Vaxxinity Announces First Participant Dosed in Phase 3 Study of Next-Generation COVID-19 Vaccine Booster

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- *Pivotal Phase 3 head-to-head study will evaluate non-inferiority of heterologous booster candidate UB-612 against authorized mRNA, adenovirus vector and inactivated virus COVID-19 vaccines*

- *Agreement reached with global regulators on trial design and data package required to support potential authorization*

DALLAS, March 28, 2022 (GLOBE NEWSWIRE) -- Vaxxinity, Inc. (Nasdaq: VAXX), a U.S. company pioneering the development of a new class of immunotherapeutic vaccines, today announced that it has begun dosing participants in a Phase 3 pivotal trial of UB-612, the Company's next-generation COVID-19 booster candidate. Vaxxinity expects to deliver a topline readout of the study in the second half of 2022, and if successful, this study may support conditional approval of UB-612, as discussed with global regulators.

"Our mission is to democratize health by developing highly accessible vaccines for global needs. We believe that UB-612 has the potential to provide an important next-generation vaccine that is better tolerated, variant-ready and more accessible to help achieve global vaccine equity," said Mei Mei Hu, chief executive officer of Vaxxinity. "We are excited at the prospects for UB-612 to meet this challenge, having demonstrated UB-612 safety and tolerability in subjects receiving two and three doses of the vaccine candidate and that when used as a homologous booster, UB-612 elicits neutralizing antibodies against multiple variants, including the Omicron variant at similar or greater titers than those reported by an approved mRNA vaccine booster."

Vaxxinity is working to develop UB-612 as a next-generation booster immunization that could be protective against current and future Variants of Concern (VOCs) for populations that have received other types of COVID-19 vaccines – including mRNA, adenovirus vector, and attenuated virus. Data from Phase 1 and 2 trials suggest UB-612 is well-tolerated, with no significant safety observations, and elicits antibodies with a 6-month half-life. Earlier this month, Vaxxinity published two articles on the UB-612 homologous booster results and binding and neutralizing activity of antibodies against multiple variants. Vaxxinity expects to launch UB-612 in low-and-middle income countries where populations remain underserved and undervaccinated.

"The world needs a COVID-19 vaccine that is not only safe and effective but can be stored and transported under more amenable conditions and has the potential for durable protection against current and future VOCs, and that's exactly what Vaxxinity is aiming to deliver with UB-612," said Ulo Palm, M.D., Ph.D., chief medical officer of Vaxxinity. "We are progressing toward a viable next-generation COVID-19 vaccine that is variant-ready, durable, well-tolerated and uses a novel approach enabling easier vaccine transportation and more accessible storage than the older generation COVID-19 vaccines already approved."

The pivotal, head-to-head Phase 3 heterologous booster trial is a global platform study that will evaluate the potential for UB-612 to boost immunity against COVID-19 in people who have been fully vaccinated with an mRNA (BNT162b2), adenovirus vector (ChAdOx1-S), or inactivated virus (Sinopharm BIBP) COVID-19 vaccine. The primary objective of this active-controlled, randomized, multicenter study is to determine non-inferiority of UB-612-stimulated neutralizing antibodies versus the three comparator vaccines. Additionally, neutralizing antibodies against Omicron and other variants, non-neutralizing functional antibodies and T cell responses will be analyzed as part of secondary and exploratory objectives.

The trial has enrolled and dosed participants under a US FDA IND at PanAmerican Clinical Research trial site in Brownsville, Texas, the first site actively enrolling in the global trial. The trial is enrolling participants 16 years of age and older who have completed a two-dose primary immunization regimen with an authorized comparator COVID-19 vaccine per respective protocols. Eligible participants will be randomized to receive a single dose of UB-612 or an authorized COVID-19 vaccine comparator. Details on the pivotal Phase 3 UB-612 clinical trial can be found at clinicaltrials.gov using Identifier NCT05293665.

About UB-612
UB-612 is the first multitope subunit protein/peptide-based vaccine candidate for SARS-CoV-2, which is designed to activate both B and T-cell arms of the immune system. Phase 1 and Phase 2 trials of UB-612 conducted in ~4000 participants have shown UB-612 to be well tolerated with no vaccine-related serious adverse events. The most striking findings were induction of long lasting virus neutralizing antibodies, broad T-cell immunity against SARS-CoV-2 variants and a strong booster memory recall inducing high levels of neutralizing antibodies against Delta and Omicron variants.

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 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 Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 24, 2022. 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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