ForPatients
by Roche

Macular DegenerationNeoangiogenesisAge-Related Macular Degeneration

Study to Evaluate Faricimab (RO6867461; RG7716) for Extended Durability in the Treatment of Neovascular Age Related Macular Degeneration (STAIRWAY)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT03038880 CR39521

The clinical trial information herein is sourced from public registries such as ClinicalTrials.gov, EuClinicalTrials.eu, and ISRCTN.com. Additional patient-friendly (lay) content has been prepared by Roche to support understanding.

Official Title:

STAIRWAY: Simultaneous Blockade of Angiopoietin-2 and VEGF-A With the Bispecific Antibody RO6867461 (RG7716) for Extended Durability in the Treatment of Neovascular Age-Related Macular Degeneration

Trial Summary:

This was a Phase II, multicenter, randomized, active comparator-controlled, 52-week study to investigate the efficacy, safety and pharmacokinetics of faricimab (RO6867461; RG7716) administered with extended dosing regimens in treatment-naive participants with neovascular age related macular degeneration (nAMD). Only one eye was chosen as the study eye.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT03038880 CR39521
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 50 Years	No

Inclusion Criteria:

- Treatment-naive CNV secondary to AMD (nAMD)

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- Subfoveal or juxtafoveal CNV with a subfoveal component related to the CNV activity by fundus fluorescein angiography (FFA) or spectral-domain optical coherence tomography (SD-OCT; as evidenced by subretinal fluid, subretinal hyperreflective material, evidence of leakage, or hemorrhage)
- CNV lesion of all types with: total lesion size (including blood, atrophy, fibrosis, and neovascularization) of 6 disc areas or less by FFA; and CNV component area of at least 50% of total lesion size by FFA; and active CNV confirmed by FFA (evidence of leakage); and CNV exudation confirmed by SD-OCT (presence of fluid)
- BCVA letter score of 73 to 24 letters (inclusive) on ETDRS-like charts (20/40-20/320 Snellen equivalent) on day 1
- Clear ocular media and adequate pupillary dilatation to allow acquisition of good-quality retinal images to confirm diagnosis

Exclusion Criteria:

- CNV due to causes other than AMD, such as ocular histoplasmosis, trauma, pathological myopia, angioid streaks, choroidal rupture, or uveitis
- Central serous chorioretinopathy at screening
- Retinal pigment epithelial tear involving the macula
- On FFA: subretinal hemorrhage, fibrosis, or atrophy of more than (>)50% of the total lesion area and/or that involves the fovea
- Any prior or concomitant treatment for CNV including (but not restricted to) IVT treatment (steroids, anti-VEGF, tissue plasminogen activator, ocriplasmin, C3F8 gas, air), periocular pharmacological intervention, argon laser photocoagulation, verteporfin photodynamic therapy, diode laser, transpupillary thermotherapy, or surgical intervention
- Cataract surgery within 3 months of baseline assessments
- Any other intraocular surgery (pars plana vitrectomy, glaucoma surgery, corneal transplant, radiotherapy)
- Prior IVT treatment (including anti-VEGF medication) except for management of cataract complication with steroid IVT treatment
- Prior periocular pharmacological intervention for other retinal diseases
- Any concurrent intraocular condition in the study eye (eg, amblyopia, aphakia, retinal detachment, cataract, diabetic retinopathy or maculopathy, or epiretinal membrane with traction) that, in the opinion of the investigator, could either reduce the potential for visual improvement or require medical or surgical intervention during the course of the study
- Active intraocular inflammation (grade trace or above) in the study eye on day 1 (before randomization)
- Current vitreous hemorrhage in the study eye
- Uncontrolled glaucoma (eg, progressive loss of visual fields or defined as IOP #25 mm Hg despite treatment with antiglaucoma medication) in the study eye
- Spherical equivalent of refractive error demonstrating more than 8 diopters of myopia in the study eye
- History of idiopathic or autoimmune-associated uveitis in either eye
- Active infectious conjunctivitis, keratitis, scleritis, or endophthalmitis in either eye on day 1 (before randomization)
- Any major illness or major surgical procedure within 1 month before screening
- Uncontrolled blood pressure (defined as systolic >180 mm Hg and/or diastolic >100 mm Hg while participant at rest). If a participant's initial reading exceeded these values, a second reading was taken later on the same day, or on another day during the screening period. If the participant's blood pressure was controlled by antihypertensive medication, the participant was taking the same medication continuously for at least 30 days before day 1
- Stroke or myocardial infarction within 3 months before day 1
- History of other disease, metabolic dysfunction, physical examination finding, or clinical laboratory findings giving reasonable suspicion of a condition that contraindicated the use of the investigational

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drug or that might affect interpretation of the results of the study or renders the participant at high risk for treatment complications in the opinion of the investigator
- Pregnant or breastfeeding, or intended to become pregnant during the study
- Known hypersensitivity to ranibizumab, fluorescein, any ingredients of the formulation used, dilating eye drops, or any of the anesthetic and antimicrobial drops used
- Treatment with investigational therapy within 3 months before initiation of study treatment

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