A Randomized Double-Blind Placebo-Controlled Phase 2A Clinical Trial of NA-831 in Patients with Mild Cognitive Impairment

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Mild cognitive impairment ("MCI") is defined as the "symptomatic pre-dementia stage" on the continuum of cognitive decline. Currently, no medications have proven effective for MCI. Preclinical experiments indicate that NA-831 is an endogenous small molecule that exhibits neuroprotection, neurogenesis, and cognitive protective properties across a range of disease models. NA-831 has been shown to be safe and well tolerated in healthy volunteers.

Methods:
A randomized Phase 2A clinical trial of NA-831 was performed in Alzheimer patients with mild cognitive impairment of vascular origin. Inclusion criteria included: (a) male or female, at 55-80 years of age at screening, (b) Mini-Mental State Exam (MMSE) score ≥20 (primary school) or ≥24 (high school or above) (d) Center for Epidemiological Studies-Depression (CES-D) score <27. A total of 56 Patients were randomly assigned to NA-831 at a daily dosage of 10 mg or matched placebo (1:1) for 24 weeks.

Results:
The effects of NA-831 on Alzheimer patients with mild cognitive impairment were measured as statistically significant reductions in scores on the BCSR, and ADAS-cog scales. Based on the BCRS, the effects of NA-831 were apparent after 8 weeks of treatment (p=0.001), with the significant improvement in the following areas: fatigue, anxiety, irritability, affective lability, disturbance to waking, daytime drowsiness, headache, and nocturnal sleep. NA-831 showed significant improvement with the ADAS-cog score changed 3.21 points (NA-831 change −4.47 vs. placebo −1.26; P = 0.001; ITT). CIBIC-Plus showed (23 [82.1%] vs. 5 [17.9%]) patients improved; P =0.01; ITT). NA-831 was well-tolerated at high dosage up to 50 mg per day. No adverse effects were reported.

Conclusions:
Over the 6-month treatment period, NA-831 was effective for improving cognitive and global functioning in patients with mild cognitive impairment. As an endogenous compound, NA-831 is well-tolerated and has excellent safety profile.

Biography

Dr. Brian Tran has completed his MD degree from St. George Medical School. He is board certified and serves at the Medical Director of NeuroActiva, Inc. Lloyd Tran is the CEO of NeuroActiva, a clinical-stage biopharmaceutical company dedicated to the discovery, development, and commercialization of new drugs to treat Alzheimer's disease.

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