

# **Alzamend Neuro Partners With the Miller School of Medicine, Interdisciplinary Stem Cell Institute at the University of Miami for ALZN002 Phase I/IIA Immunotherapy Vaccine Clinical Trial to Treat Mild to Moderate Dementia of the Alzheimer's Type**

- **Topline Data for Phase IIA Multiple Ascending Dose Clinical Trial for AL001 Treatment of Dementia Related to Alzheimer's Expected in Second Quarter of 2023**

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 is partnering with the Miller School of Medicine, Interdisciplinary Stem Cell Institute at the University of Miami for its Phase I/IIA clinical trial of 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.

"We are thrilled to add the Miller School of Medicine, Interdisciplinary Stem Cell Institute at the University of Miami to the team and have full confidence in their ability to assist us with our Phase I/IIA clinical trial of ALZN002," said Stephan Jackman, Chief Executive Officer of Alzamend. "We strongly believe that the ALZN002 patient-specific immunotherapeutic vaccine has the potential of fostering 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. We are advancing the process and expect to initiate this study in the first quarter of 2023."

[On October 5, 2022](#), Alzamend announced the addition of healthy adult subject to its Phase IIA multiple ascending dose ("**MAD**") study of AL001 in subjects with dementia related to Alzheimer's. This blinded, placebo-controlled trial (AL001-02) was initiated in May 2022 and is designed to evaluate the safety and tolerability of AL001 under multiple-dose, steady-state conditions and determine the maximum tolerated dose. This addition to the MAD study was based upon a recommendation by the U.S. Food and Drug Administration after its review and commentary on Alzamend's pre-investigational new drug briefing package for development of AL001 for bipolar disorder, MDD and PTSD. As the safety and tolerability of AL001 would need to be tested in healthy and elderly adults before Alzamend could initiate later-stage testing of AL001 for bipolar disorder, MDD and PTSD, the addition of healthy

adults to the on-going Phase IIA MAD clinical trial would expedite the timing of further clinical trials.

“We look forward to reporting topline data from the Phase IIA MAD study in the second quarter of 2023,” said Mr. Jackman. “We are one step closer to providing patients, caregivers and clinicians with a major improvement over current lithium-based treatments that can help over 40 million Americans suffering from Alzheimer’s, bipolar disorder, MDD and PTSD. We look forward to completing the Phase IIA MAD study and further advancing clinical development of this promising potential therapeutic.”

### **About ALZN002**

[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**”), which are activated white blood cells taken from each individual patient that are then 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 of this treatment approach is 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.

### **About AL001**

[AL001](#) is a patented ionic cocrystal technology delivering lithium via a therapeutic crystal-engineered combination of lithium, L-proline and salicylate, known as AL001 or LiProSal. In March 2022, Alzamend completed its Phase I first-in-human trial to determine the pharmacokinetics, safety and tolerability of AL001. During this Phase I trial, participants received a single dose of AL001 containing lithium in an amount equivalent to 150 mg lithium carbonate; at the dose proposed deemed appropriate for Alzheimer’s treatment when given three times daily. Currently, marketed lithium carbonate 300 mg are given three times daily when prescribed for manic episodes in bipolar disorder as well as maintenance therapy of bipolar disorder in patients with a history of manic episodes. The data affirmed that dose-adjusted relative bioavailability analyses of the rate and extent of lithium absorption in plasma indicated that AL001 at 150 mg dosage is bioequivalent to the marketed 300 mg lithium carbonate product and the shapes of the lithium plasma concentration versus time curves are similar.

Findings of plasma bioequivalence to a marketed lithium product may allow Alzamend to reduce the scope or eliminate the need for Phase 2 and Phase 3 studies of efficacy and/or safety of AL001 in such indications as bipolar/affective disorders in which lithium efficacy has been established. Bioequivalence may have utility for AL001 when seeking approval for the indications of currently marketed lithium products, and for new indications as a benchmark for safety.

### **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](http://www.sec.gov) and on Alzamend's website at [www.Alzamend.com](http://www.Alzamend.com).

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