Protocol Plain Language Summary

A clinical study of vibostolimab and pembrolizumab compared to durvalumab in people with lung cancer (MK-7684A-006)

Protocol Title: Open-label Phase 3 Study of MK-7684A (Coformulation of Vibostolimab with Pembrolizumab) in Combination with Concurrent Chemoradiotherapy followed by MK-7684A Versus Concurrent Chemoradiotherapy followed by Durvalumab in Participants with Unresectable, Locally Advanced, Stage III NSCLC (KEYVIBE-006)

Why is this study needed?

Researchers are looking for new ways to treat people with **locally advanced non-small cell lung cancer (NSCLC)**. Locally advanced NSCLC means that the cancer is in the lungs and in the chest but has not spread to other parts of the body. The cancer cannot be removed with surgery.

People with locally advanced NSCLC are often treated with **chemotherapy** and **radiation therapy.** Chemotherapy is medicine to destroy cancer cells or stop them from growing**.** Radiation therapy is a treatment that uses beams of intense energy (like X-rays) to shrink or get rid of tumors. Some people with NSCLC may also receive **immunotherapy**, such as **durvalumab**. Immunotherapy is a treatment that helps the immune system fight cancer.

The **study medicine** is a combination of 2 immunotherapies, **vibostolimab and pembrolizumab**. This study will compare vibostolimab and pembrolizumab to durvalumab.

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

Who will take part in this study?

About 784 people with NSCLC will be in this study. They will be age 18 years and older and:

- Have locally advanced NSCLC
- Have not received treatment for the NSCLC

What treatments are being given during the study?

During this study, everyone will receive chemotherapy for about 2 months and radiation therapy for about 6 weeks. They will also have an equal chance of receiving one of these treatments:

- **Vibostolimab and pembrolizumab**, the study medicine, starting with the first chemotherapy treatment and continuing every 3 weeks for up to about a year
- **Durvalumab**, starting after chemotherapy and radiation therapy and continuing every 2 weeks for up to about a year

The immunotherapy and chemotherapy treatments will be given through a needle in a vein as an intravenous (IV) infusion.

How is this study designed?

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 may 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.

People may be in this study for up to about 7 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 **progression-free survival (PFS)** of people who receive vibostolimab and pembrolizumab is longer than those who receive durvalumab	**PFS** is the length of time from the start of treatment until a person's cancer grows or spreads, or death from any cause. PFS will be measured for: • People whose tumors have **PD-L1** – PD-L1 is a type of protein found on cancer cells that can help the cancer hide from the body's immune system • Everyone in the study
To learn if the **overall survival (OS)** of people who receive vibostolimab and pembrolizumab is longer than those who receive durvalumab	**OS** is the length of time that people live from the start of treatment until death from any cause. OS will be measured for: • People whose tumors have PD-L1 • Everyone in the study

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 durvalumab	**ORR** is the number of people whose cancer responds to treatment (gets smaller or goes away). ORR will be measured for: • People whose tumors have PD-L1 • Everyone in the study
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
To compare the **duration of response (DOR)** of people who receive vibostolimab and pembrolizumab to those who receive durvalumab	**DOR** is the length of time from when the cancer first responds to treatment until the cancer grows, spreads, or death from any cause. DOR will be measured for: • People whose tumors have PD-L1 • Everyone in the study
To compare the **quality of life (QoL)** of people who receive vibostolimab and pembrolizumab to those who receive durvalumab	People will answer sets of questions to measure their QoL, including questions about their overall health and their ability to carry out daily tasks. QoL will be measured for people whose tumors have PD-L1 and for everyone in the study. 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 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.