Protocol Plain Language Summary
Study of vibostolimab plus pembrolizumab compared to pembrolizumab alone given after surgery in people with melanoma

Protocol title: A Phase 3, Randomized, Double-blind, Active-Comparator-Controlled Clinical Study of Adjuvant MK-7684A Versus Adjuvant Pembrolizumab in Participants with High-risk Stage II-IV Melanoma (KEYVIBE-010)

Why is this study needed?

This study compares the combination of vibostolimab plus pembrolizumab (also known as MK-7684A) to pembrolizumab alone for treating people with **melanoma** (a type of skin cancer). People with melanoma often have surgery to remove it. People who have a high chance (risk) of melanoma coming back may receive a treatment after the surgery, called **adjuvant treatment,** to improve the chance that melanoma will not come back. Standard adjuvant treatment for melanoma is **immunotherapy,** which helps the immune system fight cancer. Both treatments in this study are immunotherapies.

The goal of this study is to learn if people who receive vibostolimab plus pembrolizumab live longer without their melanoma coming back (**recurrence-free survival**) than people who receive pembrolizumab alone.

Who will take part in this study?

About 1,560 people with melanoma will be in this study. They will be ages 12 years and older and:

- Weigh at least 40 kilograms (88 pounds) if 12 to 18 years old
- Had surgery to remove melanoma
- Have a high chance of their melanoma coming back
- Have not received previous treatment for their melanoma except for surgery and radiation

How is this study designed?

People may be in this study for up to 8 years.

People will have an equal chance (1:1) of receiving vibostolimab plus pembrolizumab or pembrolizumab alone. Everyone in the study will receive pembrolizumab which is approved in some countries to treat high-risk melanoma. Neither the people in the study nor the researchers will know which study treatment a person receives (double-blinded study).

People will give blood, tumor, and urine samples, have imaging tests, and physical exams, and answer sets of questions during the entire time they are in the study.

What treatments are being studied?

During this study, people will receive one of the following through a vein as an intravenous (IV) infusion:

- Vibostolimab plus pembrolizumab once every 3 weeks for up to about 1 year (17 cycles)
- Pembrolizumab alone once every 3 weeks for up to about 1 year (17 cycles)

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

Main goal (Primary Objectives)	How it will be measured
To learn how long people who receive vibostolimab plus pembrolizumab or pembrolizumab alone, live without their cancer coming back **(recurrence-free survival)**	The average length of time from when the person starts the study until any of the following: • The cancer comes back, • The cancer spreads, or • Death due to any cause
Other goals (Secondary Objectives)	**How they will be measured**
To learn how long people who receive vibostolimab plus pembrolizumab or pembrolizumab alone, live without their cancer spreading (**distant metastasis-free survival)**	The average length of time from the when the person starts the study until either: • The cancer spreads from where it started to other parts of the body, or • Death due to any cause
To learn how long people who receive vibostolimab plus pembrolizumab or pembrolizumab alone, live **(overall survival)**	The average length of time that people are alive from the start of treatment until death due to any cause
To learn about the safety and how well people manage (tolerate) the study treatments	The number of people who: • Have an **adverse event (AE)** while on treatment or up to 90 days after their last dose. An AE is a medical problem that happens or worsens during a study and that may or may not be caused by the treatment received in the study. • Stop treatment due to an AE
To learn about how people who receive vibostolimab plus pembrolizumab or pembrolizumab alone, score on **health-related quality of life (HRQoL) questionnaires**	People will answer sets of questions to measure their **HRQoL,** including questions about their overall health and their ability to carry out daily tasks. The change in the scores from when the person starts the study until the end of the study will be measured.

What are the possible benefits and risks?

People in this study may or may not have their melanoma come back after receiving the treatments in this study. 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 for a person may be found in the Investigator's Brochure, Protocol, and Informed Consent documents.