ForPatients
by Roche

Neovascular Age-related Macular DegenerationWet Age-Related Macular DegenerationAge-Related Macular Degeneration

A clinical trial to look at the long-term safety of faricimab in patients with neovascular age-related macular degeneration (nAMD, also known as wet AMD)

A Study to Evaluate the Long-Term Safety and Tolerability of Faricimab in Participants With Neovascular Age-Related Macular Degeneration

Trial Status	Trial Runs In	Trial Identifier
Completed	27 Countries	NCT04777201 2020-004523-16 GR42691

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 Multicenter, Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of Faricimab in Patients With Neovascular Age-Related Macular Degeneration (AVONELLE-X)

Trial Summary:

This main long-term extension study is designed to evaluate the long-term safety and tolerability of faricimab 6 milligrams (mg) administered by intravitreal injection at a personalized treatment interval (PTI) to participants with neovascular age-related macular degeneration (nAMD) who enrolled in and completed one of the Phase III studies: GR40306 (NCT03823287) or GR40844 (NCT03823300), also referred to as the parent studies. Eligible patients who consent to participate in this main study will be enrolled upon completion of the end-of-study visit in the parent study. Additionally, there is a substudy that is being conducted. The aim of this substudy is to evaluate the impact of intravitreal faricimab on the health of the corneal endothelial cells in the study eyes of patients with nAMD to fulfill a U.S. Food and Drug Administration (FDA) post-marketing requirement. The fellow eyes of the same enrolled participants in the substudy will serve as the controls.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04777201 2020-004523-16 GR42691
Trial Identifiers

Eligibility Criteria:

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Gender	Age	Healthy Volunteers
All	#50 Years	No

How does the Avonelle-X (GR42691) clinical trial work?

This clinical trial is recruiting people who have neovascular age-related macular degeneration (nAMD, also known as wet AMD) and who previously participated in and completed either Study GR40306 (also known as TENAYA) or GR40844 (also known as LUCERNE).

The purpose of this clinical trial is to learn more about the effects, good or bad, of long-term use of the study treatment, faricimab, on patients with nAMD. 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 previously participated in and completed either Study GR40306 (also known as TENAYA) or GR40844 (also known as LUCERNE), without stopping the study treatment or the trial.

If you have other conditions or need to take any other medications, you may not be able to take part.

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 (who are not currently pregnant but can become pregnant) will need to either not have heterosexual intercourse or take contraceptive medication for safety reasons. Women must not donate eggs while taking part in the clinical trial.

What treatment will I be given if I join this clinical trial?

This clinical trial is split into two parts.

In Part 1 (the masked phase), everyone who joins this clinical trial will be given faricimab as an injection into the study eye. You will have study visits every four weeks for roughly 12 weeks but how often you receive injections will vary, depending on the condition of your eye. If a faricimab injection is not scheduled at a particular visit, you will have a “sham” treatment designed to feel like a real injection instead (an empty syringe without a needle will be pressed against your numbed eye).

Neither you nor your clinical trial doctor will know whether you are receiving faricimab or sham treatment at each visit. However, your clinical trial doctor can find out how often you are receiving study treatment if your safety is at risk.

In Part 2 (the open-label phase), you will only have study visits when you need a faricimab injection. You will receive faricimab either every 8, 12 or 16 weeks, depending on the condition of your eye.

How often will I be seen in follow-up appointments and for how long?

You will be given the study treatment, faricimab, for roughly 2 years. You are free to stop this treatment at any time. While being given treatment, you will still be seen regularly by the clinical trial doctor. These hospital visits will include checks to see how you are responding to the treatment and to monitor 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 https://clinicaltrials.gov/ct2/show/NCT04777201

Trial-identifier: NCT04777201

Inclusion Criteria:

Inclusion Criteria for the Main Study:

- Previous enrollment in and completion of Study GR40306 (NCT03823287) or Study GR40844 (NCT03823300), without study or study drug discontinuation
- For women of childbearing potential: agreement to remain abstinent or use contraception, and agreement to refrain from donating eggs. Women must remain abstinent or use contraceptive methods

with a failure rate of < 1% per year during the treatment period and for 3 months after the final dose of faricimab. Women must refrain from donating eggs during the same period.

Inclusion Criteria for the Substudy:

- In addition to all inclusion criteria specified in the main Study GR42691, participants in the Substudy must meet the following criteria:
- Sign an informed consent form for the Substudy
- Must be able to participate for at least 48 weeks in the Substudy and have at least the first visit while enrolled in the main Study GR42691
- A difference of <10% in corneal endothelial cell density at screening between the two eyes as measured by specular microscopy and determined by the independent reading center

Exclusion Criteria:

Exclusion Criteria for the Main Study:

- Pregnant or breastfeeding, or intending to become pregnant during the study or within 3 months after the final dose 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 study 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 study 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-related procedure preparations, dilating drops, or any of the anesthetic and antimicrobial preparations used by a patient during the study
- Requirement for continuous use of any medications or treatments indicated as prohibited therapy

Exclusion Criteria for the Substudy:

In addition to the exclusion criteria specified in the main Study GR42691, patients will be excluded from this substudy if they meet any of the following exclusion criteria:

- Prior and/or current administration of faricimab in the fellow (non-study) eye
- Prior administration of brolucizumab in the fellow (non-study) eye

Exclusion Criteria in Either Eye for the Substudy:

- Corneal endothelial cell density #1500 cells/mm2 in either eye at screening as determined by the independent corneal reading center
- Fuchs endothelial corneal dystrophy Grade #2
- Previous ocular trauma (blunt or penetrating) and/or corneal endothelial cell damage, including from blunt or surgical trauma (including complicated cataract surgery resulting in complicated lens placement such as anterior chamber intraocular lens, sulcus intraocular lens, aphakia, etc.)
- Any ocular condition that precludes obtaining an analyzable specular microscopy image
- Active or history of corneal edema
- Any active or history of corneal dystrophies, excluding Fuchs endothelial corneal dystrophy Grade <2

- Active or history of iridocorneal endothelial syndrome
- Active or history of pseudoexfoliation syndrome
- Active or history of herpetic keratitis or kerato-uveitis (including herpes simplex virus and herpes zoster virus)
- Intraocular laser therapy including selective laser trabeculoplasty, yttrium-aluminum garnet (YAG), prophylactic peripheral iridotomy within 1 year of screening, or YAG capsulotomy within 3 months of screening
- Prior vitrectomy surgery, submacular surgery, or other surgical intervention for AMD
- Prior pars plana vitrectomy surgery
- Previous intraocular device implantation excluding intraocular lenses
- Cataract surgery within 6 months of screening or planned for during the study
- History of glaucoma-filtering surgery, tube shunts, or microinvasive glaucoma surgery. Other types of prior glaucoma surgery are allowed providing that the surgery occur more than 6 months before screening
- Administration of topical Rho kinase inhibitors (e.g., Rhopressa eye drops) within 1 month prior to the screening visit
- Contact lens wear in either eye within 2 months of screening
- History of corneal transplantation, including partial-thickness corneal grafts (e.g., Descemet membrane endothelial keratoplasty, Descemet stripping endothelial keratoplasty)
- Active or history of iridocorneal endothelial syndrome
- Active or history of pseudoexfoliation syndrome