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ASIA EDITION

United Neuroscience gets positive results from Ph2a trial for Alzheimer's vaccine

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The most advanced Alzheimer's vaccine in all clinical development, UB-311 is a novel UBITh active vaccinetargeting the N-terminus of A? peptides and is designed to induce high B-cell specific responses while avoiding T-cell inflammation.

United Neuroscience (UNS), a clinical-stage biotech company pioneering a new class of medicine to treat and prevent brain disorders has announced positive top-line results from its Phase 2a clinical study of UB-311, a novel synthetic peptide vaccine targeting beta amyloid (A?) in the treatment of Alzheimer's disease.

The top-line Phase 2a data met the primary aims of safety and immunogenicity with a 96% response rate. All secondary endpoints - including Amyloid PET burden, CDR-SB, ADCS-ADL, ADAS-Cog and MMSE - pointed directionally in favor of UB-311, though not statistically significant with the study sample size.

"The positive results show that we can safely raise and maintain anti-A? antibody titers in a predictable and sustained manner," said Peter Powchik, Executive Vice President of Research and Development at UNS. "High response rates, reproducibility of response and generation of antibodies directed to relevant toxic protein species are key elements of an effective therapeutic vaccine for neurodegenerative conditions. The UNS platform is proving that it can deliver on these requirements."

Chief Executive Officer Mei Mei Hu added, "These early results suggest a clinical response and support the continued and rapid development of UB-311. The intent of this Phase 2a study was to acquire directional information on the safety, tolerability and therapeutic potential of UB-311 in patients with Alzheimer's disease. UNS is committed to transforming the lives of patients and families affected by Alzheimer's by tackling the seemingly impossible and bringing an end to Alzheimer's through a safe, effective and accessible active immunotherapy that can treat and ultimately prevent the disease."

The Phase 2a double blinded, placebo-controlled study evaluated the safety and immunogenicity of prolonged dosing with two different dosing regimens of UB-311. Subjects from the completed Phase 2a study will roll over into a long-term extension study and will be offered continued treatment with UB-311.

Additional results, including future analysis of secondary endpoints and other data, are expected to be presented at upcoming medical meetings, such as the 14th International Conference on Alzheimer's and Parkinson's Diseases, and published in peer reviewed medical journals.

About UB-311 in Alzheimer's Disease

Active vaccination of human individuals against A? has yet to be safely and effectively achieved. Other active vaccine efforts have either reported low antibody titers and responder rates or significant safety issues such as T-cell mediated encephalitis. The most advanced Alzheimer's vaccine in all clinical development, UB-311 is a novel UBITh™ active vaccine targeting the N-terminus of A? peptides and is designed to induce high B-cell specific responses while avoiding T-cell inflammation. In the Phase I study, UB-311 vaccination safely elevated anti-A? antibodies in all patients with a suggestion of cognitive stabilization.