October 2, 2023

Alzamend Neuro Receives FDA “Study May Proceed” Notification for a Phase IIA Clinical Trial of AL001, a Next-Generation Lithium Therapeutic Drug Candidate, in Bipolar Disorder Patients

- ***Alzamend’s recently completed Phase IIA study of AL001 in Alzheimer’s patients and healthy subjects identified a candidate dose that is unlikely to require therapeutic drug monitoring***
- ***Safety aspects of AL001 development may qualify for a Section (505)(b)(2) NDA pathway in support of FDA approval***

ATLANTA--(BUSINESS WIRE)-- Alzamend Neuro, Inc. (Nasdaq: ALZN) (“**Alzamend**”), a clinical-stage biopharmaceutical company focused on developing novel products for the treatment of Alzheimer’s disease (“**Alzheimer’s**”), bipolar disorder (“**BD**”), major depressive disorder (“**MDD**”) and post-traumatic stress disorder (“**PTSD**”), today announced receipt of a “Study May Proceed” letter from the U.S. Food and Drug Administration (“**FDA**”) for the initiation of study AL001-BD01, a Phase IIA clinical study of AL001 for BD type 1.

“We are grateful to receive this timely, favorable response from the FDA to initiate our first Phase IIA clinical study of AL001 for BD. Lithium was the first mood stabilizer approved by the FDA and is still a first-line treatment option (considered the “gold standard”) for BD type 1,” said Stephan Jackman, Chief Executive Officer of Alzamend. “If we are able to develop a next-generation lithium product (AL001) that would not routinely require therapeutic drug monitoring (“**TDM**”), it would constitute a major improvement over current lithium-based treatments and positively impact the 7 million Americans afflicted with BD. We are advancing the process and expect that the first patient will be dosed in the first quarter of 2024.”

About AL001

AL001 is a novel lithium-delivery system that has the potential to deliver benefits of marketed lithium salts while mitigating or avoiding currently experienced toxicities associated with lithium. Results from Alzamend’s recently completed Phase IIA multiple-ascending dose study of AL001 in Alzheimer’s patients and healthy subjects identified a maximum tolerated dose (“**MTD**”), as assessed by an independent safety review committee. This MTD is designed to be unlikely to require TDM while providing lithium at a relatively modest but effective dose. AL001 is designed to favorably distribute lithium in brain resulting in lower exposure of other body organs and an improved safety profile compared to currently marketed lithium salts. This can serve to mitigate or obviate the disadvantageously low ceiling for toxicity of marketed lithium salts that has limited their usefulness to patients and prescribers.

Lithium is a chemical entity well known for efficacy in BD type 1. Alzamend's goal is to revive the utility of lithium treatment by importantly improving the benefit-to-risk relationship of lithium treatment in clinical practice. Based on the favorable AL001 safety profile observed in the recently completed study and extensive safety data on the drug's constituent components, the AL001 development program may qualify for a Section 505(b)(2) New Drug Application ("**NDA**") pathway for FDA approval, which is available to new formulations of an approved drug.

About Bipolar Disorder

BD, previously known as manic depression, is a mood disorder characterized by periods of depression and periods of abnormally elevated happiness that last from days to weeks each. The condition is classified as BD Type 1 if there has been at least one manic episode, with or without depressive episodes, and as BD Type 2 if there has been at least one hypomanic episode (but no full manic episodes) and one major depressive episode. In the U.S., about 3% of the population is estimated to be affected by BD at some point in their life. BD is among the top 20 causes of disability worldwide and leads to substantial costs for society. The risk of suicide is high; over a period of 20 years, 6% of those with BD died by suicide, while 30% to 40% engaged in self-harm. Other mental health issues, such as anxiety disorders and substance use disorders, are commonly associated with BD.

About Alzamend Neuro

Alzamend Neuro is a clinical-stage biopharmaceutical company focused on developing novel products for the treatment of Alzheimer's, BD, 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 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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