A clinical study of treatment preference in people with early or advanced solid tumors (MK-3475A-F11)

Protocol Title: A Phase 2 Study to Evaluate Patient Reported Preference for Subcutaneous MK-3475A Over Intravenous Pembrolizumab Formulation in Participants With Multiple Tumor Types (MK-3475A-F11)

Why is this study needed?

Researchers are looking for other ways to give treatment to people with **early** or **advanced solid tumors**. **Solid tumors** are an abnormal mass of tissue that usually does not contain cysts or liquid areas. They can occur in many parts of your body such as the skin, lung, and kidneys. **Early** means the cancer has not spread to other parts of the body and can be removed with surgery. **Advanced** means the cancer has spread to other parts of the body (metastatic) and 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**. In this study, researchers will also give pembrolizumab under the skin as a **subcutaneous (SC) injection**.

Researchers want to learn how many people in this study prefer to be given pembrolizumab as an SC injection instead of an IV infusion.

Who will take part in this study?

About 144 people with early or advanced solid tumors will be in this study. They will be at least 18 years old and:

- Have a certain type of solid tumor, such as skin, lung, or kidney cancer
- Have not received certain cancer treatments

How is this study designed?

People will receive pembrolizumab for up to about 2 years, depending on their type of cancer. This study has **2 treatment periods**.

Treatment period 1: People will have an equal chance of being assigned to 1 of these 2 groups:

- **Group A**: People will receive **SC pembrolizumab** followed by **IV pembrolizumab**
- **Group B**: People will receive **IV pembrolizumab** followed by **SC pembrolizumab**

Treatment period 2: People from both groups will choose to continue to receive either SC pembrolizumab or IV pembrolizumab.

Both the people in the study and researchers will know which treatment the person takes (an open-label study). During the study, people may give blood samples, have imaging tests and physical examinations, and answer sets of questions.

A person may be in this study for up to about 2 years.

What treatments are being given during the study?

People will be given:

- **SC pembrolizumab**, given as an SC injection
- **IV pembrolizumab**, given as an IV infusion

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

Main goal	How it will be measured
To learn how many people prefer **SC pembrolizumab** instead of **IV pembrolizumab**	The number of people who prefer **SC pembrolizumab** after treatment period 1. Researchers will ask people to choose which one of these they prefer: • IV pembrolizumab • SC pembrolizumab • No preference
Other goals	**How they will be measured**
To learn why people prefer **SC pembrolizumab** instead of **IV pembrolizumab**	After treatment period 1, researchers will ask people to choose 2 reasons for why they prefer **SC pembrolizumab** or **IV pembrolizumab**
To learn about people's satisfaction with **SC pembrolizumab** and **IV pembrolizumab**	People will answer a set of questions about their experience when being treated with **SC pembrolizumab** and **IV pembrolizumab**
To learn which way people choose to receive pembrolizumab in treatment period 2	The number of people who choose to receive **SC pembrolizumab** in treatment period 2
To learn about the safety and how well people tolerate **SC pembrolizumab** and **IV pembrolizumab**	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

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.