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Alzamend Neuro Announces Positive Topline Data from Phase 1 First-in-Human Clinical Trial for AL001 Treatment of Dementia Related to Alzheimer's

Data shows that AL001 is bioequivalent to the marketed lithium carbonate product and the shapes of the lithium plasma concentration versus time curves are similar

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 positive topline data from its Phase 1 clinical trial for AL001. The purpose of the Phase 1 first-in-human study was to determine the pharmacokinetics, safety and tolerability of AL001 so as to target doses for a planned Phase 2 multiple ascending dose study in Alzheimer's patients. AL001 is a lithium-delivery system; it is a lithium-salicylate-L-proline engineered ionic co-crystal under development as an oral treatment for patients with dementia related to mild, moderate, and severe cognitive impairment associated with Alzheimer's disease.

During this Phase 1 first-in-human trial, participants received a single dose of AL001 containing lithium in an amount equivalent to 150 mg lithium carbonate; this is the dose proposed by the inventors as likely appropriate for Alzheimer's treatment when given three times daily. Currently, marketed immediate-release lithium carbonate 300 mg are given three times daily; for example, lithium carbonate 300 mg three times daily is a dose commonly used for bipolar affective disorders. It can be 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.

"This is amazing news," said Stephan Jackman, Chief Executive Officer of Alzamend. "We see the possibility of providing the benefits from lithium at up to 50% of the currently approved lithium carbonate dosage, with the potential for better outcomes and with elimination of the need for lithium therapeutic drug monitoring. Moreover, the data confirms AL001's potential as a replacement of the current lithium-based treatments and may provide a treatment to the over 40 million Americans suffering from Alzheimer's and other neurodegenerative diseases and psychiatric disorders."

Dose-adjusted relative bioavailability analyses of the rate and extent of lithium absorption indicate that AL001 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.

Such findings may allow the Company to reduce 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. Given the systemic pharmacokinetic similarity to marketed immediate-release lithium carbonate products, AL001 may be dosed three times daily in the planned Phase 2 study, a multiple ascending dose safety study in Alzheimer's patients.

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 post-traumatic stress disorder indication, 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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