

Alzamend Neuro Announces Initiation of Phase I First-in-Human Clinical Trial for AL001 for Dementia Related to Alzheimer’s Disease

Company Achieves Milestone of Dosing First Group of Participants in Six-Month Comparative Study with Lithium-Delivering Ionic Cocrystal Oral Treatment

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 the first group of healthy participants have been dosed in a six-month Phase I relative bioavailability study for [AL001](#) for dementia related to Alzheimer’s disease. The Phase I first-in-human study is for the purpose of determining potential clinically safe and appropriate dosing for AL001 in future studies. AL001 is a lithium-delivering ionic cocrystal under development as an oral treatment for patients with dementia related to mild, moderate, and severe cognitive impairment associated with Alzheimer’s disease.

“Advancing AL001 into the clinic as planned marks an important milestone for Alzamend,” said Stephan Jackman, Chief Executive Officer of Alzamend. “We believe 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 Phase I study and advancing the clinical studies of this promising potential therapeutic.”

Overview of the Phase I Clinical Study

The Phase I study will investigate the pharmacokinetics (the movement of drug through the body) of lithium following a single dose of AL001 (the “study drug”) compared to a typical single dose of a marketed 300 mg immediate-release lithium carbonate capsule (the “comparator” – currently indicated to treat mood disorders) in healthy male and female subjects. The lithium and salicylate components of AL001 will be given within the amounts already approved for use in patients. The purpose of the research study is to test the safety, tolerability, and bioavailability (how much and when drug gets in the body) of the study drug, AL001, compared to the currently marketed formulation of the comparator, lithium carbonate. This is expected to ascertain what AL001 doses should be given, and how often, in subsequent Phase 2 safety and efficacy trials involving Alzheimer’s disease patients. At least 24 healthy male and female human subjects will complete the Phase I trial.

About AL001

AL001 is a patented ionic cocrystal technology delivering lithium via a therapeutic crystal-

engineered combination of lithium, 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

We are an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, including Alzheimer's disease. 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 crystal-engineered combination of lithium, proline and salicylate, and AL002 – a patented therapeutic mutant peptide sensitized cell-based therapeutic vaccine that is targeted to augment the ability of a patient's immune system to combat Alzheimer's disease. 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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