A clinical study of pembrolizumab to treat different types of advanced cancer caused by solid tumors (MK-3475-158)

Protocol Title: A Clinical Trial of Pembrolizumab (MK-3475) Evaluating Predictive Biomarkers in Subjects with Advanced Solid Tumors (KEYNOTE 158)

Why is this study needed?

Researchers are looking for new ways to treat different types of advanced cancer caused by solid tumors. Advanced cancer are tumors that have spread to other parts of the body (**metastatic**) or cannot be removed by surgery (**unresectable**)**.**

Pembrolizumab is an **immunotherapy**, which is a treatment that helps the immune system fight cancer. In this study, researchers want to learn if pembrolizumab can help treat advanced cancer that progressed (got worse) after having been treated with a standard treatment.

The goal of this study is to learn how different types of advanced cancer respond to treatment with pembrolizumab.

Who will take part in this study?

Up to 1,609 people with advanced cancer will be in this study. They will be age 18 years and older and:

- Have a tumor sample to use for biomarker testing. **Biomarkers** are substances measured in blood, tissues, or other body fluids that show normal or abnormal activity taking place in the body. They may be a sign of an underlying condition or disease. Biomarker testing is a way to look for genes, proteins, and other substances that can provide information about a person's cancer. They may show how well the body responds to a treatment.
- Have cancer that got worse after being treated with standard treatment, **or** did not tolerate past treatments

How is this study designed?

A person may be in this study for up to 10.5 years. Both the people in the study and the researchers will know which treatment a person receives (open-label study).

During the study, people will have blood, tumor, urine, and imaging tests, have physical examinations, and answer questions about how they are feeling and their ability to carry out daily tasks.

What treatments are being given during the study?

During this study, people will receive pembrolizumab through a vein as an intravenous (IV) infusion in 1 of 2 amounts:

- **A high amount of pembrolizumab** every 6 weeks
- **A low amount of pembrolizumab** every 3 weeks

The amount of pembrolizumab will depend on the type of tumor being treated. Each person will receive treatment for up to 2 years.

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

Main goals	How it will be measured
To learn how different types of cancer respond to treatment with pembrolizumab **(objective response rate)** and to learn how the objective response rate may change with different cancers and biomarkers.	The number of people whose cancer improves or goes away after treatment. Researchers will measure this during the study.
Other goals	**How they will be measured**
To learn how long **cancer responds to treatment** and how the length of the response may change in people with different cancers and biomarkers.	Researchers will measure responses throughout the study: • **duration of response**: the average length of time from when the cancer first responds to treatment until the cancer gets worse or death due to any cause. • **progression-free survival**: the average length of time after the start of treatment, that people are alive, and the cancer does not grow or spread • **overall survival**: the average length of time that people live from the start of treatment to death due to any cause
To learn about safety and how well people tolerate the study treatments	The number of people who: • Had an **adverse event (AE)** while on treatment or up to 90 days after their last dose – an AE is a health problem that happens or worsens during the study • Stopped treatment due to an AE

What are the possible benefits and risks?

People in this study may or may not have their cancer stop growing or go away after treatment. More information about the benefits and risks for a person is in the Investigator Brochure, Protocol, and Informed Consent documents.