

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
Recruiting

Trial Runs In
2 Countries

Trial Identifier
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

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT05626114 GR44251
Trial Identifiers

Eligibility Criteria:

Gender
All

Age
#50 Years

Healthy Volunteers
No

Inclusion Criteria:

- Ability to undergo a vitreoretinal surgical procedure under monitored anesthesia care
- Diagnosis of GA secondary to AMD
- BCVA score $\geq$ 29 letters and $\leq$ 60 letters in the study eye as assessed by ETDRS

- Pseudophakic (study eye)

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