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Alzamend Neuro Announces Full Data Set From Phase 1 First-in-Human Clinical Trial for AL001 Treatment of Dementia Related to Alzheimer's

- ***Data confirm the positive topline results announced in December 2021 demonstrating AL001 in plasma is bioequivalent to the marketed lithium carbonate product***
- ***Results show that the shapes of the lithium plasma concentration versus time curves are similar to marketed 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 it has received the full data set from its Phase 1 clinical trial for AL001. The purpose of the Phase 1 first-in-human trial was to determine the pharmacokinetics, safety and tolerability of AL001. These data will help Alzamend establish doses for a planned Phase 2 multiple ascending dose study in Alzheimer's disease ("**Alzheimer's**") patients. 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 without current toxicities.

It is difficult to set the appropriate dose of lithium carbonate and other lithium products due to the small margin between effective and toxic blood levels and to avoid side effects or inadequate treatment outcomes. Studies in mice showed advantageous site-of-action (brain) penetration and persistence of lithium (Via AL001) compared to lithium carbonate, indicating the possibility of reducing the lithium dose needed for efficacy, which could reduce potential side effects and reduce or eliminate blood level monitoring requirements.

The full data set builds upon topline data previously reported on December 21, 2021. These data affirmed that dose-adjusted relative bioavailability analyses of the rate and extent of lithium absorption in plasma indicate 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. AL001 salicylate plasma concentrations were observed to be well tolerated and consistently within safe limits and the safety profiles of both AL001 and the marketed lithium carbonate capsule were benign.

During this Phase 1 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. Lithium is also prescribed off-label for major depression, often as an adjunct therapy, as well as for people with bipolar disorder without a history of mania, and treatment of post-traumatic stress disorder ("**PTSD**").

"This is excellent news for the 3+ million Americans currently taking lithium-based treatments," said Stephan Jackman, Chief Executive Officer of Alzamend. "We see the possibility of providing the benefits from AL001 containing lithium at up to 50% of the currently approved lithium carbonate dosage, with the potential for better outcomes and elimination of the need for lithium therapeutic drug monitoring. Moreover, the data confirm AL001's potential as a replacement of the current lithium-based treatment and may provide a treatment to the over 40+ million Americans suffering from Alzheimer's, Bipolar disorder, Depression and PTSD."

Based on the Phase 1 results, it has been shown that dose-normalized bioequivalence for lithium was established between AL001 and the marketed reference lithium carbonate 300 mg capsule. AL001 was shown to be safe and well-tolerated in healthy adult subjects. AL001 salicylate exposures were within safe limits. No clinically significant abnormal findings in electrocardiograms were noted during the trial. No serious adverse events and no deaths were reported during the trial.

Findings of plasma bioequivalence to a marketed lithium product may allow Alzamend to reduce the scope or eliminate the need for Phase 2 and 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.

Mr. Jackman added, "We look forward to swiftly initiating a Phase 2 multiple ascending dose study involving Alzheimer's patients in the second quarter of 2022. Additionally, we look forward to pursuing investigational new drug applications with the United States Food and Drug Administration during 2022 for bipolar disorder, depression, and PTSD indications, and given the major unfilled public health need in these indications, we intend to seek expedited regulatory interaction."

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, through two royalty-bearing exclusive worldwide licenses from the University of South Florida Research Foundation, Inc.

Based on preclinical data, AL001 treatment prevents cognitive deficits, depression, and irritability in APPSWE/PS1dE9 mice, and has shown an improvement of associative learning and memory and irritability compared with lithium carbonate treatments, supporting the potential of this lithium formulation for the treatment of Alzheimer's disease and psychiatric disorders. Lithium has been marketed for more than 35 years and human toxicology regarding lithium use has been well-characterized, potentially allowing Alzamend to rely upon this existing data, potentially reducing the regulatory burden for safety data.

About Alzamend Neuro

Alzamend Neuro 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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