Vaxxinity Announces Publication of UB-311 Safety, Tolerability, Immunogenicity, and Clinical Efficacy Data from Phase 2a Trial in Alzheimer's Disease

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Phase 2a data published in The Lancet's eBioMedicine supports further development of UB-311

The paper concludes that UB-311 is the most advanced active immunotherapy targeting beta-amyloid in the clinic

UB-311 could offer multiple competitive advantages over licensed passive immunotherapies, including less frequent dosing, a more convenient mode of administration, improved accessibility and cost-effectiveness, and potentially lower rates of ARIA-E

CAPE CANAVERAL, Fla., Aug. 10, 2023 (GLOBE NEWSWIRE) -- Vaxxinity, Inc. (Nasdaq: VAXX), a U.S. company pioneering the development of a new class of medicines, today announced the print publication of Phase 2a clinical trial data in The Lancet's eBioMedicine (Volume 94, 104665, August 2023), stating that UB-311 "was safe and well-tolerated," with early clinical data demonstrating a trend for slowing cognitive decline in mild Alzheimer's disease (AD).

UB-311 is a synthetic, peptide-based active immunotherapy that targets toxic beta-amyloid (Aβ) oligomers and fibrils and oligomers. Two passive immunotherapies – monoclonal antibodies (mAbs) targeting Aβ – have recently been authorized by the FDA, validating Aβ as a target for disease-modifying immunotherapies of AD; however, these passive immunotherapies have been associated with amyloid-related imaging abnormalities (ARIA), which can present as vasogenic edema or sulcal effusion (ARIA-E), or as hemosiderin deposits such as microhemorrhages and superficial siderosis (ARIA-H).[1,2,3] Furthermore, the FDA-licensed mAbs require IV infusions every two weeks, and are priced at $26,500 annually, which does not include the cost of administering them or monitoring for ARIA. In contrast, UB-311 has the potential to offer multiple competitive advantages, including lower rates of ARIA-E; improved convenience through less frequent dosing and ease of administration through intramuscular injection; and overall improved accessibility and cost-effectiveness for patients and health systems.

The Phase 2a data, which have been previously disclosed, describe the safety, tolerability, immunogenicity, and early clinical efficacy of UB-311 when evaluated with quarterly or biannual booster doses. The 78-week, randomized, double-blind, placebo-controlled, parallel-group, multicenter, study was conducted in Taiwan. UB-311 elicited a robust, rapid, and titrated antibody response to Aβ. UB-311 was generally well-tolerated, with no cases of ARIA-E and limited cases of asymptomatic ARIA-H.

"This publication supports the innovative work that we and our collaborators are conducting to advance UB-311 for the potential treatment, and even prevention, of Alzheimer's disease," said Mei Mei Hu, CEO of Vaxxinity. "Imagine expanding the addressable patient population of beta-amyloid immunotherapies by multiple orders of magnitude, potentially over 1,000x, and delivering life-changing medicine at a fraction of the cost. That is our vision for UB-311 and the potential power of active immunotherapies."

Jeffrey Cummings, M.D., Ph.D., Director of the Chambers-Grundy Center for Transformative Neuroscience at the University of Nevada, Las Vegas, and co-author of the paper, commented, "The UB-311 Phase 2a program accomplished its goals of establishing safety and tolerability, while generating high levels of anti-amyloid antibodies. The gradual, natural titration of antibody titers through this approach may have contributed to a lack of ARIA-E in this study. Vaccine approaches such as UB-311 represent important ways forward in advancing treatment and prevention of Alzheimer's disease and offer the potential to transform the treatment landscape by providing participants with an accessible therapeutic option."

Although the trial was not powered to make conclusions about efficacy, secondary efficacy outcomes on cognitive, functional, behavioral, and global assessments such as ADAS-Cog, MMSE, ADCS-ADL and CDR-SB were evaluated. Trends of slowing disease progression were observed across key cognitive and functional measures for UB-311-treated versus placebo-treated participants over 78 weeks of observation, including a 48% slowing of decline on CDR-SB in the UB-311 quarterly boosting group.

The publication titled, "Safety, tolerability, immunogenicity, and efficacy of UB-311 in participants with mild Alzheimer's disease: a randomised, double-blind, placebo-controlled, phase 2a study," is available online here.

About Alzheimer's Disease

Alzheimer's disease (AD), the most common form of dementia, is a progressive neurodegenerative disorder that slowly destroys memory and cognitive skills and eventually the ability to carry out simple tasks. Its symptoms include cognitive dysfunction, memory abnormalities, progressive impairment in activities of daily living and a host of other behavioral and neuropsychiatric symptoms. The exact cause of AD is unknown, but genetic and environmental factors are established contributors. Accumulation of the beta-amyloid peptide is a key component of AD pathophysiology, with current evidence supporting the hypothesis that beta-amyloid deposits in the brain contribute to disease progression. The FDA has approved two immunotherapies that target beta-amyloid pathology in the brain. AD affects more than six million people in the United States and 44 million worldwide. The economic burden of AD is expected to surpass $2.8 trillion by 2030.

About UB-311

UB-311 is a vaccine candidate targeting toxic forms of aggregated beta-amyloid in the brain to treat and prevent Alzheimer's disease. Phase 1, Phase 2a, and Phase 2a long term extension trials have shown UB-311 to be well tolerated in mild-to-moderate AD patients over three years of repeat dosing, with a safety profile comparable to placebo and no cases of amyloid-related imaging abnormalities-edema ("ARIA-E") in the Phase 2a trial. UB-311 also elicited robust and durable anti-beta-amyloid antibody responses in patients. The FDA granted UB-311 Fast Track Designation in 2022.

About Vaxxinity

Vaxxinity, Inc. is a purpose-driven biotechnology company committed to democratizing healthcare across the globe. The company is pioneering a new class of medicines aimed at disrupting the existing treatment paradigm for chronic disease, increasingly dominated by monoclonal antibodies, which suffer from prohibitive costs and cumbersome administration. The company's proprietary technology platform has enabled the innovation of novel synthetic peptide immunotherapy candidates designed to bring the efficiency of vaccines to the treatment of chronic diseases, including Alzheimer's disease, Parkinson's disease, migraine, and hypercholesterolemia. The technology is also implemented as part of a COVID-19 vaccine program. Vaxxinity has optimized its pipeline to achieve a potentially historic, global impact on human health.

For more information about Vaxxinity, Inc., visit http://www.vaxxinity.com and follow us on social media @vaxxinity.

Forward-looking Statements

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. The use of certain words, including "believe," "may," "continue," "advancing," "will" and similar expressions, are intended to identify forward-looking statements. Forward-looking statements include statements, other than statements of historical fact, regarding, among other things: the plans for, or progress, scope, initiation, duration, enrollment, results or timing for availability of results of, development of any of Vaxxinity's product candidates or programs, including timing of the data readouts of UB-311 and subsequent clinical trials of UB-311; the target indication(s) for development or approval, the size, design, population, location, conduct, cost, objective, enrollment, duration or endpoints of any clinical trial, or the timing for initiation or completion of or availability or reporting of results from any clinical trial; the potential future regulatory authorization or approval and commercialization of Vaxxinity's product candidates; the potential benefits or competitive position of any Vaxxinity product candidate or program or the commercial opportunity in any target indication; and Vaxxinity's plans, expectations or future operations, financial position, revenues, costs or expenses. These forward-looking statements involve substantial risks and uncertainties, including statements that are based on the current expectations and assumptions of Vaxxinity's management about the development of a new class of immunotherapeutic vaccines and the innovation and efficacy of Vaxxinity's product candidates. Various important factors could cause actual results or events to differ materially from those that may be expressed or implied by our forward-looking statements, including, but not limited to: whether UB-311 or any other current or future product candidate of Vaxxinity will be approved or authorized by any regulatory agency for the indications that Vaxxinity targets; any potential negative impacts of the COVID-19 pandemic, including on manufacturing, supply, conduct or initiation of clinical trials, or other aspects of Vaxxinity's business; Vaxxinity's product candidates may not be successful or clinical development may take longer and be more costly than anticipated; product candidates that appeared promising in earlier research and clinical trials may not demonstrate safety or efficacy in larger-scale or later clinical trials or in clinical trials for other indications; the timing for initiation or completion of, or for availability of data from, clinical trials, and the outcomes of such trials; Vaxxinity's reliance on collaborative partners and other third parties for development of its product candidates; Vaxxinity's ability to obtain coverage, pricing or reimbursement for any approved products and acceptance from patients and physicians for any approved indications; delays or other challenges in the recruitment of patients for, or the conduct of, Vaxxinity's clinical trials; challenges associated with supply and manufacturing activities; and Vaxxinity's accounting policies. These and other important factors to be considered in connection with forward-looking statements are described in the "Risk Factors" section of Vaxxinity's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 27, 2023. The forward-looking statements are made as of this date and Vaxxinity does not undertake any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

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[2] Barakos J, et al. AJNR Am J Neuroradiol. 2013;34(10):1958–1965

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