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
Active, not recruiting	4 Countries	NCT05224102 ML43435

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase IV, Multicenter, Open-Label, Single-Arm Study to Investigate Faricimab (RO6867461) Treatment Response in Treatment-Naive, Underrepresented Patients With Diabetic Macular Edema

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

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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.

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Potential benefits associated with the clinical trial

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

Inclusion Criteria:

Main Phase General Inclusion Criteria:

- Self-identify as Black/African American, Hispanic/Latino American, or Native American/Alaska Native/ Native Hawaiian or other Pacific Islander; or self-identify as Asian Indian residents of the Indian subcontinent
- Diagnosis of diabetes mellitus (type 1 or type 2), as defined by the World Health Organization (WHO) and/or American Diabetes Association, and current regular use of insulin or other injectable drugs (e.g., dulaglutide and liraglutide) and/or oral anti-hyperglycemic agents for the treatment of diabetes
- Hemoglobin A1c (HbA1c) #10% (Note: up to 20% of participants enrolled may have HbA1c up to 12%)
- For women of childbearing potential: Agreement to remain abstinent (refrain from heterosexual intercourse) or use acceptable contraception methods as defined in the protocol

Main Phase Ocular Inclusion Criteria for Study Eye:

- Intravitreal (IVT) treatment-naïve in the study eye (i.e., have not received previous treatment with any anti-VEGF IVT or any corticosteroids periocular or IVT in the study eye)
- Diabetic macular edema, defined as macular thickening by SD-OCT involving the center of the macula
- BCVA letter score of 73 to 20 letters (both inclusive) using the ETDRS protocol at the initial testing distance of 4 meters at the baseline visit (Day 1)
- Clear ocular media and adequate pupillary dilation to allow acquisition of good quality retinal images to confirm diagnosis

Long-Term Extension (LTE) Inclusion Criteria:

- Enrollment in and completion of the main study, without discontinuation from study or study drug treatment
- Signed LTE-phase Informed Consent Form
- Ability to comply with the study protocol, in the investigator's judgment
- For women of childbearing potential: Agreement to remain abstinent (refrain from heterosexual intercourse) or use acceptable contraception methods as defined in the protocol

Exclusion Criteria:

Main Phase General Exclusion Criteria:

- Diabetes mellitus (type 1 or type 2) that is currently medically untreated
- Previously untreated diabetes mellitus (type 1 or type 2) who started on oral or injectable anti-diabetic medication within 3 months prior to Day 1
- Any known hypersensitivity to any of the components in the faricimab injection
- Any known hypersensitivity to any contrast media (e.g., fluorescein), dilating eye drops, disinfectants (e.g., iodine), or any of the anesthetics and antimicrobial preparations used by the patient during the study
- History of other diseases, other non-diabetic metabolic dysfunction, physical examination finding, or historical or current clinical laboratory finding giving reasonable suspicion of a condition that contraindicates the use of the faricimab or that might affect interpretation of the results of the study or renders the patient at high-risk for treatment complications, in the opinion of the investigator
- Active cancer within the past 12 months prior to Day 1 except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, and prostate cancer with a Gleason score of #6 and a stable prostate-specific antigen for >12 months
- Stroke (cerebral vascular accident) or myocardial infarction within 12 months prior to Day 1
- Any febrile illness within 1 week prior to Day 1
- Pregnant or breastfeeding, or intending to become pregnant during the study or within 3 months after the final dose of faricimab
- Uncontrolled blood pressure, defined as systolic >180 mmHg and/or diastolic >100 mmHg (while patient is at rest in a sitting position); if a patient's initial reading exceeds these values, a second reading may be taken #30 minutes later on the same day
- Renal failure requiring renal transplant, hemodialysis, or peritoneal dialysis within 6 months prior to Day 1 or anticipated to require hemodialysis or peritoneal dialysis at any time during the study
- Any condition resulting in a compromised immune system that is likely to impact the aqueous humor inflammatory biomarkers
- Participation in an investigational trial that involves treatment with any drug or device (with the exception of vitamins or minerals) within 3 months (or 5 half-lives, whichever is longer) prior to Day 1, or during the course of this study
- Substance abuse occurring within 12 months prior to screening, in the investigator's judgment
- Use of systemic immunomodulatory treatments (e.g., IL-6 inhibitors) within 6 months or 5 half-lives (whichever is longer) prior to Day 1
- Use of any systemic corticosteroids within 1 month prior to Day 1
- Systemic treatment for suspected or active systemic infection
- Any prior or concomitant systemic anti-VEGF treatment within 6 months or 5 half-lives (whichever is longer) prior to Day 1
- Use of systemic medications known to be toxic to the lens, retina, or optic nerve (e.g., deferoxamine, chloroquine/hydroxychloroquine, tamoxifen, phenothiazines, or ethambutol) during the 6-months (or 5 half-lives, whichever is longer) prior to Day 1
- Receiving any treatment that leads to immunosuppression within 6 months (or 5 half-lives, whichever is longer) prior to Day 1
- Requiring continuous use of any medications or treatments listed as prohibited therapy

Main Phase Ocular Exclusion Criteria for Study Eye:

- High-risk proliferative diabetic retinopathy (PDR) in the study eye, using any of the following established criteria for high-risk PDR: Any vitreous or pre-retinal hemorrhage; Neovascularization elsewhere #1/2 disc area within an area equivalent to the mydriatic ETDRS 7 or 4 fields on clinical examination or on CFPs; Neovascularization at disc #1/3 disc area on clinical examination
- Tractional retinal detachment, pre-retinal fibrosis, vitreomacular traction, or epiretinal membrane involving the fovea or disrupting the macular architecture in the study eye, as evaluated by the central reading center
- Any history of or ongoing rubeosis iridis

- Any panretinal photocoagulation or macular laser (focal, grid or micropulse) photocoagulation treatment received in the study eye prior Day 1
- Any history of treatment with anti-VEGF or any periocular or IVT corticosteroids in the study eye prior to Day 1
- Any treatment for dry eye disease in the last month prior to Day 1 (e.g., cyclosporine eye drops, lifitegrast eye drops). Lubricating eye drops and ointments are permitted.
- Any treatment with anti-inflammatory eye drops (e.g., doxycycline) within 1 month prior to Day 1
- Any intraocular surgery (e.g., cataract surgery) within 3 months prior to Day 1 or any planned surgery during the study
- Any glaucoma surgery prior to the screening visit
- History of vitreoretinal surgery/pars plana vitrectomy, corneal transplant, or radiotherapy
- Uncontrolled glaucoma
- Any active or suspected ocular or periocular infections on Day 1
- Any presence of active intraocular inflammation on Day 1 (i.e., Standardization of Uveitis Nomenclature [SUN] criteria >0 or National Eye Institute [NEI] vitreous haze grading >0) or any history of intraocular inflammation
- Any history of idiopathic, infectious, or noninfectious uveitis
- Any current ocular condition or other causes of visual impairment for which, in the opinion of the investigator, visual acuity loss would not improve from resolution of macular edema

Main Phase Ocular Exclusion Criteria for Non-Study Eye:

- Any history of idiopathic or immune-mediated uveitis
- Active ocular inflammation or suspected or active ocular or periocular infection on Day 1
- Currently receiving treatment with brolucizumab or bevacizumab in the non-study eye and is unwilling to switch to a protocol-allowed, non-study eye anti-VEGF treatment during the study
- Any previous treatment with Iluvien® or Retisert® (fluocinolone acetonide IVT implant) in the non-study eye
- Non-functioning non-study eye, defined as either: BCVA of hand motion or worse; No physical presence of non-study eye (i.e., monocular); or, Legally blind in the patient's relevant jurisdiction

Long-Term Extension (LTE) Exclusion Criteria:

- Pregnant or breastfeeding, or intending to become pregnant during the study or within 3 months after the final IVT injection of faricimab
- Presence of other ocular diseases that give reasonable suspicion of a disease or condition that contraindicates the use of faricimab, that might affect interpretation of the results of the LTE, or that renders the patient at high risk for treatment complications
- Presence of other diseases, metabolic dysfunction, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of faricimab and that might affect interpretation of the results of the LTE, or that renders the patient at high risk of treatment complications
- History of a severe allergic reaction or anaphylactic reaction to a biologic agent or known hypersensitivity to any component of the faricimab injections, study treatment procedure, dilating drops, or any of the anesthetic and antimicrobial preparations used by a patient during the LTE phase
- Requirement for continuous use of any medications or treatments indicated as prohibited therapy (as defined in the protocol)