Protocol Plain Language Summary

A clinical study of pembrolizumab in people with classical Hodgkin's lymphoma (MK-3475-C11)

Protocol Title: Phase 2 Study of Pembrolizumab and Chemotherapy in Patients With Newly Diagnosed Classical Hodgkin Lymphoma (KEYNOTE-C11)

Why is this study needed?

Researchers are looking for new ways to treat people with early unfavorable or advanced **classical Hodgkin Lymphoma (cHL)**. **cHL** is cancer in the lymphatic system that causes swollen lymph nodes and tumors in the body. The lymphatic system is a network of tissues and organs that are part of the body's immune system. Lymph nodes are small, bean-shaped organs that are part of the lymphatic system.

Early unfavorable means cancer has not spread to other parts of the body, but there is a high chance that the cancer will come back after treatment. **Advanced** means cancer has spread to other parts of the body or cannot be removed with surgery.

Researchers want to learn about the safety and effects of pembrolizumab and chemotherapy (the study medicine) for people with early unfavorable or advanced cHL**. Pembrolizumab** is an immunotherapy, which is a treatment that helps the immune system fight cancer. **Chemotherapy** is a medicine that destroys cancer cells or stops them from growing.

The goal of this study is to learn if people who receive pembrolizumab and chemotherapy have no signs of cancer after treatment.

Who will take part in this study?

About 140 people with early unfavorable or advanced cHL will be in the study. They will be 18 years old and older and:

- Have not received any previous treatment for cHL
- Not have another type of HL

What treatments are being given during the study?

People will receive all of these treatments in this order:

1. **Pembrolizumab** every 3 weeks for 9 weeks
2. **Chemotherapy** every 4 weeks for 2 months
3. Chemotherapy every 3 or 4 weeks for up to 6 months
4. Pembrolizumab every 6 weeks for 6 months

People will receive pembrolizumab and some chemotherapy treatments through a needle into a vein as an infusion. In addition, people may receive some chemotherapy by mouth.

How is this study designed?

Both the people in the study and the researchers will know which treatment a person is getting (**open-label study**).

During the study, people may give urine and blood samples, have tumor and imaging tests, have physical examinations, and answer questions about how they are feeling and their ability to carry out daily tasks.

A person may be in this study for up to 6 years.

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

Main goal	How it will be measured
To learn if the **complete response rate (CRR)** of people who receive pembrolizumab and chemotherapy is more than 80% (8 out of every 10 people)	**CRR** is the number of people who have no signs of cancer after treatment. Doctors who are not part of this study will measure this.
Other goals	**How they will be measured**
To learn the **CRR** of people who receive pembrolizumab and chemotherapy	**CRR** is the number of people who have no signs of cancer after treatment. Study researchers will measure this.
To learn the **duration of complete response (DurCR)** of people who receive pembrolizumab and chemotherapy	**DurCR** is the length of time from when cancer goes away after treatment until cancer grows or spreads, or death from any cause
To learn the **cancer response** of people who receive pembrolizumab and chemotherapy	The number of people who do not have signs of cancer on PET scan images. A PET scan is an imaging test that uses a radioactive substance called a tracer to show cancer cells. This will be measured after people have completed treatment with: • Pembrolizumab • Initial Chemotherapy • Additional Chemotherapy followed by Pembrolizumab • Possibility of additional scan after study treatment completion
To learn if pembrolizumab and chemotherapy are **safe** and how well people **tolerate** them	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. More information about the benefits and risks is in the Investigator Brochure, Protocol, and Informed Consent documents.