



Home OCT longitudinal home-based study with patient self-operated device has begun

Treating retina specialists monitor disease activity remotely in wet age-related macular degeneration patients

Manassas, VA (June 18, 2020) – Notal Vision is proud to announce the enrollment of patients in the first longitudinal home-based study with its investigational home optical coherence tomography (OCT) remote monitoring device. The study will explore the daily dynamics of retinal fluid in patients receiving anti-VEGF treatment for wet age-related macular degeneration (AMD). The Home OCT System pipeline technology is designed to provide home-based, 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.

“The study is an important milestone for our Home OCT pipeline program,” said Kester Nahen, PhD, CEO of Notal Vision. “We look forward to expanding the remote patient monitoring services our Notal Vision Diagnostic Clinic provides to referring physicians. Home OCT is designed to be part of the next step in an AMD patient’s journey after ForeseeHome, which monitors patients with intermediate dry AMD at risk of converting to wet.”

The study will include up to 15 wet AMD patients recruited by two medical centers in Tel Aviv, Israel – Tel Aviv Medical Center and Assuta HaShalom. Patients participating in the study will perform a daily scan of their eye(s) for one month with the easy-to-use home-based device, which captures dense OCT volume scans of the macula. OCT scans will be automatically uploaded to the Notal Health Cloud, a secure cloud-based system used to process, store, and manage data. OCT images will then be reviewed remotely by study investigators through the system’s Web Viewer, an interactive interface that displays patients’ testing information over time.



“Home OCT will provide treating physicians with inter-visit disease knowledge and help us reduce the treatment and monitoring burden on patients and their caregivers” said Anat Loewenstein, MD, the study’s principal investigator and the Director of the Department of Ophthalmology at Tel Aviv Medical Center. “Daily monitoring of disease activity will aid retina specialists in achieving the desired visual acuity outcomes for their patients using existing and emerging treatment modalities.”

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. 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.

Notal Vision will present a company update, including information about the home-based study, during the virtual Ophthalmology Innovation Summit (OIS) Israel 2020 investor conference on June 18 from 1-3pm EDT <https://ois.net/ois-israel-2020/>.

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

The ForeseeHome AMD Monitoring Program is an FDA-cleared diagnostic that monitors visual changes in 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.

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 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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