



## **Vaxxinity Announces First Parkinson's Disease Patient Dosed in Part B of Phase 1 Clinical Trial of UB-312**

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DALLAS, Jan. 12, 2022 (GLOBE NEWSWIRE) -- Vaxxinity, Inc. (Nasdaq: VAXX), a U.S. company pioneering the development of a new class of immunotherapeutic vaccines, today announced that the first patient with Parkinson's disease (PD) has been dosed with UB-312 in Part B of a double-blinded, placebo-controlled Phase 1 clinical trial, following completion of Part A of the Phase 1 trial in healthy volunteers.

UB-312 is a synthetic peptide vaccine targeting toxic forms of aggregated  $\alpha$ -synuclein (aSyn), a protein that plays a central role in synaptic functions and regulation of neurotransmitter release at the synapse. Mutations of aSyn increase the risk of developing PD and other synucleinopathies, including dementia with Lewy bodies (DLB) as well as multiple system atrophy (MSA). UB-312 was granted an orphan designation for MSA by the European Medical Agency (EMA).

"We are delighted to achieve another milestone for Vaxxinity as we initiate the next part of our clinical program in Parkinson's, an indication with clear unmet needs for a large patient population," said Mei Mei Hu, Chief Executive Officer of Vaxxinity. "Part A of our Phase 1 study demonstrated that UB-312 was generally safe and well tolerated at multiple dose levels, and that it successfully generated robust levels of titers against aggregated aSyn that crossed the blood brain barrier at meaningful levels of approximately 0.2%. Developing vaccines that target chronic and difficult-to-treat diseases like Parkinson's are integral to our vision of providing cheaper, safer and more effective medicines to the world."

The study is enrolling up to 20 patients with PD, Hoehn and Yahr stage  $\leq$  III, at the Center for Human Drug Research in the Netherlands. Patients will be enrolled in one of two dosing cohorts with the primary objectives of safety and immunogenicity. The study will also assess exploratory biomarker endpoints for target engagement including Protein Misfolding Cyclic Amplification, supported by a grant from the Michael J. Fox Foundation, and in collaboration with Mayo Clinic and University of Texas.

More information about the trial is available at <https://clinicaltrials.gov/ct2/show/NCT04075318>.

### **About Parkinson's Disease**

Parkinson's disease currently affects approximately one million people in the United States and more than 10 million people worldwide. PD is a chronic and progressive neurodegenerative disorder that affects predominately dopamine-producing ("dopaminergic") neurons in the substantia nigra area of the brain. While today's approved products are aimed at providing symptomatic relief, they often produce significant side effects and lose their beneficial effects over time. There are no currently approved disease-modifying therapeutics for PD. Alpha-synuclein is a protein highly expressed in neurons, mostly at presynaptic terminals, suggesting a role in synaptic vesicle trafficking, synaptic functions and in regulation of neurotransmitter release at the synapse. Mutations in the gene encoding aSyn are known to cause or increase the risk of developing PD or DLB and have been shown to alter the secondary structure of aSyn, resulting in misfolded and aggregated forms of the protein (i.e., pathological forms). While mutations in the aSyn gene are rare, aggregates of aSyn in the form of Lewy bodies ("LB") and Lewy neurites are common neuropathological hallmarks of both familial and sporadic PD, suggesting a key role of aSyn in PD neuropathogenesis. Immunotherapy approaches targeting aSyn have been shown to ameliorate aSyn pathology as well as functional deficits in mouse models of PD and are now being investigated in the clinic.

### **About UB-312**

UB-312 is a vaccine candidate targeting pathological forms of aSyn for the disease-modifying treatment of PD and other synucleinopathies such as DLB and MSA. Preclinical data indicated that UB-312 elicits antibodies that preferentially recognize pathological forms of aSyn, and improves motor performance in mouse models of synucleinopathies. Clinical data from Part A of the Phase 1 trial indicate that UB-312 elicits antibody levels sufficient to cross the BBB (i.e., detectable in CSF). The European Medical Agency ("EMA") has granted UB-312 orphan designation for MSA.

### **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 synthetic, peptide-based immunotherapeutic vaccines 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 pipeline candidates designed to bring the efficiency of vaccines to the treatment of chronic diseases, including Alzheimer's, Parkinson's, 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 [www.vaxxinity.com](http://www.vaxxinity.com) and follow us on social media @vaxxinity.

### **Forward-looking Statement**

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," and "will" and similar expressions, are intended to identify forward-looking statements. 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. Additional important factors to be considered in connection with forward-looking statements are described in the "Risk Factors" section of the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on December 23, 2021. 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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