Neurogenesis Hypothesis and NA-901 for the treatment of Major Depressive Disorder

Lloyd L. Tran
Biomed Industries, Inc.
San Jose, CA, USA
LTran@biomedind.com
Tel. 1-800-824-5135

Major depressive disorder (MDD) presents significant challenges due to its potential for social, occupational, and educational impairment. While various drugs exist for depression management, a considerable number of patients develop treatment-resistant depression alongside notable adverse effects.

NA-901, a small molecule drug developed for MDD treatment, following the guidance under the neurogenesis hypothesis. This hypothesis suggests that stressful experiences inhibit neurogenesis in the dentate gyrus's sub-granular zone, thereby playing a pivotal role in depression pathology and treatment.

NA-901 not only acts as a neurogenesis agent but also elevates extracellular levels of serotonin (5-HT), noradrenaline, dopamine, acetylcholine, and histamine in the rat prefrontal cortex and hippocampus.

Our Phase 1B pilot study, a randomized, double-blind, fixed-dose, placebo-controlled investigation, assessed the efficacy, safety, and tolerability of two fixed doses (20 and 40 mg/d) of NA-831 compared to placebo over a 6-week treatment period in 32 adult MDD patients. Venlafaxine XR, an FDA-approved depression drug, served as the active reference. The primary efficacy analysis demonstrated significant improvements with both NA-901 doses compared to placebo. Notably, the difference in the Montgomery-Åsberg Depression Rating Scale (MADRS) scores of approximately 7 points between active treatment and placebo translated to a clinically relevant difference in response rates, surpassing those of average antidepressants approved by USA and European health authorities.

The NA-901 treatment group reported mild adverse effects such as headache and dry mouth, contrasting with the venlafaxine group, which experienced more severe symptoms including nausea, headache, loss of strength, blurred vision, chest pain, rapid or irregular heartbeat, and suicidal ideation. Venlafaxine XR was included to validate the study methodology and demonstrated effectiveness in the primary efficacy analysis.

Overall, NA-901 treatment proved well-tolerated and effective in alleviating depressive and anxious symptoms in MDD patients. Further discussion on clinical results and the neurogenesis hypothesis will be provided.

Biography of Presenter about 100 words:

Lloyd L. Tran, PhD is the Chief Scientific Officer of Biomed Industries, Inc.

Lloyd has 25 years of experience in drug discovery and business development.