Protocol Plain Language Summary

A clinical study of pembrolizumab and olaparib to treat lung cancer (MK-7339-008)

Protocol Title: A Phase 3 Study of Pembrolizumab in Combination with Carboplatin/Taxane (Paclitaxel or Nab-paclitaxel) Followed by Pembrolizumab with or without Maintenance Olaparib in the First-line Treatment of Metastatic Squamous Non-small Cell Lung Cancer (NSCLC)

Why is this study needed?

Researchers are looking for new ways to treat people with **metastatic non-small cell lung cancer (NSCLC)**. **Metastatic** means the cancer has spread to other parts of the body.

Current treatments for metastatic NSCLC are chemotherapy and immunotherapy. **Chemotherapy** is medicine that destroys cancer cells or stops them from growing. **Immunotherapy** is a treatment that helps the immune system fight cancer.

Pembrolizumab and **olaparib** are the study medicines. Pembrolizumab is an immunotherapy. Olaparib is a **targeted therapy**, which works to control how specific types of cancer cells grow and spread. Researchers want to learn if adding olaparib to pembrolizumab can treat metastatic NSCLC.

The goal of this study is to learn if people who receive pembrolizumab with olaparib live longer overall and without the cancer getting worse compared to people who receive pembrolizumab with placebo. A **placebo** looks like the study medicine but has no study medicine in it. Using a placebo helps researchers better understand the effects of a study medicine.

Who will take part in this study?

About 857 people will be in this study. They will be at least 18 years old and:

- Have squamous metastatic NSCLC—squamous cells are flat cells that line the inside of the airways in the lungs
- Have not received treatments for metastatic NSCLC

What treatments are being given during the study?

People will receive 3 of these treatments:

- **Pembrolizumab**, given every 3 weeks
- **Olaparib**, taken twice a day
- **Chemotherapy**, given every 1 or 3 weeks
- **Placebo**, taken twice a day

People will receive pembrolizumab through a needle into a vein as an intravenous (IV) infusion for up to about 2 years. People will take olaparib or placebo by mouth as a tablet until the cancer gets worse or the person doesn't tolerate it. People will receive 2 types of chemotherapy through an IV infusion for up to 3 months.

How is this study designed?

This study has 2 parts:

Part 1: Everyone in the study will receive **pembrolizumab and chemotherapy** for about 3 months as their first treatment (also called induction therapy).

Part 2: People who complete induction therapy and don't have the cancer get worse will receive more treatment (called maintenance therapy). In Part 2, people will have an equal chance to receive either:

- **Pembrolizumab with olaparib**
- **Pembrolizumab with placebo**

In Part 2, neither the people in the study nor the researchers will know which study treatments a person is getting (double-blind study). During the study, people will give urine and blood samples, have tumor and imaging tests, have physical examinations, and answer questions about how they are feeling and their ability to carry out daily tasks.

Researchers will follow up with people until they are no longer alive, they no longer want to be in the study, or the study ends. A person may be in this study and followed for about 5 years.

After a planned review of results, the sponsor has decided to have people stop taking placebo but continue in the study. People may continue olaparib with the researcher's approval.

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

Main goals	How they will be measured
To learn if the **progression-free survival (PFS)** of people who receive pembrolizumab with olaparib is longer than those who receive pembrolizumab with placebo	**PFS** is the length of time from when the person starts Part 2 until the cancer grows or spreads, or death from any cause
To learn if the **overall survival (OS)** of people who receive pembrolizumab with olaparib is longer than those who receive pembrolizumab with placebo	**OS** is the length of time that people live from the start of Part 2 until death from any cause

Other goals	How they will be measured
To learn about the **safety** and how well people **tolerate** pembrolizumab with olaparib compared to pembrolizumab with placebo	The number of people who: • Had an **adverse event (AE)** – An AE is a health problem that happens or worsens during a study • Stopped treatment due to an AE
To compare the **quality of life (QoL)** of people who receive pembrolizumab with olaparib to those who receive pembrolizumab and placebo	People will answer questions to measure their **QoL**, including questions about their overall health, lung cancer symptoms, and their ability to carry out daily tasks. Researchers will measure: • The change in the scores during the study • The length of time from the start of Part 2 until people's QoL gets worse

What are the possible benefits and risks?

Clinical studies may have benefits and risks. People may benefit because the study medicines may treat metastatic NSCLC or stop it from getting worse. There may be risks because the study medicines may not work or may cause health problems.

This study has a group of experts, separate from the researchers, who oversee the benefits and risks. If they decide that the study medicines are not safe or don't show benefit, the study can be stopped. More information about the benefits and risks is in the protocol.