April 11, 2022

Alzamend Neuro Contracts with Altasciences and iResearch Atlanta to Manage and Conduct Its Phase IIA Study in Patients with Alzheimer's

Full Data Set from Phase I First-in-Human Helped Establish Doses for Phase IIA Multiple Ascending Dose Study

ATLANTA--(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 contracted with Altasciences Clinical Kansas ("**Altasciences**") and iResearch Atlanta, LLC ("**iResearch**") to manage and conduct, respectively, its Phase IIA multiple ascending dose ("**MAD**") study in patients with mild to moderate Alzheimer's Disease ("**Alzheimer's**"). The Phase IIA Study, which is expected to commence enrollment in May 2022, is for the purposes of evaluating the safety and tolerability of AL001 under multiple-dose, steady-state conditions, and to determine the maximum tolerated dose in patients with mild to moderate Alzheimer's. AL001 is a novel lithium-delivery system; it is a lithium-salicylate-L-proline engineered ionic co-crystal under development as an oral treatment for patients with dementia related to mild, moderate, and severe cognitive impairment associated with Alzheimer's. AL001 has the potential to deliver the clinical benefits of marketed lithium carbonate but with reduced risk of side effects.

"Our Phase I study was successfully conducted with Altasciences and we are excited to continue this partnership," said Stephan Jackman, Chief Executive Officer of Alzamend. "We are also thrilled to add iResearch Atlanta to the team and have full confidence in their ability to execute our Phase IIA MAD study. 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 and other neurodegenerative diseases and psychiatric disorders. We look forward to providing more details following the commencement of the Phase II MAD study for AL001."

About AL001 Phase I Study

During this Phase 1 trial, participants received a single dose of AL001 containing lithium in an amount equivalent to 150 mg lithium carbonate, a dose proposed as likely appropriate for Alzheimer's treatment when given three times daily. Currently, marketed lithium carbonate 300 mg capsules are given three times daily when prescribed for manic episodes in bipolar disorder as well as for maintenance therapy of bipolar disorder in patients with a history of manic episodes. It can be difficult to control the appropriate dose of lithium salt formulations, including lithium carbonate, due to the small margin between effective and toxic blood levels, and therefore it can be challenging to avoid side effects or inadequate treatment outcomes.

The data affirmed that dose-adjusted relative bioavailability analyses of the rate and extent of lithium absorption in plasma indicate that AL001 at 150 mg dosage is bioequivalent when dose-normalized to the marketed 300 mg lithium carbonate product and the shapes of the lithium plasma concentration versus time curves are similar. Based on the Phase 1 results, it has been shown that dose-normalized bioequivalence for lithium was established between AL001 and the marketed reference lithium carbonate 300 mg capsule. AL001 was shown to be safe and well-tolerated in healthy adult subjects.

Findings of plasma bioequivalence to a marketed lithium product may allow Alzamend to reduce the scope or eliminate the need for Phase 2 and 3 studies of efficacy and/or safety of AL001 in such indications as bipolar/affective disorders in which lithium efficacy has been established. Demonstrated bioequivalence also may have utility for AL001 when seeking approval for the indications of currently marketed lithium products, and for new indications as a benchmark for safety.

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.

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Source: Alzamend Neuro, Inc.