A MULTICENTER, OPEN-LABEL EXTENSION STUDY TO EVALUATE THE LONG-TERM SAFETY AND TOLERABILITY OF FARICIMAB IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION

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This study will evaluate the long-term safety and tolerability of IVT faricimab in patients with nAMD who have completed either of the Phase III (GR40306 or GR40844) studies. Additional assessments relating to efficacy, pharmacokinetics,...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Retina, choroid and vitreous haemorrhages and vascular disorders
Study type	Interventional

Summary

ID

NL-OMON50774

Source
ToetsingOnline

Brief title
AVONELLE

Condition

- Retina, choroid and vitreous haemorrhages and vascular disorders

Synonym
neovascular age-related macular degeneration, wet AMD

Research involving
Human

Sponsors and support

Primary sponsor: Roche Nederland B.V.
Source(s) of monetary or material Support: Roche Nederland B.V.

Intervention

Keyword: Faricimab, nAMD, neovascular age-related macular degeneration, Open-Label

Outcome measures

Primary outcome

The primary objective is to evaluate the long-term ocular and systemic safety and tolerability of faricimab in all patients who have enrolled in the long-term extension (LTE) study who have received at least one injection of faricimab during the LTE, regardless of adherence to treatment or to the protocol, on the basis of the following endpoints:

- Incidence and severity of ocular adverse events
- Incidence and severity of non-ocular adverse events.

Secondary outcome

The exploratory efficacy objective of this study is to assess the long-term efficacy of IVT faricimab for the management of nAMD in all patients who have enrolled in the LTE study who have received at least one injection of faricimab during the LTE

See section 2 of the protocol for all exploratory, pharmacokinetic,

immunogenicity and biomarker objectives

Study description

Background summary

Neovascular age-related macular degeneration (nAMD) (also known as wet AMD) is a form of advanced AMD that causes rapid and severe visual loss and remains a leading cause of visual impairment in the elderly. The Sponsor is currently investigating the efficacy and safety of faricimab 6 mg in nAMD in two identical, global, Phase III, randomized, double-masked, active comparator-controlled trials. Approximately 1280 patients have been randomized in a 1:1 ratio to one of two treatment arms. The aim of the Phase III program is to evaluate the efficacy, safety, durability, and pharmacokinetics of the 6-mg dose of faricimab administered at up to 16-week intervals compared with aflibercept monotherapy Q8W in patients with nAMD. See protocol section 1.2

Study objective

This study will evaluate the long-term safety and tolerability of IVT faricimab in patients with nAMD who have completed either of the Phase III (GR40306 or GR40844) studies. Additional assessments relating to efficacy, pharmacokinetics, immunogenicity, and biomarkers will be performed.

Study design

Approximately 1280 patients are expected to participate in this extension study after completion of the parent studies, and will follow a single faricimab 6 mg PTI regimen. In this extension study, the study eye will be the same as that randomized in the parent studies, GR40306 and GR40844.

Patients will be required to attend monthly study assessment visits between Day 1 and Week 12 (the masked period of the study) in order to preserve masking of a patient*s treatment assignment in the parent study. From Week 16 until approximately Week 104, patients will attend study visits at intervals as scheduled by the IxRS system based on the PTI algorithm. A final Safety Follow-Up visit will take place at least 28 days after the final faricimab treatment visit (see Figure 1).

Intervention

Patients taking part in the study will be treated with sham or faricimab in the blind phase (12 weeks) every 4 weeks. Thereafter every 8-16 weeks with faricimab.

Study burden and risks

First 3 months patients need to come to the site more often than with standard care, and also undergo a possible sham procedure to maintain the masking of the parent study. Patients also need to undergo more scans, blood is drawn and need to answer questionnaires. All risks are listed in the ICF.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Previous enrollment in and completion of Study GR40306 (TENAYA) or Study GR40844 (LUCERNE), 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.

Exclusion criteria

• Pregnant or breastfeeding, or intending to become pregnant during the study or within 28 days 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

Study design

Design

Study phase:	3
Study type:	Interventional
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-12-2021
Enrollment:	4
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	onbekend
Generic name:	Faricimab

Ethics review

Approved WMO Date:	21-04-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-07-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-10-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	07-11-2021
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-01-2022

Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	11-05-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	25-08-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	08-10-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	16-10-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	18-12-2023
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
EudraCT	EUCTR2020-004523-16-NL
ClinicalTrials.gov	NCT04777201
CCMO	NL76733.056.21