A clinical study is shedding new light on lupus.

Consider participating in the LUMUS study.

A quick reference guide for conversations with potential LUMUS study participants

Thank you for your interest in learning about the LUMUS study. This fact sheet provides more details about the study that you can share with interested individuals. If an individual has any questions or would like to know more, please direct them to call the local study site at the number on the back.

What is this study?

The LUMUS study is evaluating an investigational oral drug called ESK-001 in adults with systemic lupus erythematosus (SLE). Researchers will evaluate ESK-001 to find out if it is safe and effective compared to placebo. A study drug (or investigational drug) is one that is not approved for use by the general public. Placebo is a substance that looks like the study drug but has no active drug in it.

Who is this study enrolling?

Approximately 388 participants will be assigned to a study drug group in this study. This study is for adults 18 to 70 years of age who have been diagnosed with SLE for at least 6 months.

Why is this study important?

SLE is the most common form of lupus. It can cause inflammation of multiple organs or organ systems in the body, such as the heart, lungs, kidneys, or brain. Currently, there is no cure for SLE. Researchers continue to explore investigational drugs for people with SLE through clinical studies.

How is the study drug being tested?

In this study, participants will be randomly assigned (like drawing straws) to a study drug group and receive 1 of 3 dose levels of the study drug (ESK-001) or placebo. Participants will have a 75% (3 in 4) chance of receiving ESK-001 and a 25% (1 in 4) chance of receiving placebo. Participants, the study doctor, and study staff will not know the study group assignment.

During the 48-week study treatment period, participants will take ESK-001 or placebo oral tablets by mouth twice daily. Participants will continue to take their current medication(s) for SLE during the study.

How long will this study last?

Participants will be in this study for approximately 57 weeks, which includes a screening period (approximately 5 weeks), study treatment period (48 weeks), and follow-up period (4 weeks). If a participant is eligible, they may be offered the opportunity to skip the follow-up period and continue to receive the study drug long-term in an extension study. Participants should ask their study doctor if they have questions about enrollment in the extension study.

How will participants' health be monitored in this study?

During the study, participants will visit the study site regularly for health checks and several types of tests and assessments. These may include:

- Physical examinations
- Vital signs measurements (body temperature, breathing rate, blood pressure, and heart rate)
- Electrocardiograms (to measure the electrical activity of the heart)
- Blood and urine tests
- Questionnaires

Not all of these activities will occur at every visit.

What are the benefits and risks of being in this study?

There is no guarantee that participants will receive any benefits. However, participants will be helping others by contributing to medical research. Any study has risks, which may include things that could make participants feel sick or uncomfortable or could cause harm. Also, as with all drugs, the study drug may cause side effects. The study team may be able to prevent or manage some of these and many go away quickly. The study staff will review potential risks with participants before study enrollment.

Is participating in this study mandatory?

Taking part in a clinical study is voluntary. Those eligible to enroll may choose to join the study but leave at a later date for any reason at any time. Regardless of whether an individual chooses to enroll or leave the study early, their healthcare won't be affected.

How can someone learn more about this study?

To learn more, call our local study site at the number below. The study team can also schedule a screening appointment to explain the study in detail.

Study site name:

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Study site phone number:

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a lupus study