Protocol Plain Language Summary

# A clinical study of vibostolimab and pembrolizumab in people with solid tumors (MK-7684A-005)

**Protocol Title:** A Multicenter, Open-label, Phase 2 Basket Study of MK-7684A, a Co-formation of Vibostolimab (MK-7684) With Pembrolizumab (MK-3475), With or Without Other Anticancer Therapies in Participants With Selected Solid Tumors (KEYVIBE-005)

## Why is this study needed?

Researchers are looking for new ways to treat people with certain types of advanced solid tumors. **Solid tumors** are cancers mostly in body organs and tissues, not in the blood or other body liquids. **Advanced** means the cancer has spread to other parts of the body (metastatic) or cannot be removed with surgery.

Current treatments for solid tumors include chemotherapy, immunotherapy, and targeted therapy. **Chemotherapy** is a treatment that uses medicine to shrink or get rid of cancer. **Immunotherapy** is a treatment that helps the immune system fight cancer. **Targeted therapy** is a treatment that works to control how specific types of cancer cells grow and spread.

The **study medicine**, called **MK-7684A,** is a combination of 2 immunotherapies, **vibostolimab** and **pembrolizumab**.

The main goals of this study are to learn how different types of cancer respond (get smaller or go away) and how long people live without the cancer getting worse after receiving treatment. Researchers want to learn if people who have a certain type of cancer and receive MK-7684A have a better response to treatment and live longer without the cancer getting worse compared to those who receive pembrolizumab alone.

## Who will take part in this study?

About 610 people will be in this study. They will be at least 18 years old and:

- Have certain types of advanced solid tumors
- Have not had another type of cancer in the past 3 years

## What treatments are being given during the study?

People will be assigned to receive one or more of these treatments based on the type of solid tumor:

- **MK-7684A**, given through a needle into a vein as an intravenous (IV) infusion every 3 weeks
- **Pembrolizumab**, an immunotherapy, given by IV infusion every 3 weeks
- **Bevacizumab or similar treatments**, which are targeted therapies, given by IV infusion every 3 weeks
- **Lenvatinib,** a targeted therapy, given by mouth up to once a day
- **Chemotherapy**, given by IV infusion up to once a week or given by mouth 2 times a day for 2 weeks

People may receive treatment for up to 3 years, until the cancer gets worse, the person can't tolerate treatment, or the study ends. During the study, some people may have surgery to remove the cancer.

## How is this study designed?

People will be assigned to one of these treatment groups based on their type of solid tumor:

- **Group 1:** will receive **MK-7684A alone**
- **Group 2:** will receive **pembrolizumab alone**

- **Groups 3 and 4:** will receive **MK-7684A and lenvatinib**
- **Groups 5, 6, 7, and 9:** will receive **MK-7684A and chemotherapy**
- **Group 8:** will receive **MK-7684A, chemotherapy, and bevacizumab**

A person may be in this study for about 5 and a half years, including visits before and after treatment. 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 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 goals | How they will be measured |
|---|---|
| To learn about the **cancer response** in people who receive:<br>• MK-7684A alone compared to those who receive pembrolizumab alone<br>• MK-7684A with or without other treatments | Researchers will measure how the cancer responds in people with certain tumor types during the study:<br>• **Objective response rate (ORR):** the number of people whose cancer responds to treatment (gets smaller or goes away)<br>• **Progression-free survival (PFS):** the length of time from the start of treatment until the cancer grows or spreads (gets worse), or death from any cause |
| **Other goals** | **How they will be measured** |
| To learn about the **cancer response** in people who receive either:<br>• MK-7684A alone<br>• MK-7684A with other treatments<br>• Pembrolizumab alone | Researchers will measure how the cancer responds during the study:<br>• **Overall survival (OS)** is the length of time that people live from the start of treatment until death from any cause<br>• **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<br>• **PFS**<br>• **ORR** |
| To compare the **quality of life** (**QoL**) of people with certain tumor types | 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. |
| To learn about the **safety** and how well people **tolerate** MK-7684A alone or with other treatments | During the study, the number of people who:<br>• Have an **adverse event (AE)** – An AE is a health problem that happens or worsens<br>• 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. There are risks to being in any clinical study. One risk is that the treatment may not help treat the cancer, or it may make the cancer worse. More information about the benefits and risks is in the protocol.