Protocol Plain Language Summary

Clinical study of olaparib and pembrolizumab compared to chemotherapy and pembrolizumab given after a previous treatment for breast cancer (MK-7339-009)

Protocol Title: An Open-label, Randomized, Phase 2/3 Study of Olaparib Plus Pembrolizumab Versus Chemotherapy Plus Pembrolizumab After Induction of Clinical Benefit With First-line Chemotherapy Plus Pembrolizumab in Participants With Locally Recurrent Inoperable or Metastatic Triple Negative Breast Cancer (TNBC) (KEYLYNK-009)

Why is this study needed?

Researchers are looking for new ways to treat a type of breast cancer called **Triple Negative Breast Cancer (TNBC)** that has spread to other parts of the body (**metastatic**) or cannot be removed with surgery. Researchers want to learn if giving olaparib and pembrolizumab after first treating with chemotherapy and pembrolizumab works better for treating metastatic TNBC (mTNBC) than continuing treatment with chemotherapy and pembrolizumab**.**

Pembrolizumab is a type of **immunotherapy**, which helps the immune system fight cancer. It treats cancers that have a protein called PD-L1. **Olaparib** is a **targeted therapy** (a treatment that only targets certain cells) that works by causing the cancer cells to die. Olaparib treats cancers that have BReast CAncer (BRCA) gene mutations (changes). These genes raise the chance of getting breast cancer.

The goal of this study is to learn if people who get olaparib and pembrolizumab after first receiving chemotherapy and pembrolizumab live longer (**overall survival**) compared to people who get chemotherapy and pembrolizumab alone. This study will also compare how long people live without their breast cancer growing or spreading (**progression-free survival**).

Who will take part in this study?

About 460 people will be in this study. They will be age 18 and older and have mTNBC that:

- Is either **metastatic** (cancer that has spread) or **unresectable** (cannot be removed with surgery)
- Responded (got smaller or stopped growing) to previous **treatment** with pembrolizumab and chemotherapy

How is this study designed?

A person may be in this study for up to 5 years.

Both the people in the study and the researchers will know which treatment a person receives (open-label study). People will have an equal chance of receiving 1 of the 2 treatments in the study.

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

What treatments are being given during this study?

During this study, people will receive one of these treatments:

- **Pembrolizumab and chemotherapy** given through a vein as an intravenous (IV) infusion – pembrolizumab given once every 3 weeks and chemotherapy given twice every 3 weeks
- **Pembrolizumab and Olaparib** – pembrolizumab given as an IV infusion once every 3 weeks and olaparib taken by mouth 2 times a day

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

Main goals	How it will be measured
To compare how long people live without their cancer growing or spreading	**Progression free survival:** the average length of time that people are alive and/or their cancer does not grow or spread after joining the study. Researchers will compare this throughout the study.
To compare how long people live	**Overall survival:** the average length of time that people are alive after joining the study. Researchers will compare this throughout the study.

Other goals	How they will be measured
To compare how long people with BRCA gene mutations or with PD-L1 protein on the tumor live without their cancer growing or spreading	**Progression free survival** Researchers will compare this throughout the study.
To compare how long people with BRCA gene mutations or with PD-L1 protein on the tumor live	**Overall survival** Researchers will compare this throughout the study.
To learn how people score on **health-related quality of life (HRQoL)** questions.	People will answer sets of questions about their overall and emotional health, treatment side effects, and their ability to carry out daily tasks. Researchers will look at the change in scores from people with or without BRCA gene mutations from when the person starts the study until the end of the study.
To learn how long it takes for a person's **health-related quality of life (HRQoL)** score to worsen	People will answer sets of questions about their overall and emotional health, treatment side effects, and their ability to carry out daily tasks. Researchers will measure the average length of time from the start of treatment until the scores worsen in people with or without BRCA gene mutations. This will be measured throughout the study.
To learn about the safety and how well people **tolerate** treatment	The number of people who: • Had an **adverse event (AE)** up to 90 days after their last dose – an AE is a health problem that happens or worsens during the 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 after treatment. More information about the benefits and risks for a person may be found in the Investigator Brochure, Protocol, and Informed Consent documents.