ForeseeHome AMD home monitoring real-world data analysis demonstrates substantial benefit for patients' vision

81% of patients diagnosed with wet AMD at 20/40 or better, superior to current standard of care

Manassas, VA (April 6, 2021) – Real-world data on the performance of the ForeseeHome® AMD Monitoring Program, a home-based diagnostic that helps detect the conversion from intermediate dry to wet age-related macular degeneration (AMD), was recently published in the *Journal of Clinical Medicine* as part of the "Diagnosis, Treatment and Prevention of Age-Related Macular Degeneration" special issue[1]. The large scale data analysis of 3.2 million tests showed that the use of ForeseeHome provided a significant benefit to patients by helping to detect their wet AMD earlier with better visual acuity, a factor previously shown[2] to improve long-term visual outcomes of anti-VEGF treatment.

The retrospective analysis of medical records from the Notal Vision Diagnostic Clinic in Manassas, VA, medical provider of the ForeseeHome remote monitoring program, identified 306 eyes that converted to wet AMD between October 2009 and September 2018. Functional vision (20/40 or better) at conversion was maintained in 81% of patients in the real-world ForeseeHome cohort compared to only 34% in the IRIS® Registry real-world data using standard of care.[2]

Standard of care is defined by routine office visits and use of an Amsler grid, developed in the 1940s, is often recommended. Testing with the Amsler grid alone does not often result in early detection[3] and wet AMD may be present for 6-12 months before detection and treatment, meaning that when a distortion is noticed on the Amsler grid, vision loss may have already progressed.[4] It is difficult for physicians to rely on their patients to notice and report distortions, since compliance is often poor and difficult to verify.

"This real-world data analysis confirms that the use of ForeseeHome provides a significant benefit to patients as a means of increasing the early detection of wet AMD when vision is good," said Allen C. Ho, MD, the study's principal author and Director of Retina Research of Wills Eye Hospital and Professor of Ophthalmology at the Kimmel School of Medicine at Thomas Jefferson University. "Earlier detection of wet AMD with this FDA-cleared device is a strong predictor of better vision over time with current anti-VEGF therapy. ForeseeHome can be a useful strategy to monitor at-risk intermediate AMD and help protect vision. The era of at-home digital monitoring of medical conditions including AMD continues to evolve and improve for patient benefit."

Additional authors of the paper include Jeffrey Heier, MD, Nancy Holekamp, MD, Richard Garfinkel, MD, Byron Ladd, MD, Carl Awh, MD, Rishi Singh, MD, Michael Elman, MD, Anat Loewenstein, MD and David Eichenbaum, MD. "Dry age-related macular degeneration is a chronic, slowly progressive disease that is characterized by gradual visual changes. The acute onset of wet disease can be difficult to detect with conventional means such as infrequent office visits and home Amsler Grid testing," added Dr. Heier, Director of the Vitreoretinal Service and Director of Retina Research at Ophthalmic Consultants of Boston. "Artificial-intelligence enabled home monitoring between office visits could be extremely helpful in early

detection of conversion and the ForeseeHome program is a meaningful complement to the at-risk dry AMD patient's care plan."

ForeseeHome is part of a comprehensive monitoring program provided by the Notal Vision Diagnostic Clinic, which includes patient engagement, compliance monitoring and alert generation services. Patients perform a short, daily test on an easy-to-use device and their results are automatically transmitted to the Diagnostic Clinic. When a statistically significant change in visual distortion is detected, the Diagnostic Clinic alerts the referring physician so they can determine the best course of action for the patient.

"The newly published real-word data shows that the performance of the ForeseeHome program resembles the findings from the randomized controlled AREDS2-HOME[5] study, which ultimately led to Medicare coverage," said Kester Nahen, PhD, CEO of Notal Vision. "The Notal Vision Diagnostic Clinic is proud to partner with physicians by providing complementary care for their patients."

References

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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 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 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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