May 17, 2022

Alzamend Neuro Announces Pre-IND Submission for AL001 as a Treatment of Bipolar Disorder, Major Depressive Disorder and Post-Traumatic Stress Disorder

- ***Topline data expected in December 2022 from ongoing Phase IIA multiple ascending dose clinical trial for AL001 treatment of dementia related to Alzheimer's***

ATLANTA--(BUSINESS WIRE)-- Alzamend Neuro, Inc. (Nasdaq: ALZN) ("**Alzamend**"), an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, today announced that it has submitted a Pre-IND (investigational new drug) meeting request for AL001 and supporting briefing documents to the U.S. Food and Drug Administration ("**FDA**") for the treatment of bipolar disorder, major depressive disorder and post-traumatic stress disorder ("**PTSD**").

AL001 is a novel lithium-delivery system; it is a lithium-salicylate-L-proline engineered ionic cocrystal under development as an oral treatment for patients with dementia related to mild, moderate, and severe cognitive impairment associated with Alzheimer's disease ("**Alzheimer's**"). AL001 has the potential to deliver benefits of marketed lithium carbonate while mitigating or avoiding current toxicities associated with lithium. In a Phase I relative bioavailability comparison of AL001 to lithium carbonate completed in March 2022, AL001 was shown to provide dose-normalized bioequivalent plasma pharmacokinetics and the observed safety profile was benign. A phase IIA, Multiple Ascending Dose ("**MAD**") clinical trial for the treatment of dementia related to Alzheimer's is currently underway.

"We are excited about pursuing three additional indications for AL001," said Stephan Jackman, Chief Executive Officer of Alzamend. "We are one step closer to showing that AL001 can potentially provide clinicians with a major improvement over current lithium-based treatments and may constitute a means of treating over 40 million Americans suffering from Alzheimer's and other neurodegenerative diseases and psychiatric disorders. We look forward to receiving FDA feedback and advice regarding the appropriateness and acceptability of the proposed development program and clinical plan."

Lithium was the first mood stabilizer and is still a first-line treatment option, but is underutilized perhaps because of the need for therapeutic drug monitoring ("**TDM**") to assure safe and effective blood concentrations, and the availability of newer treatments. Lithium is a commonly prescribed drug for manic episodes in bipolar disorder as well as maintenance therapy of bipolar disorder in patients with a history of a manic episode. The primary target symptoms of lithium are mania and unstable mood. Lithium is also prescribed off-label for

major depressive disorder (often as an adjunct therapy), bipolar disorder (without a history of mania), and treatment of PTSD, among other neurodegenerative, neurological and neuropsychiatric disorders.

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 bipolar disorder when using lithium salts. Excursions above this range can be toxic. AL001 may enhance lithium distribution into target tissues in the central nervous system (brain) but at lower systemic exposures, resulting in an improved safety profile compared to lithium salts, including the possibility of mitigating lithium side effects and the current requirement for TDM.

About AL001 Phase IIA Study

The ongoing Phase IIA study is evaluating the safety and tolerability of AL001 under multiple-dose, steady-state conditions and is determining the maximum tolerated dose in patients diagnosed with mild to moderate Alzheimer's. Lithium has been well characterized for safety and is approved/marketed in multiple formulations for bipolar disorder. Lithium dosing for the MAD cohorts consists of fractions of a usual dose for treatment of bipolar disorder. In each cohort, consisting of 6 active and 2 placebo patients (as per randomization), multiple ascending doses are being administered three times daily for 14 days under fasted conditions (at least 1 hour before or 4 hours after meals) up to tolerability/safety limits for this fragile Alzheimer's population. The lithium and salicylate components of AL001 are to be given within the amounts already approved for use in patients for other indications. Up to 40 subjects will complete the Phase IIA trial. The maximum tolerated dose will then be used for further studies. The Phase IIA study commenced on May 5, 2022. More information can be found at www.clinicaltrials.gov, identifier: NCT05363293.

About Alzamend Neuro

Alzamend is an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, including Alzheimer's. 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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Source: Alzamend Neuro, Inc.