November 19, 2025

Alzamend Neuro Announces Completion of Clinical Portion of Phase II Clinical Trial of AL001 "Lithium in Brain" Study Conducted at Massachusetts General Hospital

- ***Topline data expected in first quarter of 2026***
- ***Head-to-head studies of AL001 versus a marketed lithium carbonate product was conducted for comparisons of lithium blood and brain/brain-structure pharmacokinetics in healthy subjects***

ATLANTA, Nov. 19, 2025 /PRNewswire/ -- 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 completion of the clinical portion of its first Phase II clinical study of AL001, in healthy human subjects.

In collaboration with Massachusetts General Hospital as the clinical trial site, Alzamend is investigating the distinctive characteristics of AL001. The primary objective is to assess how AL001 delivers lithium to the brain compared to marketed lithium salts, evaluating its ability to achieve better therapeutic efficacy while minimizing systemic side effects. This clinical study utilized a unique, engineered head coil developed by Tesla Dynamic Coils BV ("**Tesla**"). This one-of-a-kind technology grants the capability for high-resolution, whole-brain lithium imaging, which allows for the precise quantification of lithium within specific brain

structures. The resulting proprietary imaging data sets will be used to establish a foundational reference, helping Alzamend accurately identify the optimal, disease-specific target doses of AL001. These findings will inform the planned Phase II clinical trials in Alzheimer's, BD, MDD, and PTSD, which are all expected to be initiated next year, and confirm that AL001 offers a superior balance of safety and efficacy compared to conventional lithium carbonate. Prior research in mice has demonstrated that AL001 achieves superior brain uptake while keeping blood lithium levels lower, setting the stage for safer and more effective therapies.

By potentially removing the requirement for lithium therapeutic drug monitoring ("**TDM**"), AL001 could transform treatment for at-risk patient groups and enhance clinical outcomes. Lithium is widely recognized as a highly effective first-line option for managing manic episodes and maintenance in BD, yet its adoption has been limited by TDM challenges. Lithium salts approved by the U.S. Food and Drug Administration currently face a narrow therapeutic index, necessitating frequent clinician-monitored plasma lithium and blood chemistry tests to prevent adverse effects. Through reduced systemic exposure, Alzamend's innovative AL001 formulation may represent a paradigm shift in treating disorders such as Alzheimer's, by lowering the risks of kidney and thyroid complications commonly associated with conventional lithium regimens.

"The completion of the clinical portion of our Phase II trial of AL001 marks a pivotal milestone in our mission to deliver a next-generation lithium therapy with improved safety, superior brain penetration, and no need for TDM," said Stephan Jackman, Chief Executive Officer of Alzamend. "We extend our heartfelt gratitude to the patients and investigators for their invaluable time and dedication to this study. Their contributions were essential to its successful completion. We look forward to reporting topline data in the first quarter of 2026 and further advancing clinical development of this promising potential therapeutic."

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.

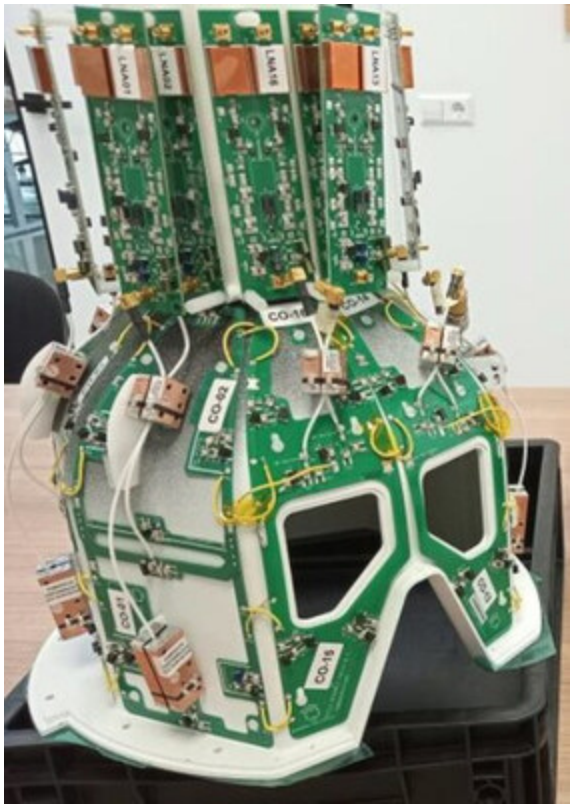
About Alzamend Neuro

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 atwww.Alzamend.com/.



View original content to download multimedia:https://www.prnewswire.com/news-releases/alzamend-neuro-announces-completion-of-clinical-portion-of-phase-ii-clinical-trial-of-al001-lithium-in-brain-study-conducted-at-massachusetts-general-hospital-302619879.html

SOURCE Alzamend Neuro, Inc.