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A randomized double-blind placebo-controlled Phase 2A clinical trial of NA-831 in patients with mild cognitive impairment**Brian H Tran and Lloyd L Tran**
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Statement of the Problem: 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: (1) Male or female, at 55-80 years of age at screening, (2) Mini-Mental State Exam (MMSE) score ≥ 20 (primary school) or ≥ 24 (high school or above) (3) 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.

Conclusion: 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.

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