

Alzamend Neuro Receives Positive Pre-IND Response from FDA for AL002, a Cell-Based Therapeutic Vaccine That Seeks to Restore the Ability of Patients' Immunological System to Combat Alzheimer's Disease

FDA Agrees to Alzamend's Plan to Conduct a Combined Phase 1 and 2 Clinical Trial for AL002

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 received a written response to its meeting request relating to its Type B Pre-Investigational New Drug ("**IND**") application from the U.S. Food and Drug Administration (the "**FDA**") providing a path for Alzamend's planned clinical development of AL002. 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.

"We appreciate the thorough and meaningful response from the FDA, which provides us with the information and clarity needed to submit the IND application to initiate a clinical trial for AL002," said Stephan Jackman, Alzamend's Chief Executive Officer. "Preclinical work supports AL002 being associated with a positive anti-inflammatory response and a decrease in brain amyloid contents. Based on AL002's positive toxicology results, the biologic nature of this product and the urgent need to deliver treatments for Alzheimer's to patients, Alzamend proposed, and the FDA agreed, to conduct a combined Phase 1/2 study. We appreciate the FDA's recommendations, guidance and other helpful advice. We plan to augment our proposed clinical trial protocols and proceed accordingly."

Based on the FDA's written feedback, Alzamend anticipates filing the IND by the end of November 2021 and initiating the clinical trial of AL002 in the first quarter of 2022.

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 disease. 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 that subsequently block the neurological brain signals, ultimately leading to the symptoms and onset of Alzheimer's.

About Alzamend Neuro

We are early clinical stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, including Alzheimer's. Our mission is to rapidly develop and market safe and effective treatments. Our current pipeline consists of two novel therapeutic drug candidates, AL001 - a patented ionic cocrystal technology delivering lithium via 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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Email: Info@Alzamend.com or call: 1-844-722-6333

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