ForPatients
by Roche

Macular DegenerationGeographic AtrophyAge-Related Macular Degeneration

The long-term study of a new medicine (galegenimab) in people with a type of eye disease (geographic atrophy secondary to age-related macular degeneration)

A Study Assessing the Long-Term Safety and Tolerability of RG6147 in Participants With Geographic Atrophy Secondary to Age-Related Macular Degeneration

Trial Status	Trial Runs In	Trial Identifier
Terminated	1 Country	NCT04607148 GR42558

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 Multicenter, Open-Label Extension Study to Evaluate the Long-Term Safety and Tolerability of Intravitreal Injections of FHTR2163 in Patients With Geographic Atrophy Secondary to Age-Related Macular Degeneration

Trial Summary:

This clinical trial investigated a new medicine called “galegenimab.” People with a type of eye disease, “geographic atrophy secondary to age-related macular degeneration,” joined this study to find out if galegenimab treatments were safe and tolerable when given over a long time. Injections were given in the study eye, once every 4 or 8 weeks. The study treatment was planned for about 3 years. People underwent detailed eye examinations throughout the study. They were monitored for side effects, taking into consideration their nature, frequency, and severity.

Genentech, Inc. (A part of F. Hoffmann-La Roche Ltd., Switzerland)	Phase 2
Sponsor	Phase

NCT04607148 GR42558
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#60 Years	No

Inclusion Criteria:

- Completed the parent study (NCT03972709/GR40973) through the Week 76 visit without early treatment discontinuation
- Sufficiently clear ocular media, adequate pupillary dilation, and fixation to permit acceptable fundus imaging.

Ocular Inclusion Criteria: Study Eye - If the study eye best corrected visual acuity (BCVA) letter score is #69 letters (Snellen equivalent of 20/40 or better), the non-study eye must have a BCVA letter score of #44 letters (Snellen equivalent of 20/125 or better) on visit Day 1 of the open label extension (OLE)/Week 76 of parent study.

Ocular Inclusion Criteria: Non-Study Eye

- The non-study eye must have a BCVA letter score of #44 letters (Snellen equivalent of 20/125 or better) if the study eye BCVA letter score is #69 letters (Snellen equivalent of 20/40 or better) on visit Day 1 OLE/Week 76 of parent study.

Exclusion Criteria:

Ocular Exclusion Criteria:

- Active uveitis and/or vitritis (grade trace or above) in either eye
- Active, infectious conjunctivitis, keratitis, scleritis, or endophthalmitis in either eye
- Active or history of choroidal neovascularization (CNV) in study eye that requires anti-vascular endothelial growth factor (anti-VEGF) treatment
- Active or recent history (i.e., since enrollment in parent study) of optic neuritis in either eye
- Retinal pigment epithelium (RPE) tear that involves the macula in either eye
- Moderate or severe non-proliferative diabetic retinopathy in either eye
- Proliferative diabetic retinopathy in either eye
- Central serous retinopathy in either eye
- Recent history of recurrent infectious or inflammatory ocular disease in either eye
- Recent history of idiopathic or autoimmune-associated uveitis in either eye
- Any concurrent ocular or intraocular condition in the study eye that contraindicates 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.