Clinical Study Protocol Synopsis

A study to learn about the safety and tolerability of MORAb-202 and how well it may work in people with certain solid tumors

Full Study Title:	A Multicenter, Open-Label Phase 1/2 Trial Evaluating the Safety, Tolerability, and Efficacy of MORAb-202, a Folate Receptor Alpha (FRα)-Targeting Antibody-Drug Conjugate (ADC) in Subjects With Selected Tumor Types		
EU Clinical Study Number:	2023-506868-14	**US Clinical Study Number:**	NCT04300556
Study Sponsor:	Eisai, Ltd, Hatfield, UK Eisai, Inc., Nutley, NJ, USA	Telephone number:	+44 845 676 1400 +1 201-692-1100

Why is this research needed?

Researchers are looking for a different way to treat people who have solid tumors. Standard treatments for people with solid tumors include surgery to remove tumors and treatments that help shrink the tumors.

MORAb-202 might be able to help treat people with solid tumors by targeting and shrinking the tumor.

A **solid tumor** is an uncontrolled growth that forms an abnormal mass of tissue.

In this 3-part study, researchers want to learn about the safety of MORAb-202 and how well it may work in participants with certain solid tumors, either when given alone or with lenvatinib.

What treatment is being studied?

Participants will receive MORAb-202 as an infusion through the vein (or IV infusion).

Study doctors will give MORAb-202 in 21-day periods called treatment cycles.

The dose of MORAb-202 may be different in each of the 3 study parts.

In Part 3, some participants will also take lenvatinib capsules once per day.

Everyone involved in the study will know which dose the participants will receive.

What are the goals of this study?

The primary objectives are to investigate the safety and tolerability of MORAb-202 and how well it works when given alone or with lenvatinib.

The secondary objectives are to investigate in more detail how MORAb-202 works, when given alone or with lenvatinib, and the movement of MORAb-202 and lenvatinib within the body.

What are the measurements in this study?

1. **Main measurement:** To investigate the primary objectives, researchers will find out the highest tolerable dose, the safety of MORAb-202, and how well it works, when given alone or with lenvatinib. They will also collect information on any medical problems that participants may have during the study.
2. **Secondary measurements:** To investigate the secondary objectives, researchers will use other ways to measure how well MORAb-202 works, when given alone or with lenvatinib, and will find out what the body does to MORAb-202 and lenvatinib.

The researchers will also collect other information about MORAb-202 and lenvatinib, but the measurements described above are the most important for this study.

What will happen during the study?

Before participants take part in the study, study doctors will explain the study to participants and answer any questions they may have.

This study has 3 parts:

- **In Part 1**, researchers want to learn the highest tolerable dose and the safety of MORAb-202 in participants with certain solid tumors.
- **In Part 2**, researchers want to learn more about the safety and how well different doses of MORAb-202 work in participants with cancer of the uterus and ovaries.
- **In Part 3**, researchers want to learn more about the safety and how well different doses of MORAb-202 work in participants with cancer of the ovaries, when given alone or with lenvatinib.

The chart below shows what will happen in all parts of the study.

Before the participants take study treatment

1 or more visits at study site during the 28 days before the treatment begins

All participants will complete consent forms.

The study doctors will:

- check participants' health to make sure they can join the study

The study doctors will also:

- examine tumor tissue to check if participants can take part in the study
- take blood and urine samples
- check participants' heart health using an electrocardiogram, also called ECG
- take imaging scans of a participant's brain, bone, lung, and body to assess their tumor

While the participants are taking study treatment

Multiple visits at study site

Participants will receive MORAb-202 as an IV infusion in 21-day treatment cycles, either alone or with lenvatinib capsules once per day.

Participants will continue to receive their assigned treatment until:

- their cancer gets worse
- they have an intolerable medical problem
- they choose to leave the study

The study doctors will:

- take blood and urine samples
- check participants' heart health using ECG
- take imaging scans every 6 weeks of a participant's brain, bone, lung, and body to assess their tumor
- ask about medical problems participants may have and medicines participants are taking

After the participants finish or stop taking study treatment

Participants who stop taking study treatment will visit the study site within **28 days of the last dose**.

During this time, study doctors will check participants' health and ask about medical problems and medicines participants are taking.

Study doctors or staff will contact participants **every 12 weeks** to check on their health until participants withdraw their consent.

Who can and cannot take part in this study?

People can take part in this study if they:

- are 18 years or older
- have certain types of ovary, uterus, breast, or lung cancer
- have adequate organ function
- complete the consent form

People cannot take part in this study if they:

- have any other cancer that requires treatment
- have abnormal lung function

These are just some of the main study entry guidelines. Study doctors will check all of these to see if a person can join this study. Participation in this study is voluntary. Participants can leave the study at any time.

What are the potential benefits and risks of taking part in this study?

Potential Benefits (Advantages): MORAb-202, when received alone or with lenvatinib, may help to treat the participant's solid tumor. The information collected in this study may help doctors learn more about MORAb-202 that could help the participants and other people with solid tumors.

Potential Risks (Disadvantages): MORAb-202, when received alone or with lenvatinib, may not help to treat the participant's solid tumor, or they might have side effects from MORAb-202 or lenvatinib. There may be additional risks that are unknown and unexpected.