A PHASE III, MULTICENTER, RANDOMIZED, DOUBLE-MASKED, ACTIVE COMPARATOR-CONTROLLED STUDY TO EVALUATE THE EFFICACY AND SAFETY OF FARICIMAB IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (TENAYA)

Published: 23-04-2019
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The purpose of this study is to investigate the efficacy, safety, durability, and pharmacokinetics of faricimab administered at up to 16-week intervals to treatment-naive patients with nAMD.

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

Summary

ID

NL-OMON49876

Source
ToetsingOnline

Brief title
TENAYA

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: Aflibercept, Dubble Blind, Faricimab, Wet AMD

Outcome measures

Primary outcome

Primary Efficacy Objective:

To evaluate the efficacy of IVT injections of the 6-mg dose of faricimab on

BCVA outcomes compared with aflibercept

Corresponding Endpoint:

Change from baseline in BCVA (as measured on the ETDRS chart at a starting

distance of 4 meters) based on an average at Weeks 40, 44, and 48

Secondary outcome

To evaluate the ocular and non-ocular

safety and tolerability of faricimab

To evaluate the efficacy of faricimab on

patient-reported vision-related functioning

and quality of life using the NEI VFQ-25

To characterize the systemic

pharmacokinetics of faricimab

For a full list, please see protocol section 2

Study description

Background summary

Currently available and approved injection-based treatments for nAMD, such as aflibercept, only target VEGF. These medications can improve outcomes in patients with nAMD, but frequent treatments are required and not everyone responds to treatment. Studies have shown that Ang-2 may also play an important role in nAMD. Therefore, for some patients, blocking both VEGF and Ang-2 may be more effective and may also allow for treatments to be given less frequently.

Study objective

The purpose of this study is to investigate the efficacy, safety, durability, and pharmacokinetics of faricimab administered at up to 16-week intervals to treatment-naive patients with nAMD.

Study design

Approximately 640 patients will be enrolled globally and randomized in a 1:1 ratio to one
of two treatment arms:
* Group 1 will receive faricimab, given as an injection in the study eye every 4 weeks for the first 4 injections and then every 8, 12, or 16 weeks for 2 years. The frequency of injections in the first year will be decided on the basis of the condition of the study eye at Weeks 20 and 24. In Year 2, the frequency of injections may be changed based on the condition of the eye, but injections will still be given every 8, 12, or 16 weeks.
* Group 2 will receive aflibercept given as an injection in the study eye every 4 weeks for the first 3 injections and then every 8 weeks for 2 years.

Patients in both treatment arms will complete scheduled study visits Q4W for the entire study duration (112 weeks). A sham procedure will be administered to patients in both treatment arms at study visits with no study treatment administration to maintain masking among treatment arms

Intervention

Patietns taking part in the study will be treated with faricimab or aflibercept every 4 weeks, with possible sham injections

Study burden and risks

Patients will have to come to the research center every 4 weeks for treatment or sham treatment. This is a higher number of visits and injections, or sham injections than standard care. This is necessary to maintain the blinding between different treatment periods. Roche offers a taxi service to bring the patients to and from home.

The combined evidence from the Phase II studies BP29647 and CR39521 indicates that the 6-mg dose of faricimab can be administered to patients with nAMD at various treatment intervals (Q4W, Q8W, Q12W, and Q16W) to deliver similar efficacy compared with 0.5 mg of ranibizumab Q4W, and importantly, has the potential to be given at substantially less-frequent treatment intervals (up to Q16W), while still achieving comparable visual (BCVA) and anatomic (OCT) outcomes. Based on the totality of evidence from the Phase I and Phase II studies, and taking into account evidence from the murine and non-human primate preclinical and toxicology models, it is anticipated that the additional anti*Ang-2 mechanism of action of the faricimab molecule will not negatively impact the safety profile compared with IVT anti-VEGF monotherapy, while less-frequent dosing may offer a more favorable benefit*risk profile.

Taken together, data from nonclinical, Phase I and Phase II studies, as well as the clear unmet need for less-frequent dosing in nAMD, support the positive benefit*risk assessment for the initiation of this Phase III study to assess the efficacy, safety, durability, and pharmacokinetics of faricimab administered up to Q16W to patients with nAMD.

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

- Age >< = 50 years , - Ability to comply with the study protocol, - For women of childbearing potential: agreement to remain abstinent or use acceptable contraceptive methods during the treatment period and for at least 3 months after the final dose of study treatment, - Treatment-naïve choroidal neovascularization (CNV) secondary to AMD (nAMD) in the study eye, - BCVA of 20/32 to 20/320 (letter score of 78 to 24) in the study eye at the initiation of treatment

Exclusion criteria

- Uncontrolled blood pressure, - Pregnancy or breastfeeding, or intention to become pregnant during the study, - CNV due to causes other than AMD in the study eye, - Any history of macular pathology unrelated to AMD affecting vision or contributing to the presence of intraretinal or subretinal fluid in the study eye, - Presence at screening of central serous chorioretinopathy in the study eye, - Retinal pigment epithelial tear involving the macula on Day 1 in the study eye, - On FFA/ Color fundus photograph: , o Subretinal hemorrhage of > 50% of the total lesion area and/or that involves the fovea, o Fibrosis or atrophy of > 50% of the total lesion area and/or that involves the fovea, - Any concurrent intraocular condition in the study eye that, in the opinion of the investigator, could either reduce the potential for visual improvement or require medical or surgical intervention during the study , - Current vitreous hemorrhage on Day 1 in the study eye, - Uncontrolled glaucoma in the study eye, - Spherical equivalent of refractive error demonstrating more than 8

diopters of myopia in the study eye, - Any prior or concomitant treatment for CNV or vitreomacular-interface abnormalities in the study eye, - Any cataract surgery or treatment for complications of cataract surgery with steroids or YAG laser capsulotomy in the study eye within 3 months prior to Day 1, - Any other intraocular surgery in the study eye, - Prior periocular pharmacological or IVT treatment for other retinal diseases in the study eye, - Prior IVT administration of faricimab in either eye, - Active ocular inflammation or suspected or active ocular or periocular infection in either eye

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2019
Enrollment:	15
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Eylea
Generic name:	Aflibercept
Registration:	Yes - NL intended use
Product type:	Medicine
Brand name:	unkown

Generic name:	faricimab

Ethics review

Approved WMO Date:	23-04-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	17-07-2019
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-08-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	29-08-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-10-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	15-10-2019
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	24-12-2019
Application type:	Amendment

Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	10-06-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-07-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	20-07-2020
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	22-12-2020
Application type:	Amendment
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:	17-10-2021
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	EUCTR2018-002152-32-NL
ClinicalTrials.gov	NCT03823287
CCMO	NL68873.056.19