ForPatients
by Roche

Macular DegenerationAge-Related Macular Degeneration

Study of the Efficacy and Safety of the Ranibizumab Port Delivery System for Sustained Delivery of Ranibizumab in Patients With Subfoveal Neovascular Age-Related Macular Degeneration (LADDER)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT02510794 GX28228

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:

A Phase II, Multicenter, Randomized, Active Treatment-Controlled Study of the Efficacy and Safety of the Ranibizumab Port Delivery System for Sustained Delivery of Ranibizumab in Patients With Subfoveal Neovascular Age-Related Macular Degeneration

Trial Summary:

This is a Phase II multicenter, dose-ranging, randomized, active treatment (monthly ITV injection)-controlled study to evaluate the efficacy, safety, and pharmacokinetics of ranibizumab delivered through the Implant using three ranibizumab formulation arms (10 mg/mL, 40 mg/mL, and 100 mg/mL) compared with the control arm (0.5-mg monthly ITV injections of 10-mg/mL formulation) in participants with subfoveal neovascular age-related macular degeneration (nAMD).

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT02510794 GX28228
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#50 Years	No

Inclusion Criteria:

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- Newly diagnosed with wet AMD within 9 months of screening visit
- Participant must have received at least 2 prior ITV anti-vascular endothelial growth factor (VEGF) injections. However, the most recent anti-VEGF injection must have been ranibizumab and must have occurred at least 7 days prior to the screening visit
- Demonstrated response to prior ITV anti-VEGF treatment
- Best Corrected Visual Acuity (BCVA) using Early Treatment Diabetic Retinopathy Study (ETDRS) charts of 20/20-20/200 Snellen equivalent

Exclusion Criteria:

- Treatment with ITV anti-VEGF agents other than ranibizumab within 1 month prior to the randomization visit in either eye
- Study eye treatment with ITV anti-VEGF agents other than ranibizumab within 1 month prior to the randomization visit
- History of laser photocoagulation, Visudyne®, ITV corticosteroid injection, vitrectomy surgery, submacular surgery, device implantation, or other surgical intervention for AMD in the study eye
- Prior participation in a clinical trial involving anti-angiogenic drugs, other than ranibizumab, in either eye within 2 months of the randomization visit
- Subretinal hemorrhage in the study eye that involves the center of the fovea
- Subfoveal fibrosis, or atrophy in the study eye
- Choroidal neovascularization (CNV) in either eye due to other causes, such as ocular histoplasmosis, trauma, or pathologic myopia
- Uncontrolled ocular hypertension or glaucoma in the study eye
- History of glaucoma-filtering surgery, tube shunts, or microinvasive glaucoma surgery in the study eye
- Uncontrolled blood pressure
- Uncontrolled atrial fibrillation within 3 months of informed consent
- History of myocardial infarction or stroke within the last 3 months prior to informed consent
- History of other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding giving reasonable suspicion of a disease or condition that contraindicates the use of ranibizumab or placement of the Implant, that might affect interpretation of the results of the study or renders the participant at high risk of treatment complications
- Use of oral corticosteroids
- Current treatment for any active systemic infection
- Use of anticoagulants, anti-platelets (other than aspirin), or medications known to exert similar effects
- Active malignancy within 12 months of randomization
- History of allergy to fluorescein
- Previous participation in any non-ocular (systemic) disease studies of investigational drugs within 1 month preceding the informed consent (excluding vitamins and minerals)

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