Notal Vision Announces FDA Grants Breakthrough Device Designation for Pioneering Patient-Operated Home Optical Coherence Tomography (OCT) System

First-of-its-kind artificial intelligence-enabled technology for monitoring exudative age-related macular degeneration (AMD)

Manassas, Virginia (December 3, 2018) - Notal Vision, Ltd., ("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 U.S. Food and Drug Administration (FDA) granted the Notal Vision Home-based Optical Coherence Tomography (OCT) System with "Breakthrough Device" designation for the agreed upon indications for use. This designation indicates that FDA intends to provide interactive and timely communication with the sponsor during device development and throughout the review process for various types of premarket submissions.

FDA's Breakthrough Devices Program was established in late 2016 to help patients gain timely access to breakthrough technologies that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases, for which no approved or cleared treatment exists or that offer significant advantages over existing or cleared alternatives.

The indication for use statement for Notal's Home OCT System conveys that it is "an Artificial Intelligence (AI)-based Home Use device indicated for automated identification of intra- and/or subretinal fluid in the central 10 degrees of eyes diagnosed with exudative age-related macular degeneration (eAMD). The Notal Home OCT device is intended for testing at home between regularly scheduled clinic assessments and not intended to replace standard-of-care regularly scheduled examinations and clinical testing by an ophthalmic retinal specialist."

Dr. Susan Orr, Chief Medical Officer at Notal Vision and incoming Chief Executive Officer as of January 1, 2019 stated, "We are very pleased with the FDA's acceptance of our request for Breakthrough Designation. We are eager to work closely with them to bring home-OCT testing to patients with exudative AMD, leveraging leading-edge technology to the benefit of patients, caregivers, and eye care providers alike."

The Notal Home OCT is a patient-friendly light-weight device designed for technician-free operation by eAMD patients from the comfort of their home. Once a patient completes the test, a proprietary machine-learning algorithm, the Notal OCT Analyzer (NOA™), performs an automated analysis. If retina fluid is detected, a report is generated by NOA™ which is then conveyed to the treating physician by the Notal Vision Diagnostic Clinic. The Notal Vision Home OCT will complement current disease monitoring strategies by providing retinal specialists with immediate notification if recurrent disease activity is detected, thereby reducing the time from fluid onset to next treatment.

"The FDA's Breakthrough Devices Program is designed to help expedite patient access to novel technologies through intensive interaction and guidance," said Quinton Oswald, CEO of Notal Vision. "This designation validates and reaffirms our belief that home-based OCT addresses a high unmet need for clinicians and their patients. We are excited about the FDA's recognition of the potential clinical benefit to the over one million Americans living with exudative AMD."

Notal Vision anticipates bringing the Notal Vision Home OCT System to the market in 2020.

About Notal Vision's Cloud-Based Platform
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®, 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 eAMD. 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 eAMD 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.

About Notal Vision, Ltd.
Notal Vision was founded by two ophthalmologists and is committed to providing the eyecare community with innovative, home-based, diagnostic technologies that advance retinal disease management. To learn more, visit www.notalvision.com.