ForPatients
by Roche

Neovascular Age-related Macular DegenerationWet Age-Related Macular Degeneration

A Study of the Efficacy, Safety, and Pharmacokinetics (PK) of the Port Delivery System With Ranibizumab (PDS) in Chinese Participants With Neovascular Age-related Macular Degeneration (nAMD)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	1 Country	NCT05562947 YR42983

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 Phase III, Multicenter, Randomized, Visual Assessor-masked, Active-comparator Study of the Efficacy, Safety, and Pharmacokinetics of the Port Delivery System With Ranibizumab in Chinese Patients With Neovascular Age-related Macular Degeneration

Trial Summary:

This study will evaluate the efficacy, safety, and PK of ranibizumab 100 milligrams per milliliter (mg/mL) delivered every 24 weeks (Q24W) via the PDS implant compared with ranibizumab 0.5 milligrams (mg) delivered every 4 weeks (Q4W) as intravitreal (IVT) injection in chinese participants with nAMD.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT05562947 YR42983
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#50 Years	No

Inclusion Criteria:

- Initial diagnosis of nAMD within 9 months prior to the screening visit

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- Previous treatment with at least three anti-vascular endothelial growth factor (VEGF) IVT injections for nAMD per standard of care within 6 months prior to the screening visit
- Demonstrated response to prior anti-VEGF IVT treatment since diagnosis
- Availability of historical VA data prior to the first anti-VEGF treatment for nAMD up to the screening visit
- BCVA of 34 letters or better (20/200 or better approximate Snellen equivalent), using Early Treatment Diabetic Retinopathy Study (ETDRS) chart at a starting distance of 4 meters
- All subtypes of nAMD lesions are permissible
- Sufficiently clear ocular media and adequate pupillary dilation to allow for analysis and grading by the central reading center of fundus photography (FP), fluorescein angiography (FA), indocyanine green angiography (ICGA), fundus autofluorescence (FAF), and optical coherence tomography (OCT) images

Exclusion Criteria:

A. Prior Ocular Treatment Study Eye

- History of vitrectomy surgery, submacular surgery, or other surgical intervention, all for AMD
- Prior treatment with Visudyne, external-beam radiation therapy, or transpupillary thermotherapy
- Previous treatment with corticosteroid IVT injection
- Previous intraocular device implantation (not including intraocular lens implants)
- Previous laser (any type) used for age-related macular degeneration (AMD) treatment
- Treatment with anti-VEGF agents other than ranibizumab within 1 month prior to the randomization visit
- Prior treatment with intravitreal treatments for geographic atrophy
- Concurrent conjunctival, Tenon's capsule, and/or scleral condition in the supero-temporal quadrant of the eye that may affect the implantation, subsequent tissue coverage, and refill-exchange procedure of the PDS implant

Either Eye

- Prior treatment with brolucizumab
- Prior gene therapy for nAMD or other ocular diseases
- Previous participation in any ocular disease studies of investigational drugs and/or devices, within 3 months or five elimination half-lives of the investigational therapy, whichever is longer, preceding the screening visit

B. Choroidal Neovascularization (CNV) Lesion Characteristics

Study Eye

- Subretinal hemorrhage that involves the center of the fovea, if the hemorrhage is greater than 0.5 disc area (1.27 millimeter square [mm^2]) in size at screening
- Subfoveal fibrosis or subfoveal atrophy

Either Eye • CNV due to other causes, such as ocular histoplasmosis, trauma, central serous chorio-retinopathy, or pathologic myopia

C. Concurrent Ocular Conditions Study Eye

- Retinal pigment epithelial tear
- Any concurrent intraocular condition
- Active intraocular inflammation (grade trace or above)
- History of vitreous hemorrhage

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- History of rhegmatogenous retinal detachment
- History of rhegmatogenous retinal tears or peripheral retinal breaks within 3 months prior to the randomization visit
- History of pars plana vitrectomy surgery
- Aphakia or absence of the posterior capsule
- Spherical equivalent of the refractive error demonstrating more than 8 diopters of myopia
- Preoperative refractive error that exceeds 8 diopters of myopia, for participants who have undergone prior refractive or cataract surgery
- Intraocular surgery (including cataract surgery) within 3 months preceding the randomization visit
- Uncontrolled ocular hypertension or glaucoma
- History of glaucoma-filtering surgery, tube shunts, or microinvasive glaucoma surgery
- History of corneal transplant

Fellow (Non-Study) Eye

• Non-functioning fellow eye

Either Eye

- Any history of uveitis
- Active infectious conjunctivitis, keratitis, scleritis, or endophthalmitis

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