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Alzamend[®]

Alzamend Neuro Announces Pre-IND Submission for AL002 as a Cell-Based Therapeutic Vaccine That Seeks to Restore the Ability of Patient's Immunological System to Combat Alzheimer's

TAMPA, Fla.--(BUSINESS WIRE)-- [Alzamend Neuro, Inc.](#) (Nasdaq: ALZN) ("**Alzamend**"), an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, today announced that it has submitted a pre-IND meeting request for AL002 and supporting briefing documents to the Center for Biological Evaluation and Research of the U.S. Food and Drug Administration. [AL002](#) is a patented method using a mutant-peptide sensitized cell as a cell-based therapeutic vaccine that seeks to restore the ability of a patient's immunological system to combat Alzheimer's.

"Preclinical work supports AL002 being associated with a positive anti-inflammatory response and a decrease in brain amyloid contents. Based on AL002's recent positive good laboratory practices toxicology results, we are proposing to conduct a first-in-human Phase 1 study. We believe AL002 could potentially reverse the effects of Alzheimer's," said [Stephan Jackman](#), the Chief Executive Officer of Alzamend.

Overview of the proposed clinical study

The Phase 1 clinical study will be a controlled clinical trial conducted at [Emory University School of Medicine](#), with Ihab Hajjar, MD, as the principal investigator, with the involvement of the Emory Personalized Immunotherapy Center. This initial study will be a placebo-controlled, double-blinded, clinical trial in patients with early stage, mild to moderate, Alzheimer's, designed to evaluate feasibility based on efficacy measures, toxicity, safety, and tolerability of AL002 treatment. Participants will be enrolled and dosed for six months, and then followed for another six months for safety, for a total enrollment of one year. An interim statistical analysis is planned after six months which follows the multiple-dosing phase of the study.

About AL002

AL002 is a patented method using a mutant-peptide sensitized cell as a cell-based therapeutic vaccine that reduces beta-amyloid plaque and seeks to restore the ability of the patient's immunological system to combat Alzheimer's. This therapy is intended to work by stimulating the body's own immune system to prevent the formation and breakdown of beta amyloids, which build up in the brain to form a plaque and subsequently block the neurological brain signals, ultimately leading to the symptoms and onset of Alzheimer's.

About Alzamend Neuro

We are an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, including Alzheimer's. With our product candidates, we aim to bring treatments or cures to market as quickly as possible. Our current pipeline consists of two novel therapeutic drug candidates, AL001 – a patented ionic cocrystal technology delivering a therapeutic combination of lithium, proline and salicylate, and AL002 – a patented method using a mutant-peptide sensitized cell as a cell-based therapeutic vaccine that seeks to restore the ability of a patient's immunological system to combat Alzheimer's. Both of our product candidates are licensed from the [University of South Florida Research Foundation](#), Inc. pursuant to royalty-bearing exclusive worldwide licenses.

Forward-Looking Statements

This press release contains "forward looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "believes," "plans," "anticipates," "projects," "estimates," "expects," "intends," "strategy," "future," "opportunity," "may," "will," "should," "could," "potential," or similar expressions. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties. Forward-looking statements speak only as of the date they are made, and Alzamend undertakes no obligation to update any of them publicly in light of new information or future events. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors. More information, including potential risk factors, that could affect Alzamend's business and financial results are included in Alzamend's filings with the U.S. Securities and Exchange Commission. All filings are available at www.sec.gov and on Alzamend's website at www.Alzamend.com.

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