ForPatients
by Roche

Geographic AtrophyAge-Related Macular Degeneration

A Study to Investigate Safety, Tolerability, Pharmacokinetics (PK), Pharmacodynamics (PD), and Immunogenicity of RO7669330 in Participants With Geographic Atrophy (GA) Secondary to Age-related Macular Degeneration (AMD)

Trial Status	Trial Runs In	Trial Identifier
Not yet recruiting		NCT06961370 BP45482

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 I, Multi-center, Multi-part Study to Investigate Safety, Tolerability, PK, PD, and Immunogenicity of RO7669330 Intravitreal Injections in Participants With GA Secondary to AMD: Part 1A: Open-label, MAD; Part 1B: Randomized PD Pilot; Part 2: Masked, Randomized, Active-comparator-controlled

Trial Summary:

The main purpose of this study is to assess the ocular and systemic safety and tolerability of RO7669330 in GA secondary to AMD after multiple unilateral intravitreal (IVT) doses.

Hoffmann-La Roche Sponsor	**Phase 1** Phase

NCT06961370 BP45482
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#55 Years	No

Inclusion Criteria:

- Adequately clear ocular media, adequate pupillary dilation, and fixation to allow acquisition of good quality fundus imaging
- GA that resides completely within the fundus autofluorescence (FAF) imaging field
- Presence of hyperautofluorescence of either banded or diffuse pattern adjacent to the GA area on FAF

- Study eye has early treatment of diabetic retinopathy study (ETDRS) best-corrected visual acuity (BCVA) score as follows:
- Part 1A: 19 to 48 letters inclusively
- Part 1B: > 19 letters
- Part 2: # 24 letters
- Total GA lesion size must be as follows:
- Parts 1A and 1B: # 1.25 square millimeter (mm^2) and # 17.5 mm^2)
- Part 2: # 2.5 mm^2 and # 17.5 mm^2

Exclusion Criteria:

Ocular Exclusion Criteria for the Study Eye:

- Aphakic or pseudophakic with intraocular lens outside of the capsular bag
- Previous laser photocoagulation or IVT anti-vascular endothelial growth factor (VEGF) for CNV, diabetic macular edema (DME), retinal vein occlusion (RVO), or proliferative diabetic retinopathy

Ocular Exclusion Criteria for the Non-Study Eye:

- Non-functioning non-study eye, defined as either: BCVA of hand motion or worse and/or no physical presence of eye

Ocular Exclusion Criteria for Both Eyes:

- Macular atrophy in either eye due to causes other than AMD
- Evidence of prior or active CNV
- Prior treatment with any approved therapy for GA (Syfovre, Izervay) in either eye for Part 1A and Part 2. For Part 1B, prior treatment with any approved therapy for GA (Syfovre, Izervay) in the study eye # 20 weeks prior to Day 1