Amydis Announces Successful Completion of a Pre-IND Meeting with the FDA for the Development of a First-in-Class Retinal Tracer Targeting TDP43 for the Diagnosis of ALS

SAN DIEGO, Dec. 06, 2021 (GLOBE NEWSWIRE) -- Amydis Inc., a biotechnology company developing novel ocular contrast agents (“tracers”) targeting CNS biomarkers in the eye, today announced the successful completion of a pre-IND (Investigational New Drug) meeting with the U.S. Food and Drug Administration (FDA) regarding the development plans for a small-molecule tracer to detect TDP43 in the retina of amyotrophic lateral sclerosis (ALS) patients. The FDA agreed with the overall design of the proposed Phase 1/2a first-in-human clinical study in ALS patients. Amydis is planning to initiate the clinical trial by first half of 2022. The design of the planned study may allow for an early read-out on the potential ability of the retinal tracer to aid in the diagnosis and management of patients with ALS.

ALS is a neurodegenerative disease that leads to progressive paralysis and death, usually within 3-5 years of diagnosis. Currently, there are no objective diagnostics to detect, quantify, and monitor the most defining biomarker protein associated with ALS, called TDP43. A buildup of TDP43 deposits occurs in ~97% of ALS and ~50% of Frontal Temporal Dementia (FTD) cases, which shares genetic underpinnings with ALS, and is thought to be a central driver of disease pathogenesis.

“We are thrilled to have FDA’s clear guidance on the development path to introduce our novel retinal tracer to address the unmet need in ALS,” said Stella Sarraf PhD, Founder and Chief Executive Officer of Amydis. “The potential benefits of a retinal test for ALS to visualize TDP43 with commercially available and routinely used ophthalmic imaging devices represents a potentially game-changing breakthrough in clinical care of ALS patients. This may also aid in the clinical development of next generation therapeutics for this devastating disease through enhanced patient recruitment and monitoring.”

In collaboration with Target ALS, a non-profit medical organization committed to the search for new ALS treatments, Amydis was the first to explore whether TDP43 manifests in the retina, which as an accessible part of the CNS is widely considered to be a “window to the brain”.

Dr. Merit Cudkowicz, Director of the Sean M. Healey and AMG Center for ALS at Mass General Hospital, commented, “To my knowledge, exploring a diagnosis of ALS through the eye is a novel and unique approach and we are excited to collaborate with Amydis in their future ALS clinical trial.”

About Amydis, Inc.

Amydis is developing novel, patent-protected ocular tracers, which enable direct visualization of CNS disease-related molecular changes (biomarkers) in the eye. The Company’s discovery platform and proprietary know-how uniquely positions it with first mover advantage to explore the eye for a broad spectrum of neurodegenerative diseases, which have historically required long-term clinical evaluation and the use of invasive testing for definitive diagnosis. Amydis aims to become a global leader in developing ocular tracers for neurodegenerative and systemic diseases. For more information on the Company, please visit www.amydis.com.

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