Study to Evaluate Efficacy and Safety of ONL1204 in Patients With GA Associated With AMD

NCT06659445

Status	RECRUITING
Phase	Phase 2
Sponsor	ONL Therapeutics
Enrollment	324 participants

Key Eligibility Criteria

Inclusion (16)

- years of age or older at Screening.
- Able and willing to give informed consent and attend study visits.
- Women or intersex individuals must be willing to use 2 forms of effective contraception during the study and for at least 90 days following the last dose of study drug, be postmenopausal for at least 12 months prior to study entry, or surgically sterile. If of childbearing potential, a negative urine pregnancy test is required at Screening and prior to the administration of study drug at each visit.
- Men or intersex individuals with partners of childbearing potential must be willing to use permissible methods of contraception and refrain from sperm donation during the study and for at least 90 days following the last dose of study drug.
- If currently using Age-related Eye Disease Study 2 (AREDS, AREDS2, or similar nutraceutical therapy at Screening, patient must be willing to continue use for the duration of the study. If not currently using AREDS2 or similar, patient must be willing to continue not to use therapy for the duration of the study. Patient must agree to choose either approach.

... and 11 more (see full listing online)

Exclusion (25)

- Current or planned participation in another investigational clinical study or use of any other investigational drugs or devices at least 6 months prior to enrollment or during the study period without prior written Sponsor approval.
- Previous ophthalmic disease gene therapy or planned participation in any gene therapy clinical study during the study period.
- Current or planned use of systemic complement inhibitors during the study period.
- Any ocular or systemic condition that, in the opinion of the Investigator, makes the patient unsuitable for treatment with an investigational drug or that would compromise the safety or efficacy assessments of the study.
- Treatment with any ocular or systemic medication that is known to be toxic to the lens, retina, or optic nerve (including, but not limited to, aminoglycosides, vancomycin, hydroxychloroquine, interferon, tacrolimus, cisplatin, bis-chloroethyl nitrosourea, carmustine, ethambutol, and tamoxifen) within 90 days prior to Screening or anticipated during the study period.

... and 20 more (see full listing online)

Locations (28 total)

Associated Retina Consultants, Gilbert, Arizona, United States
Associated Retina Consultants, Phoenix, Arizona, United States
Doheny Image Reading Center, Pasadena, California, United States
... and 25 more locations

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