COVAXX and United Neuroscience are now Vaxxinity

April 1, 2021

New U.S. corporation consolidates chronic and infectious disease vaccines and immunotherapeutics to democratize health on a global scale

DALLAS, TX (April 1, 2021) – COVAXX and United Neuroscience today announced the consolidation of their vaccine development efforts under the newly formed holding company, Vaxxinity, Inc. The U.S. corporation is based in Dallas, Texas, with operations in Asia, Europe, Latin America, and the United States. COVAXX and United Neuroscience are now wholly-owned subsidiaries of Vaxxinity. Lou Reese, Executive chairman of COVAXX, has been appointed Executive Chairman of Vaxxinity. Mei Mei Hu, CEO of COVAXX, has been appointed CEO of Vaxxinity.

Vaxxinity will continue developing vaccines for COVID-19, neurological disorders including Alzheimer's and Parkinson's diseases, as well as prevalent chronic disorders, including migraine and hypercholesterolemia. The lead candidate in Vaxxinity's pipeline is UB-612, a vaccine candidate to fight SARS-CoV-2. Additionally, Vaxxinity has deployed hundreds of thousands of SARS-CoV-2 ELISA tests, which have received U.S. FDA Emergency Use Authorization (EUA).

"We are passionately dedicated to delivering transformative medicine through the discovery, development and commercialization of vaccines for chronic and infectious diseases," said Mei Mei Hu, CEO of Vaxxinity. "Merging our pipelines leveraging the same platform into one company will strengthen our ability to advance these urgently needed vaccines around the world."

Fighting the COVID-19 pandemic with UB-612

COVAXX, a Vaxxinity company, has employed its proprietary synthetic peptide technology platform to develop the first multitope protein/peptide-based vaccine candidate for COVID-19. This platform also allows flexible adaption to new viral variants. The vaccine candidate, UB-612, is designed to activate both B and T-cell arms of the immune system to fight against SARS-CoV-2. In a Phase 1 study, UB-612 appeared to be generally well-tolerated with a low incidence of mild local and systemic adverse events and no serious adverse events. UB-612 generated high titers of neutralizing antibodies in all participants. Subjects who received 100µg of UB-612 generated neutralizing antibodies at or above human convalescent serum from hospitalized patients who recovered from COVID-19. UB-612 has entered a Phase 2 clinical trial in Taiwan, and global Phase 2/3 trials in Brazil, India, and other countries will begin in Q2 2021. Additionally, Vaxxinity partnered with the University of Nebraska Medical Center (UNMC) for a Phase 2 trial in the United States.

Through partnerships with Aurobindo in India and the global shipping company, Maersk, Vaxxinity has the manufacturing and logistics capabilities in place to produce UB-612 at scale and safely deliver hundreds of millions of doses worldwide using existing infrastructure.

Democratizing Health through Vaccines for Alzheimer's, Parkinson's and other Chronic Diseases

Vaxxinity is pioneering a new class of immunotherapeutic vaccines to treat and prevent neurodegenerative diseases, including Alzheimer's and Parkinson's disease, as well as other chronic diseases for migraine and hypercholesterolemia. Unlike vaccines designed to prevent exogenous diseases, Vaxxinity's chronic disease pipeline can train the body to produce its own antibodies against internal targets of disease. This comes with practical administrative and cost advantages versus monoclonal antibodies, e.g., infrequent IM injection vs. frequent IV infusion, and lower cost of goods.

"By essentially turning the body into its own monoclonal manufacturer, our technology platform has the potential to truly disrupt and displace traditional biologics and mAbs with something that is accessible around the world and to everyone," says Lou Reese, Executive Chairman, Vaxxinity.

Vaxxinity's Alzheimer's vaccine candidate, UB-311, has completed a Phase 2a clinical trial and will enter Phase 3 trials soon. UB-311 targets toxic oligomeric forms of β-amyloid (Aβ). Phase 1, 2a, and 2a LTE studies have shown that UB-311 can safely generate high levels of antibody titers specific to toxic forms of Aβ. In Phase 2a, a dose-dependent slowing of cognitive decline was observed, and while not statistically significant, was directionally consistent across secondary efficacy endpoints including CDR-SB, ADAS-Cog, ADCS-ADL, and fMRI at 78 weeks. An independent statistical analysis by Suzanne Hendrix (Pentara Group) confirms these findings, and a post hoc composite efficacy endpoint performed by this group suggests marginal significance vs. placebo (p=0.0808).

In 2020, Vaxxinity's Phase 1 Parkinson's vaccine candidate, UB-312, became the first active vaccine we know of to induce antibodies observed to cross the blood-brain barrier (BBB) and enter the CNS. UB-312 targets pathologic forms of alpha-synuclein (aSyn). Antibodies induced by UB-312 against aSyn were observed in CSF at 0.2% ratio to serum levels. UB-312 has been generally safe and well tolerated so far at multiple dose levels.

Other candidates in Vaxxinity's chronic disease portfolio include vaccines against well validated targets, e.g., CGRP for migraine, and PCSK9 for hypercholesterolemia. Vaxxinity will begin IND-enabling studies for its anti-CGRP migraine vaccine UB-313 in mid-2021.

About Vaxxinity, Inc.

Vaxxinity, Inc. is a U.S.-based global biotechnology company pioneering a new class of medicines to democratize health. Headquartered in Dallas, TX, with operations in the United States, Latin America, Europe and Asia, the company's proprietary technology platform has enabled the innovation of synthetic peptide vaccines designed to treat and prevent infectious diseases, including COVID-19, and chronic diseases, including Alzheimer's, Parkinson's, migraine, and hypercholesterolemia. Vaxxinity has optimized its pipeline to achieve a potentially historic, global impact on human health. The key to the platform is the proprietary library of UBITh peptides, which are immunosilent, avoiding inflammation, and when linked to custom-designed target antigens, can elicit highly specific antibodies.

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

Diane Murphy, COVAXX, A Vaxxinity Company
+1.310.658.8756; diane@covaxx.com

David Schull, Russo Partners
+1 (212) 845.4271; david.schull@russopartnersllc.com