Protocol Plain Language Summary

A clinical study of pembrolizumab and lenvatinib in people with uterus cancer (MK-7902-001)

Protocol Title: A Phase 3 Randomized, Open-Label, Study of Pembrolizumab (MK-3475) Plus Lenvatinib (E7080/MK-7902) Versus Chemotherapy for First-line Treatment of Advanced or Recurrent Endometrial Carcinoma (LEAP-001)

Why is this study needed?

Researchers are looking for new ways to treat advanced or recurrent uterine or endometrial cancer (EC). **EC** is the cancer that starts in the tissues inside the uterus (womb). **Advanced** means the cancer has spread in the body (metastatic) or cannot be removed with surgery. **Recurrent cancer** means the cancer comes back after treatment.

Standard treatment for advanced or recurrent EC includes immunotherapy and chemotherapy. Immunotherapy is a treatment that helps the immune system fight cancer. **Chemotherapy** is a medicine that destroys cancer cells or stops them from growing.

Researchers want to learn about the safety and effects of giving pembrolizumab and lenvatinib (the study medicine) to people with EC. **Pembrolizumab** is an immunotherapy. **Lenvatinib** is a targeted therapy, which is a treatment that works on specific types of cancer cells to stop them from growing.

The goal of this study is to learn if people who receive pembrolizumab and lenvatinib live longer overall and live longer without cancer growing or spreading compared to people who receive chemotherapy.

Who will take part in this study?

About 875 people with advanced or recurrent EC will be in the study. They will be at least 18 years old and:

- Have received previous treatment for EC
- Have given a tumor tissue sample

What treatments are being given during the study?

During this study, people will be assigned by chance to receive one of these treatments:

- **Pembrolizumab and lenvatinib,** the study medicine
- Chemotherapy, which is **paclitaxel and carboplatin**

People will receive pembrolizumab or chemotherapy every 3 weeks through a needle into a vein as an intravenous (IV) infusion. People will take lenvatinib by mouth every day.

How is this study designed?

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 and blood samples, have tumor and imaging tests, 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 4 years.

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

Main goals	How they will be measured
To learn if the **progression-free survival (PFS)** of people who receive pembrolizumab and lenvatinib is longer than those who receive chemotherapy	**PFS** is the length of time from the start of treatment until a person's cancer grows or spreads, or death from any cause. Researchers will measure this for: • Everyone in the study • People who have certain gene mutations (changes) in cancer cells
To learn if the **overall survival (OS)** of people who receive pembrolizumab and lenvatinib is longer than those who receive chemotherapy	**OS** is length of time that people live from the start of treatment to death from any cause. Researchers will measure this for: • Everyone in the study • People who have certain gene mutations in cancer cells
Other goals	**How they will be measured**
To compare the **objective response rate (ORR)** of people who receive pembrolizumab and lenvatinib to those who receive chemotherapy	**ORR** is the number of people whose cancer responds to treatment (the cancer gets smaller or goes away) during the study. Researchers will measure this for: • Everyone in the study • People who have certain gene mutations in cancer cells
To compare the **health-related quality-of-life (HRQoL)** of people who receive pembrolizumab and lenvatinib to those who receive chemotherapy	During the study, people will answer questions to measure their **HRQoL**, including questions about how they are feeling, EC symptoms, and their ability to carry out daily tasks. Researchers will measure: • The change in the scores during the study
To learn about the **safety** and how well people **tolerate** pembrolizumab, and lenvatinib compared to chemotherapy	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, which means the cancer may or may not get smaller or go away. The 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.