



## **Notal Vision Engages Wasatch Photonics Bringing AI-Enabled Home-Based Optical Coherence Tomography Closer to Market**

First U.S. clinical trial initiated with patient-operated home OCT device for monitoring patients diagnosed with exudative age-related macular degeneration (eAMD)

Manassas, Virginia (December 17, 2018) - Notal Vision, Inc., ("Notal") a privately-held ophthalmic diagnostic services company, focused on advancing eye care by extending ophthalmic disease management from the clinic to the home, has announced the achievement of a significant milestone in its plan to develop and commercialize a home-based, patient-operated, spectral-domain optical coherence tomography (SD-OCT) system. The first targeted application of the Notal Home OCT is to monitor exudative (wet) age-related macular degeneration (eAMD) patients between scheduled, standard-of-care examinations by their treating retinal specialist.

Notal Vision has leveraged Wasatch's expertise in modular OCT system design to advance the development of their reliable, cost-optimized "OCT engine", a key component of the Notal Home OCT System. The home diagnostic testing system will include a light-weight, patient-operated (technician-free) OCT device easily utilized by elderly, visually-impaired patients with eAMD. The device will generate OCT images to be analyzed by a proprietary Artificial Intelligence (AI) algorithm at the Notal Vision Diagnostic Clinic (NVDC). A patient's physician will have access to their daily tests as well as notification of changes in disease.

Following several clinical studies in Israel, the first U.S. study was initiated in October 2018 at Elman Retina Group in Baltimore, MD. The trial is enrolling eAMD patients with visual acuity as low as 20/400 to evaluate the performance and patient experience self-operating the device. Michael J. Elman, MD, Principal Investigator noted, "Early user experience results indicate that elderly patients with advanced AMD and reduced visual acuity can effectively self-operate the Notal Home OCT with minimal training. Patient feedback specific to device simplicity, usability, and ease of testing has been exceedingly positive."

Images produced by the Notal Home OCT System were shared with leading retina specialists at the American Academy of Ophthalmology (AAO) 2018 meeting which recently took place in Chicago. The images were deemed to be of excellent quality, allowing clear identification of retinal pathology and in concordance with commercial OCT imaging performed in parallel.

"The initiation of our first U.S. based home OCT clinical trial is an important step towards bringing this leading-edge technology to eAMD patients, their caregivers, and the eye care community," said Dr. Susan Orr, Chief Medical Officer at Notal Vision and incoming Chief Executive Officer. "Our collaboration with Wasatch Photonics will continue to be instrumental to our organization as the U.S. Food and Drug Administration (FDA) recently granted our Home Optical Coherence Tomography (OCT) System with 'Breakthrough Device Designation', a program designed to expedite patient access to novel technologies."

"As a team, we are excited to be making an impact in addressing one of the most critical unmet needs in retina with the Home OCT device", said Dr. David Creasey, Chief Executive Officer at Wasatch Photonics. Nishant Mohan, Vice President OCT Division added, "We believe the innovation that has led to



development of self-operated OCT for in-home patient use marks a critical juncture for this modality. As home-based OCT realizes its scale, its use and the data generated from it will be transformative to the future of ophthalmic instrumentation."

The Notal Home OCT System is intended for testing at home between regularly scheduled clinic assessments and not intended to replace standard-of-care examinations or clinical testing by a retinal specialist. Notal Vision will expand its ongoing U.S. clinical trial program in 2019.

### **About Notal Vision**

Notal Vision leverages artificial intelligence via a cloud-based platform that connects healthcare providers, Notal Vision's Diagnostic Clinic, and their patients through personalized, remote management of ophthalmic diseases. ForeseeHome<sup>®</sup>, the first application of Notal Vision's cloud-based platform, is an FDA-cleared diagnostic device that uses this platform to monitor visual changes in patients at risk of vision loss from undiagnosed exudative AMD. ForeseeHome is covered by Medicare and most private insurances. To learn more, visit <http://www.foreseehome.com>.

The Notal Home OCT, the next application of Notal's cloud-based platform, will enable exudative AMD patients to perform technician-free OCT testing at home with rapid, self-guided fixation – critical components, especially for elderly patients potentially with pre-existing vision loss. The Notal OCT Analyzer (NOA), a proprietary machine-learning algorithm developed in-house, performs automated analysis of the Notal Home OCT scans and generates a report to the physician when disease activity is detected. The Notal Vision Diagnostic Clinic sends reports to the treating physician which characterize changes in fluid and in addition, physicians are provided access to all B-scan images from each home OCT test. Following a report, patients may be brought to the office for evaluation and treatment at the physician's discretion. The NOA can also analyze the output of other commercial OCT devices, and published study data indicate that the performance of the NOA in detecting disease activity was similar to that of retina physicians when each was compared to a panel of experts. The Notal Home OCT has the potential to truly individualize retinal disease management.