

## **Notal Vision Reports Publication of First U.S. Home OCT Study Results**

*Digital health service targets remote monitoring of disease activity in wet AMD patients*

Manassas, VA (March 8th, 2022) – Digital healthcare provider Notal Vision today announced that results of the first U.S.-based study with its investigational home-based optical coherence tomography (OCT) platform have been published in *Ophthalmology Retina*<sup>1</sup>. The Notal Home OCT pipeline technology is designed to provide patient-initiated retinal OCT scans to support the management of patients with wet age-related macular degeneration (AMD), complementing existing standard of care treatments as well as emerging longer acting drugs and drug delivery systems.

Investigators from Ophthalmic Consultants of Boston and Pepose Vision Institute in St. Louis report findings comparing patient self-operated Notal Home OCT using proprietary Notal OCT Analyzer (NOA™) artificial intelligence (AI), with the standard of care in-office OCT analyzed by retina specialists. The investigators found over 95% agreement when comparing retinal fluid detection capability, a primary marker for treatment guidance, between Notal Home OCT and in-office OCT.

The results are highly significant for management of patients suffering from wet AMD, the leading cause of blindness in the United States. Several wet-AMD treatments have been developed over the last 2 decades. However, they require frequent visits by the patients to the physicians for assessment of the fluid status, placing a huge burden on physicians, patients and caregivers, which has limited the real-world efficacy of these treatments.



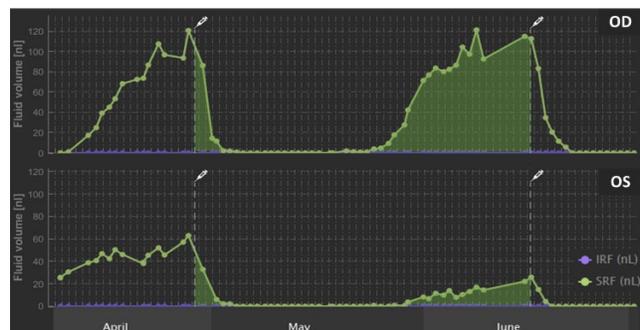
“Insights of disease dynamics and treatment response gained from AI-based analysis of up to daily home OCT images provide new opportunities for personalized treatment and potentially better outcomes” said Jeffrey S. Heier, MD, one of the study’s principal investigators and director of the retinal service and retinal research at Ophthalmic Consultants of Boston. “Remote monitoring services can help retina specialists extend care to patients’ homes and provide timely treatment in the office as needed.”

The study evaluated the ability of subjects with AMD to perform sequential daily self-imaging of their eyes for three months. The cohort included 15 patients and 29 eyes demonstrating 95% successful completion rate over approximately 2500 scans performed. Each scan took less than 40 seconds per eye

to complete. Following self-setup at home, subjects used the device an average of 5.7 days per week, and a median of one scan reminder call was provided by the patient engagement and compliance monitoring service of the Notal Vision Monitoring Center, future medical provider of the Notal Home OCT program. In addition, patients responded positively 97% of times in the survey regarding ease of use and convenience of daily imaging.

“The consistency of achieving high image quality was amazing considering the patient self-operation of the device”, said Nancy M. Holekamp, MD, co-principal investigator of the study and director of retina services at Pepose Vision Institute. “The ease-of-use of the Home OCT stands out recognizing that trained staff is usually needed to acquire such images in an office setting.”

Built in cellular connectivity allowed automatic transmission of Home OCT images to the digital healthcare providers’ secure cloud for analysis and remote physician review. Novel fluid volume trajectories gave deep insights to the heterogeneity of disease dynamics and treatment response. In some cases, pre-



scheduled treat-and-extend office visits exposed the retina to reoccurring or persistent fluid over an extended period. These findings confirmed the need for an alert mechanism based on physician defined eye-specific fluid volume thresholds, which is currently under development. Moreover, the parametric description of fluid volume trajectories that was reported from the study may support disease and treatment response classification.

"The excellent performance of our Home OCT platform in the first U.S. study supports the goals set for the ongoing regulatory trials towards FDA clearance," said Kester Nahen, PhD, CEO of Notal Vision, Inc. "We would like to thank Genentech, a member of the Roche group, for their financial support of the study."

Notal Vision’s home-based OCT pipeline technology received FDA Breakthrough Device designation and is in the process of obtaining FDA clearance. In January 2020 the American Medical Association established three category III Current Procedural Terminology (CPT®) codes for reporting patient-initiated remote retinal OCT scans, facilitated by Notal Vision’s home-based OCT. The physician review,

interpretation and documentation of AI-based analyses will be billable every 30 days.

Reference:

1. Liu Y., Holekamp N.M. & Heier J.S., Prospective, longitudinal study: daily self-imaging with home OCT in neovascular age-related macular degeneration, *Ophthalmology Retina* (2022), doi: <https://doi.org/10.1016/j.oret.2022.02.011>

**About Notal Vision**

Notal Vision is a remote monitoring services company that operates the Notal Vision Monitoring Center, a medical provider with a proven platform for engaging patients and AI-enabled analyses of high-volume personalized health data that extends disease management from the clinic to the home to improve vision outcomes, reduce treatment burden, and improve health economics. [www.notalvision.com](http://www.notalvision.com)

The ForeseeHome® AMD Monitoring Program is a comprehensive platform, which includes an FDA-cleared device that monitors visual changes in intermediate dry AMD patients at risk of vision loss from undiagnosed wet AMD. The clinical utility for ForeseeHome was established in the Home Monitoring of The Eye (HOME) Study, part of the National Eye Institute-sponsored AREDS2 study, in which 94% of patients using ForeseeHome twice weekly who progressed to wet AMD, maintained 20/40 or better vision compared to only 62% of patients in a control arm whose diagnosis was at a routine eye exam, or a visit triggered by symptoms. Based upon the robust level-1 evidence and compelling clinical outcomes demonstrating the ability to detect choroidal neovascularization (CNV) earlier, the ForeseeHome AMD Monitoring Program gained Medicare coverage in 2016. To learn more, visit [www.foreseehome.com](http://www.foreseehome.com).

Notal Vision's Home OCT system will enable wet AMD patients to perform technician-free OCT testing at home with rapid and self-guided fixation – critical components, especially for elderly patients frequently with pre-existing vision loss. The Notal OCT Analyzer (NOA™), a proprietary deep learning algorithm, developed in-house, performs automated analysis of the Home OCT scans and generates a report to the physician when a physician specified change in disease activity is detected. The Notal Vision Diagnostic Clinic provides referring physicians patient data via an online portal. In addition, physicians will be provided 24/7 access to all of their patients' B-scan images from each Home OCT test with the location of the fluid annotated on each B-scan. Following physician receipt of an alert report,

patients may be brought to the office for evaluation and treatment at the doctor's discretion. NOA can also analyze the output of other commercial OCT devices, and published study data indicate that the performance of NOA in detecting disease activity was similar to that of retina physicians when each was compared to a panel of experts. Notal Vision's Home OCT has the potential to support current and future advances in retinal disease management.