Vaxxinity UB-312 Parkinson's Trial Results Published in Nature Medicine

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UB-312 is the first Parkinson's candidate to reduce pathology as measured by a seed amplification assay, and suggest clinical improvement on motor experiences of daily living.

Data demonstrates target engagement and immunogenicity of the active immunotherapy UB-312 targeting pathological alpha-synuclein.

CAPE CANAVERAL, Fla., June 20, 2024 (GLOBE NEWSWIRE) -- Vaxxinity, Inc. (OTC: VAXX), a U.S. company pioneering the development of a new class of medicines known as AIMs (active immunotherapy medicines), announced today that *Nature Medicine* has published groundbreaking exploratory data from the Company's Phase 1 clinical trial of UB-312 in patients with Parkinson's disease (PD). The successful trial included measures of clinical efficacy, as well as exploratory research funded by The Michael J. Fox Foundation (MJFF) assessing target engagement in collaboration with the Mayo Clinic and UTHealth Houston.

UB-312-induced antibodies significantly decreased levels of aggregated α-synuclein (αSyn), a key pathology in PD and other synucleinopathies, as measured by a semi-quantitative seed amplification assay (SAA). This suggests that UB-312 can help to eliminate the buildup of harmful, toxic forms of the protein αSyn in the brain. Patients with detectable UB-312-induced antibodies in cerebrospinal fluid (CSF) exhibited significant improvement in motor experiences of daily living as measured by the MDS-UPDRS Part II, a commonly accepted clinical scale. This marks a potentially significant milestone in the pursuit of innovative PD care. The Phase 1 successfully met its primary outcome measures, demonstrating UB-312 was generally well-tolerated and induced anti-αSyn antibody responses in healthy volunteers and PD patients. 12 out of 13 PD patients who completed dosing developed anti-αSyn antibodies.

"The publication of this data in *Nature Medicine* immortalizes the profound impact of UB-312, leading the charge against the very core of Parkinson's," added Lou Reese, Co-Founder and Executive Chairman of Vaxxinity. "It sparks a beacon of hope and anticipation for a future where Parkinson's no longer determines the trajectory of lives. This is more than just a scientific breakthrough; it's a battle cry for change, declaring that the status quo in Parkinson's care is no longer acceptable."

Parkinson's disease, a progressive neurodegenerative condition, currently lacks an approved disease-modifying treatment. Alpha-synuclein, a key protein in PD pathology, forms aggregates known as Lewy bodies that contribute to neuronal degeneration. UB-312 is designed to stimulate a targeted immune response against pathological forms of αSyn.

Notable highlights from the exploratory Phase 1 data published in *Nature Medicine* include:

- Two exploratory CSF biomarkers show promise as measures of target engagement.
  - aggregated αSyn, as measured by an SAA
  - phosphorylated αSyn (pS129-αSyn)
- PD patients with UB-312-induced antibodies in CSF had significantly less αSyn aggregation ($p < 0.01$) and pS129-αSyn ($p < 0.05$) compared to patients without detectable CSF antibody titers.
- PD patients with UB-312-induced antibodies in CSF showed significant improvement in the MDS-UPDRS Part II motor experiences of daily living compared to patients without detectable CSF antibody titers ($p<0.05$).
- *In vitro*, UB-312-induced antibodies preferentially bind to aggregated forms of αSyn as measured by dot blot, and slow the aggregation of αSyn as measured by seed amplification.

"UB-312 has the potential to become an important and potent disease-modifying therapy for Parkinson's disease. It would be truly amazing if we could vaccinate people against Parkinson's disease in the future!" says Professor Geert Jan Groeneveld, neurologist and principal investigator of the Phase 1 clinical trial performed at the Centre for Human Drug Research in Leiden, the Netherlands.

The publication in *Nature Medicine* follows the completion of Part B of the Phase 1 clinical trial, which involved 20 patients with early PD (Hoehn & Yahr stage ≤ III) dosed with one of two priming regimens of UB-312 or placebo, and followed for 24 weeks of observation. Vaxxinity plans to continue its research and development efforts to advance UB-312 as candidate for PD. Results from Part A of the trial in 50 healthy volunteers, aged 40 to 85 years, were published in Movement Disorders in 2022 (Yu et al.). The exploratory biomarker and target engagement research portion of the trial was funded by The Michael J. Fox Foundation (MJFF), and marked a two-year collaborative project between Vaxxinity, the Mayo Clinic, and UTHealth Houston to analyze CSF collected from patients.

About UB-312
UB-312 is an AIM designed to slow or stop Parkinson's progression by addressing the root cause of the disease. In the first patient trial, it safely induced antibodies against toxic alpha-synuclein (αSyn) aggregates, representing a potential disease-modifying therapy. It is the first active immunotherapy to demonstrate target engagement in patient CSF using the αSyn seed amplification assay.

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 known as AIMs (active immunotherapy medicines) with the goal of 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 AIM technology platform has enabled the innovation of novel synthetic peptide immunotherapy candidates designed to bring the efficiency of active

immunotherapies 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.

About the Centre for Human Drug Research
The Centre for Human Drug Research (CHDR) is an independent institute that specializes in cutting-edge, early-phase clinical drug research. CHDR develops and uses state-of-the-art methods and research tools to collect as much information as possible about candidate drugs in the early phases of clinical development, helping sponsors make informed decisions regarding the further development of their product. For more information about CHDR, visit: www.chdr.nl.

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, 2024. 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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