



AsclepiX Therapeutics partners with Notal Vision on Home OCT remote monitoring in DME and AMD clinical trials

The technology could set new standards for data enrichment and patient-centric conduct of clinical trials

Manassas, VA (February 23, 2021) – Notal Vision, Inc. announced today that the company will provide AsclepiX Therapeutics with Home OCT monitoring services through its Notal Vision Diagnostic Clinic to support AsclepiX’s AXT107 phase 1 clinical trial program. The exploratory application of the investigational home monitoring platform will add new valuable data points between the regulary scheduled study office visits.

Study subjects with diabetic macular edema (DME) and wet age-related macular degeneration (AMD), who participate in the CONGO and SHASTA study sponsored by AsclepiX Therapeutics, will perform sequential daily self-imaging of their eyes with the user-friendly, self-operated Notal Home OCT device in their homes. The Notal Vision Diagnostic Clinic, future provider of the Home OCT program, will monitor patient compliance for daily self-imaging and provide remote support as needed. Data from the Home OCT device will be automatically transmitted via a built-in cellular modem to the secure Notal Health Cloud, where the AI-based Notal OCT Analyzer (NOA™) will identify and quantify intra- and subretinal fluid from each daily OCT volume scan. Home OCT images and temporal fluid volume trajectories will be shared with AsclepiX and can be made available to the investigators through the Notal Physician Portal.

“Remote OCT monitoring of patients with exudative retinal diseases in a regulatory clinical trial allows AsclepiX Therapeutics to capture critical data points while potentially reducing the burden of frequent office visits” said Dr. Arshad M. Khanani, MD, MA, one of the study’s investigators and Director of Clinical Research at Sierra Eye Associates in Reno, NV. “The clinical value and potential benefit of such an approach is even more crucial now in light of the COVID-19 pandemic.”

“Home OCT monitoring opens new opportunities to enrich clinical trial datasets with inter-visit disease and treatment response knowledge,” said Kester Nahen, PhD, CEO of Notal Vision, Inc. “We are excited to partner with AsclepiX Therapeutics and contribute our remote diagnostic services to their early phase clinical trial program”.

Notal Vision’s Home OCT pipeline technology is designed to provide patient-initiated retinal OCT scans to support the management of patients with exudative retinal diseases, complementing existing standard of care treatments as well as emerging longer acting drugs. Technology received FDA Breakthrough Device designation at the end of 2018, and is in the process of obtaining FDA clearance. In January 2020 the American Medical Association established three category III Current Procedural Terminology (CPT®) codes for reporting patient-initiated remote retinal OCT scans, facilitated by Notal Vision’s home-based OCT. The physician review, interpretation and documentation of AI-based analyses will be billable every 30 days.

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.

###