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

- ***Safety aspects of AL001 development may qualify for (505)(b)(2) pathway for FDA approval***
- ***Alzamend's recently completed a Phase IIA Study of AL001 in Alzheimer's and healthy patients that identified a candidate dose that is 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-BD01, a Phase IIA clinical study of AL001 for BD.

Lithium is a commonly prescribed drug for manic episodes in BD type 1 as well as maintenance therapy of BD in patients with a history of a manic episode. 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 labeling 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 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 and healthy patients identified a maximum tolerated dose ("**MTD**"), as assessed by an independent safety review committee. This MTD, providing lithium at a lithium carbonate equivalent dose of 240 mg 3-times daily ("**TID**"), is designed to be unlikely to require TDM. Moreover, this dose 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 and thereby avoiding clinical disadvantages.

Once the IND is cleared by the FDA, Alzamend intends to initiate the Phase IIA study to determine relative increased lithium levels in the brain compared to a marketed lithium salt in BD patients, based on published mouse studies that predict that lithium can be given at lower doses for equivalent therapeutic benefit when treated with AL001. Alzamend's goal is

to replace a 300 mg TID lithium carbonate dose for treatment of BD with a 240 mg TID AL001 lithium equivalent, which represents a daily decrease of 20% of lithium given to a patient. Alzamend believes this program may qualify for the 505(b)(2) pathway for FDA approval, which is available to new formulations of an approved drug.

“This IND submission represents a key milestone for Alzamend as we continue to 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 7 million Americans afflicted with BD. We look forward to providing more details regarding the study’s timeline and market opportunity in the near future.”

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 US, 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, BPD, 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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Email: Info@Alzamend.com or call: 1-844-722-6333

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