November 20, 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 Major Depressive Disorder Patients

- ***Alzamend’s recently completed Phase IIA study of AL001 in Alzheimer’s patients and healthy subjects showed a benign safety profile and identified a candidate dose that is unlikely to require therapeutic drug monitoring***
- ***Safety aspects of AL001 development may qualify for a 505(b)(2) NDA pathway for 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-MDD01, a Phase IIA clinical study of AL001 for treatment of patients with MDD.

“We are grateful to receive this timely, favorable response from the FDA to initiate our first Phase IIA clinical study of AL001 for MDD. Although lithium does not have an FDA approved indication for augmentation of an antidepressant in MDD, it has been prescribed off-label for this purpose for decades,” said Stephan Jackman, Chief Executive Officer of Alzamend. “If we can 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 21 million Americans afflicted with MDD. 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.

While a wide variety of medications have been used historically for augmentation of an antidepressant in MDD, lithium is one of the few agents that has demonstrated efficacy in multiple randomized controlled trials. 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 Major Depressive Disorder

MDD, also known simply as depression, is a mental disorder characterized by at least two weeks of pervasive low mood, low self-esteem, and loss of interest or pleasure in normally enjoyable activities. Those affected may also occasionally have delusions or hallucinations. Introduced by a group of U.S. clinicians in the mid-1970s, the term was adopted by the American Psychiatric Association for this symptom cluster under mood disorders in the 1980 version of the Diagnostic and Statistical Manual of Mental Disorders (DSM-III) and has become widely used since. The diagnosis of MDD is based on the person's reported experiences and a mental status examination. There is no laboratory test for the disorder, but testing may be done to rule out physical conditions that can cause similar symptoms. The most common time of onset is in a person's 20s, with females affected about twice as often as males. The course of the disorder varies widely, from a single episode lasting months, to a lifelong disorder with recurrent major depressive episodes. MDD is believed to be caused by a combination of genetic, environmental, and psychological factors, with about 40% of the risk being genetic. Risk factors include a family history of the condition, major life changes, certain medications, chronic health problems, and substance use. It can negatively affect a person's personal life, work life, or education as well as sleeping, eating habits, and general health. According to the World Health Organization, approximately 280 million people (3.8% of the world's population) in the world suffer from MDD.

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, salicylate and L-proline, and ALZN002 - 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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