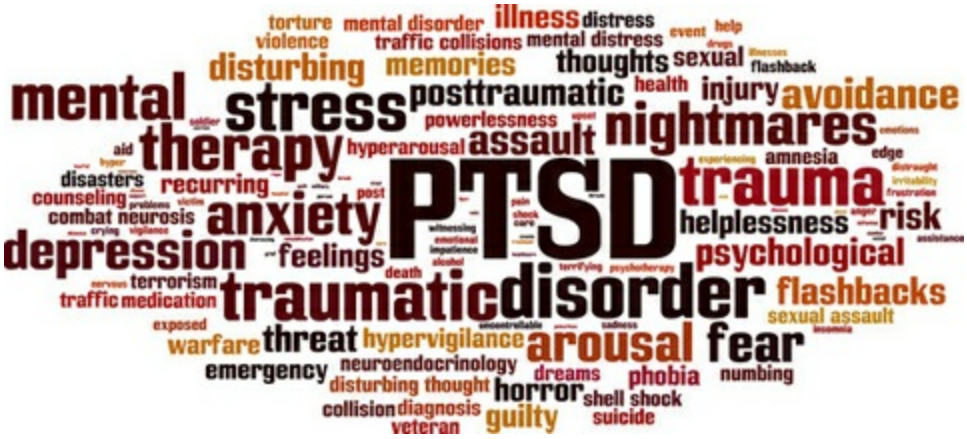
December 11, 2023

Alzamend Neuro Receives FDA “Study May Proceed” Notification for a Phase IIA Clinical Trial of AL001, a Next-Generation Lithium Therapeutic Drug Candidate, in Post-Traumatic Stress Disorder Patients

- ***Alzamend’s recently completed Phase IIA study of AL001 in Alzheimer’s patients and healthy subjects showed a benign safety profile and identified a candidate dose that is unlikely to require therapeutic drug monitoring***
- ***Safety aspects of AL001 development may qualify for a 505(b)(2) NDA pathway for FDA approval***

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 receipt of a “Study May Proceed” letter from the U.S. Food and Drug Administration (“**FDA**”) for the initiation of study AL001-PTSD01, a Phase IIA clinical study of AL001 for treatment of patients with PTSD.

This press release features multimedia. View the full release here: https://www.businesswire.com/news/home/20231211519845/en/



PTSD Symptom Word Soup. All rights reserved @2023 licensed from Adobe Stock

“We are grateful to receive this timely, favorable response from the FDA to initiate our first Phase IIA clinical study of AL001 for PTSD. Although lithium does not have an FDA-approved indication for PTSD, it has been prescribed off-label for this purpose for decades,” said Stephan Jackman, Chief Executive Officer of Alzamend. “If we can develop a next-generation lithium product (AL001) that would not routinely require therapeutic drug monitoring ('TDM'), it would constitute a major improvement over current lithium-based treatments and positively impact the 9 million Americans afflicted with PTSD. We are advancing the process and expect that

the first patient will be dosed in the first quarter of 2024. We have now received 'Study May Proceed' letters from the FDA during the last three months for Phase IIA clinical studies of AL001 for treatment of patients with BD, MDD and PTSD."

About AL001

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

Although lithium products do not have an FDA-approved indication for PTSD, case reports suggest that lithium treatment may be useful for treating PTSD patients. Specifically, treatment with low doses (300–600 mg/day) of lithium carbonate have been reported to provide effective treatment in reduction of inappropriate anger, irritability, anxiety, and insomnia in patients with PTSD. Alzamend's goal is to revive the utility of lithium treatment by importantly improving the benefit-to-risk relationship of lithium treatment in clinical practice. Based on the favorable AL001 safety profile observed in the recently completed study and extensive safety data on the drug's constituent components, the AL001 development program may qualify for a Section 505(b)(2) New Drug Application ("**NDA**") pathway for FDA approval, which is available to new formulations of an approved drug.

About Post-Traumatic Stress Disorder

PTSD is a mental and behavioral disorder that can develop because of exposure to a traumatic event, such as sexual assault, warfare, traffic collisions, child abuse, domestic violence, or other threats on a person's life (American Psychiatric Association DSM-5-TR, 2020; Mayo Clinic, 2022). People who experience interpersonal violence, such as rape, other sexual assaults, being kidnapped, stalking, physical abuse by an intimate partner, and incest or other forms of childhood sexual abuse, are more likely to develop PTSD than those who experience non-assault-based trauma, such as accidents and natural disasters. Symptoms may include disturbing thoughts, feelings, or dreams related to the events, mental or physical distress in response to trauma-related cues, attempts to avoid trauma-related cues, alterations in the way a person thinks and feels, and an increase in the fight-or-flight response. These symptoms last for more than a month after the event (American Psychiatric Association DSM-5-TR, 2020). A person with PTSD is at a higher risk of suicide and intentional self-harm. According to the NIH, about 3.6%, or roughly 9 million, adults in the U.S. have PTSD in a given year, and 9% of people develop it at some point in their life. In much of the rest of the world, rates for a given year are between 0.5% and 1% of the population.

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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