

Macular DegenerationAge-Related Macular Degeneration

Study of RO7250284 in Participants With Neovascular Age-Related Macular Degeneration

Trial Status Recruiting	Trial Runs In 2 Countries	Trial Identifier NCT04567303 BP41670
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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 Three-Part, Phase I/II Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Efficacy of Zifibancimig Following Intravitreal Administration of Multiple Ascending Doses and Continuous Delivery From the Port Delivery in Patients With Neovascular Age-Related Macular Degeneration

Trial Summary:

This is a first in-human study to investigate the safety, tolerability and efficacy of zifibancimig administered through intravitreal (IVT) injections and via the Port Delivery (PD) implant in participants with neovascular age-related macular degeneration (nAMD)

Hoffmann-La Roche Sponsor	Phase 1/Phase 2 Phase
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NCT04567303 BP41670
Trial Identifiers

Eligibility Criteria:

Gender All	Age #50 Years	Healthy Volunteers No
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Inclusion Criteria:

Part 1, Part 2 and Part 3 Inclusion Criteria:

- Willing to allow AH collection.

Part 1 and Part 2 Ocular Inclusion Criteria for Study Eye:

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- Choroidal neovascularization (CNV) exclusively due to age-related macular degeneration (AMD).
- Anti-vascular endothelial growth factor (VEGF) or anti-VEGF/Angiopoietin-2 (Ang-2) IVT treatment-naïve, or pre-treated with anti-VEGF or anti-VEGF/Ang-2 no less than two months prior to Day 1.
- Sufficiently clear ocular media and adequate pupillary dilatation to allow for analysis and grading by the central reading center of fundus photography (FP), fluorescein angiography (FA), fundus autofluorescence (FAF), and spectral domain optical coherence tomography (SD-OCT) images.
- Decreased BCVA attributable primarily to nAMD, with BCVA letter score of 78 to 34 letters (inclusive) on ETDRS-like charts at screening. In case both eyes of a participant are eligible, the eye with the lower BCVA score should become the study eye.

Part 3 Ocular Inclusion Criteria for Study Eye:

- CNV exclusively due to AMD.
- Diagnosis of nAMD within 36-months prior to the screening visit.
- Previous treatment with at least one IVT anti-VEGF or anti-VEGF/Ang-2 administrations IVT for nAMD. The last IVT administration must have occurred at least 21 days prior to the screening visit.
- Demonstrated response to prior IVT anti-VEGF or anti-VEGF/Ang-2 treatment since diagnosis.
- Availability of historical VA data prior to the first anti-VEGF or anti-VEGF/Ang-2 treatment for nAMD.
- Sufficiently clear ocular media and adequate pupillary dilatation to allow for analysis and grading.
- Decreased BCVA attributable primarily to nAMD with letter score of 78 to 34 letters (inclusive) or better on ETDRS-like charts.

Ocular Exclusion Criteria for Study Eye:

- History of vitrectomy surgery, submacular surgery, other intraocular surgery, or any planned surgical intervention during the study period.
- Cataract surgery without complications within three months preceding the screening visit or planned during the study period.
- Aphakia or absence of the posterior capsule. Previous violation of the posterior capsule is also an exclusion criterion, unless it occurred as a result of yttrium-aluminum garnet laser posterior capsulotomy in association with prior, posterior chamber intraocular lens implantation.
- Prior macular treatment with verteporfin, external beam radiation therapy, transpupillary thermotherapy, or any type of laser photocoagulation.
- Prior treatment with IVT corticosteroids or implant (e.g., triamcinolone, ozurdex, iluvien).
- Subretinal hemorrhage >50% of the total lesion area and/or involving the fovea.
- Subfoveal fibrosis or subfoveal atrophy.
- Retinal pigment epithelial tear involving the macula.
- History of vitreous hemorrhage, rhegmatogenous retinal detachment, glaucoma-filtering surgery, tube shunts, or microinvasive glaucoma surgery, and corneal transplant.
- History of rhegmatogenous retinal tears or peripheral retinal breaks within three months prior to the screening visit.
- Actual or history of myopia >-8 diopters.
- Uncontrolled ocular hypertension or glaucoma (defined as intraocular pressure (IOP) >25 millimeters of mercury (mm Hg) or a cup to disc ration >0.8, despite treatment with antiglaucoma medication) and any such condition the Investigator determines may require a glaucoma-filtering surgery during a participant's participation in the study.
- Concurrent intraocular conditions (e.g., cataract, diabetic retinopathy, epiretinal membrane with traction, macular hole) that, in the opinion of the Investigator, could either:
 - Require medical or surgical intervention during the study period to prevent or treat visual loss that might result from that condition; or
 - Likely contribute to loss of BCVA over the study period if allowed to progress untreated; or
 - Preclude any visual improvement due to substantial structural damage.

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- Concurrent conjunctival, Tenon's capsule, and/or scleral condition in the supero-temporal quadrant of the eye (e.g., scarring, thinning, mass) that may affect the implantation, subsequent tissue coverage, and refill-exchange procedure of the PD implant.
- Prior treatment with any medication for geographic atrophy during the last 3 months prior to screening.
- Prior treatment with any anti-VEGF-C or anti-VEGF-D inhibitors.

Exclusion Criteria:

Exclusion Criteria for Fellow Eye

- BCVA letter score using ETDRS charts of < 34 letters.
- Treatment with IVT anti-VEGF or anti-VEGF/Ang-2 agents within one week prior to Day 1 (concurrent treatment with SUSVIMOTM in the fellow eye is not exclusionary).

Exclusion Criteria for Either Eye

- CNV due to causes other than nAMD, such as ocular histoplasmosis, trauma, pathological myopia, angioid streaks, choroidal rupture, uveitis or central serous chorioretinopathy.
- Prior participation in a clinical trial involving anti-VEGF drugs within six months prior to the screening visit, other than ranibizumab, aflibercept, or faricimab including approved biosimilars.
- Active intraocular inflammation (grade trace or above), infectious conjunctivitis, keratitis, scleritis, or endophthalmitis.
- History of uveitis, including history of any intraocular inflammation following intravitreal therapy.
- Prior treatment with brolocizumab.
- Prior gene therapy for nAMD