Vaxxinity Announces Positive Topline Pivotal Phase 3 COVID-19 Booster Data for UB-612

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Vaxxinity's next-generation COVID-19 booster candidate UB-612 achieves primary and key secondary immunogenicity endpoints in a pivotal head-to-head heterologous booster trial against three authorized vaccine platforms: mRNA (Pfizer-BioNTech's BNT162b2), adenovirus vector (AstraZeneca's ChAdOx1-S), and inactivated virus (Sinopharm's BIBP)

UB-612 elicits superior neutralizing antibody titers and seroconversion rates against both Wuhan and Omicron BA.5 variants compared to adenovirus vector (ChAdOx1-S) and inactivated (BIBP) vaccines

UB-612 continues to be generally safe and well tolerated

Vaxxinity expects to submit the final sections of its marketing application to the MHRA and the TGA in 1H 2023 for conditional/provisional approval in the UK and Australia

DALLAS, Dec. 02, 2022 (GLOBE NEWSWIRE) -- Vaxxinity, Inc. (Nasdaq: VAXX), a U.S. company pioneering the development of a new class of immunotherapeutic vaccines, announced today that its next generation UB-612 COVID-19 vaccine, when administered as a single heterologous booster dose, elicited strong neutralizing antibodies against SARS-CoV-2 when compared head-to-head to three globally authorized platform vaccines administered as homologous boosters, confirming success in meeting the primary and key secondary immunogenicity endpoints of its pivotal global Phase 3 trial.

When delivered as a heterologous booster in three separate substudies in populations previously vaccinated with Pfizer-BioNTech's BNT162b2, AstraZeneca's ChAdOx1-S, or Sinopharm's BIBP, UB-612 was shown to generate neutralizing antibody titers 28 days after administration that were:

- Statistically non-inferior* to, and directionally higher than, BNT162b2: 1.04 GMR against Wuhan (95% CI: 0.89, 1.21; p=0.6147), 1.11 GMR against Omicron BA.5 (95% CI: 0.94, 1.31; p=0.2171)
- Statistically superior to ChAdOx1-S: 1.92-fold higher geometric mean titers against Wuhan with UB-612 (GMR=1.92; CI: 1.44, 2.56; p<0.0001), 2.85-fold higher against Omicron BA.5 (GMR=2.85; CI: 2.00, 4.05; p<0.0001)
- Statistically superior to BIBP: 5.77-fold higher geometric mean titers against Wuhan with UB-612 (GMR=5.77; CI: 4.62, 7.20; p<0.0001), 5.93-fold higher against Omicron BA.5 (GMR=5.93; CI: 4.60, 7.65; p<0.0001)

"We have tested UB-612 head-to-head against three of the major global market COVID-19 vaccine platforms, collectively administered to over 3.5 billion people in over 180 countries, and achieved superior or non-inferior results in each instance. Given these Phase 3 topline results, and UB-612's generally lower cost structure and ease of distribution, we believe UB-612 has the potential to serve as an optimal choice for boosting, especially in developing countries, as COVID-19 enters an endemic stage," said Mei Mei Hu, CEO of Vaxxinity. "After multiple clinical trials, we have consistently shown that UB-612 is well tolerated, continues to elicit broad coverage against emerging variants, and generates a durable neutralizing antibody titer. It's the vaccine that I'd give to my loved ones. These results also serve as further validation of our technology and our ability to rapidly design and develop vaccines to address major diseases on a global basis."

Vaxxinity intends to complete rolling submissions with the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom, and the Therapeutic Goods Administration (TGA) in Australia, to support potential conditional and provisional marketing authorizations, respectively, of UB-612 in the first half of 2023. Vaxxinity expects that achieving authorizations in these high income countries will open up the door to authorizations in low and middle income countries and to the WHO's Emergency Use Listing (EUL), both of which align with Vaxxinity's mission of democratizing health across the globe.

Topline data from the Phase 3 trial also indicate that seroconversion rates at day 29 (SCR, defined as ≥4-fold increase of neutralizing antibody titers from baseline) of UB-612 were statistically non-inferior** to and directionally higher than BNT162b2, statistically superior to ChAdOx1-S, with 1.9-fold higher SCR against Wuhan (23.6% absolute difference, p=0.0009) and 2.0-fold higher SCR against Omicron BA.5 (29.2% absolute difference, p<0.0001), and statistically superior to BIBP, with 8.3-fold higher SCR against Wuhan (56.8% absolute difference, p<0.0001) and 5.8-fold higher SCR against Omicron BA.5 (58.0% absolute difference, p<0.0001).

Preliminary safety data show that UB-612 continues to be generally well tolerated; no serious adverse events were reported. The study is ongoing, and the long-term safety profile continues to be evaluated.

The Phase 3 international, randomized, active-controlled platform trial compares the safety and immunogenicity of a booster dose of UB-612 in people who have received primary immunizations with BNT162b2, ChAdOx1-S, or BIBP head-to-head against those of a homologous boost. The trial recruited 944 participants aged 16 years and older across seven centers in the U.S., Panama, and Philippines. The primary endpoints of the trial are safety, tolerability, and live virus neutralizing antibody titers against the Wuhan strain of SARS-CoV-2 at day 29. Secondary immunogenicity endpoints include neutralizing antibody titers against Omicron at day 29, seroconversion rates at day 29, and kinetics of neutralizing and RBD binding IgG antibody responses through 12 months.

The Coalition for Epidemic Preparedness Innovations (CEPI) is co-funding this trial, which will conclude in the second half of 2023, with additional long term follow up data on safety, T-cell immunity, and durability of immune responses.

Dr. Melanie Saville, Executive Director of R&D at CEPI, said, "COVID-19 is with us for the long term, so the world continues to need a range of vaccine

options to combat the virus and its variants. We at CEPI are proud to support this clinical trial to generate valuable evidence to inform booster strategies for those previously vaccinated with shots distributed through COVAX."

The topline Phase 3 data support findings from Phases 1 and 2 that UB-612 elicits neutralizing antibodies against a broad array of SARS-CoV-2 variants: data from Phases 1 and 2 suggest a UB-612 booster stimulated broadly reactive antibodies to the RBDs of 14 divergent variants including Alpha, Beta, Gamma, and Delta, and were published in the Journal of Infectious Diseases. UB-612 is formulated with an RBD protein, a key antigen target for neutralizing antibodies, and peptide antigens which contain epitopes that have remained highly conserved across variants. UB-612-generated antibodies have a half-life of 6 months, longer than the published half-lives of antibodies generated by mRNA, adenovirus vector, and inactivated virus vaccines, suggesting that immunity from UB-612 may last longer against emerging variants.

* GMR (geometric mean ratio) non-inferiority defined by lower bound of 95% confidence interval > 0.67.
**SCR non-inferiority defined by lower bound of 95% confidence interval for UB-612 SCR – comparator SCR difference > -10%.

About UB-612

UB-612 is the first multitope subunit protein/peptide-based vaccine candidate for SARS-CoV-2, designed to activate both B- and T-cell arms of the immune system directed against multiple structural viral antigens. Phase 1 and Phase 2 trials of UB-612 conducted in >4,250 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 humoral and T-cell immunity, and a strong booster memory recall inducing high levels of neutralizing antibodies against Delta, Omicron, and other SARS-CoV-2 variants. The pivotal Phase 3 trial of UB-612, co-funded by the Coalition for Epidemic Preparedness Innovations (CEPI), is designed to evaluate the ability of UB-612 to boost COVID-19 immunity in people immunized with one of three authorized COVID-19 vaccines. More details on the trial can be found at clinicaltrials.gov using Identifier NCT05293665.

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 "look forward," "if," "plan," "may," "could," "expect," "potentially," "will" and similar expressions, are intended to identify forward-looking statements. These forward-looking statements involve substantial risks and uncertainties, and are based on the current expectations and assumptions of Vaxxinity's management. Forward-looking statements include statements about the development of a new class of immunotherapeutic vaccines; the innovation, safety and potential efficacy of Vaxxinity's product candidates; and the anticipated outcomes from the studies we are conducting or will conduct for our product candidates.

Drug development and commercialization involve a high degree of risk and only a small number of research and development programs result in commercialization of a product. Results in early-stage clinical trials may not be indicative of full results or results from later stage or larger scale clinical trials and do not ensure regulatory approval. You should not place undue reliance on these statements, or the scientific data presented.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements, including without limitation, uncertainty of success in the development and potential commercialization of Vaxxinity's product candidates; unexpected concerns may arise from additional data, analysis or results of clinical studies of Vaxxinity's product candidates; regulatory authorities may require additional information or further studies, or may fail or refuse to approve or may delay approval of Vaxxinity's drug candidates, including UB-312, UB-313, VXX-401 and UB-612; the occurrence of adverse safety events; the risks of other unexpected costs or delays; failure to protect and enforce intellectual property and other proprietary rights and uncertainties relating to intellectual property claims and challenges; third party collaboration risks; and the direct and indirect impacts of general economic, political, demographic and business conditions. The foregoing does not list all of the factors that could cause actual results to differ from Vaxxinity's expectations in any forward-looking statement. Investors should consider this cautionary statement as well as the risk factors identified in Vaxxinity's most recent annual or quarterly report and in other reports Vaxxinity has filed with the U.S. Securities and Exchange Commission.

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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