Neuronascent Announces NIA Grant Award for NNI-362 to Reach Phase 2 Clinical Trials for Mild to Moderate Alzheimer's Disease

NEURONASCENT, INC., MARYLAND, August 22nd, 2023 (Newswire) -- Neuronascent Inc., a privately-held neuron regeneration therapeutics company, today announced that the National Institute of Aging (NIA), has awarded a U01 grant to Neuronascent, with the CEO, Dr. Judith Kelleher-Andersson being the principal investigator. The grant, titled "Completion of Non-clinical long-term GLP safety and GMP manufacture for first-in-class neuron regenerative therapy, NNI-362 Phase 2 POC AD trial," will allow for the longer-term assessment of Neuronascent's investigational drug, in a proof-of-concept clinical trial.

Neuronascent discovered experimental therapeutic NNI-362 through a novel screening program aimed at identifying small molecules that should enter the human brain and promote new adult-born neurons to replace those lost in aging and disease. Key to its efficacy is the unique allosteric *modulation* of the pleiotropic kinase, p70S6 kinase, where this mechanism-of-action avoids the safety concerns observed with many kinase *inhibitors*. This first-in-class investigational therapy has received support from the NIA twice previously, first to complete short term GLP safety testing for submission of the Investigational New Drug application, and secondly for the completion of the Phase 1a clinical safety trial in healthy aged population.

Alzheimer's is a disease of aging, the greatest risk-factor, and even with new therapies aimed at slowing early progression into Alzheimer's disease, there remains a great unmet need for a disease-modifying treatment for the 6.7 million patients, in the United States alone, already suffering from cognitive and functional deficits. Dr. R. Scott Turner, Prof. Neurology and Director Memory Disorders Program at Georgetown University said, "There is still a need for therapies to actually halt and potentially reverse the disease at the next stage of disease progression from pre-AD to severe AD."

This grant award should allow the further long-term safety testing and further GMP manufacture of NNI-362 required before running a critical trial to assess whether NNI-362 will indeed address the *next stage* of AD disease progression by halting and potentially reversing disease back to a time when the patient had greater memory and executive function.

Neuronascent expects that NNI-362 will provide benefit for any number of age-related disorders beyond just Alzheimer's; that is, those disorders that occur due to loss of adult-born neurons in cognitive and motor regions of the brain. Neuronascent's Dr. Kelleher-Andersson said, "With therapeutics that address the different stages of disease, we may finally be at the point of obtaining precision medicine for age-related neurodegenerative disorders such as Alzheimer's and Parkinson's disease."

About NNI-362

NNI-362 is Neuronascent's lead patented investigational therapeutic aimed at reversing age-related disorders by producing new neurons to replace those lost in chronic age-related neurodegenerative disorders. Orally delivered NNI-362 has completed a NIA-supported and FDA-cleared Phase 1a clinical trial in healthy aged volunteers that assessed safety, pharmacokinetics and a plasma biomarker of Alzheimer's disease progression.

About Neuronascent, Inc.
Neuronascent was founded to discover and develop novel therapies to halt and/or reverse diseases of the central nervous system, an area of vast unmet need. Through its proprietary phenotypic screening platform, Neuronascent has discovered a pipeline of small molecule oral regenerative candidates with patents issued.

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