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

- ***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 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-PTSD01, a Phase IIA plasma/brain pharmacokinetics clinical study of AL001 for treatment of patients with PTSD.

Although lithium products do not have an FDA-approved indication for PTSD, case reports suggest that lithium treatment may be useful for treating PTSD patients. In particular, treatment with low doses (300–600 mg/day) of lithium carbonate have been reported to provide effective treatment in reduction of inappropriate anger, irritability, anxiety, and insomnia in those patients. The clinical observation of mood swings beyond the normal range, but milder than those associated with BD, reportedly suggested the presence of a sub-threshold mood disorder in these PTSD patients. It has also been proposed that treatment of trauma with lithium to forestall the development of PTSD may be provided by pharmacological induction of a mild transient amnesia.

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**"), that is, routine monitoring of lithium drug levels in blood to help assure safety and effectiveness. 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 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. This MTD was assessed to be unlikely to require TDM.

After receipt of a "study may proceed" communication from 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 PTSD patients. Alzamend anticipates that the new drug application ("**NDA**") development program for PTSD may, for safety, qualify for a 505(b)(2) NDA pathway to FDA approval, which can be available to new formulations of an approved drug.

"There are only two drugs approved by the FDA and currently available in generic form for PTSD patients," 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 9 million Americans afflicted with PTSD. We look forward to providing more details regarding the study's timeline and market opportunity in the near future."

About Post-Traumatic Stress Disorder

PTSD is a mental and behavioral disorder that can develop because of exposure to a traumatic event, such as sexual assault, warfare, traffic collisions, child abuse, domestic violence, or other threats on a person's life (American Psychiatric Association DSM-5-TR, 2020; Mayo Clinic, 2022). People who experience interpersonal violence, such as rape, other sexual assaults, being kidnapped, stalking, physical abuse by an intimate partner, and incest or other forms of childhood sexual abuse, are more likely to develop PTSD than those who experience non-assault-based trauma, such as accidents and natural disasters. Symptoms may include disturbing thoughts, feelings, or dreams related to the events, mental or physical distress in response to trauma-related cues, attempts to avoid trauma-related cues, alterations in the way a person thinks and feels, and an increase in the fight-or-flight response. These symptoms last for more than a month after the event (American Psychiatric Association DSM-5-TR, 2020). A person with PTSD is at a higher risk of suicide and intentional self-harm. According to the NIH, about 3.6%, or roughly 9 million, adults in the U.S. have PTSD in a given year, and 9% of people develop it at some point in their life. In much of the rest of the world, rates for a given year are between 0.5% and 1% of the population.

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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