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Alzamend Neuro Receives FDA “Study May Proceed” Letter for Phase 1 Clinical Study Under Its Investigational New Drug Application for AL001 for Dementia Related to Alzheimer’s Disease

TAMPA, Fla.--(BUSINESS WIRE)-- [Alzamend Neuro, Inc.](#) (Nasdaq: ALZN) (“**Alzamend**”), an early clinical-stage stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, today announced receipt of U.S. Food and Drug Administration (“**FDA**”) study may proceed letter for a Phase 1 study under the Company’s Investigational New Drug application for AL001, a lithium-based ionic cocrystal oral therapy for patients with dementia related to mild, moderate, and severe cognitive impairment associated with Alzheimer’s disease.

“We are grateful to receive this timely, favorable response from the FDA to initiate a Phase 1 trial with AL001,” said [Stephan Jackman](#), the Chief Executive Officer of Alzamend. “We are advancing the process and expect that the first patient will be dosed in September 2021.”

About AL001

[AL001](#) is a patented ionic cocrystal technology delivering a therapeutic 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 Alzamend Neuro

We are an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, including Alzheimer’s Disease. With our product candidates, we aim to bring treatments or cures to market at a reasonable cost as quickly as possible. Our current pipeline consists of two novel therapeutic drug candidates, AL001 – a patented ionic cocrystal technology delivering 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

Disease. 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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