NOTAL VISION™
The Ophthalmic Remote Monitoring Services Provider

Clinical trials results demonstrate value of home OCT at international meetings

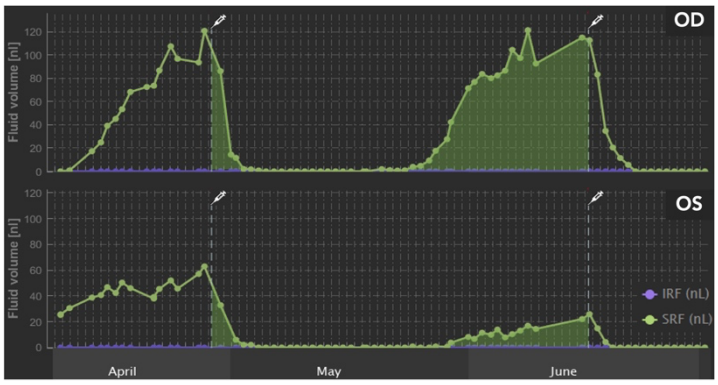
Robust clinical studies bring novel digital health service closer to market

Manassas, VA (February 22, 2023) Notal Vision, Inc. reported today that the latest data on its investigational home-based optical coherence tomography (OCT) and how the service can be used to manage wet age-related macular degeneration (AMD) were recently presented at the Angiogenesis, Exudation, and Degeneration and Macula Society 2023 meetings. The patient-centric ophthalmic remote monitoring service provider, extending retinal disease monitoring from the clinic to the home, is developing technology 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.

A presentation by Nancy Holekamp, MD, Pepose Vision Institute, reviewed several clinical trials that show the progress toward implementing home OCT in the management of patients with wet AMD. With participation of over 200 subjects and more than 8 retina specialists, the trials assessed the usability of the device by patients, demonstrated extended use of the device at home by patients, the interpretation of the home OCT images by a reading center, and driving patient management with AI-based notifications and physician review of home OCT data under IRB approved protocol.

“The experience with home OCT has given me an understanding of the value of missing information in between the office visits,” Dr. Holekamp said. “I believe the technology will have a twofold impact: individualizing the care of patients and better understanding the dynamics of AMD.”

The Notal Vision Home OCT incorporates a deep learning-based algorithm, called Notal OCT Analyzer (NOA), for automatic quantification of retinal fluid, a key biomarker in wet AMD treatment efficacy, which provides physicians with additional information not currently provided by the standard of care clinical evaluations. Presentations from Anat Loewenstein, MD, professor and director of the Department of Ophthalmology at Tel Aviv Medical Center in Tel Aviv, Israel, provided further insights into data generated by near daily self-imaging and quantification of home OCT derived retinal fluid volumes. She reviewed the characteristics of disease reactivation, treatment responses, and demonstrated heterogeneity across the studied patients.



Fluid volume trajectories of (up to) daily Home OCT images processed by NOA deep learning algorithm

“The purpose was to evaluate the effect of timely treatment and the implications and benefits of incorporating home OCT into patient care,” said Prof. Loewenstein. “I think home OCT will change significantly the way we manage the patient.”

Dinah Zur, MD from the Tel Aviv Medical Center also reviewed the use of NOA in analyzing in-office OCT images of 4,485 eyes from 3,637 patients in the BIRAX project with the University of Belfast and Tel Aviv

Medical Center, which aims to provide measurable indicators to enable models for personalized treatment approaches in wet AMD.

Home OCT has received a "Breakthrough Device" designation by the U.S. Food and Drug Administration (FDA). Designated reimbursement codes for the Notal Vision Monitoring Center's device supply and monitoring services, as well as physician monthly report review, have already been established with support by the American Academy of Ophthalmology (AAO). Notal Vision looks forward to releasing Home OCT in Q4 2023, following an FDA premarket review, to US-based clinics that partner with its Medicare-accredited Monitoring Center through patient referral.

"The studies presented at the Angiogenesis and Macula Society meetings show critical milestones in bringing home OCT to market and expanding our digital health offerings in ophthalmology," said Kester Nahen, PhD, CEO of Notal Vision.

About Notal Vision

Notal Vision is a patient-centric ophthalmic remote monitoring services provider extending retinal disease monitoring from the clinic to the home, providing physicians with remote monitoring services to support their patient care between office visits. With a proven approach to home-based, self-operated diagnostics, AI-enabled data analysis, and patient engagement, we help preserve patients' vision. www.notalvision.com

The Notal Vision Monitoring Center is a remote, Medicare credentialed ophthalmic monitoring center and the epicenter of patient engagement. Led by practicing ophthalmologists and supported by certified ophthalmic professionals, the Monitoring Center offers a comprehensive nationwide age-related macular degeneration (AMD) home monitoring service for patients.

The ForeseeHome® AMD Monitoring Program is a comprehensive program, 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 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, 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 Monitoring Center provides 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 a change notification, patients may be brought to the office for further evaluation if warranted. The investigational 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 like 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.

###