Protocol Plain Language Summary

A clinical study to compare MK-2870 with pembrolizumab to pembrolizumab alone in people with lung cancer (MK-2870-007)

Protocol Title: A Randomized, Open label, Phase 3 Study of MK-2870 in Combination with Pembrolizumab Compared to Pembrolizumab Monotherapy in the First-line Treatment of Participants with Metastatic Non-small Cell Lung Cancer with PD-L1 TPS ≥ 50%

Why is this study needed?

Researchers are looking for new ways to treat metastatic **non-small cell lung cancer (NSCLC)**. NSCLC is a type of lung cancer. **Metastatic** means the cancer has spread from where it started to other parts of the body.

Current treatments for NSCLC may not work, or may stop working, for some people. **MK-2870 (study medicine)** works on specific cancer cells to stop them from growing. **Pembrolizumab** is an immunotherapy, which is a treatment that helps the immune system fight cancer. Researchers want to know if people who receive MK-2870 with pembrolizumab live longer overall than people who receive pembrolizumab alone.

Who will take part in this study?

About 614 people will be in this study. They will be 18 years old and older and:

- Have newly diagnosed NSCLC and has not been treated.
- Have provided a tumor tissue sample where the **Programmed death-ligand 1 (PD-L1)** is present in more than half of tumor cells. **PD-L1** is a type of protein found on cancer cells that can help the cancer hide from the body's immune system. It is a type of biomarker (substance made by cancer) that doctors can test for in blood, tissues, or other body fluids.
- Do not have NSCLC with an **epidermal growth factor receptor (EGFR)** gene mutation or certain other gene mutations. A **gene mutation** is a change in the order of DNA.

What treatments are being given during the study?

During this study, people will have an equal chance to receive 1 of 2 treatments:

- **MK-2870 with pembrolizumab**
- **Pembrolizumab**

People will receive their treatment through a needle into a vein as an intravenous (IV) infusion. MK-2870 will be given once every 2 weeks until the cancer gets worse, or the researcher decides to stop treatment. Pembrolizumab will be given every 6 weeks for about 2 years.

How is this study designed?

Each person could be in the study for up to 6 years including treatment period and follow-up period. Both the people in the study and the researchers will know which treatment the person receives (called an open-label study). During the study, people will give blood, urine, and tumor tissue, will have imaging tests and physical examinations, and answer questions about how they are feeling.

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

Main goals	How will it be measured
To learn if the **overall survival (OS)** of people who receive MK-2870 with pembrolizumab is longer than those who receive pembrolizumab alone	**OS** is the length of time that people live from the start of treatment until death from any cause.
Other goals	**How they will be measured**
To learn if the **progression free survival (PFS)** of people who receive MK-2870 with pembrolizumab is longer than those who receive pembrolizumab alone	**PFS** is the average length of time people live from the start of treatment until a person's cancer grows or spreads, or death from any cause.
To learn the **cancer response** of people who receive MK-2870 with pembrolizumab compared to those who receive pembrolizumab alone	Researchers will measure how the cancer responds in all people in the study. • **Objective response** is the number of people whose cancer responds to treatment (the cancer gets smaller or goes away) during the study. • **Duration of response** is the length of time from when the cancer first responds to treatment until the cancer grows, spreads, or death from any cause.
To learn the **quality of life (QoL)** of people who receive MK-2870 with pembrolizumab compared to those who receive pembrolizumab alone	People will answer questions to measure their **QoL**, including questions about how they are feeling and their ability to carry out daily tasks**.** Researchers will measure this in all people in the study. • The change in the scores during the study • The length of time from the start of the study until people's QoL gets worse
To learn about the **safety** of MK-2870 and how well people **tolerate** it	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

What are the possible benefits and risks?

People may or may not benefit from the treatment received during the study. This study has an external group of experts that will oversee the overall risk and benefit. If this group of experts decides that the study treatment is not safe or does not show benefit, the study can be stopped. More information about the benefits and risks is in the Investigator Brochure, Protocol, and Informed Consent documents.