A clinical study of MK-4830 and pembrolizumab to treat ovarian cancer (MK-4830-002)

Protocol Title: A Randomized, Phase 2 Study of Pembrolizumab And Chemotherapy With or Without MK-4830 as Neoadjuvant Treatment for High-Grade Serous Ovarian Cancer

Why is this study needed?

Researchers are looking for better ways to treat **advanced high-grade serous ovarian cancer (HGSOC)**:

- **Serous ovarian cancer** includes cancer that starts in cells that cover the ovaries, the lining of the abdomen (called primary peritoneal cancer or PPC) and in the fallopian tubes (called fallopian tube cancer)
- **Advanced** means the cancer has spread to other parts of the body
- **High-grade** means the cancer cells look more abnormal under the microscope

The **standard treatment** for advanced HGSOC is chemotherapy before and after debulking surgery. **Chemotherapy** is medicine that destroys cancer cells or stops them from growing. **Debulking surgery** is surgery that removes as much of the cancer as possible.

MK-4830 and **pembrolizumab**, the study medicines, are immunotherapies. **Immunotherapy** is a treatment that helps the immune system fight cancer.

The goal of this study is to learn if people who receive MK-4830 and pembrolizumab with standard treatment have a bigger decrease in the amount of **circulating tumor DNA (ctDNA)** than people who receive pembrolizumab alone with standard treatment. **ctDNA** is DNA from cancer cells that are found in the blood. This may be used to measure the amount of cancer a person has.

Who will take part in this study?

About 160 people with HGSOC will be in this study. They will be at least 18 years old and:

- Have been assigned female at birth
- Can have debulking surgery
- Can receive chemotherapy before and after surgery
- Did not have prior treatment for ovarian cancer

What treatments are being given during the study?

Everyone in the study will receive 2 types of chemotherapy and 1 or both of these immunotherapies before and after surgery:

- **MK-4830**
- **Pembrolizumab**

People will receive their treatment once every 3 weeks through a needle into a vein as an intravenous (IV) infusion. The second type of chemotherapy given will be based on the researcher's choice.

How is this study designed?

People will have an equal chance to be assigned to 1 of 2 groups:

- **Group A:** People will receive MK-4830 with pembrolizumab and chemotherapy for about 2 months before surgery and 2 months after.
- **Group B**: People will receive pembrolizumab and chemotherapy for about 2 months before surgery and about 2 months after.

Researchers may give people **Avastin** or a biosimilar (a similar treatment made by a different company) after surgery. **Avastin** is a medicine that stops the cancer from growing blood vessels.

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 will give urine, blood, and tumor samples, have imaging tests and physical examinations.

A person may be in this study for about 3 years.

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

Main goal	How it will be measured
To learn if people in Group A have less **ctDNA** than those in Group B	After the start of treatment, the amount of **ctDNA** in the blood before surgery

Other goals	How they will be measured
To learn about the cancer **response** before and after surgery for people in Groups A and B	Researchers will measure in people: • **ctDNA** • **Pathological complete response (pCR)**—pCR means there are no signs of cancer in the tissues removed during surgery • **Chemotherapy response score (CRS)**—CRS measures how the tumor **responds** (gets smaller or goes away) to chemotherapy
To compare the **pCR** and **CRS** for people in Group A to those in Group B	Researchers will measure the **pCR** and **CRS** in the tissues removed during surgery
To learn about the **safety** of the treatments in Groups A and B and how well people **tolerate** them	The number of people who: • Have an **adverse event (AE)** – An AE is a health problem that happens or worsens during a study • Stop 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 Protocol.