Vaxxinity’s COVID-19 Vaccine Candidate UB-612 Produces High Levels of Neutralizing Antibodies Against Omicron and Other Variants of Concern

February 11, 2022

- Investigator-sponsored studies show UB-612 induces high antibody activity against multiple variants, including Alpha, Beta, Delta, Gamma and Omicron, at levels similar to or higher than approved vaccines
- UB-612 elicits >3 times higher titers of neutralizing antibodies against Omicron variant than reported by an approved mRNA vaccine

DALLAS, Feb. 11, 2022 (GLOBE NEWSWIRE) -- Vaxxinity, Inc. (Nasdaq: VAXX), a U.S. company pioneering the development of a new class of immunotherapeutic vaccines, today announced results from studies demonstrating the ability of UB-612, its COVID-19 vaccine candidate, to elicit a broad immune response against multiple variants of concern, and specifically more than three-times higher titers of neutralizing antibodies against the Omicron variant of SARS-CoV-2 than an approved mRNA vaccine with boosters.

“The ability of these sera to neutralize Omicron at these high levels is extraordinary and unprecedented considering that Omicron has more than 30 potential immune evading mutations and deletions across its spike protein, 15 of which are in the RBD region where our UB-612 vaccine is directed. Such data show that UB-612 could potentially be a unique vaccine candidate that is highly effective at mobilizing the immune system against a broad range of both current and future SARS-CoV-2 variants,” said Farshad Guirakhoo, Ph.D., Chief Scientific Officer at Vaxxinity.

The studies were conducted by David Goldblatt, M.B. Ch.B., Ph.D., at University College London (UCL) and VisMederi, a Coalition for Epidemic Preparedness Innovations (CEPI)-centralized laboratory.

Sera from 92 participants from UB-612’s Phase 2 study including 8 placebos (randomized and tested blinded) and up to 36 participants in the Phase 1 study, half of the latter boosted with a third dose of UB-612, were used in these studies to analyze binding of IgG and neutralization against multiple Variants of Concern and Variants of Interest, including Omicron.

Key results from the studies include:
- Three doses of UB-612 elicited neutralizing antibody titers of GMT VNT50 of 335 against the Omicron variant of SARS-CoV-2, over 3-fold higher than reported after three doses of an approved mRNA vaccine [1].
- The receptor-binding domain (RBD)- and spike (S) protein-binding IgG antibodies after booster immunization with UB-612 produced high cross-reactivity against multiple SARS-CoV-2 variants, including Alpha, Beta, Delta, Gamma and Omicron, similar to or higher than those of approved vaccines and boosters [2].
- The RBD-binding antibodies against the Wuhan strain reported for several authorized vaccines are predictive of UB-612 vaccine efficacy against COVID-19 at approximately 95% after three doses [2].

Vaxxinity plans to publish these data and present the findings at World Vaccine Congress in April 2022. UB-612 has been evaluated in Phase 1 and Phase 2 studies and is preparing to launch a global pivotal booster study later this year.

Mei Mei Hu, CEO of Vaxxinity, said, “We are highly encouraged by these data as they show that UB-612 produces levels of neutralization comparable or exceeding current market leading vaccines while achieving a striking breadth of coverage against multiple variants of concern. Our hope is that we can provide a safe alternative vaccine option that can address not only today’s COVID but also tomorrow’s and the next day’s mutations.”

About the IgG Binding and Neutralization Studies

UCL performed multiple RBD- and Spike protein-binding assays on the UB-612 sera against multiple Variants of Concern/Variants of Interest and compared these to historical data generated with sera from subjects immunized with relevant approved comparator mRNA and Adenovirus COVID-19 vaccines in the same assays.

VisMederi assessed neutralization of UB-612 in live VNT assays against a Wuhan-like prototype strain (Italy INM1 strain), Omicron and Delta. VisMederi is part of the CEPI laboratory network and has developed validated live VNT assays referenced in regulatory submissions and scientific publications.

About UB-612

UB-612 is the first multitope protein/peptide-based vaccine candidate for SARS-CoV-2. The vaccine candidate is designed to activate both B and T-cell arms of the immune system. Phase 1 and Phase 2 trials of UB-612 have shown UB-612 to be well tolerated with no significant safety findings to date, while observing UB-612 generated antibodies that can bind to the S1-RBD protein and neutralize SARS-CoV-2, in addition to driving a T-lymphocyte response.

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 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.

Investor Contact
Claudia Styslinger
vaxxinity@argotpartners.com

Press Contact
Philip Cowdell
mediad@vaxxinity.com

[1] For further details on the method, please see Muik, A. et al, Science. 2022. Data from UB-612 were generated at the same laboratory as part of the CEPI centralized laboratory network. There may be minor differences that could have influenced the outcome of the study, including but not limited to sample size, virus dose amount used, and the fact that samples were not tested head-to-head.