

Now enrolling: the OCEAN study for adults with eosinophilic granulomatosis with polyangiitis (EGPA)

A quick reference guide for patient advocacy groups

Thank you for your interest in learning about the OCEAN study. This fact sheet provides more details about the study that you can share with patients. If patients have any questions or would like to know more, please direct them to visit www.gskoceanclinicaltrial.com, scan the code on the back of this sheet, or call the local study site at the number below.

What is this study?

The OCEAN clinical research study is looking for participants who are 18 years of age or older with eosinophilic granulomatosis with polyangiitis (EGPA) that has worsened or returned after previous treatment. Study doctors are testing an investigational drug given as injections, to find out if it works compared to an approved drug, and to determine the investigational drug's safety in people living with EGPA.

Half of the study participants will receive the investigational drug (depemokimab) and the other half will receive an approved drug (mepolizumab). Both study groups will also receive placebo injections plus standard EGPA therapy as prescribed by a doctor.

An 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. Participants' study group assignment will be blinded, meaning neither they nor the study doctor will know which study group they are in.

Who is this study enrolling?

Approximately 160 participants will take part in this study. Patients may qualify for this study if they:

- Are at least 18 years of age or older
- Have EGPA that has worsened or returned after previous treatment
- Are currently taking a corticosteroid or immunosuppressant (your doctor will let you know if you may be eligible based on your current therapy)

Why is this study important?

EGPA is a rare condition where certain types of cells in the body swell. EGPA can affect several body organs including the heart, lungs, skin, gastrointestinal tract, kidneys, and nervous system. People living with EGPA are in need of more effective therapies for this condition. The purpose of this study is to evaluate the safety and effectiveness of an investigational drug (depemokimab) administered every 26 weeks compared to mepolizumab administered every 4 weeks.

How are the study drugs being tested?

In this study, participants will be assigned to a study drug group. They will receive either:

- An investigational drug (depemokimab) given as injections every 26 weeks (plus placebo injections every 4 weeks and standard EGPA therapy as prescribed by their doctor)

OR

- An approved drug (mepolizumab) given as injections every 4 weeks (plus placebo injections every 26 weeks and standard EGPA therapy as prescribed by their doctor)

Participants will not be told which group they are in.

How long will this study last?

After the 4-week screening period, participants will receive study injections for up to 52 weeks, and then receive 1 follow-up phone call about 4 weeks after their last study injections so study staff can ask safety questions.

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 exams
- Vital signs measurements (body temperature, blood pressure, and heart rate)
- Electrocardiograms (to measure the electrical activity of the heart)
- Blood and urine tests
- Questionnaires from study staff and in the eDiary (at Visit 1, participants will be trained on how to use the eDiary at home to complete some questionnaires)

Not all of these activities will occur at every visit.

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

One benefit of taking part in this study is that participants' health will be monitored frequently. However, there is no guarantee that this study will improve a participant's health. It may stay the same or it may get worse. Also, as with all drugs, the study drugs may cause side effects. We may be able to prevent or manage some of these and many go away quickly. Any study has risks, which may include things that could make participants feel sick or uncomfortable or could cause harm. The study staff will review potential risks 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 a patient chooses to enroll or leave the study early, their future healthcare won't be affected.

How can patients learn more about this study?

To learn more, please direct patients to visit www.gskoceanclinicaltrial.com, scan the code below, or 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 phone number: _____

