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Alzamend®

New Immunomodulatory Therapeutic Vaccine that Targets Oligomeric Amyloid-β Could be Step Towards Halting Alzheimer's Disease Progression

TAMPA, Fla., Oct. 27, 2020 (GLOBE NEWSWIRE) -- Alzheimer's disease affects more than 5.8 million Americans at an estimated cost at over $305 billion in 2020 according to the Alzheimer's Association. Currently, Amyloid-β buildup in the brain is believed to be the cause of Alzheimer's among many researchers. There have been many attempts to prevent or reverse the disease by targeting Amyloid-β including the first vaccine clinical trial as AN-1792 in 2002 by Elan, which targeted Amyloid-β proteins. Unfortunately, the AN-1792 vaccine was suspended by FDA due to adverse effects. The long-term follow-up result to the vaccine responders demonstrated positive benefit from the vaccine, indicating that vaccine against Alzheimer's disease with Aβ is promising if the treatment can overcome the adverse effects.

The study, published in the Journal of Alzheimer's Disease on October 15, 2020, shows that this novel vaccine, using immune cells known as dendritic cells loaded with a modified Aβ known as E22W42, could be a significant step in halting Alzheimer's. Testing of this new vaccine was conducted on mice genetically engineered to develop high levels of Aβ and behavioral/cognitive abnormalities that mimic human Alzheimer's disease, also known as transgenic[1] mice. Testing has shown that all responders to the vaccine had slowed memory decline. Researchers compared two sets of mice; one set that was administered the vaccine and one set that was not, in a cognitive test called a "Radial Arm Water Maze". This maze is composed of a large central area with six paths or "arms," with a hidden escape platform found at the end of one of the arms. Mice were given a pass/fail depending on their ability to find the path with the hidden exit through a total of 15 trials. The results showed that the vaccinated mice showed fewer errors in working memory than the control transgenic mice, which showed a decrease in working memory like that seen in Alzheimer's patients.

On top of better performances in the water maze, the vaccinated mice were tested to have a higher level of Amyloid-β antibodies. Since antibodies function as the body's targeting system for foreign/unwanted materials, the antibodies will be responsible for breaking down the protein buildup, thus preventing neural degeneration.

Previous vaccine attempts have failed in the clinical trial steps due to unwanted immune system side effects. Inflammation is a primary symptom of Alzheimer's disease, so any possible treatment that causes neural inflammation as a side effect is essentially "pouring gas on a fire." This is where the E22W42 vaccine shows one of its most important qualities. As described in the study, there was no significant difference in the quantity of immune elements that cause inflammation in the plasma of the vaccinated mice vs. the control mice. The researchers conclude that the E22W42 vaccine has little potential for over priming or

otherwise inducing an adverse inflammatory reaction by the immune system. The predicted reason for the lack of inflammation is due to the vaccine being developed as a dendritic cell vaccine, acting as a natural adjuvant, as it uses dendritic cells to generate the antibodies. This is important as dendritic cells can induce a moderate amount of antibody response, thus helping to minimize adverse effects.

“This therapeutic vaccine uses the body’s own immune cells to target the toxic Aβ molecules that accumulate harmfully in the brain. And, importantly, it provides strong immunomodulatory effects without inducing an unwanted, vaccine-associated autoimmune reaction in the aging mice. We are confident that this mutant-peptide sensitized dendritic cell vaccine can overcome all major adverse events of vaccines against Alzheimer’s disease and will bring great hope to Alzheimer’s disease patients once the vaccine is available to the public,” said Dr. Cao.

In 2012, USF was granted a patent related to this technology (USPTO #8,188,046), and the patent has been exclusively licensed to Alzamend Neuro® (“**Alzamend®**” or the “**Company**”), a Tampa-based biotechnology company dedicated to finding a prevention, treatment and cure for Alzheimer’s disease. The Company’s goal is to move the technology out of preclinical testing and into human clinical trials during the first quarter of 2021 with the assistance of TAMM Net, Inc. (“**TAMM Net**”) a contract research organization located in Marietta, Georgia.

“Our Company is committed to supporting the full product development life-cycle of treatment and cures for Alzheimer’s disease,” said Stephan Jackman, CEO of Alzamend Neuro®. “We believe that strong support of research is the foundation for true innovation, and we are excited to be working with Dr. Cao, the University of South Florida and TAMM Net to further develop E22W42 (also known as CAO22W or AL002) to alleviate the burden created by Alzheimer’s disease, the nation’s 6th leading cause of death and ‘most feared disease.’”

“Modified cell therapies, especially dendritic cells, may provide a safer and more patient-specific active immunization. Ex-vivo modification of dendritic cells as a modality of treatment has been previously used in oncological therapeutics,” said Art Spalding, CEO of TAMM Net. “It has been shown to be relatively safe and is able to engage the immune system to attack the target tissues with success. Its use in Alzheimer’s therapeutics is relatively recent. We are excited to conduct a first-in-human phase 1 study of E22W42 in 2021.”

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[1] The term “transgenic mice” refers to mice that have had DNA from another source put into their DNA. The foreign DNA is put into the nucleus of a fertilized mouse egg. This enables science to transform mice into those that mimic having certain attributes i.e. having dementia or Alzheimer’s disease.

About Alzamend Neuro

Alzamend Neuro®, Inc., (“Alzamend®)” is a Delaware corporation with its corporate headquarters in Tampa, Florida with nexus in California. The mission of Alzamend® is to help the Alzheimer’s community by supporting the full product development life cycle of treatment and cures for Alzheimer’s Disease (“AD”) driven by the belief that strong support of research is the foundation for true innovation. Alzamend® is currently working to transition two therapeutics targeting Alzheimer’s disease (“AD”) from the preclinical stage at the

University of South Florida into the clinical stage and towards full commercialization. Alzamend® has licensed both a patented mutant-peptide immunotherapeutic (AL002 or E22W42) for use as a treatment or vaccine and a lithium based ionic cocrystal therapy (AL001) that may greatly reduce or eliminate the symptoms of agitation and other endpoints for mild to moderate stage patients diagnosed with AD. There are no profound treatments today for Alzheimer's disease. With AL001 and AL002, the Company believes that we can change that.

About TAMM Net, Inc.
TAMM Net is a fully integrated contract research organization providing biomedical companies with expertise in; obtaining reimbursement, researching government funding resources, providing solutions to regulatory issues and applications, and supplying distribution to closed systems. Everyone on the TAMM Net team has over 20 years of experience in their fields with documented success.

About USF Health
USF Health (www.health.usf.edu) is dedicated to creating a model of health care based on understanding the full spectrum of health. It includes the University of South Florida's Colleges of Medicine, Nursing, and Public Health; the Schools of Biomedical Sciences as well as Physical Therapy & Rehabilitation Sciences; and the USF Physicians Group. With more than $360 million in research grants and contracts last year, USF is one of the nation's top 63 public research universities and one of 39 community-engaged, four-year public universities designated by the Carnegie Foundation for the Advancement of Teaching.

About the Journal of Alzheimer's Disease
The Journal of Alzheimer's Disease (http://www.j-alz.com) is an international multidisciplinary journal to facilitate progress in understanding the etiology, pathogenesis, epidemiology, genetics, behavior, treatment and psychology of Alzheimer's disease. The journal publishes research reports, reviews, short communications, book reviews, and letters-to-the-editor. Groundbreaking research that has appeared in the journal includes novel therapeutic targets, mechanisms of disease and clinical trial outcomes. The Journal of Alzheimer's Disease has an Impact Factor of 5.101 according to Thomson Reuters' 2008 Journal Citation Reports. The Journal is published by IOS Press (http://www.iospress.nl).

Forward-looking Statements
Certain statements in this news release may contain forward-looking information within the meaning of Rule 175 under the Securities Act of 1933 and Rule 3b-6 under the Securities Exchange Act of 1934, and those statements are subject to the safe harbor created by those rules. All statements, other than statements of fact, included in this release, including, without limitation, statements regarding potential plans and objectives of the Company, are forward-looking statements that involve risks and uncertainties. There can be no assurance that such statements will prove to be accurate and actual results and future events could differ materially from those anticipated in such statements. The Company cautions that these forward-looking statements are further qualified by other factors. The Company undertakes no obligation to publicly update or revise any statements in this release, whether as a result of new information, future events or otherwise.

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