

FOR IMMEDIATE RELEASE

OcuDyne Announces Positive Results for the OPTiC System[™] 6-Month Clinical Trial in the Treatment of Geographic Atrophy

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OcuDyne, Inc, a medical device company employing a novel approach to the treatment of ocular disease, announced today successful completion of a pilot study using the proprietary OPTiC System in the treatment of Age-Related Macular Degeneration (AMD).

- Procedural feasibility of ophthalmic artery angioplasty in the treatment of vascular lesions associated with geographic atrophy has been demonstrated, with a positive safety profile.
- Secondary and exploratory endpoints associated with subjective and objective evidence of visual function preservation at 6 months, has been demonstrated.

Interim data from this clinical trial were accepted and presented at the annual Association for Research in Vision and Ophthalmology (ARVO) meeting in Seattle, WA in May 2024. Final data is now available, is supporting a pivotal trial application in Argentina, and will be presented to the FDA as conversations with the Agency continue.

Safety

- All ocular adverse events with procedural causality were transient and resolved without treatment or sequalae.
- All systemic adverse events with procedural causality were expected potential events, treated, and resolved without sequalae.
- There were no device related adverse events reported.

Effectiveness

Subjective evidence of visual function improvement was demonstrated in Best-Corrected Visual Acuity, MNRead Acuity, Critical Print Size, and Reading Speed, as well as Patient Reported Outcomes associated with Mobility and Independence and Reading and Accessing Information. Objective evidence of visual function preservation and increased choroidal perfusion were demonstrated in growth inhibition of geographic atrophy and postoperative increase in sub-foveal choroidal thickness, respectively.

"The completion of this trial is the culmination of a decade of focused scientific research into perfusion of the retina and how it affects macular function. We are very excited with the trial results and how these data support the OcuDyne hypothesis. Our next focus will be the development of additional data to support a pathway for regulatory approval." Jeff Franco, CEO.

About Chronic Ischemic AMD and OcuDyne

The potential influence of a chronic ischemic environment secondary to atherosclerotic vascular disease in the ophthalmic artery, on the development of geographic atrophy in age-related macular degeneration, is beginning to be more widely recognized and understood. AMD is a complex disease that includes genetic, life style, and environmental influences. Ischemia has long been understood to cause hypoxia and hypoxia is known to be present in retinal atrophy. OcuDyne, Inc. is a clinical stage company dedicated to exploring the potential causative implications of cardiovascular disease on AMD and treating this disease with cardiovascular therapies.

Investor Relations Contact

Jeff Franco, CEO jfranco@ocudyne.com