Neuronascent Releases Positive Topline Phase 1a Safety Results of NNI-362 for Alzheimer's Disease

Rockville, MD, September 29, 2021 (PR Newswire) -- Neuronascent Inc., a clinical-stage pharmaceutical company developing first-in-class neuron generating therapeutics, today announced the completion of its Phase 1a trial of NNI-362 for Alzheimer's disease. This placebo-controlled, randomized trial was fully supported by a grant from the National Institute on Aging (NIA), part of the National Institutes of Health. The primary goal of this trial was to assess the safety and tolerability of oral NNI-362 in a healthy aged population of subjects 50-72 years of age.

In topline results, oral liquid-formulated NNI-362 administration in single and multiple ascending doses never reached a Maximum Tolerated Dose (MTD). NNI-362, administered from 10 to 240 milligrams orally, once daily, showed no serious adverse events and no dose-dependent adverse events. This Phase 1a trial enrolled 56 subjects who were randomized to receive placebo or NNI-362. Neuronascent studied a lipid formulation and an aqueous formulation in this Phase 1a trial. Any potential drug-related adverse events were of a mild-grade and corrected themselves without concomitant medication, and no subject dropped from these studies. The use of an aged population, with greater than 60% female volunteers, modeled the targeted Alzheimer's disease patient population. Alzheimer's is a disease of aging, the greatest risk-factor, but there is not a single therapy available to halt or reverse this chronic neurodegenerative disorder. There remains significant unmet need for a disease-modifying treatment for the 5.3 million patients in the US suffering from this debilitating disorder

NNI-362 targets adult-born neuron regeneration through a unique mechanism to promote translation (Sumien et al., 2021: https://doi.org/10.1186/s13287-020-02126-3) in models of age-related disorders. This disease-agnostic neuron replacement / enhancement therapy aims to be a first-in-class oral therapy to halt and reverse Alzheimer's and age-related behavioral deficits.

"Research to discover treatments for Alzheimer's disease, and associated cognitive decline and dementia should not be restricted to anti-amyloid approaches. Instead, we must seek multiple novel treatment strategies – particularly those with the potential to preserve and even restore cognitive function that can be lost with aging and neurodegeneration," noted R. Scott Turner, MD, PhD, Director of the Memory Disorders Program, Georgetown University, and the newest member of the Neuronascent Scientific Advisory Board. He went on to state, "The innovative therapy developed by Neuronascent (NNI-362) shows promising results in animal models of aging and disease. We are excited as this innovative compound moves forward toward proof-of-concept clinical trials." Dr. Turner will be presenting this data at the Clinical Trials on

Alzheimer's Disease (CTAD) conference in November 2021 as one of the accepted late breaking posters.

“We certainly appreciate each of the numerous volunteers involved in this safety/tolerability trial who consented to test Neuronascent’s first-in-class neuron regenerative therapy. We were pleased to learn that even in the highest dosing group (240mg) a “maximum tolerated dose” was never reached, reflecting the safety and tolerability that had been documented in preclinical animal studies. This is very encouraging as we move toward a Phase 2 proof-of-concept trial in mild to moderate AD patients”, stated founder and CEO, Judith Kelleher-Andersson, PhD.

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About NNI-362

NNI-362 is Neuronascent’s lead, patented, new chemical entity developed to reverse age-related disorders by producing new 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, where endogenous neuron regeneration in the brain is lessened, supports the drug’s use to halt and reverse Alzheimer’s disease and other age-related neurodegenerative disorders.

About Neuronascent, Inc.

Neuronascent, Inc., [www.neuronascent.com] 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 neural 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.

Safe Harbor Statement

This release contains forward-looking statements, which are made pursuant to the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements are commonly identified by words such as “would,” “may,” “will,” “expects,” and other terms with similar meaning. Forward-looking statements are based on current beliefs, assumptions and expectations and speak only as of the date of this release and involve risks and uncertainties that could cause actual results to differ materially from current expectations.

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