Protocol Plain Language Summary

A clinical study of vibostolimab plus pembrolizumab in people with lung cancer (MK-7684A-002)

Protocol title: A Phase 2, Multicenter, Randomized Study to Compare the Efficacy and Safety of MK-7684A or MK-7684A Plus Docetaxel Versus Docetaxel Monotherapy in the Treatment of Participants With Metastatic Non-small Cell Lung Cancer With Progressive Disease After Treatment With a Platinum Doublet Chemotherapy and Immunotherapy

Why is this study needed?

Researchers are looking for new ways to treat metastatic (spread to other parts of the body) non-small cell lung cancer (mNSCLC) that has progressed after treatment with chemotherapy and immunotherapy. **Immunotherapy** is a treatment that works with the immune system to fight cancer. **Chemotherapy** is a type of medicine intended to destroy cancer cells or stop them from growing. Doctors often use immunotherapy together with chemotherapy to treat people with mNSCLC, but the benefit of treatment can lessen over time and the cancer can come back. There are currently very limited treatment options for people who lose benefit from treatment.

Researchers want to know if using 2 different immunotherapies together with chemotherapy will work well to treat mNSCLC that has come back after previous treatment.

The goal of this study is to learn if people who receive 2 types of immunotherapies with chemotherapy live longer without their lung cancer coming back, growing, or spreading.

Who will take part in this study?

About 240 people with mNSCLC will be in this study. They will be age 18 years and older and:

- Have had their lung cancer get worse after receiving treatment with immunotherapy and chemotherapy
- Have never gotten the chemotherapy called docetaxel

What treatments are being given during this study?

During this study, people will have an equal chance of receiving 1 of these treatments every 3 weeks through a vein as an intravenous (IV) infusion:

- **2 immunotherapies** (vibostolimab and pembrolizumab) **and chemotherapy** (docetaxel) for up to about 2 years
- **2 immunotherapies alone** (vibostolimab and pembrolizumab) for up to about 2 years
- **chemotherapy** (docetaxel) **and placebo** until people cannot tolerate treatment, treatment is stopped, or the study ends

How is this study designed?

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

For the people who receive chemotherapy, neither the people in the study nor the researchers will know if they are receiving the chemotherapy with immunotherapy or chemotherapy and placebo (**double-blinded study**). A placebo looks like the study medicine but has no study medicine in it. Using a placebo helps researchers better understand the real effects of the study medicine.

For the people who receive 2 immunotherapies alone (vibostolimab plus pembrolizumab), both the people in the study and the researchers will know they are receiving this treatment (**open-label study**).

During the study, people will have blood, tumor, urine, and imaging tests, and have physical examinations.

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

Main goal	How it will be measured
To compare the length of time without the cancer coming back, growing, or spreading	The average length of time from when people start treatment until the cancer grows, spreads, or death due to any cause **(progression-free survival).** Researchers will compare this during the study.
Other goals	**How they will be measured**
To compare how many people have their cancer respond (shrink or go away) and how long people live without their cancer coming back	Researchers will measure responses during the study: • **Objective response rate**: the number of people with cancer that responds to treatment • **Overall survival**: the average length of time that people live from the start of treatment until death due to any cause • **Duration of response**: the average length of time from when cancer first responds to treatment until cancer gets worse or death due to any cause
To learn about the safety and how well people tolerate the study treatments	The number of people who: • Had an **adverse event** (**AE**) during treatment or up to 90 days after their last dose. 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 in this study may or may not have their cancer stop growing or go away. This study has a Data Monitoring Committee that oversees the study's overall risk and benefit. If this committee 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's Brochure, Protocol, and Informed Consent documents.