ForPatients
by Roche

Wet Age-Related Macular Degeneration

A Study of 36-Week Refill Exchanges of Port Delivery System (PDS) With Ranibizumab in nAMD

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT06847542 2024-516924-32-00 MR45625

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 IIIb, Multicenter, Single-arm Study Assessing the Effectiveness, Safety and Patient Reported Outcomes of a 36-week Refill Exchange Regimen for the Port Delivery System With Ranibizumab in Patients With Neovascular Age-related Macular Degeneration

Trial Summary:

The purpose of this study is to evaluate the effectiveness, safety, and PROs of the port delivery system with ranibizumab 100 milligrams/milliliters (mg/mL) refilled every 36 weeks (Q36W) in participants with nAMD.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT06847542 2024-516924-32-00 MR45625
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#50 Years	No

Inclusion Criteria:

- Initial diagnosis of nAMD within 24 months prior to screening
- Previous treatment with at least 3 anti-vascular endothelial growth factor (VEGF) IVT injections for nAMD per standard of care within 6 months prior to screening
- Demonstrated response to prior anti-VEGF IVT treatment since diagnosis
- Availability of historical VA data obtained at or after nAMD diagnosis and prior to the first anti-VEGF treatment for nAMD

- Availability of historical OCT image data obtained at or after nAMD diagnosis and prior to the first anti-VEGF treatment for nAMD
- BCVA of 34 letters or better using ETDRS chart at a starting distance of 4 meters at screening and enrollment visits

Exclusion Criteria:

A. Prior Ocular Treatment

Study Eye:

- History of vitrectomy surgery, submacular surgery, or other surgical intervention for age-related macular degeneration (AMD)
- Previous treatment with corticosteroid intravitreal injection
- Previous intraocular device implantation
- History of vitreous hemorrhage
- History of rhegmatogenous retinal detachment
- History of glaucoma-filtering surgery, tube shunts, or microinvasive glaucoma surgery
- History of corneal transplant

Either Eye:

- History of a severe allergic reaction or anaphylactic reaction to a biologic agent or known hypersensitivity to any component of the ranibizumab injections, study-related procedure preparations (including fluorescein), dilating drops, or any of the anesthetic and antimicrobial preparations used by a participant during the study
- Prior participation in a clinical trial involving any experimental therapies for nAMD
- Prior treatment with brolucizumab or gene therapy for nAMD

B. Macular Neovascularization/Choroidal Neovascularization (MNV/CNV) Lesion Characteristics:

Study Eye:

- Subretinal hemorrhage that involves the center of the fovea
- Subfoveal fibrosis or subfoveal atrophy

Either Eye:

- CNV due to other causes, such as ocular histoplasmosis, trauma, central serous chorioretinopathy, or pathologic myopia
- CNV masquerading lesions

C. Concurrent Ocular Conditions:

Study Eye:

- Subfoveal and/or juxtafoveal retinal pigment epithelial tear
- Any concurrent intraocular condition that would either require surgical intervention during the study to prevent or treat visual loss that might result from that condition or affect interpretation of study results

- Active intraocular inflammation
- Retinal tears or peripheral retinal breaks on depressed fundus exam that are untreated or treated within 3 months prior to the enrollment visit
- Aphakia or absence of the posterior capsule
- Uncontrolled ocular hypertension or glaucoma
- History or presence of severe posterior blepharitis, recurrent chalazia or hordeolum, severe dry eye syndrome, or severe allergic conjunctivitis
- Trichiasis
- Corneal neuropathy
- Lagophthalmos or incomplete blink
- Active or history of facial nerve palsy/paresis

Fellow (Non-study) Eye:

- Non-functioning non-study eye defined as either: BCVA of hand motion or worse OR no physical presence of non-study eye (i.e., monocular)

Either Eye:

- Any active or history of uveitis
- Active or history of keratitis, scleritis, endophthalmitis, or chronic blepharitis
- Suspected or active ocular or periocular infectious conjunctivitis or endophthalmitis
- Active or history of floppy eyelid syndrome
- Active thyroid eye disease

D. Concurrent Systemic Conditions:

- Uncontrolled blood pressure
- Active or history of autoimmune diseases
- History of stroke within the last 3 months prior to informed consent
- Atrial fibrillation diagnosed or worsened within the last 3 months prior to informed consent
- History of myocardial infarction (MI) within the last 3 months prior to informed consent
- Confirmed active systemic infection
- History of other disease, metabolic dysfunction, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of ranibizumab or placement of the implant and that might affect interpretation of the results of the study
- Use of any systemic anti-VEGF agents
- Chronic use of oral corticosteroids
- Active cancer within 12 months of enrollment except for appropriately treated carcinoma in situ of the cervix, non-melanoma skin carcinoma, and prostate cancer