November 19, 2024

Alzamend Neuro Announces Full Data Set from its Nonclinical Study: Comparing Brain and Plasma Lithium Exposures between AL001 and Lithium Carbonate in Alzheimer's Transgenic Mice

- ***Alzamend is developing AL001, a lithium product designed for enhanced safety and efficacy compared to currently available FDA-approved and marketed lithium therapies***
- ***At a low dose, AL001 evidenced consistently higher lithium concentrations than lithium carbonate within critical brain regions comprising target tissue for efficacy, which may provide therapeutic benefits with less risk in multiple neurological disorders***
- ***Data will guide upcoming "Lithium in Brain" Phase II clinical trials in partnership with Massachusetts General Hospital***

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 finished analyzing the final full data set from a nonclinical study comparing brain and plasma lithium exposures between AL001 and lithium carbonate in Alzheimer's transgenic mice. The study was conducted at the University of South Florida and the bioanalytical procedures for determination of lithium concentration in the brain and plasma samples were conducted under good laboratory practice standards by Sannova Analytical LLC.

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 ("**FDA**") 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.

Key Findings:

- *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.

Clinical Implications:

These results 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.

"This is a major step towards potentially providing an important treatment innovation for the 43+ million Americans afflicted with Alzheimer's, BD, MDD and PTSD. These results demonstrated 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. "We appreciate the extraordinary efforts of our colleagues and partners. We look forward to further evaluating AL001 in five 'Lithium in Brain' Phase II clinical trials in healthy subjects and patients diagnosed with mild to moderate Alzheimer's, BD, MDD and PTSD, in partnership with Massachusetts General Hospital at the dosing level observed to be appropriate in this nonclinical study."

About Alzamend Neuro

Alzamend is an early 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 AL002 - a patented method using a mutant-peptide sensitized cell as a cell-based therapeutic biologic 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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