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Alzamend Neuro Announces Initiation Date of First Phase II Clinical Trial of AL001 to take Place at Massachusetts General Hospital

Head-to-head studies of AL001 versus a marketed lithium carbonate product will be conducted for comparisons of lithium blood and brain/brain-structure pharmacokinetics in healthy human subjects

ATLANTA, Feb. 25, 2025 (GLOBE NEWSWIRE) -- 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 its plans to initiate the first of five highly anticipated phase II clinical studies of AL001, with the first study, in healthy human subjects, expected to commence in the second quarter of 2025. This study follows the successful development of a novel head coil by Tesla Dynamic Coils BV, a key component of the clinical trial.

In collaboration with Massachusetts General Hospital as its contract research organization, Alzamend aims to explore the unique properties of AL001 and its effects on lithium delivery in the brain compared to marketed lithium salts. The study in healthy human subjects will serve as a baseline and could illuminate the path forward in Alzheimer's, BD, MDD, and PTSD patients by demonstrating AL001's targeted effectiveness and reduced systemic side effects. Previous studies in mice have shown that AL001 ensures better brain absorption while maintaining lower levels of lithium in the blood, paving the way for safer and more efficient treatments.

By offering a treatment that potentially eliminates the need for lithium therapeutic drug monitoring ("**TDM**"), AL001 could revolutionize care for vulnerable patient populations and improve treatment outcomes. Lithium, renowned for its efficacy as a first-line therapy for manic episodes and maintenance in BD, has long been underutilized due to the complexities of TDM. Current U.S. Food and Drug Administration-approved lithium salts (carbonate and citrate) are limited by a narrow therapeutic window that requires regular TDM of plasma lithium levels and blood chemistry by a clinician to mitigate adverse events. Since conventional lithium salts are eliminated relatively quickly, multiple administrations throughout the day are required to safely reach therapeutic plasma concentrations. By reducing the systemic burden, Alzamend's novel AL001 formulation could signify a major shift in managing conditions like Alzheimer's disease, by minimizing risks associated with kidney and thyroid side effects traditionally linked to lithium therapies.

"With AL001, we can potentially introduce a next-generation lithium treatment that offers enhanced safety, better brain targeting, and no need for TDM, promising a leap forward from

the current, burdensome options," stated Stephan Jackman, Chief Executive Officer of Alzamend. "This advancement stands to potentially enhance the lives of over 43 million Americans suffering from Alzheimer's, BD, MDD and PTSD by providing a more effective and user-friendly therapeutic option, potentially reshaping current treatment paradigms and improving patient quality of life substantially."

About AL001

AL001 is a novel lithium-delivery system that has the potential to provide the benefits of marketed lithium salts while mitigating or avoiding currently experienced toxicities associated with lithium. Results from Alzamend's 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 the 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.

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 by removing beta-amyloid from the brain. The latter is a second-generation active-immunity approach designed to mitigate the disadvantages of approved passive immunity marketed antibody products, particularly by reducing the required frequency and costs of dosing associated with antibody products. 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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