ForPatients
by Roche

Diabetic Macular Edema

A clinical trial to look at new ways of measuring how faricimab works in patients with diabetic macular edema

A Study to Investigate Aqueous Humor and Multimodal Imaging Biomarkers in Treatment-Naïve Participants With Diabetic Macular Edema Treated With Faricimab

Trial Status	Trial Runs In	Trial Identifier
Completed	7 Countries	NCT04597918 2020-001174-30 MR41926

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:

An Exploratory, Prospective, Multi-Center, Open-Label, Single-Arm, Interventional, Phase IIB Study to Investigate Aqueous Humor and Multimodal Imaging Biomarkers in Treatment-Naïve Patients With Diabetic Macular Edema Treated With Faricimab (RO6867461) - ALTIMETER STUDY

Trial Summary:

This is an exploratory, prospective, multicenter, open-label, single-arm, interventional, Phase IIb study designed to explore the associations over time between clinical assessments, multimodal imaging assessments, aqueous humor (AH) biomarker patterns, and genetic polymorphisms in participants with diabetic macular edema (DME) who are treated with faricimab.

Hoffmann-La Roche
Sponsor

Phase 2
Phase

NCT04597918 2020-001174-30 MR41926
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

How does the ALTIMETER clinical trial work?
This clinical trial is recruiting people who have a type of diabetic eye disorder. In order to take part, patients must have diabetic macular edema.

The purpose of this clinical trial is to look at new ways to measure the effect of faricimab in patients with diabetic macular edema. If you take part in this clinical trial, you will receive faricimab.

How do I take part in this clinical trial? To be able to take part in this clinical trial, you must have been diagnosed with diabetic macular edema due to diabetes mellitus (Type I or Type II) and you must be at least 18 years old.

You cannot join the trial if you are pregnant or breastfeeding. You must not have received any previous treatment for the study eye (the one receiving treatment), including laser treatments, injection-based treatments, corticosteroids or compounds that block VEGF.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, women (if you are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons.

What treatment will I be given if I join this clinical trial? Everyone who joins this clinical trial will be given faricimab, given as an injection into the study eye, every 4 weeks for around 20 weeks.

How often will I be seen in follow-up appointments and for how long? You will be given the clinical trial treatment faricimab for approximately 20 weeks up to a maximum of 6 treatments. You are free to stop this treatment at any time. Before your first and fifth treatment, doctors will take a small sample of fluid from your eye to check for any changes. You will also be seen regularly by the clinical trial doctor every 4 weeks until you complete treatment, and then around 4 to 5 weeks after your last injection. These hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having.

What happens if I am unable to take part in this clinical trial?
If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatient page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT04597918

Inclusion Criteria:

- Diagnosis of diabetes mellitus (Type 1 or Type 2), as defined by the World Health Organization (WHO) and/or American Diabetes Association
- Hemoglobin A1c (HbA1c) #10%
- Patients who are intravitreal (IVT) treatment-naïve in the study eye
- Diabetic macular edema (DME) defined as macular thickening by spectral-domain optical coherence tomography (SD-OCT) involving the center of the macula. This inclusion criterion is to be assessed by the central reading center (CRC).
- Decreased visual acuity (VA) attributable primarily to DME
- Clear ocular media and adequate pupillary dilation to allow acquisition of good quality retinal images to confirm diagnosis

Exclusion Criteria:

- Currently untreated diabetes mellitus or previously untreated patients who initiated 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, dilating eye drops, or any of the anesthetics and antimicrobial preparations used by the patient during the study
- Any major illness or major surgical procedure within 1 month before the Day 1. One re-screening for this criterion is permitted
- History of other diseases, other non-diabetic metabolic dysfunction, physical examination finding, 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 or myocardial infarction within 12 months prior to the Day 1. One re-screening for this criterion is permitted
- Any febrile illness within 1 week prior to Day 1. One re-screening for this criterion is permitted
- Pregnant or breastfeeding, or intending to become pregnant during the study or within 3 months after the final dose of faricimab
- 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 (AH) inflammatory biomarkers.

- Patients who are currently enrolled in or have participated in any other clinical study involving an investigational product or device, or in any other type of medical research, within 3 months or 5 half-lives prior to Day 1 and up to completion of the current study
- Substance abuse occurring within 12 months prior to screening, in the Investigator's judgment
- Use of systemic immunomodulatory treatments within 6 months or 5 half-lives prior to Day 1
- Use of any systemic corticosteroids (including inhaled corticosteroids from inhalers used regularly, e.g., pulmonary disease, asthma, or seasonal allergy) within 1 month prior to Day 1
- Any prior or concomitant systemic anti-VEGF treatment within 6 months or 5 half-lives prior to Day 1
- Use of systemic medications known to be toxic to the lens, retina or optic nerve used during the 6-month period or 5 half-lives prior to Day 1 or likely need to be used
- Received a blood transfusion within 3 months prior to the screening visit
- Received any treatment that leads to immunosuppression within 6 months or 5 half-lives prior to Day 1

Ocular Exclusion Criteria for Study Eye:

- High-risk PDR. This exclusion criterion is to be assessed by the CRC
- Any history of or ongoing rubeosis iridis
- Any panretinal photocoagulation or macular laser photocoagulation treatment received in the study eye prior to the screening visit or expected to be received between the screening visit and Day 1
- Any history of treatment with anti-VEGF or any periocular or IVT corticosteroids in the study eye and no such treatment planned for the time between screening and Day 1
- Any treatment for dry eye disease in the last month prior to Day 1. Lubricating eye drops and ointments are permitted.
- Any treatment with anti-inflammatory eye drops within 1 month prior to Day 1
- Any intraocular surgery within 3 months prior to Day 1 or any planned surgery during the study
- Any glaucoma surgery/laser procedure involving the iris, trabecular meshwork, or ciliary body prior to the screening visit. Only iris surgery/laser might be allowed if they occurred more than 6 months prior to Day 1.
- History of vitreoretinal surgery/pars plana vitrectomy, corneal transplant, or radiotherapy
- Any active or suspected ocular or periocular infections on Day 1
- Any presence of active intraocular inflammation on Day 1 or any history of intraocular inflammation
- Any history of idiopathic, infectious, or noninfectious uveitis
- Any current or history of ocular disease other than DME that may confound assessment of the macula or affect central vision
- Any current ocular condition or other causes of visual impairment for which, in the opinion of the Investigator, VA loss would not improve from resolution of macular edema

Ocular Exclusion Criteria for Fellow Eye:

- Patient is currently receiving treatment with brolucizumab or bevacizumab in the non-study eye and is unwilling to switch to a protocol allowed non-study eye treatment during the study
- Any previous treatment with Iluvien® or Retisert® in the non-study eye
- Non-functioning non-study eye