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Notal Vision Announces Completion of 4 Millionth ForeseeHome® AMD Home-Monitoring Test

Milestone demonstrates the diagnostic platform's growing role in clinical care.

Manassas, VA – July 19, 2018 – Notal Vision, Inc., a pioneer in home-based ophthalmic disease monitoring, celebrates the completion of four million tests 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 uses a patented technology, Preferential Hyperacuity Perimetry (PHP), that can identify minute changes in the central visual field before the patient has any visual symptoms. During the test, which takes 3-5 minutes, a total of 500 data points are evaluated 3-5 times across the central 14 degrees of the macula to detect statistically significant changes in metamorphopsia, distortion of the vision. These ForeseeHome testing results are sent to the diagnostic clinic via Notal Vision's cloud-based ecosystem. If there is a significant change in metamorphopsia, the adaptive test will generate an alert which is provided to the patient's eye doctor by the diagnostic clinic. The patient is then evaluated by the doctor to determine if there is a conversion from intermediate to wet AMD.

ForeseeHome's clinical utility 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 at least twice weekly and 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. The HOME study was halted at the interim analysis because patients using ForeseeHome demonstrated significantly better vision at choroidal neovascularization (CNV) detection compared with standard care. Based on level-1 evidence and compelling clinical outcomes demonstrating the ability to detect CNV while patients retained functional vision, \geq 20/40, the ForeseeHome AMD Monitoring Program gained Medicare coverage in 2016.



"Notal Vision has developed an integrated cloud-based platform that allows physicians to monitor their patient's vision at home between eye exams, facilitating earlier ocular disease detection," said Quinton Oswald, Chief Executive Officer of Notal Vision. "Patients' test results are sent to a monitoring clinic that alerts the physician's office when a significant change from baseline occurs.

ForeseeHome is the first application of Notal Vision's cloud-based monitoring platform. The company is developing a second product, home-based optical coherence tomography (OCT) testing, that will also leverage the platform. "Notal Vision Home OCT testing will allow patients to perform self-operated home testing, and a proprietary artificial intelligence-based algorithm will identify the presence of fluid associated with retinal vascular diseases. The system will then generate a physician alert, indicating the need for the physician to evaluate the Home OCT images remotely," added Mr. Oswald. "We seek to lead the ophthalmic home diagnostic monitoring category, and our platform moves eye care towards the goal of individualizing and optimizing retinal disease management."

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 dry AMD 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 Notal Vision, Inc.

Notal Vision was founded by two ophthalmologists and is committed to providing the eyecare community with innovative, home-based, diagnostic technologies that support visual health in patients with retinal diseases. ForeseeHome is the first FDA-cleared remote diagnostic testing device that detects and characterizes visual distortion in AMD patients as an aid to monitoring choroidal neovascularization progression. To learn more, visit www.notalvision.com.

