November 30, 2021

Alzamend Neuro Announces Date for Delivery of Topline Data for Phase 1 First-in-Human Clinical Trial for AL001 for Dementia Related to Alzheimer's

IND Submission for Combined AL002 Phase 1/2 Clinical Trial Expected in Second Quarter of 2022

TAMPA, Fla.--(BUSINESS WIRE)-- Alzamend Neuro, Inc. (Nasdaq: ALZN) ("**Alzamend**"), an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, today announced that it has received confirmation that topline data for its Phase 1 clinical trial for AL001 for dementia related to Alzheimer's will be delivered mid- to late-December 2021. The Phase 1 first-in-human study is for the purpose of determining potential clinically safe and appropriate dosing for AL001 in a planned Phase 2 multiple ascending dose study. AL001 is a lithium-delivering ionic cocrystal under development as an oral treatment for patients with dementia related to mild, moderate, and severe cognitive impairment associated with Alzheimer's.

"We are very excited about this important milestone for Alzamend," said Stephan Jackman, Chief Executive Officer of Alzamend. "We believe these data will confirm AL001's potential as a replacement of the current lithium-based treatments and may provide a treatment to the over 40 million Americans suffering from Alzheimer's and other neurodegenerative diseases and psychiatric disorders. We look forward to utilizing these data to move swiftly into a Phase 2 multiple ascending dose study involving Alzheimer's patients in the first quarter of 2022."

In late September 2021, Alzamend received positive feedback from the U.S. Food and Drug Administration ("**FDA**") regarding the AL002 clinical development plan, including Alzamend's proposal, to which the FDA agreed, to conduct a combined Phase 1/2 study. AL002 is 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. The FDA agreeing to the combined Phase 1/2 study has extended the timeline for the submission on the investigational new drug ("**IND**") application to be submitted to the FDA.

"We have augmented our clinical trial preparations and executions related to the AL002 combined Phase 1/2 study," said Stephan Jackman. "The unique nature of our therapeutic is difficult to produce and has required an extended timeline to identify the right manufacturing partner to provide our study drug materials. We also appreciate the FDA's thorough response, which provided us with significant clarity and advice. We believe it is important to incorporate all of the FDA's recommendations and guidance, and now anticipate submitting our IND for AL002 in the second quarter of 2022 and commencing a combined Phase 1/2 clinical trial as soon as possible after approval of the IND from the FDA."

About AL001

AL001 is a patented ionic cocrystal technology delivering lithium via a therapeutic crystal-engineered combination of lithium, proline and salicylate, known as AL001 or LiProSal, through two royalty-bearing exclusive worldwide licenses from the University of South Florida Research Foundation, Inc.

Based on preclinical data, AL001 treatment prevents cognitive deficits, depression, and irritability in APPSWE/PS1dE9 mice, and has shown an improvement of associative learning and memory and irritability compared with lithium carbonate treatments, supporting the potential of this lithium formulation for the treatment of Alzheimer's disease and psychiatric disorders. Lithium has been marketed for more than 35 years and human toxicology regarding lithium use has been well-characterized, potentially allowing Alzamend to rely upon this existing data, potentially reducing the regulatory burden for safety data.

About AL002

AL002 is a patented method using a mutant-peptide sensitized cell as a cell-based therapeutic vaccine that reduces beta-amyloid plaque and seeks to restore the ability of the patient's immunological system to combat Alzheimer's. This therapy is intended to work by stimulating the body's own immune system to prevent the formation and breakdown of beta amyloids, which build up in the brain to form a plaque and subsequently block the neurological brain signals, ultimately leading to the symptoms and onset of Alzheimer's.

About Alzamend Neuro

Alzamend Neuro is an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, including Alzheimer's. 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, proline and salicylate, and AL002 - 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.

View source version on businesswire.com:
https://www.businesswire.com/news/home/20211130005474/en/

Email: Info@Alzamend.com or call: 1-844-722-6333

Source: Alzamend Neuro