible benefits and risks?

People may or may not benefit from the treatment received during the study.

More information about the benefits and risks is in the Investigator Brochure, Protocol, and Informed Consent documents.