Neuronascent Releases Further Positive Results of NNI-362 in A Randomized Phase 1a Trial for Alzheimer's Disease

Rockville, MD, March 30, 2022 (GlobeNewswire) -- Neuronascent Inc., is a clinical-stage pharmaceutical company discovering and developing novel regenerative therapies for age-related brain disorders. A Phase 1 study of Neuronascent's NNI-362, completed in 2021, demonstrated NNI-362 to have a favorable safety profile, and in March 2022, showed a significant reduction of an Alzheimer's disease pathological biomarker. This indicates an initial step toward demonstrating NNI-362's potential to affect disease progression.

Neuronascent aims to develop NNI-362 as the first potential non-invasive, oral, neuron regenerating therapy to halt or reverse Alzheimer's and other age-related diseases progression.

Following completion of a National Institute on Aging (NIA) - supported Phase 1a randomized trial of NNI-362 versus placebo, for safety and tolerability, topline results were presented in November 2021 at the CTAD conference in Boston. These results demonstrated NNI-362 to be generally well tolerated in healthy aged individuals following single and multiple daily oral dosing. Recent advances in detecting Alzheimer's disease biomarkers in plasma, such as p-tau^{181}, enabled Neuronascent to utilize plasma collected from the Phase 1 trial to assess the drug's ability to modify brain levels of p-tau^{181} using the Mayo Clinic's Simoa™ method. NNI-362, at the two highest multi-doses, 120 mg and 240 mg, was shown to significantly reduce p-tau^{181} levels versus the pre-treatment levels in study participants.

"A truly effective treatment for Alzheimer's disease is one of the largest, if not the largest, unmet needs in all of medicine", said R. Scott Turner, MD, PhD, Director of the Memory Disorders Program, Georgetown University, and head of Neuronascent's Scientific Advisory Board. Dr. Turner continued: "Currently available treatments provide only modest, temporary, and palliative benefits at best. Patients, families, and researchers are looking for more effective treatments. New findings with this innovative compound show a reduction in the blood-based marker of neurodegeneration p-tau^{181}. Together with a favorable safety profile, we must now investigate the potential benefits of this compound in proof-of-concept clinical trials - with a goal of slowing, halting, or perhaps even reversing progressive cognitive decline."

NNI-362 targets adult-born neuron regeneration through a unique allosteric mechanism to turn-on translation in neural progenitors (Sumien et al., 2021) in models of aging and neurodegenerative disorders, while also promoting neuroprotection of these new neurons.

"This exciting early data, demonstrating our novel allosteric oral therapy, NNI-362, can normalize the plasma p-tau^{181} - a biomarker correlated with Alzheimer's disease brain pathology and progression, supporting the need to further test NNI-362 in long-term trials," stated founder and CEO, Judith Kelleher-Andersson, PhD. "Running of a Phase 2 trial in mild to moderate Alzheimer's disease patients could assess longer-term amelioration of p-tau^{181} levels and to determine if this intervention could consequently improve quality of life for patient and caregiver."

About NNI-362

NNI-362 is Neuronascent's lead, patented, new chemical entity aimed at reversing age-related disorders by producing new adult-born neurons to replace those lost due to chronic neurodegenerative disorders. NNI-362's ability to produce new neurons to replace lost neurons

or enhance numbers in aging patients, when endogenous neuron regeneration in the brain is slowed, and to be neuroprotective of new and remaining neurons, supports the drug's use to halt and reverse Alzheimer's disease and other age-related neurodegenerative disorders.

About Neuronascent, Inc.

Neuronascent, Inc., a privately-held, clinical-stage pharmaceutical company, was founded to discover and develop novel therapies that treat CNS disorders with high-unmet need by replacing and enhancing neuron numbers, not just connections. Through its proprietary phenotypic screening platform, Neuronascent has discovered a pipeline of small molecule regenerative candidates with patents issued, including NNI-351 for pediatric rare disorder Fragile X syndrome. Neuronascent website: www.neuronascent.com

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