Notal Vision Celebrates 3 Millionth ForeseeHome® AMD Home-Monitoring Test

Milestone achievement expands the reach of this sight-saving platform

Manassas, Virginia (October 5, 2017) - Notal Vision, Inc., a pioneer in home-based ophthalmic disease monitoring, announced the completion of the three millionth home test performed with ForeseeHome®, the first FDA-cleared home monitoring device for patients with intermediate dry age-related macular degeneration (AMD) at risk for developing wet AMD. ForeseeHome is the only device proven in a randomized controlled clinical trial to detect the onset of wet AMD earlier than standard care. Patients using ForeseeHome had significantly better visual acuity (VA) at the time of wet AMD detection when compared to standard care.

Patients with dry AMD are at risk of developing the wet form of the disease, which can progress rapidly, causing substantial and irreversible vision loss. Studies have shown that early detection and subsequent intervention can minimize vision loss and optimize treatment outcomes. Pivotal trials of anti-VEGF therapy for AMD have demonstrated that the best predictor of final visual outcome is VA at the time of treatment initiation, underscoring the role that timely detection plays in minimizing vision loss and maintaining functional vision.

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.

“Notal Vision has established a seamless, cloud-based infrastructure that connects healthcare providers and their patients through personalized, home-based monitoring designed to facilitate earlier ocular disease detection,” said Quinton Oswald, Chief Executive Officer of Notal Vision. “ForeseeHome® uses a patented technology based upon Preferential Hyperacuity Perimetry (PHP) to identify minute changes in the central visual field before the patient notices any visual symptoms, and is the first application of Notal Vision’s cloud-based monitoring platform. Notal Vision is developing a second product that will leverage the platform; home-based optical coherence tomography (OCT) testing. Notal Home OCT testing will generate an alert to the physician indicating the presence of fluid associated with retinal vascular diseases, and allow doctors to view OCT images remotely. We strive to lead the ophthalmic remote patient monitoring category, with the ultimate goal of truly individualizing and optimizing retinal disease management. These innovative monitoring systems move us closer to this goal.”

About the AREDS2 HOME study

The AREDS2 (Age Related Eye Disease Study 2) HOME (HOme Monitoring of the Eye) study, a phase 3, randomized, controlled trial of 1,520 patients, compared VA at the time of CNV diagnosis between at-

risk patients randomized to use the ForeseeHome device plus standard care (self-monitoring and routine clinic visits) and patients utilizing standard care alone. Of the patients who tested with ForeseeHome at least twice a week, 94% maintained 20/40 or better visual acuity, compared with 62% of eyes in the standard care arm (*P*=0.014). In addition, those same patients lost significantly fewer letters when compared with the standard care arm (-3 letters and -9 letters, respectively, *P*=0.003) when the alert was triggered between prescheduled office visits. Wet AMD was 16 times more likely to be detected from a visit triggered by ForeseeHome versus a pre-scheduled visit, and the lesions were ~300% larger at diagnosis when detected during a routine office visit versus a ForeseeHome-triggered visit. The HOME study was halted at the interim analysis because patients using ForeseeHome demonstrated significantly better vision at detection compared to standard care alone.

About Age-Related Macular Degeneration (AMD) and Early Detection

Age-related macular degeneration (AMD) is the leading cause of severe vision loss and blindness in adults over age 50. The early stage of the disease, known as dry AMD, causes damage to the part of the retina called the macula, which is responsible for detailed central vision tasks like reading, driving and facial recognition. Patients with dry AMD may progress to the wet form of AMD, in which blood vessels form and may leak fluid and blood onto the retina. Several studies indicate that early detection of disease progression provides patients with the best chance to initiate therapy and maintain good vision and a better quality of life. Data on the VA of patients with intermediate AMD and their VA at the time of neovascular AMD diagnosis suggest that patients are typically losing an average of 3 to 5 lines of vision and possibly more between the time that intermediate AMD progresses to wet AMD and when the diagnosis is made. There is ample evidence that wet AMD patients with better baseline VA achieve better absolute post-treatment vision outcomes. The best chance of maintaining good vision is with prompt disease detection and immediate treatment.

About Notal Vision™

Notal Vision was founded by two ophthalmologists, and is committed to providing the eye care community with innovative, home-based, technology solutions that support visual health in patients with retinal diseases. The company's ForeseeHome device is the first FDA-cleared home telemonitoring device that detects and characterizes visual distortion in AMD patients as an aid to monitoring choroidal neovascularization progression. To learn more, visit http://www.foreseehome.com/about-notal.html.