

# Amydis Receives NIH Grant Award to Develop a Novel TDP-43 Retinal Tracer in Patients with ALS and FTD

SAN DIEGO, Aug. 18, 2022 (GLOBE NEWSWIRE) -- Amydis Inc., a leading ocular tracer pharmaceutical company with a broad portfolio of diagnostic drug candidates targeting CNS biomarkers in the eye, today announced a new Phase 1 grant award from the National Institute of Aging at the National Institutes of Health (NIH). The grant supports the development of a novel small-molecule retinal tracer targeting the biomarker TAR DNA-binding protein 43 (TDP-43) in patients with amyotrophic lateral sclerosis (ALS) and frontotemporal dementia (FTD).

ALS is a devastating neurodegenerative disease that can be challenging to diagnose due to clinical overlaps with other conditions. Currently, no definitive diagnostic technology is available for ALS and FTD. At a molecular level, the accumulation of cytoplasmic TDP-43 occurs in ~97% of ALS cases and is believed to play a role in disease pathogenesis. FTD and ALS overlap genetically, clinically and pathologically, with approximately half of FTD patients manifesting cytoplasmic TDP-43 aggregates similar to those seen in ALS. An early and non-invasive diagnostic test that can detect the presence of TDP-43 aggregates in CNS tissue would greatly enhance diagnostic sensitivity and specificity of ALS and FTD, and aid in guiding therapy and assessing the state of disease pathogenesis in vivo at the molecular level. This would be transformative for physicians, patients, and their families.

"The ability to detect and monitor TDP-43 at micron-level precision in CNS tissue could significantly facilitate regenerative medicine research focused on slowing progression of ALS and FTD," stated Dr. Clive Svendsen, Executive Director of the Cedars-Sinai Board of Governors Regenerative Medicine Institute, a consultant on the grant who is unaffiliated with Amydis.

Amydis' non-invasive, easily accessible, and affordable test to detect and quantify TDP-43 deposits in the retina provides this capability for the first time and can be performed using commercially available and widely utilized diagnostic cameras. In addition, the Amydis technology has the potential to be used as an outcome marker in clinical trials focused on evaluating therapies that may slow down or stop disease progression, and to enroll ALS and FTD patients in clinical trials at earlier stages of disease.

Dr. Stella Sarraf, CEO and Founder of Amydis, stated, "We are thrilled to have gained the support of the NIH for our ALS/FTD program. Amydis is the only company dedicated to exploring a broad spectrum of biomarkers in the eye to improve patient outcomes with our novel platform."

## **About Amydis, Inc.**

Amydis is developing novel, patent-protected drugs - "ocular tracers"- that enable direct visualization of CNS disease-related molecular changes (biomarkers) in the eye. The Company has a discovery platform and proprietary know-how which uniquely positions them with first mover advantage to explore the eye for a broad spectrum of diseases that have to date required long-term clinical evaluation and the use of invasive testing for definitive diagnosis. Amydis is positioned as a global leader in developing ocular tracers for human diseases. The future of effective, sustainable healthcare depends on knowledge gained through early diagnostics.

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