

## Neuronascent Announces Progress for Lead Candidate NNI-362: Publication of Phase 1a Clinical Trial Results and FDA Grants Waiver of Fee for Canine Cognitive Disorder 2025 Submissions

NEURONASCENT, INC., MARYLAND, August 19, 2025 (Newswire) -- Neuronascent Inc., a privately-held neuron regeneration therapeutics company, today announced that the Phase 1a trial in aged human subjects of its NNI-362 therapy was published in *Alzheimer's Research and Therapy* (2025) 17:185, with the company's CEO, Dr. Judith Kelleher-Andersson, as the lead author.

The article, "First in-human study of neuron regenerative therapy NNI-362 to evaluate the safety, pharmacokinetics, and pharmacodynamics in healthy aged population," demonstrated the agent to be well tolerated and able to reduce the plasma pTau181 over pre-treatment levels (i.e., pharmacodynamics).

"Neuronascent discovered NNI-362 through a novel screening program aimed at identifying small molecules that easily enter the human brain and promote nascent, adult-born neurons to replace those lost in aging and disease," said Kelleher-Andersson. "This first-in-class investigational therapy has received support from the National Institute on Aging (NIA), including for the Phase 1a trial." These clinical results along with further completed safety and manufacturing, also supported by the NIA, further support entering Phase 2 trials of NNI-362 in AD.

Alzheimer's disease (AD) is a disease of aging and there remains a great unmet need for a disease-modifying treatment for the ~6.7 million patients, in the US alone, that already suffer from this devastating disorder.

Although NNI-362 has been shown to be effective in pre-clinical studies across multiple disease-relevant models and with positive pharmacodynamic results in the aged human trial, additional proof-of-concept studies are needed. A rational and viable strategy to demonstrate both proof-of-concept of cognitive efficacy and a path to commercialization of NNI-362 can occur in a natural model that mimics AD, known as Canine Cognitive disorder (CCD). Neuronascent has taken the first step toward testing NNI-362 in a field study of aged dogs with CCD, by obtaining a waiver of the Animal Drug User Fee Act sponsor fee. There is a significant need for therapies to actually halt and potentially reverse the cognitive and neuron loss as the disease progresses for both Alzheimer's and Canine Cognitive disorder, where older dogs with CCD suffer an unknown fate. "With proof-of-concept data in aged CCD dogs this may allow for the improved health and lifespan of our furry companions, and allow for the commercialization of Neuronascent's first-in-class therapy", said Kelleher-Andersson.

Neuronascent expects that NNI-362 will provide benefit for any number of age-related disorders beyond just Alzheimer's and CCD; including disorders that occur due to loss of neurons in cognitive and motor regions of the brain. Kelleher-Andersson additionally said, "We are thrilled to be able to demonstrate a clean human safety profile and positive effects on biomarkers of progressive disease and now be able to move toward true efficacy evaluation that could improve so many human lives and those of our companion animals".

### **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 AD progression.

### **About Neuronascent, Inc.**

Neuronascent was founded to discover and develop novel therapies to halt and even 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 neuron regenerative candidates with patents issued.

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### **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.