Protocol Plain Language Summary

A clinical study to compare vibostolimab and pembrolizumab to atezolizumab in people with lung cancer (MK-7684A-008)

Protocol Title: A Phase 3, Randomized, Double-Blind Study of MK-7684A in Combination with Etoposide and Platinum Followed by MK-7684A vs Atezolizumab in Combination with Etoposide and Platinum Followed by Atezolizumab for the First-Line Treatment of Participants with Extensive-Stage Small Cell Lung Cancer (KEYVIBE-008)

Why is this study needed?

Researchers are looking for other ways to treat people with a type of lung cancer called **extensive stage small-cell lung cancer (ES-SCLC)**. Extensive stage means the cancer has spread throughout the lung, to the other lung, or to other parts of the body.

People with ES-SCLC are often first treated with chemotherapy and immunotherapy. **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, **vibostolimab** (also called MK-7684) and **pembrolizumab**. This study will compare vibostolimab and pembrolizumab with chemotherapy to **atezolizumab**, another immunotherapy, 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 atezolizumab with chemotherapy.

Who will take part in this study?

About 450 people with ES-SCLC will be in this study. They will be at least 18 years old and:

- Have not yet received treatment for ES-SCLC
- Have not had another type of cancer that was treated 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, also called MK-7684A, with chemotherapy
- Atezolizumab with chemotherapy

People will receive vibostolimab and pembrolizumab or atezolizumab until the cancer gets worse or the person can't tolerate treatment. People will receive chemotherapy for up to 3 months.

To make sure people do not know which treatment they are receiving, people will receive a placebo with their first treatment. They may also receive a placebo with later treatments. A **placebo** looks like the study medicine but has no study medicine in it. Using a placebo helps researchers better understand the effects of a study medicine.

How is this study designed?

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

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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 and blood samples, have imaging tests and 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 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 atezolizumab 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 atezolizumab with chemotherapy	Researchers will measure how the cancer responds during the study: • 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 (OR): 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 learn about the safety of vibostolimab and pembrolizumab and how well people tolerate it	 The number of people who: Have an adverse event (AE)—an AE is a health problem that happens or worsens during a study Stop treatment due to an AE
To compare the quality of life (QoL) of people who receive vibostolimab and pembrolizumab with chemotherapy to those who receive atezolizumab 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

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.