Vaxxinity Announces Positive Target Engagement Data from Phase 1 Clinical Trial for Parkinson's Disease at AD/PD™ 2024

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UB-312 is first immunotherapy to show reduction of pathological alpha-synuclein in cerebrospinal fluid of Parkinson's patients

LISBON, Portugal, March 07, 2024 (GLOBE NEWSWIRE) -- Vaxxinity, Inc. (NASDAQ: VAXX), a U.S. company pioneering the development of a new class of medicines, announced positive clinical data from its UB-312 program in Parkinson's disease (PD) presented by Jean-Cosme Dodart, PhD, SVP of Research at Vaxxinity in an oral session at the AD/PD™ 2024 International Conference on Alzheimer's and Parkinson's Disease, held virtually and in Lisbon, Portugal from March 5 to March 9, 2024. UB-312 is the first active immunotherapy candidate to show reduction of pathological alpha-synuclein (aSyn) in cerebrospinal fluid (CSF) of PD patients.

UB-312 is designed to target aggregated forms of aSyn, the toxic species that underlies PD and other synucleinopathies. As part of the randomized, double-blind, placebo-controlled Phase 1 clinical trial, The Michael J. Fox Foundation (MJFF) funded a 2-year collaborative project between Vaxxinity, the Mayo Clinic, and UTHealth Houston to analyze CSF collected from patients, and to conduct exploratory research to assess target engagement.

The UB-312-induced antibodies showed preferential binding to aggregated aSyn and almost no binding to normal monomeric aSyn, as measured by dot blot. After a single priming regimen, those treated with UB-312 in the 300/100/100µg dosing group showed a 20% decrease from baseline in aggregated aSyn in the CSF compared to a 3% increase in the placebo group ($p<0.05$), as measured by a Seed Amplification Assay (SAA). Further, a *post hoc* analysis showed that patients with detectable UB-312-induced antibodies in the CSF exhibited improvement in activities of daily living as measured by the MDS-UPDRS II clinical scale ($p<0.01$). These data also suggest a correlation between reduction in aggregated aSyn in the brain and change in MDS-UPDRS II ($R=0.52$, $p=0.001$).

"What we see from our UB-312 program is the potential to change the whole conversation around Parkinson's treatment and prevention," says Lou Reese, Co-Founder and Executive Chairman of Vaxxinity. "Our findings suggest UB-312 could transform Parkinson's care, offering hope for improved outcomes with a disease-modifying treatment. The future isn't decades away: today's Parkinson's patients may have hope for the near, not distant future."

The aforementioned results come from Part B of the Phase 1 clinical trial in 20 PD patients. Vaxxinity expects to publish these results in a peer reviewed scientific journal soon. Results from Part A of the trial in healthy volunteers were published in *Movement Disorders* in 2022 (Yu et al.). Both parts of the trial showed UB-312 to be generally well tolerated (most adverse events were mild and transient) and immunogenic, with antibodies detectable in serum and CSF.

"Currently, there are no treatments that address the underlying conditions of Parkinson's, and we are very excited about this target engagement data. This provides us confidence that we are going after the right target and in a way that is statistically and clinically relevant to patients. There is new hope on the horizon," said Jean-Cosme Dodart, PhD, SVP Research at Vaxxinity. "With Parkinson's being the fastest growing neurodegenerative disease in the world, Vaxxinity remains committed to developing safe, convenient, and effective disease-modifying active immunotherapies for all."

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

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.

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; 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, UB-312, UB-313, VXX-401, UB-612 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 for UB-311, UB-312, UB-313, VXX-401 or UB-612, 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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