ForPatients
by Roche

Diabetic Macular Edema

A clinical trial to look at how well faricimab works to reduce certain signs of diabetic macular edema, or DME, in patients who self-identify as Black/African American, Hispanic/Latino American, or Native American/Alaska Native/Native Hawaiian or other Pacific Islander, and have never had any anti-VEGF treatment in the study eye.

A Study to Investigate Faricimab Treatment Response in Treatment-Naive, Underrepresented Patients With Diabetic Macular Edema

Trial Status	Trial Runs In	Trial Identifier
Recruiting	4 Countries	NCT05224102 ML43435

The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.

Trial Summary:

This study is designed to investigate treatment response in treatment-naïve underrepresented patients with diabetic macular edema (DME) who are treated with faricimab. The study population will consist of participants #18 years of age who self-identify as Black/African American, Hispanic/Latino American, or Native American/Alaska Native/Native Hawaiian or other Pacific Islander; in addition, a cohort of Asian Indian participants will be enrolled in India.

Genentech, Inc. Sponsor	**Phase 4** Phase

NCT05224102 ML43435
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is the Elevatum clinical trial needed?

This trial’s studying an investigational treatment (faricimab) to see the effects, good or bad, that faricimab has on patients with DME. DME affects many populations, such as

those who self-identify as Black/African American, Hispanic/Latino American, or Native American/Alaska Native/Native Hawaiian or other Pacific Islander. Clinical trials need the representation of real patients with this disease in order to learn the effects of the study treatment. Having diversity in clinical trials such as Elevatum is important so we can expand the knowledge of how the treatment works for the people it is meant for; so that better knowledge of the possible benefits and risks are known for people of all different backgrounds. The individuals enrolled in a clinical trial should represent the types of people who are likely to use the therapy.

2. How does the Elevatum clinical trial work?

This clinical trial is recruiting people who have a health condition called diabetic macular edema, or DME. People can take part if they self-identify as one of the specified groups mentioned above and if they meet some of the additional inclusion criteria or criteria that our intended participants must have to be included in the study.

The purpose of this clinical trial is to compare the effects, good or bad, of faricimab in people with diabetic macular edema in patients who self-identify as Black/African American, Hispanic/Latino American, or Native American/Alaska Native/Native Hawaiian or other Pacific Islander, and have never had any anti-VEGF treatment in the study eye. All patients who take part in this clinical trial will receive faricimab. There is no placebo or “sugar pill” group.

Participants will be given an injection of the clinical trial treatment (faricimab) by their clinical trial doctor. The injection will be given to the numbed study eye every 4 weeks up to week 20 and then every 8 weeks up to week 52 for a total of 12 visits and10 injections (one injection of study drug per visit). The visits will include checks to see how the participant is responding to the treatment and any side effects they may be having. Participants’ total time in the clinical trial will be roughly 56 weeks. Participants are free to stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the Elevatum clinical trial?

The main clinical trial endpoint (the main result that is measured in the trial to see if the medicine has worked) is the change in a measurement called best corrected visual acuity, or BCVA, from baseline to week 56 (the end of the study). BCVA is the best possible vision that an eye can achieve with the use of glasses or contact lenses. This will be done by sitting and reading from a chart called the Early Treatment Diabetic Retinopathy Study (ETDRS) chart.

4. Who can take part in this clinical trial?

People can take part in this trial if they are at least 18 years old, have a confirmed diagnosis of DME, self identify as one of the specified groups (Black/African American,

Hispanic/Latino American, or Native American/Alaska Native/Native Hawaiian or other Pacific Islander), are being treated for type 1 or type 2 diabetes, have an HbA1c of less than or equal to 10%, (up to 20% of patients enrolled may have HbA1c up to 12%), have never had any anti-VEGF treatment in the study eye, are not using certain medications, and have no history of other serious eye conditions or certain treatments/procedures.

5. What treatment will participants be given in this clinical trial?

Everyone who joins this clinical trial will be given the same treatment. This is an “open-label” trial which means both the clinical trial doctor and the patients know what treatment is being given. There will be no placebo group meaning no “sugar pill.” If you join this trial, you will be given:

Faricimab, given as an eye injection every 4 weeks up to week 20 and then every 8 weeks up to week 52.

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant, although it may not be greater than the risks related to routine medical care or the natural progression of the health condition. Potential participants will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. These will all be described in an informed consent document (a document that provides people with the information they need to make a decision to volunteer for a clinical trial). A potential participant should also discuss these with members of the research team and with their usual health care provider. Anyone interested in taking part in a clinical trial should know as much as possible about the trial and feel comfortable asking the research team any questions about the trial.

Risks associated with the clinical trial drug

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drug used in this clinical trial. Side effects can be mild to severe and even life threatening, and can vary from person to person.

Faricimab

Faricimab will be administered to the numbed eye intravitreally and participants will be told about known side effects of the administration route.

Potential benefits associated with the clinical trial

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Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

For more information about this clinical trial see the For Expert tab on the specific ForPatients page or follow this link to ClinicalTrials.gov https://clinicaltrials.gov/ct2/show/NCT05224102?term=ML43435&draw=2&rank=1