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Alzamend Neuro Announces Initiation of Phase IIA Multiple Ascending Dose Clinical Trial for AL001 Treatment of Dementia Related to Alzheimer's

- ***Topline data expected in December 2022***
- ***Full data from Phase I first-in-human study demonstrated AL001 in plasma is bioequivalent to the marketed lithium carbonate product***

ATLANTA--(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 the first patient with mild to moderate Alzheimer's disease ("**Alzheimer's**") has been dosed in a 12-month Phase IIA multiple ascending dose ("**MAD**") study for dementia related to Alzheimer's. The MAD study is for the purpose of evaluating the safety and tolerability of AL001 under multiple-dose, steady-state conditions and determining the maximum tolerated dose in patients diagnosed with mild to moderate Alzheimer's. AL001 is a novel lithium-delivery system; it is a lithium-salicylate-L-proline engineered ionic cocrystal under development as an oral treatment for patients with dementia related to mild, moderate, and severe cognitive impairment associated with Alzheimer's. AL001 has the potential to deliver benefits of marketed lithium carbonate while mitigating or avoiding current toxicities associated with lithium.

"Advancing AL001 into a Phase IIA clinical trial as planned marks an important milestone for Alzamend," said Stephan Jackman, Chief Executive Officer of Alzamend. "We are one step closer to proving that AL001 could potentially provide clinicians with a major improvement over current lithium-based treatments and may constitute a means of treating over 40 million Americans suffering from Alzheimer's and other neurodegenerative diseases and psychiatric disorders. We look forward to completing the MAD study and further advancing clinical development of this promising potential therapeutic."

About AL001 Phase IIA Study

The Phase IIA study will evaluate the safety and tolerability of AL001 under multiple-dose, steady-state conditions and determine the maximum tolerated dose in patients diagnosed with mild to moderate Alzheimer's. Lithium has been well characterized for safety and is approved/marketed in multiple formulations for bipolar affective disorders. Lithium dosing for the MAD cohorts is based on a fraction of the usual dose for treatment of bipolar affective disorder (i.e., AL001 lithium content at a lithium carbonate equivalent of 300 mg 3-times daily ("**TID**"), daily total of 900 mg), with the target dose for Alzheimer's treatment at half of that lithium carbonate equivalent value (150 mg TID, daily total of 450 mg). In each cohort, consisting of 6 active and 2 placebo patients (as per randomization), multiple ascending doses will be administered TID for 14 days under fasted conditions (at least 1 hour before or

4 hours after meals) up to tolerability/safety limits. The lithium and salicylate components of AL001 will be given within the amounts already approved for use in patients. Up to 40 subjects will complete the Phase IIA trial. The maximum tolerated dose will then be used for further studies.

About AL001 Phase I Study

During this Phase I trial, participants received a single dose of AL001 containing lithium in an amount equivalent to 150 mg lithium carbonate, a dose proposed as likely appropriate for Alzheimer's treatment when given TID. Currently, marketed lithium carbonate 300 mg capsules are given TID when prescribed for manic episodes in bipolar disorder as well as for maintenance therapy of bipolar disorder in patients with a history of manic episodes. It can be difficult to control the appropriate dose of lithium salt formulations, including lithium carbonate, due to the small margin between effective and toxic blood levels, and therefore it can be challenging to avoid side effects or inadequate treatment outcomes.

The data affirmed that dose-adjusted relative bioavailability analyses of the rate and extent of lithium absorption in plasma indicate that AL001 at 150 mg lithium carbonate equivalent dosage is bioequivalent when dose-normalized to the marketed 300 mg lithium carbonate product and the shapes of the lithium plasma concentration versus time curves are similar. Based on the Phase I results, it has been shown that dose-normalized systemic bioequivalence for lithium was established between AL001 and the marketed reference lithium carbonate 300 mg capsule. Findings of plasma bioequivalence to a marketed lithium product may allow Alzamend to reduce the scope or eliminate the need for Phase II and III studies of efficacy and/or safety of AL001 in such indications as bipolar affective disorders in which lithium efficacy has been established. Demonstrated bioequivalence also may have utility for AL001 when seeking approval 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 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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