A clinical study of MK-2870 and chemotherapy in people with endometrial cancer (MK-2870-005)

Protocol Title: A Phase 3, Randomized, Active-controlled, Open-label, Multicenter Study to Compare the Efficacy and Safety of MK-2870 Monotherapy Versus Treatment of Physician's Choice in Participants With Endometrial Cancer Who Have Received Prior Platinum-based Chemotherapy and Immunotherapy (MK-2870-005/ENGOT-en23/GOG-3095)

Why is this study needed?

Researchers are looking for new ways to treat people with **endometrial cancer (EC)** who have previously received treatment**.** EC is a type of cancer that starts in the tissues inside the uterus (womb). EC may be treated with chemotherapy and immunotherapy. **Chemotherapy** is medicine that destroys cancer cells or stops them from growing. **Immunotherapy** is a treatment that helps the immune system fight cancer.

MK-2870, the study medicine, is a type of targeted therapy. A **targeted therapy** is a treatment that works to control how specific types of cancer cells grow and spread.

This clinical study will compare MK-2870 to chemotherapy. The goal of the study is to learn if people who receive MK-2870 live longer overall and without the cancer getting worse compared to people who receive chemotherapy.

Who will take part in this study?

About 710 people with EC will be in this study. They will be at least 18 years old and:

- Have previously received immunotherapy and certain chemotherapy to treat EC
- Not have certain heart diseases

What treatments are being given during the study?

People will have an equal chance of receiving either:

- **MK-2870**, the study medicine, given once every 2 weeks
- **Chemotherapy** of the researcher's choice, which is either:
  - Doxorubicin, given once every 3 weeks
  - Paclitaxel, given once a week for 3 out of every 4 weeks

People will receive their assigned treatment through a needle into a vein as an intravenous (IV) infusion. People will continue their treatment until the cancer gets worse or the person doesn't tolerate treatment.

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

A person may be in this study for about 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 MK-2870 is longer than those who receive chemotherapy	**PFS** is the length of time from the start of treatment until the cancer grows or spreads, or death from any cause
To learn if the **overall survival (OS)** of people who receive MK-2870 is longer than those who receive chemotherapy	**OS** is the length of time that people live from the start of treatment until death from any cause

Other goals	How they will be measured
To compare the **cancer response** in people who receive MK-2870 to those who receive chemotherapy	Researchers will measure how the cancer responds during the study: • **Objective Response (OR)**: the number of people whose cancer responds to treatment (gets smaller or goes away) • **Duration of Response (DOR)**: the length of time from when the cancer first responds to treatment until the cancer grows or spreads, or death from any cause
To learn about the **safety** of MK-2870 and how well people tolerate it	During the study, the number of people who: • Have an **adverse event (AE)** – An AE is a health problem that happens or worsens • Stop treatment due to an AE
To compare the **health-related quality of life (HRQoL)** of people who receive MK-2870 to those who receive chemotherapy	People will answer sets of questions to measure their **HRQoL**, including questions about their overall health and their ability to carry out daily tasks. Researchers will measure the change in scores during the study.

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 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.