Protocol Plain Language Summary

A clinical study of long-term safety and efficacy of pembrolizumab in people on treatment or in follow-up in a pembrolizumab study (MK-3475-587)

Protocol Title: A Multicenter, Open-label, Phase 3 Study to Evaluate the Long-term Safety and Efficacy in Participants who are Currently on Treatment or in Follow-up in Studies That Include Pembrolizumab

Why is this study needed?

The purpose of this clinical study is to learn more about the long-term safety and effects of pembrolizumab in people with cancer. **Pembrolizumab** is an immunotherapy, which is a treatment that helps the immune system fight cancer. This is an **extension study,** which means it invites people who were treated in other studies of pembrolizumab to join. This extension study will let them continue to take treatment and follow them long-term to learn about its safety and effects. The first study that a person was in is called the **parent study**.

Who will take part in this study?

About 2,300 adults with cancer will take part in this study. All people in this study will have been treated in a parent study of pembrolizumab.

How is this study designed?

Each person in this study and researchers will know what treatment the person is receiving (an open-label study). Each person will join this study in 1 of 3 phases. The phase they join is based on whether the cancer got worse and whether they had completed treatment in their parent study. The 3 phases are:

- **First treatment phase**: People whose cancer didn't get worse and were still being treated in the parent study will continue treatment in this study for up to 2 years. Some people who were being treated without pembrolizumab in the parent study and the cancer gets worse may also be able to be treated with pembrolizumab for 2 years.
- **Second treatment phase**: People whose cancer got worse will receive treatment with pembrolizumab alone or with treatment from the parent study for up to 1 year.
- **Survival follow-up phase** (after treatment ends): People who are not currently being treated will be followed every 6 months as long as they are alive, until they leave this study, or until the study ends.

People may give urine samples, have blood and imaging tests, have physical examinations, and answer sets of questions during the study.

Protocol Plain Language Summary

What treatments are being given during this study?

People will receive the same treatment they received in their parent study, which is any of these:

- **Pembrolizumab** at a lower dose given through a vein as an intravenous (IV) infusion every 3 weeks
- **Pembrolizumab** at a higher dose given as an IV infusion every 6 weeks
- **Pembrolizumab combined with parent study treatment**, such as chemotherapy
- **Parent study treatment without pembrolizumab**, pembrolizumab was not given in their parent study

Some people receiving a lower dose of pembrolizumab may switch to a higher dose but would not be able to switch back.

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

Main goal (Primary Objectives)	How it will be measured
To learn how long people who receive pembrolizumab live (**overall survival**)	The average length of time that people are alive from the start of treatment in the parent study until death due to any cause

Other goals (Secondary Objectives)	How they will be measured
To learn how long people who receive pembrolizumab live without their cancer getting worse (**duration of response**)	The average length of time from when cancer first responds (shrinks or stops growing) in the parent study until cancer gets worse or death due to any cause
To learn how long from when cancer completely disappears to when it comes back (**duration of complete response**)	The average length of time from the date of complete response (no signs of cancer) in the parent study until cancer gets worse or death due to any cause
To learn about the **safety** and how well people manage the different treatments (**tolerability**) with pembrolizumab	The number of people who have: • A **serious adverse event (SAE)** during the study. SAEs are serious medical problems that happen or worsen during a study. • An **AE of special interest (AEOSI**) during the study. An AE is a medical problem that happens or worsens during a study. • **Events of clinical interest (ECI)** during the study. ECI are specific medical problems that researchers are interested in learning about. • Stop 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. More information about the benefits and risks is in the Investigator Brochure, Protocol, and Informed Consent documents.