ForPatients
by Roche

Age-Related Macular DegenerationChoroidal neovascularization

A Proof-of-Concept Study of Faricimab (RO6867461) in Participants With Choroidal Neovascularization (CNV) Secondary to Age#Related Macular Degeneration (AMD) (AVENUE)

A Proof-of-Concept Study of Faricimab (RO6867461) in Participants With Choroidal Neovascularization (CNV) Secondary to Age-Related Macular Degeneration (AMD)

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT02484690 BP29647

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 Multiple-Center, Multiple-Dose and Regimen, Randomized, Active Comparator Controlled, Double-Masked, Parallel Group, 36 Week Study to Investigate the Safety, Tolerability, Pharmacokinetics, and Efficacy of RO6867461 Administered Intravitreally in Patients With Choroidal Neovascularization Secondary to Age-Related Macular Degeneration

Trial Summary:

This multiple-center, multiple-dose and regimen, randomized, double-masked active comparator-controlled, double-masked, five parallel group, 36-week study will evaluate the efficacy, safety, tolerability, and pharmacokinetics of faricimab (RO6867461) in participants with choroidal neovascularization (CNV) secondary to age-related macular degeneration (AMD). The study was designed to allow the evaluation of RO6867461 in a treatment-naive population (comparison of Arms A, B, C, and D) and an anti-VEGF-incomplete responder population that met a predefined criterion at Week 12 (comparison between Arms A and E). Only one eye per participant was chosen as the study eye.

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT02484690 BP29647
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers

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All	#50 Years	No

Inclusion Criteria:

- Treatment-naive with CNV secondary to AMD, with subfoveal CNV or juxtafoveal CNV with a subfoveal component related to the CNV activity by FFA or SD-OCT
- Active CNV

Exclusion Criteria:

- CNV due to causes other than AMD
- Subretinal hemorrhage, fibrosis, or atrophy involving either the fovea or more than 50% of the total lesion area
- Cataract surgery within 3 months of baseline, or any other previous intraocular surgery
- Major illness or surgery within 1 month prior to Screening
- Glycosylated hemoglobin (HbA1c) above 7.5%
- Uncontrolled blood pressure