



## **Notal Vision Launches First U.S. Home OCT Longitudinal Study with Patient Self-operated Device**

*The technology is designed to support retina specialists and help monitor disease activity remotely in wet AMD patients*

Manassas, VA (January 12, 2021) – Notal Vision, Inc. announced today that the company initiated the first US-based study using its investigational home-based optical coherence tomography (OCT) platform. The study will evaluate the ability of subjects with wet age-related macular degeneration (AMD) to perform sequential daily self-imaging of their eyes with the user-friendly, self-operated Notal Home OCT device in their homes. The Home OCT pipeline technology is designed to provide patient-initiated retinal OCT scans to support the management of patients with wet AMD, complementing existing standard of care treatments as well as emerging longer acting drugs and drug delivery systems.

“Remote OCT monitoring of wet AMD patients has the potential to personalize anti-VEGF treatment and improve outcomes while minimizing treatment burden by reducing the number of office visits,” said Jeffrey S. Heier, MD, one of the study’s principal investigators and co-president and medical director of Ophthalmic Consultants of Boston. “The importance and potential benefit of such an approach is even more important now in light of the COVID-19 pandemic.”

Led by Dr. Heier and Nancy Holekamp, MD, of the Pepose Vision Institute, the longitudinal study will remotely monitor 15 wet AMD patients receiving standard of care anti-VEGF therapy for 90 days to track the presence of retinal fluid, which may require a change in treatment regimen. Data from the Home OCT device will be automatically transmitted via a built-in cellular modem to the secure Notal Health Cloud, where the AI-based Notal OCT Analyzer (NOA™) will identify and quantify intra- and subretinal fluid from each daily OCT volume scan. The analyzer will also apply novel metrics and associated terminology that characterize the spatial and temporal dynamics of retinal fluid describing the disease burden. Study investigators will have remote access to the Notal Home OCT images through a web viewer, an interactive interface that displays patient testing information. The Notal Vision Diagnostic Clinic, future provider of the Home OCT program, will monitor patient compliance with the self-imaging schedule and provide remote support as needed. The study is being partially funded by Genentech, a member of the Roche Group.

“The start of the first US study marks a key milestone for our Home OCT program,” said Kester Nahen, PhD, CEO of Notal Vision, Inc. “We are excited about support from Genentech given its storied history in ophthalmology and commitment to integrating digital technologies into the care paradigm to make personalized healthcare a reality for patients”.

Notal Vision’s home-based OCT pipeline technology received FDA Breakthrough Device designation at the end of 2018, 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. Results from a clinic-based trial using the final form factor of the Home OCT presented earlier this year showed that the areas of fluid seen on the system’s intra- and subretinal fluid thickness maps correlated with the locations of abnormal vessels seen on OCT angiography, as well as leakage areas on fluorescein angiography, demonstrating the technology’s ability to track disease status. In the same study 90% of

wet AMD patients self-imaged successfully on the Home OCT device demonstrating the ease of use in an elderly patient population. The image quality was shown to be sufficient for a human grader to identify fluid in one of three consecutive tests with a sensitivity and specificity of 97% and 95%, respectively.

### **About Notal Vision**

Notal Vision is a diagnostic services company that operates the Notal Vision Diagnostic Clinic, 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 an FDA-cleared diagnostic 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 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 machine 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.

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