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Alzamend Neuro Partners with Massachusetts General Hospital for a Phase II Clinical Trial of AL001, a Next-Generation Lithium Therapeutic Drug Candidate, involving Patients with Bipolar Disorder

- ***Harvard University Associate Professor, Dr. Ovidiu Andronesi MD, PhD, will be the principal investigator of the study***
- ***Head-to-head study of AL001 versus a marketed lithium carbonate product will be conducted; the goal is to compare lithium in human brain and brain structures to identify a potentially ideal dose of AL001 that is safe and effective as current products***

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 is partnering with Massachusetts General Hospital as its contract research organization ("**CRO**") to conduct first of its kind Phase II clinical study of AL001 for treatment of patients with BD. Massachusetts General Hospital is the original and largest clinical education and research facility of Harvard Medical School/Harvard University and houses the world's largest hospital-based research program.

Alzamend and Mass General have contracted with Dr. Ovidiu Andronesi, MD, PhD, to be the principal investigator on the study. Dr. Andronesi is an Associate Professor of Radiology at Harvard University and the Director of Multinuclear Metabolic Imaging, Martinos Center for Biomedical Imaging, Department of Radiology, Massachusetts General Hospital, Harvard Medical School.

Lithium was the first mood stabilizer approved by the U.S. Food and Drug Administration ("**FDA**") and is still a first-line treatment option (considered the "gold standard") for BD. Moreover, lithium has been marketed for more than 35 years and human toxicology regarding its use has been well characterized, potentially mitigating the regulatory burden for safety data. The objective of this novel trial is to assess the comparative increase in lithium levels within the brain and its structures as opposed to a commonly marketed lithium salt among BD patients. By examining the lithium content in the brains and brain structures of patients during treatments, Alzamend aims to predict the minimum dose necessary to achieve the equivalent effectiveness and safety of AL001 in contrast to established lithium salts. Alzamend is optimistic that this study will assist in meeting the regulatory safety standards through the Section 505(b)(2) pathway for approval by the U.S. Food and Drug

Administration, which is specifically designed for new formulations/delivery systems of an approved drug.

Alzamend previously completed a Phase IIA multiple ascending dose clinical trial, in which it successfully identified a maximum tolerated dose ("**MTD**") for development of AL001, as assessed by an independent safety review committee. This dose, providing lithium at a lithium carbonate equivalent dose of 240 mg 3-times daily, is designed to be unlikely to require lithium therapeutic drug monitoring ("**TDM**"). Current FDA-approved lithium salts (carbonate and citrate) are limited by a narrow therapeutic window that requires regular TDM of plasma lithium levels and blood chemistry by a clinician to mitigate adverse events. Since conventional lithium salts are eliminated relatively quickly, multiple administrations throughout the day are required to safely reach therapeutic plasma concentrations. Existing lithium drugs suffer from chronic toxicity, poor physicochemical properties, and poor brain bioavailability. However, because lithium is so effective at reducing manic episodes in patients with BD, it is still used clinically despite its narrow therapeutic index.

"We are elated to partner with Massachusetts General Hospital and Dr. Andronesi in this pivotal study for our lead therapeutic candidate AL001," said Stephan Jackman, Chief Executive Officer of Alzamend. "If we can develop a next-generation lithium product (AL001) with an improved safety profile and enhanced biodistribution in the brain that would not routinely require TDM, it would constitute a major improvement over current lithium-based treatments and positively impact the 7+ million Americans afflicted with BD. We look forward to providing more details regarding the study's timeline and market opportunity in the near future."

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 completed Phase IIA multiple-ascending dose study of AL001 in Alzheimer's patients and healthy subjects identified an 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 the 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.

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 by removing beta-amyloid from the brain. The latter is a second-generation active-immunity approach designed to mitigate the disadvantages of approved passive immunity marketed antibody products, particularly by reducing the required frequency and costs of dosing associated

with antibody products. 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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