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Amydis Launches Phase 2 Glaucoma Clinical Program Using Novel Retinal Tracer to Detect Amyloid Beta

Glaucoma is leading cause of irreversible blindness worldwide, projected to affect 112 million people by 2040

SAN DIEGO, Nov. 02, 2023 (GLOBE NEWSWIRE) -- Amydis Inc., a privately held clinical-stage company pioneering a platform of ocular tracers to enable imaging of disease biomarkers in the eye, today announced it has launched a Phase 2 clinical program for its novel retinal tracer, AMDX-2011P, to detect amyloid-beta in glaucoma patients.

Glaucoma is an age-related neurodegenerative disease associated with the loss of retinal ganglion cells and characteristic vision loss. It is the leading cause of irreversible blindness worldwide, projected to affect 112 million people by 2040. The rate of glaucoma progression can vary across patients; and diagnosis, defining prognosis, establishing progression, and developing optimal interventions can be challenging.

Multiple diagnostic tests detect structural and vascular changes in the retina associated with glaucoma while visual function tests can evaluate visual loss associated with the disease. However, the relationship between and time of onset of these structural, vascular and visual function changes are not well established. The addition of another in-vivo diagnostic modality such as detection of molecular changes would add significant clarity to the pathogenesis of the disease. Converging data indicate that amyloid beta, best known for its association with Alzheimer's disease, is a key factor in glaucoma pathogenesis. The extensive links between Alzheimer's disease and glaucoma have prompted the notion that glaucoma is an "ocular Alzheimer's disease".

The Amydis patented retinal tracer, AMDX-2011P, is a small molecule designed to enable detection and quantification of amyloid beta deposits in the retina using imaging devices already incorporated as part of a patient's standard office visit. Thus, as a widely adoptable, simple and accessible technology, the Amydis test will greatly increase the capture rate of glaucoma while improving clinical management through earlier intervention and, potentially, facilitation of amyloid beta targeted neuroprotective therapies. In collaboration with the University of California-San Diego (UCSD), Amydis completed critical proof-of-concept studies demonstrating the Amydis tracers detect amyloid beta in post-mortem human eyes of glaucoma patients, but not healthy subjects. The results have been submitted for publication.

"We are thrilled to launch a new clinical program for an eye disease. Enabling micron-level in-vivo tracking of retinal amyloid beta formation in glaucoma patients will add a gain-of-function test to current loss-of-function testing, empowering doctors to deliver better patient care," said Dr. Stella Sarraf, Amydis founder and chief executive officer. "Our goal is to also facilitate the development of neuroprotective agents to help provide more therapeutics for patients."

Amydis has launched a Phase 2 open label, blinded endpoint assessment study of AMDX-2011P as a retinal tracer in subjects with primary open angle glaucoma. This trial is being conducted at three sites in Southern California to collect multi-modal retinal imaging data on 40 subjects. This multi-modal data will include optical coherence tomography (OCT) and OCT Angiography (OCT-A), enabling Amydis to map retinal amyloid beta, retinal structure (OCT), and retinal vascular (OCT-A)

signatures and monitor their relative changes to better understand the pathophysiology of glaucoma.

“If successful, the creation of a molecular endpoint with the Amydis technology has the potential to enhance standard of care for glaucoma patients by enabling improved diagnostic and prognostic evaluation, as well as being used as an endpoint to develop neuroprotective therapies,” said Dr. Robert N. Weinreb, Chair of the Amydis Scientific Advisory Board, Chair and Distinguished Professor of Ophthalmology at UCSD and Director of Shiley Eye Institute.

About Amydis, Inc.

Amydis is developing novel, patent-protected molecules, “ocular tracers”, which enable direct visualization of central nervous system disease-related molecular changes (biomarkers) in the eye. With this first-in-class capability, Amydis is poised to revolutionize the ability of physicians and researchers to explore the eye for a broad spectrum of diseases, which have to date required long-term clinical evaluation and the use of invasive testing for definitive diagnosis. The company has a discovery platform and proprietary know-how that position it as first mover and a global leader in developing ocular tracers for human diseases. The future of effective, sustainable healthcare depends on knowledge gained through early diagnostics.