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Alzamend Neuro Submits IND Application for AL001 for Dementia Related to Alzheimer's Disease

TAMPA, Fla.--(BUSINESS WIRE)-- [Alzamend Neuro®](#), Inc. (Nasdaq: ALZN) ("Alzamend"), a preclinical stage biopharmaceutical company, today announced that it submitted an investigational new drug ("IND") application to the U.S. Food and Drug Administration ("FDA") for the initiation of a Phase 1 clinical study of [AL001](#) on June 30, 2021. The Phase 1, first-in-human study is for the purpose of determining potential clinically safe and appropriate AL001 dosing in future studies. AL001 is a lithium-based ionic cocrystal oral therapy for patients with dementia related to mild, moderate, and severe cognitive impairment associated with Alzheimer's disease.

Following completion of this initial study, Alzamend intends to initiate a Phase 1/2a clinical trial designed to evaluate the safety, tolerability, pharmacokinetics, pharmacodynamics, and preliminary efficacy of AL001 in Alzheimer's disease patients. Presuming favorable data, a subsequent Phase 2b program is planned to target appropriate doses for the pivotal Phase 3 safety/efficacy clinical program required for regulatory approval.

"This IND submission represents a key milestone for Alzamend as we continue to advance our proprietary pipeline. We believe AL001 could potentially provide clinicians with a major improvement over current lithium-based treatments and may constitute a means of treating Alzheimer's disease and other neurodegenerative diseases and psychiatric disorders. We look forward to providing more details on the timeline and market opportunity following FDA clearance of the IND, if obtained," commented [Stephan Jackman, Chief Executive Officer](#) of Alzamend.

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.

Alzamend's mission is to help the Alzheimer's disease community by supporting the full product development life cycle of treatment and cures for dementia and Alzheimer's disease driven by the belief that strong support of research is the foundation for true innovation. Dementia is not a normal part of aging, and there are numerous symptoms that can indicate cognitive and neurological impairments. Alzheimer's disease is the most common form of dementia. This disease robs people of their loved ones, as memories are erased and personalities are diminished. Alzamend's vision statement nicely sums up their mission: ***"Together We Can 'Make Alzheimer's Just a Memory!'"™***.

The economic impact of Alzheimer's disease can be as devastating as the emotional stress. Over 47 million people in the world currently live with Alzheimer's disease or dementia, with over 6.2 million in the U.S. (two-thirds are women). The lifetime cost of care for an Alzheimer's disease patient is estimated at \$374,000 in the U.S. According to the Alzheimer's Association, it is estimated that Alzheimer's and dementia deaths increased more than 16% in 2021 due to COVID-19. In 2021, Alzheimer's and dementia will cost the U.S. an estimated \$355 billion with the costs expected to rise into the trillions in the next 25 years. In, addition, Medicare and Medicaid is expected to pay approximately \$239 billion, or 67% of the treatment and long-term care costs associated with Alzheimer's disease and dementia, with another \$79 billion of out-of-pocket costs. According to the Alzheimer's Association, eleven million Americans provide an estimated 15.3 billion hours of unpaid care per year, valued at \$257 billion, for these patients with two-thirds of these being women, and one-third being daughters.

About Alzamend Neuro

We are a preclinical stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, including Alzheimer's disease. With our two current and future 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.AlzamendNeuro.com.

References:

1. Alzheimer's Association. <https://www.alz.org/alzheimers-dementia/facts-figures>. Accessed June 22, 2021.

2. Standard of Care: A Repository of Knowledge in the Field of Medicine.
<https://standardofcare.com/showarticle.php?artid=1231>. Accessed June 22, 2021.

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