A clinical study of MK-1484 to treat advanced solid tumors (MK-1484-001)

Protocol Title: A Phase 1, Open-Label, Multicenter Study to Assess the Safety and Tolerability of MK-1484 as a Monotherapy and in Combination with Pembrolizumab in Participants with Advanced or Metastatic Solid Tumors

Why is this study needed?

Researchers are looking for new ways to treat people with advanced cancer in solid tumors. **Solid tumors** are mostly in body organs and tissues, not in the blood or other body liquids. **Advanced** means that the cancer has spread to other parts of the body (metastatic) and cannot be removed with surgery.

MK-1484, the study medicine, is designed to treat advanced solid tumors. MK-1484 is an **immunotherapy**, which is a treatment that helps the immune system fight cancer.

This is the first study in which MK-1484 will be given to people. The goal of this study is to learn about:

- The safety of MK-1484 and how well people tolerate it when given alone and with pembrolizumab. **Pembrolizumab** is another immunotherapy.
- The highest dose of MK-1484 that is well tolerated when given alone and with pembrolizumab.

Who will take part in this study?

About 70 people with advanced solid tumors will be in this study. They will be at least 18 years old and:

- Have received standard treatment for advanced solid tumors, or did not tolerate standard treatment
- Have not had other certain cancer treatments within the past month

What treatments are being given during the study?

People will receive one or both of these treatments once every 3 weeks for up to about 2 years:

- MK-1484, given as an injection (shot) under the skin at different dose levels (amounts)
- **Pembrolizumab**, given through a needle into a vein as an intravenous (IV) infusion at one dose level

How is this study designed?

A person may be in this study for up to 2 years. Researchers will assign people to 1 of 2 groups:

- Group 1: people will receive up to 8 different dose levels of MK-1484 alone
- **Group 2**: people will receive about 4 different dose levels of MK-1484 with pembrolizumab

In both groups, researchers will check to see if there are any safety concerns before giving people the next higher dose of MK-1484. People in Group 1 may switch over to Group 2 if the cancer grows or spreads.

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

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

Main goals	How they will be measured
To learn about safety of MK-1484 and how well people tolerate it alone and with pembrolizumab	 During the study, the number of people who: Had a dose limiting toxicity (DLT) during the first 3 weeks of treatment. A DLT is a medical problem related to study treatment that prevents giving a higher dose Had an adverse event (AE) – An AE is a health problem that happens or worsens Stopped treatment due to an AE
Other goal	How it will be measured
To learn what happens to different dose	Researchers will measure the amount of MK-
levels of MK-1484 alone and with	1484 in people's blood samples at different
pembrolizumab in the body over time	times 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.