Protocol Plain Language Summary

A clinical study of pembrolizumab in people with ovarian cancer (MK-3475-B96)

Protocol Title: A Phase 3, Randomized, Double-Blind Study of Pembrolizumab versus Placebo in Combination With Paclitaxel With or Without Bevacizumab for the Treatment of Platinum-resistant Recurrent Ovarian Cancer (KEYNOTE-B96 / ENGOT-ov65)

Why is this study needed?

Researchers are looking for new ways to treat people with recurrent ovarian cancer. **Recurrent** means the cancer came back after treatment. **Ovarian cancer** is cancer in the ovaries (the pair of organs in a female's body where eggs are made). Ovarian cancer may include cancer in the fallopian tubes (connect the ovaries to the womb) or tissue lining the inside of the belly.

People with recurrent ovarian cancer may receive more **standard treatment** after the first treatment. One example of standard treatment is chemotherapy with or without immunotherapy. **Chemotherapy** is medicine that destroys cancer cells or stops them from growing. **Immunotherapy** is a treatment that helps the immune system fight cancer.

The goal of this study is to learn if people who receive pembrolizumab and standard therapy live longer without the cancer getting worse than those who receive placebo and standard treatment. **Pembrolizumab** (the study medicine) is an immunotherapy. A **placebo** looks like the study medicine but has no study medicine in it. Using a placebo helps researchers better understand if the study medicine works.

Who will take part in this study?

About 616 females with recurrent ovarian cancer will be in the study. They will be 18 years old and older and:

- The ovarian cancer came back after previous treatment with certain chemotherapy
- Not have had cancer treatment with medicines within the last month
- Not have had radiation treatment for cancer in the last 2 weeks

What treatments are being given during the study?

People will have an equal chance of receiving either:

- **Pembrolizumab and standard treatment**
- **Placebo and standard treatment**

Standard treatment is paclitaxel (a chemotherapy) with or without bevacizumab (an immunotherapy).

Treatments will be given through a needle into a vein as an infusion. Pembrolizumab or placebo is given every 6 weeks for about 2 years. Some people may receive another year of pembrolizumab. Paclitaxel is given every week and bevacizumab is given every 2 weeks until cancer gets worse, or the person doesn't tolerate treatment.

How is this study designed?

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

Neither the people in the study nor the researchers will know which treatment a person is taking (**double-blind 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.

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

Main goal	How it will be measured
To learn if people who receive pembrolizumab and standard treatment have longer **progression-free survival (PFS)** compared to people who receive placebo and standard treatment	**PFS** is the length of time from the start of treatment until a person's cancer grows or spreads, or death from any cause. Study researchers will measure this in: • People with **programmed cell death ligand 1 (PD-L1)** positive tumors. PD-L1 is a type of protein found on cancer cells that can help the cancer hide from the body's immune system. • All people

Other goals	How they will be measured
To learn about the **overall survival (OS)** of people who receive pembrolizumab and standard treatment compared to people who receive placebo and standard treatment	**OS** is the length of time that people live from the start of treatment until death from any cause. Study researchers will measure this in: • People with PD-L1 positive tumors • All people
To learn about the **PFS** of people who receive pembrolizumab and standard treatment compared to people who receive placebo and standard treatment	During the study, researchers who are not involved with the study will measure **PFS** in: • People with PD-L1 positive tumors • All people
To learn if pembrolizumab and standard treatments 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
To learn the **quality of life (QoL)** of people who receive pembrolizumab and standard treatment compared to people who receive placebo and standard treatment	People will answer questions during the study to measure their **QoL**, including questions about how they are feeling and their ability to carry out daily tasks**.** Study researchers will measure this in people with PD-L1 positive tumors and in all people in the study. Study researchers will compare: • The change in the scores during the study • The length of time from the start of the study until people's QoL gets worse

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.