

December 18, 2024



Alzamend Neuro to Present Non-Clinical Data Update at the Society of Toxicology 2025 Annual Meeting and ToxExpo

Presentation Topic is the Pharmacokinetics of AL001, a Lithium Salicylate/L-Proline Co-crystal, as a Potentially Beneficial Lithium Sparing Treatment for Bipolar Disorder Type 1, Alzheimer's Disease, Major Depressive Disorder and Post-Traumatic Stress Disorder

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 it will have a poster presentation at the Society of Toxicology ("SOT") Annual Meeting and ToxExpo, being held from March 16-20, 2025, in Orlando, Florida.

"Our poster presentation at SOT in 2025 with data from our non-clinical study: *Comparing Brain and Plasma Lithium Exposures between AL001 and Lithium Carbonate in Alzheimer's Transgenic Mice*, demonstrates the potential of AL001 to enhance brain-specific lithium delivery while minimizing systemic exposure in an Alzheimer's disease mouse model, guiding development of enhanced lithium effectiveness and safety in human diseases," said Stephan Jackman, Chief Executive Officer of Alzamend. "Following successful results from this study and our Phase I and IIA trials, AL001 is positioned for five Phase II trials in partnership with Massachusetts General Hospital in 2025. These trials aim to redefine lithium therapy across neurodegenerative and neuropsychiatric conditions by leveraging a lower-dose, high-efficacy approach anticipated to qualify for the U.S. Food and Administration 505(b)(2) approval pathway."

Abstract 3266/H393 – Poster presentation:

Title: Pharmacokinetics of AL001, Lithium Salicylate/L-Proline Co-crystal: A Potentially Beneficial Lithium Sparing Treatment for Bipolar Disorder Type 1 (BD1), Alzheimer's Disease (AD), Major Depressive Disorder (MDD) and Post-traumatic Stress Disorder (PTSD)

Session Title: Pharmaceutical Safety and Drug Discovery

Session Date and Time: Monday, March 17, 2025; 9:15AM ET – 11:45AM ET

Session Location: Orange County Convention Center, ToxExpo Hall

Presenting Author: Darrell Sawmiller, Ph.D, Assistant Professor, Center of Excellence for Aging & Brain Repair, University of South Florida, Tampa, FL, USA

Summary: No Undue Adverse Effects: Both treatments had no negative impact on the mice's body weight or clinical signs during the treatment period. Reduced Systemic Exposure: AL001 showed lower plasma lithium levels than lithium carbonate, reducing the risk of adverse systemic effects, suggesting an expansion for safety of lithium's therapeutic index. Enhanced Brain Penetration: AL001 showed consistently higher lithium

concentrations in brain tissues, particularly at lower doses, compared to lithium carbonate. *Targeted Brain Structures:* The study found that different brain regions absorb and retain lithium differently. This means treatments can potentially be tailored to target specific brain areas, allowing for more precise treatment of various brain-related conditions when applied in human studies.

Further information can be found at

<https://www.toxicology.org/events/am/AM2025/index.asp>.

About AL001 Non-Clinical Study

The study involved administering AL001, a good manufacturing practices-quality active pharmaceutical ingredient (“**API**”) to 5XFAD mice, a recognized model for Alzheimer’s research, to compare its effects against lithium carbonate, a U.S. Food and Drug Administration approved and marketed API. Mice received either high or low doses scaled to humans of both AL001 and lithium carbonate over a 14-day period to observe pharmacokinetic steady-state drug conditions. On the 15th day, the mice were analyzed to assess how the treatments affected lithium concentrations in different brain regions and in their plasma. The results mentioned in the summary highlight the potential clinical advantages of AL001 for conditions like Alzheimer’s, BD, MDD and PTSD at low doses. By reducing the systemic burden, AL001 could lessen the risk of side effects such as thyroid and kidney complications often associated with extant lithium therapies. This positions AL001 as a promising candidate for safer long-term treatment options, without the need for routine blood lithium monitoring. This innovation is specifically designed to address the needs of fragile populations, such as elderly and Alzheimer’s patients, by offering a potentially more efficient and safer alternative to existing treatments.

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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