A clinical study of MK-3475A and pembrolizumab in people with advanced solid tumors (MK-3475A-C18)

Protocol Title: A Phase 1 Clinical Study to Evaluate the Bioavailability of Pembrolizumab via Subcutaneous Injection of MK-3475A, a Formulation of Pembrolizumab With MK-5180, in Participants With Advanced Solid Tumors

Why is this study needed?

Researchers are looking for other ways to give treatment to people with **advanced solid tumors**. **Solid tumors** are abnormal masses of tissue that usually do not contain cysts or liquid areas. Solid tumors can occur in many parts of the body such as the skin, lung, and kidneys. **Advanced** means the cancer has spread to other parts of the body (metastatic) or cannot be removed with surgery.

Pembrolizumab is an immunotherapy, which is a treatment that helps the immune system fight cancer. Pembrolizumab is usually given through a needle into a vein as an **intravenous (IV) infusion**. **MK-3475A (study treatment)** is pembrolizumab combined with hyaluronidase (also called MK-5180). MK-3475A is given under the skin as a **subcutaneous (SC) injection.** Hyaluronidase helps pembrolizumab easily move into and through the body.

Researchers want to learn if MK-3475A is safe and how well people tolerate it. Researchers will also learn what happens to MK-3475A in a person's body over time.

Who will take part in this study?

About 128 people with advanced solid tumors will be in this study. They will be at least 18 years old and:

- Have a certain type of skin, lung, or kidney cancer
- Have not received cancer treatments within 1 month before starting the study

What treatments are being given during the study?

People may be given:

- **MK-3475A**, given as an SC injection
- **Pembrolizumab**, given as an IV infusion
- **Chemotherapy**, given as an IV infusion. Chemotherapy is a treatment that uses medicine to shrink or get rid of cancer.

How is this study designed?

This study has **4 treatment groups**.

- **Groups 1 and 2:** People will receive MK-3475A and pembrolizumab. People in groups 1 and 2 may also receive chemotherapy.
- **Group 3**: People will receive MK-3475A and pembrolizumab. People in group 3 will also receive chemotherapy.
- **Group 4**: People will receive MK-3475A.

Both the people in the study and researchers will know which treatment the person receives (open-label study). During the study, people may give urine and blood samples, have imaging tests and physical examinations, and answer questions about how they are feeling after SC injections.
A person may be in this study for up to 5 years.

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

Main goals	How they will be measured
To learn what happens to MK-3475A in a person's body over time	Researchers will measure the amount of MK-3475A in people's blood samples at many time points
To learn about the **safety** and how well people **tolerate** MK-3475A	During the study, the number of people who: • Have a **dose limiting toxicity (DLT)** during the first 3 weeks of treatment (Group 3 only). **DLTs** are medical problems related to the amount of study medicine. • Have an **adverse event** (**AE**)—an AE is a health problem that happens or worsens • Stop treatment due to an AE • Had pain, itching, swelling or redness at the injection site approximately 1 hour after SC injection
Other goal	**How it will be measured**
To learn if a person's immune system makes antibodies against MK-3475A	The number of people who have a positive test for antibodies against MK-3475A 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.