Clinical Study Protocol Synopsis

A study to learn how well E6742 may work and its safety profile in people with systemic lupus erythematosus

Full Study Title:	A Phase 2, Randomized, Double-Blind, Placebo-Controlled, Multicenter, Dose Response Study to Evaluate the Efficacy and Safety of E6742 in Subjects With Systemic Lupus Erythematosus
EU Clinical Study Number:	N/A
US Clinical Study Number:	NCT07515014
Study Sponsor:	Eisai Co., Ltd., Tokyo, Japan

Why is this research needed?

Researchers are looking for a different way to treat people who have systemic lupus erythematosus (SLE). **SLE** is a long-term disease, where the body's defense (immune) system mistakenly attacks its own tissues, causing inflammation and damage in organs like the skin, joints, or kidneys. Standard treatment for SLE includes medicines that help control SLE symptoms or stop the body from attacking an organ.

E6742 may be able to help people with SLE by blocking proteins responsible for inflammation and the development of SLE.

In this main study, researchers want to learn how well E6742 may work and its safety profile. Once the main study ends, participants may enter the extension phase, where they will take E6742.

What treatment is being studied?

Participants will take either **E6742** or placebo tablets daily. Placebo looks like E6742 but does not have medicine in it.

Participants will take **E6742** or placebo for 24 weeks (about 5 and a half months). Participants joining the extension phase will take E6742 for another 24 weeks.

No one involved in the study will know which treatment the participants will take. This is called a **double-blind** study.

What are the goals of this study?

The primary and key secondary objectives are to investigate how well E6742 improves SLE symptoms after 24 weeks of treatment.

The other secondary objectives are to further investigate how well E6742 improves SLE symptoms, how the participants' bodies handle E6742, and the safety profile of E6742.

What are the measurements in this study?

1. **Main measurement:** To investigate the primary objective, researchers will check the number of participants who have improved SLE symptoms after 24 weeks of treatment using a survey called the British Isles Lupus Assessment Group-Based Composite Lupus Assessment.

2. **Key secondary measurement:** To investigate the key secondary objective, researchers will check the number of participants who have improved overall SLE disease after 24 weeks of treatment using a survey called SLE Responder Index-4.

   Other secondary measurements: To investigate the other secondary objectives, researchers will use other SLE surveys; measure the level of E6742 in the blood; and check for any medical problems and/or unusual laboratory measurements, vital signs (like blood pressure), and other findings related to safety during the study.

The researchers will also collect other information about E6742, but the measurements described above are the most important for this study.

What will happen during the study?

The chart below shows what will happen in the study.

Before the participants can take the study treatment

1 or more visits to the study site during the 1 month 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:

- Use different questionnaires and surveys to measure participants' SLE symptoms
- Take blood and urine samples
- Check participants' heart health using an electrocardiogram, also called ECG
- Send study diaries to eligible participants

While the participants are taking the study treatment

Multiple visits to the study site for up to 24 weeks

All participants will take E6742 or placebo as tablets daily for 24 weeks.

The study doctors will:

- Use different questionnaires and surveys to measure participants' SLE symptoms

The study doctors will also:

- Ask participants to record the dose of study treatment taken
- Take blood and urine samples
- Check participants' heart health using ECG
- Ask about medical problems participants may have and medicines participants are taking

After the participants finish or stop taking the study treatment

After **treatment ends**, participants will have a final study visit 1 month after their last dose of study treatment. Participants who choose to enter the extension phase do not need to have this final visit.

If a **participant stops treatment early**, they will have an early study visit.

Who can and cannot take part in this study?

People can take part in this study if they:

- Are 18 to 75 years old
- Are diagnosed with SLE

People cannot take part in this study if they:

- Are pregnant or breastfeeding women
- Have certain medical conditions that require treatment

These are just some of the main study entry guidelines. Study doctors will check all of the study requirements 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): E6742 may help treat SLE. The information collected in this study may help doctors learn more about E6742 that may help people with SLE.

Potential Risks (Disadvantages): E6742 may not help to treat SLE, or participants might have a side effect from E6742. There may be additional risks that are unknown and unexpected.