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Alzamend Neuro Submits IND Application for Phase I/IIA Trial for an Immunotherapy (ALZN002) to Treat Mild to Moderate Dementia of the Alzheimer's Type

ATLANTA--(BUSINESS WIRE)-- Alzamend Neuro, Inc. (Nasdaq: ALZN) ("Alzamend"), an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of Alzheimer's disease ("Alzheimer's"), bipolar disorder, major depressive disorder ("MDD") and post-traumatic stress disorder ("PTSD"), today announced that it submitted an investigational new drug ("IND") application to the U.S. Food and Drug Administration ("FDA") for its immunotherapy product candidate ALZN002. The product candidate is designed to treat mild to moderate dementia of the Alzheimer's type. ALZN002 is a proprietary "active" immunotherapy product, which means it is produced by each patient's immune system. It consists of autologous dendritic cells ("DCs") that are activated white blood cells taken from each individual patient so that they can be engineered outside of the body to attack Alzheimer's-related amyloid-beta proteins. These DCs are pulsed with a novel amyloid-beta peptide (E22W) designed to bolster the ability of the patient's immune system to combat Alzheimer's; the goal being to foster tolerance to treatment for safety purposes while stimulating the immune system to reduce the brain's beta-amyloid protein burden, resulting in reduced Alzheimer's signs and symptoms. Compared to passive immunization treatment approaches that use foreign blood products (such as monoclonal antibodies), active immunization with ALZN002 is anticipated to offer a more robust and long-lasting effect on the clearance of amyloid. This could provide a safer approach due to its reliance on autologous immune components, using each individual patient's own white blood cells rather than foreign cells and/or blood products.

The submitted IND supports initial deployment of a clinical trial, ALZN002-01, a first-in-human, randomized, double-blind, placebo-controlled, parallel-group, Phase I/IIA clinical trial. The purpose of this trial will be to assess the safety, tolerability, and efficacy of multiple ascending doses of ALZN002 compared with that of placebo in 20-30 subjects with mild to moderate dementia of the Alzheimer's type. Also, the trial will be designed to determine the optimal dosage of ALZN002, allowing for induction of anti-Amyloid-beta antibody responses that can target Alzheimer's-associated brain proteins while maintaining safety. The primary goal of this initial clinical trial is to determine an appropriate dose of ALZN002 for treatment of patients with Alzheimer's in a larger Phase IIB efficacy and safety clinical trial (ALZN002-02), which Alzamend expects to initiate within three months of receiving data from the initial trial.

ALZN002 immunotherapy is intended to treat patients diagnosed with Alzheimer's by inducing the patient's own antibodies. These are targeted to remove Aβ1-42 protein, reducing deposition of amyloid plaque in the brain and thereby reducing the progression of disease-associated clinical signs and symptoms. The ALZN002 DC treatment is, by

definition, an individual-patient-specific therapy since these autologous DCs are administered to the same patient from whom they were removed. Each patient will undergo leukapheresis, i.e., removal and return to the body of white blood cells. This procedure will isolate each patient's peripheral blood monocytes from the obtained white blood cells. These are subsequently differentiated outside the body into DCs that are engineered to induce immunogenicity (search and destroy capability) towards amyloid, the protein associated with Alzheimer's in the patient's body, but to be otherwise tolerated as natural to the body to avoid adverse side effects.

Multiple pre-clinical studies have been conducted using a transgenic (or genetically modified) mouse model of Alzheimer's disease at Charles River Laboratories that reported encouraging Alzheimer's disease-related measurements and neurobehavioral effects, supporting this IND application. Strong evidence of significant ALZN002-mediated amyloid plaque reductions was observed in mouse disease models. There were no undue adverse findings in a good laboratory practices toxicology study, which consisted of five injections administered over a 90-day period and evaluated for 90 days after the last dose. Histopathology results demonstrated that there were no indication of T-cell infiltration or meningoencephalitis, suggesting that ALZN002 is safe and tolerable. In addition, there were no treatment-related mortalities or reports of adverse effects on clinical observations, body weight parameters, organ weight parameters, clinical pathology parameters, gross pathology observations, or histopathologic observations during the main study or the recovery phase.

"This IND submission represents a key milestone for Alzamend as we continue to advance our proprietary pipeline. There remains a need to develop new therapies that alter the progression of Alzheimer's and prevent, reverse or slow neurodegeneration and cognitive decline," said Stephan Jackman, Chief Executive Officer of Alzamend. "We strongly believe that the ALZN002 patient-specific immunotherapeutic vaccine has the potential to achieve these objectives and bring aid to the 6+ million Americans afflicted with this devastating disease. We look forward to providing more details on the timeline following FDA clearance of the IND, if obtained."

About Alzamend Neuro

Alzamend is an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of Alzheimer's, bipolar disorder, MDD and PTSD. 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 ALZN002 - 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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