Efficacy and Safety Study of Ixoberogene Soroparvovec (Ixo-vec) in Participants With Neovascular Age-related Macular Degeneration (AQUARIUS)

NCT07482176

Status	RECRUITING
Phase	Phase 3
Sponsor	Adverum Biotechnologies, Inc.
Enrollment	284 participants

Key Eligibility Criteria

Inclusion (6)

- Able and willing to provide informed consent (or have a legally authorized representative who is able and willing to provide informed consent) prior to any study assessments and procedures and comply with the study requirements and visits.
- Male or female with a diagnosis of CNV secondary to nAMD in the study eye, with nAMD disease activity at Screening Visit 1.
- At least 50 years old at Screening Visit 1.
- An ETDRS BCVA letter score of 35 - 78 (approximate Snellen equivalent of 20/200 to 20/32) in the study eye at Screening Visit 1.
- Demonstrated a meaningful anatomic response to anti-VEGF therapy during screening.

... and 1 more (see full listing online)

Exclusion (27)

- History of a medical condition giving reasonable suspicion of a condition that contraindicates the use of Ixo-vec, compromises the participant's ability to comply with the planned study activities, or that might affect the interpretation of the results of the study or render the participant at high risk for treatment complications in the opinion of the Investigator. History of severe coronavirus disease (COVID-19) infection may meet this exclusion criterion if, in the opinion of the Investigator, it is likely to lead to any important complications.
- Received any prior gene therapy.
- Prior treatment with any non-gene therapy investigational medicinal product (IMP) or medical device in the study eye within 3 months of Screening Visit 1 or 5 half-lives of the IMP prior to dosing with Ixo-vec, whichever is longer.
- Female participants who are pregnant or breastfeeding or who intend to become pregnant or breastfeed in the future.
- History or evidence of any of the following cardiovascular diseases:

... and 22 more (see full listing online)

Locations (2 total)

Adverum Clinical Site 231, The Woodlands, Texas, United States
Adverum Clinical Site 199, Lynchburg, Virginia, United States