A clinical study of vibostolimab and pembrolizumab compared to pembrolizumab alone in people with lung cancer (MK-7684A-003)

Protocol Title: A Phase 3, Multicenter, Randomized, Double-Blind Study of MK-7684 with Pembrolizumab as a Coformulation (MK-7684A) Versus Pembrolizumab Monotherapy as First Line Treatment for Participants With PD-L1 Positive Metastatic Non-Small Cell Lung Cancer (KEYVIBE-003)

Why is this study needed?

Researchers are looking for new ways to treat people with metastatic **non-small cell lung cancer (NSCLC)** that is PD-L1 positive.

- **Metastatic** means cancer that has spread to other parts of the body.
- **PD-L1 positive** means that PD-L1 is found on the cancer cells. **PD-L1** is a protein that can help the cancer hide from the body's immune system.

The **study medicine** is a combination of 2 immunotherapies, **vibostolimab and pembrolizumab**. **Immunotherapy** is a treatment that helps the immune system fight cancer.

The goal of this study is to learn if people who receive vibostolimab and pembrolizumab live longer overall and without the cancer getting worse than people who receive pembrolizumab alone.

Who will take part in this study?

About 1,246 people with metastatic NSCLC will be in this study. They will be age 18 years and older and:

- Have NSCLC that is PD-L1 positive
- Have not received treatment for metastatic NSCLC

What treatments are being given during the study?

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

- **Vibostolimab and pembrolizumab**, the study medicine
- **Pembrolizumab** alone

People will receive their assigned treatment through a needle in a vein as an intravenous (IV) infusion every 3 weeks for up to 2 years.

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 may give urine and blood samples, have tumor and imaging tests until the cancer grows or spreads, have physical examinations, and answer questions about how they are feeling and their ability to carry out daily tasks.

People may be in this study for up to about 3 years.

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 vibostolimab and 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
To learn if the **progression-free survival (PFS)** of people who receive vibostolimab and pembrolizumab is longer than those who receive pembrolizumab alone	**PFS** is the length of time from the start of treatment until the cancer grows or spreads, or death from any cause

Other goals	How they will be measured
To compare the **objective response rate (ORR)** of people who receive vibostolimab and pembrolizumab to those who receive pembrolizumab alone	**ORR** is the percent of people whose cancer responds to treatment (gets smaller or goes away)
To compare the **duration of response (DOR)** of people who receive vibostolimab and pembrolizumab to those who receive pembrolizumab alone	**DOR** is the length of time from when the cancer first responds to treatment until the cancer grows or spreads, or death from any cause
To compare the **quality of life (QoL)** of people who receive vibostolimab and pembrolizumab to those who receive pembrolizumab alone	People will answer sets of questions to measure their QoL, including questions about their overall health, 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
To learn about **safety** and how well people **tolerate** the study treatments	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 who 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.