Protocol Plain Language Summary

A clinical study of vibostolimab and pembrolizumab to treat lung cancer (MK-7684A-007)

Protocol Title: A Randomized, Double-Blind, Phase 3 Study of Pembrolizumab/Vibostolimab Coformulation (MK-7684A) in Combination with Chemotherapy Versus Pembrolizumab Plus Chemotherapy as First Line Treatment for Participants with Metastatic Non-Small Cell Lung Cancer (MK-7684A-007/KEYVIBE-007)

Why is this study needed?

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

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

The **study medicine** is a combination of 2 immunotherapies (called a coformulation), **vibostolimab** and **pembrolizumab**. This study will compare vibostolimab and pembrolizumab with chemotherapy to pembrolizumab with chemotherapy.

The goal of this study is to learn if people who receive vibostolimab and pembrolizumab with chemotherapy live longer overall compared to people who receive pembrolizumab with chemotherapy.

Who will take part in this study?

About 700 people with metastatic NSCLC will be in this study. They will be at least 18 years old and:

- Have not received prior treatments for metastatic NSCLC
- Have not had other certain types of cancer in the past 3 years

What treatments are being given during the study?

People will have an equal chance to receive one of these treatments once every 3 weeks through a needle into a vein as an intravenous (IV) infusion:

- **Vibostolimab and pembrolizumab**, the study medicine, with **chemotherapy**
- **Pembrolizumab** with **chemotherapy**

People will receive vibostolimab and pembrolizumab or pembrolizumab for up to about 2 years unless the cancer gets worse or the person can't tolerate treatment. People will receive chemotherapy for about 3 months. People with a certain type of NSCLC may continue chemotherapy until the study ends.

How is this study designed?

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

A person may be in this study for about 5 years.

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

Main goal	How it will be measured
To learn if the **overall survival (OS)** of people who receive vibostolimab and pembrolizumab with chemotherapy is longer than those who receive pembrolizumab with chemotherapy	**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 compare the **cancer response** in people who receive vibostolimab and pembrolizumab with chemotherapy to those who receive pembrolizumab with chemotherapy	During the study, researchers will measure: • **Progression-free survival (PFS):** the length of time from the start of treatment until the cancer grows or spreads, or death from any cause • **Objective response rate (ORR):** the number of people whose cancer responds to treatment (gets smaller or goes away) • **Duration of response (DOR):** the length of time from when the cancer first responds to treatment until the cancer grows, spreads, or death from any cause
To compare the **quality of life** (**QoL**) of people who receive vibostolimab and pembrolizumab with chemotherapy to those who receive pembrolizumab with chemotherapy	People will answer sets of questions to measure their **QoL**, including questions about their overall health 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
To learn about the **safety** and how well people **tolerate** vibostolimab and pembrolizumab with chemotherapy compared to pembrolizumab with chemotherapy	During the study, the number of people who: • Have an **adverse event (AE)** – An AE is a health problem that happens or worsens • Stop 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.