Protocol Plain Language Summary

A clinical study of pembrolizumab and lenvatinib in people with lung cancer (MK-7902-008)

Protocol Title: A Phase 3, multicenter, randomized, open-label trial to compare the efficacy and safety of pembrolizumab (MK-3475) in combination with lenvatinib (E7080/MK-7902) versus docetaxel in previously treated participants with metastatic non-small cell lung cancer (NSCLC) and progressive disease (PD) after platinum doublet chemotherapy and immunotherapy (LEAP-008)

Why is this study needed?

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

Standard treatment for metastatic or progressive NSCLC includes immunotherapy and chemotherapy. **Pembrolizumab** is an immunotherapy, which is a treatment that helps the immune system fight cancer. **Docetaxel** is a chemotherapy, which is a medicine that destroys cancer cells or stops them from growing.

Researchers want to learn about the safety and effects of giving pembrolizumab and lenvatinib (a study treatment) to people with NSCLC. **Lenvatinib** is a study treatment that is a type of targeted therapy, which is a treatment that works to control how specific types of cancer cells grow and spread.

The goal of this study is to learn if people who receive pembrolizumab and lenvatinib live longer overall and live longer without the cancer growing or spreading compared to people who receive docetaxel.

Who will take part in this study?

About 405 people with metastatic NSCLC will be in the study. They will be at least 18 years old and:

- Had NSCLC progress (get worse) after previous treatment for NSCLC with 1 immunotherapy and a certain combination of chemotherapy called platinum-doublet chemotherapy
- Not have had previous treatment with docetaxel or lenvatinib

What treatments are being given during the study?

During this study, people will be assigned by chance to receive 1 of 3 treatments:

- **Pembrolizumab and lenvatinib,** the study treatment
- **Docetaxel**, a standard treatment
- **Lenvatinib alone,** a study treatment

People will receive pembrolizumab and docetaxel every 3 weeks through a needle into a vein as an intravenous (IV) infusion. People will take lenvatinib once a day by mouth as a capsule.

People will receive pembrolizumab for about 2 years or until the cancer gets worse or they don't tolerate it. Some people may receive another year of pembrolizumab with or without lenvatinib with researcher approval.

People will receive lenvatinib and docetaxel until the cancer gets worse or they don't tolerate it.

How is this study designed?

A person may be in this study for up to 5 years.

Both the people in the study and the researcher will know which study treatment a person is getting (**open-label 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.

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

Main goals	How they will be measured
To learn if the **overall survival (OS)** of people who receive pembrolizumab and lenvatinib is longer than those who receive docetaxel	**OS** is the length of time that people live from the start of study treatment assignment until death from any cause
To learn if the **progression free survival (PFS)** of people who receive pembrolizumab and lenvatinib is longer than those who receive docetaxel	**PFS** is the length of time from the start of study treatment assignment until the cancer grows or spreads, or death from any cause

Other goals	How they will be measured
To learn about the **cancer response** of people who receive pembrolizumab and lenvatinib compared to those who receive docetaxel or lenvatinib alone	Researchers will measure: • **Objective Response (OR),** which is the number of people whose cancer responds to treatment (the cancer gets smaller or goes away) during the study • **Duration of Response (DOR),** which 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 about the **safety** and how well people **tolerate** pembrolizumab, lenvatinib, and docetaxel	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 learn the **quality of life (QoL)** of people who receive pembrolizumab and lenvatinib compared to those who receive docetaxel	During the study, people will answer questions to measure their **QoL**, including questions about how they are feeling, NSCLC 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 the study until people's QoL gets worse

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.