

A Safety and Efficacy Study of a One-time Intravitreal Injection of SAR446597 in Participants With Geographic Atrophy Secondary to Age-related Macular Degeneration

NCT07215234

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Sanofi
Enrollment	104 participants

Key Eligibility Criteria

Inclusion (4)

- years old or above
- Participants with diagnosis of GA secondary to age-related macular degeneration (AMD)
- Study eye with best corrected visual acuity (BCVA) ETDRS Snellen equivalent for dose escalation (Part I) between 20/40 and 20/320 and for expansion (Part II) equal or better than 20/200
- Study eye with GA lesion measuring between 2.5 and 17.5 mm² for dose escalation (Part I) and between 2.5 and 14.0 mm² for expansion (Part II). For multifocal disease, study eye with at least one single lesion of more than 1.25mm² for both Part I and Part II

Exclusion (13)

- GA in the study eye caused by a disease different than AMD
 - Presence of neovascularization or a history of treatment with an anti vascular endothelial growth factor agent in the study eye
 - Any condition or treatment (ocular or systemic) or medical or surgical history in the study eye that may prevent visual acuity improvement or interfere with ocular safety or efficacy assessments
 - Current or history of systemic complement targeting treatment in the past 12 months
 - Use of ocular corticosteroids for 4 months (for ocular or periocular injections), 6 months (for intraocular implants) or 3 years (for long lasting intraocular implants) prior to screening in the study eye
- ... and 8 more (see full listing online)

Locations (13 total)

Associated Retina Consultants - Peoria- Site Number : 8400011, Peoria, Arizona, United States
Retina Macula Institute of Arizona- Site Number : 8400028, Scottsdale, Arizona, United States
Vitreous Retinal Associates - Gainesville- Site Number : 8400004, Gainesville, Florida, United States
... and 10 more locations