ForPatients
by Roche

Geographic Atrophy

A Study to Optimize Subretinal Surgical Delivery and to Evaluate Safety and Activity of Opregen in Participants With Geographic Atrophy Secondary to Age-Related Macular Degeneration (GAlette)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	2 Countries	NCT05626114 GR44251

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 IIa, Multicenter, Open-label, Single-Arm Study to Optimize Subretinal Surgical Delivery and to Evaluate Safety and Activity of Opregen in Patients With Geographic Atrophy Secondary to Age-Related Macular Degeneration

Trial Summary:

This study will evaluate the success and safety of subretinal surgical delivery as well as the preliminary activity of OpRegen in participants with geographic atrophy (GA) secondary to age-related macular degeneration (AMD). All endpoints are assessed for the study eye unless otherwise indicated. The substudy will evaluate the operational feasibility and scientific interpretability of incorporating AO retinal imaging using the EarlySight Cellularis® Discovery device. Participants who have fulfilled the eligibility requirements for the parent study and meet the substudy's eligibility criteria will have the option to participate in the substudy. The EarlySight Cellularis® Discovery device will be used only as an assessment tool and data obtained from this device will not be used to guide clinical care or influence clinical outcomes for participants.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT05626114 GR44251
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#50 Years	No

Inclusion Criteria:

- Ability to undergo a vitreoretinal surgical procedure under monitored anesthesia care
- Diagnosis of GA secondary to AMD
- Best corrected visual acuity (BCVA) score # 29 letters and # 60 letters in the study eye as assessed by Early Treatment Diabetic Retinopathy Study (ETDRS)
- Pseudophakic (study eye)
- Participants must meet all of the inclusion criteria described in the parent study GR44251 and have the ability to comply with the substudy protocol

Exclusion Criteria:

- Pregnancy or breastfeeding
- History of cognitive impairment or dementia
- Any type of systemic disease or its treatment, in the opinion of the investigator, including any medical conditions that could be expected to progress, recur, or change to such an extent that it may bias the assessment of the clinical status of the participant to a significant degree or put the participant at special risk

Ocular Exclusion Criteria for Study Eye:

- Any current or history of ocular disease other than GA that may confound assessment of the macula
- History of retinal detachment
- History of vitrectomy, glaucoma-filtering surgery, or corneal transplant
- Uncontrolled glaucoma or advanced glaucoma
- Any cataract surgery or intraocular surgery within 3 months prior to subretinal surgical delivery of OpRegen
- History of other ocular or intraocular conditions that contraindicate the use of an investigational drug or may affect interpretation of the study results or may render the participant at high risk for treatment complications
- Any existing posterior segment device or implant

Substudy:

- Participants who meet any exclusion criteria listed in the parent study GR44251
- Past history of seizures, or epileptic seizures due to any cause except for a single febrile seizure in childhood