Amydis Announces Enrollment of First Participants in PROBE, a Phase 1/2a Trial Evaluating a Novel Retinal Tracer in People with Amyotrophic Lateral Sclerosis or Parkinson's Disease

SAN DIEGO, Sept. 22, 2022 (GLOBE NEWSWIRE) -- Amydis Inc., a privately held clinical-stage company pioneering a platform of diagnostic drug candidates targeting CNS biomarkers in the eye, today announced dosing of the first patients in the company's Phase 1/2a trial evaluating AMDXP-2011P, a proprietary small molecule retinal imaging agent "retinal tracer" targeting deposits of alpha synuclein (ASYN) and the TAR DNA-binding protein 43 (TDP-43) in patients with Parkinson's disease (PD) and amyotrophic lateral sclerosis (ALS), respectively.

The PROBE trial (NCT05542576) initiated by Amydis is a Prospective Randomized Open, Blinded Endpoint study designed to evaluate safety, tolerability, pharmacokinetics (PK), and the activity of a single IV bolus dose of AMDX-2011P to detect retinal deposits of ASYN and TDP-43 in people living with PD or ALS, respectively. The primary objective of the study is the assessment of safety of AMDX-2011P in the target patient populations. Other objectives include determining the PK profile and the ability of AMDX-2011P to detect disease biomarkers in the retina of participants. The trial is being conducted at two sites in Southern California. Additional information regarding the Phase 1/2a trial may be found at https://probeclinicaltrial.com/home.

"Beginning clinical evaluation of the first compound from our broad portfolio of ocular tracers marks a significant milestone in our efforts to serve the unmet needs of people with PD and ALS," said Stella Sarraf, PhD, chief executive officer and founder of Amydis. "AMDX-2011P is the first imaging agent to be investigated for direct visualization of ASYN and TDP-43 biomarkers in the retina, an accessible part of the CNS that can be imaged non-invasively at micron-level resolution."

Currently, there are no approved diagnostics to detect ASYN and TDP-43. This leads to delays in final diagnosis and receiving appropriate medical care. The eye provides an easy, affordable way to assess the presence of these biomarkers associated with various diseases. AMDX-2011P is a fluorescent, non-radioactive imaging agent designed to detect and quantify ASYN, TDP-43 and other disease-related protein biomarkers in the retina during a simple eye scan using multi-modal ocular imaging devices already in wide use.

"This is an important step forward in the field of ALS," stated Dr. Merit Cudkowicz, Chief of Neurology and Director of Healey & AMG Center for ALS, Massachusetts General Hospital, Julieanne Dorn Professor of Neurology, Harvard Medical School, and member of the Safety and Monitoring Committee for PROBE. "To my knowledge, exploring a diagnosis of ALS through the eye is a novel and unique approach which may help us identify people at risk earlier in the disease and potentially help with drug development." The Healey Center for ALS at Massachusetts General Hospital has created the first ALS platform trial accelerating the path to development of new ALS therapeutics by testing multiple treatments at once, reducing the cost of research by 30%, decreasing the trial time by 50%, and increasing patient participation by 67%.

About Amydis, Inc.

Amydis is developing novel, patent-protected molecules- "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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