Protocol Plain Language Summary

A clinical study of favezelimab with pembrolizumab in people with Hodgkin lymphoma (MK-4280A-008)

Protocol Title: A Phase 3 Randomized Clinical Study of MK-4280A (co-formulated favezelimab [MK-4280] plus pembrolizumab [MK-3475]) Versus Physician's Choice Chemotherapy in PD-(L)1-refractory, Relapsed or Refractory Classical Hodgkin Lymphoma (KEYFORM-008)

Why is this study needed?

Researchers are looking for a way to treat classical Hodgkin lymphoma (cHL) that is relapsed or refractory. **cHL** is cancer in the lymphatic system that causes swollen lymph nodes and tumors in the body. The lymphatic system is part of the body's immune system. **Relapsed** means the cancer has come back after treatment**. Refractory** means current treatment has stopped working to slow or stop cancer growth.

Standard treatment for cHL includes chemotherapy. **Chemotherapy** is medicine that destroys cancer cells or stops them from growing. Some people have cHL become relapsed or refractory.

MK-4280A, the **study medicine**, is a combination of 2 immunotherapies, **favezelimab** and **pembrolizumab**. **Immunotherapy** is a treatment that helps the immune system fight cancer.

Researchers want to learn if people who receive **MK-4280A** live longer without the cancer getting worse compared to those who receive chemotherapy.

Who will take part in this study?

About 360 people with cHL will be in this study. They will be at least 18 years old and:

- Have cHL that is either relapsed or refractory
- Have not had a severe reaction to favezelimab or pembrolizumab

What treatments are being given during the study?

During this study, people will receive one of these treatments through a needle into a vein as an intravenous (IV) infusion:

- **MK-4280A,** the study medicine
- **Chemotherapy,** the researcher's choice of either bendamustine or gemcitabine

How is this study designed?

During this study, people will have an equal chance of receiving one of these treatments:

- **MK-4280A** given once every 3 weeks for up to 2 years
- **Chemotherapy** given for up to 6 months. People will receive either:
    - **Bendamustine** given twice every 3 or 4 weeks
    - **Gemcitabine** given twice every 3 weeks

People who receive chemotherapy and had the cancer grow or spread may be able to receive MK-4280A.

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 blood, urine, and tumor samples, have imaging tests, have physical examinations, and answer questions about their health. Some people may have a sample of bone marrow taken, called a bone marrow biopsy.

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

Main goal	How it will be measured
To learn if the **progression free survival (PFS)** of people who receive MK-4280A is longer than people who receive chemotherapy	**PFS** is the length of time from the start of treatment until the cancer grows or spreads, or death from any cause.
Other goals	**How they will be measured**
To learn if the **overall survival (OS)** of people who receive MK-4280A is longer than people who receive chemotherapy	**OS** is the length of time people live from the start of treatment until death from any cause
To learn the **cancer response** of people who receive MK-4280A to people who receive chemotherapy	Researchers will measure: • **Objective response**: the number of people whose cancer responds to treatment (the cancer gets smaller or goes away) during the study • **Duration of response**: 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 MK-4280A and how well people **tolerate** it	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

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.