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Alzamend Neuro Submits IND Application for a Phase IIA Clinical Trial in Major Depressive Disorder Patients of its Next-Generation Lithium Therapeutic Drug Candidate AL001

- ***Safety aspects of AL001 development may qualify for a 505(b)(2) NDA pathway for FDA approval***
- ***Alzamend recently completed a Phase IIA Study of AL001 in Alzheimer's patients and healthy subjects showing a benign safety/ tolerability profile while characterizing dosing levels unlikely to require therapeutic drug monitoring***

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 that it has submitted an investigational new drug ("**IND**") application to the U.S. Food and Drug Administration ("**FDA**") for the initiation of study AL001-MDD01, a Phase IIA plasma/brain pharmacokinetics clinical study of AL001 for adjunctive treatment of patients with 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. While a wide variety of medications have been used historically in this capacity, lithium is one of the few agents that has demonstrated efficacy in multiple randomized controlled trials. Although the ideal role for lithium augmentation has yet to be established, there is evidence to support the clinical practice of adding lithium to conventional antidepressants in pursuit of MDD remission. Lithium augmentation has been cited as a strategy for depressed patients not responding to an antidepressant, lithium prophylaxis for recurrent unipolar depression as an alternative to prophylaxis with an antidepressant, and for lithium's anti-suicidal properties, where appropriate.

Lithium was the first mood stabilizer approved by the FDA and is still a first-line treatment option (considered the "gold standard") for BD but is underutilized perhaps because of the need for therapeutic drug monitoring ("**TDM**"). Lithium was the first drug that required TDM by regulatory authorities in product labelling because the effective and safe range of therapeutic drug blood concentrations is narrow and well-defined for treatment of BD when using lithium salts. Excursions above this range can be toxic, and below can impair effectiveness.

AL001 is a novel lithium-delivery system that has the potential to provide 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**") that was vetted by an independent safety review committee. This MTD, which is designed to distribute more lithium to the brain but at lower systemic exposure, resulting in an improved safety profile compared to currently marketed lithium salts, was assessed to be unlikely to require TDM.

After receipt of a "study may proceed" communication from the FDA, Alzamend plans to initiate a Phase IIA study to characterize AL001 improvements of lithium levels in the brain compared to a marketed lithium salt in MDD patients. Alzamend anticipates that this program may, based on safety, qualify for a 505(b)(2) NDA pathway to FDA approval, which is available to new formulations of an approved drug.

"This IND submission represents the next key milestone for Alzamend as we further advance our proprietary pipeline," said Stephan Jackman, Chief Executive Officer of Alzamend. "Being able to develop a next-generation lithium product (AL001) that would not routinely require TDM could positively impact the 21 million Americans afflicted with MDD. We look forward to providing more details regarding the study's timeline and market opportunity in the near future."

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 one 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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Email: Info@Alzamend.com or call: 1-844-722-6333

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