Vaxxinity Initiates Rolling Submission for UB-612 COVID-19 Vaccine with MHRA (UK)

September 12, 2022

DALLAS, Sept. 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 it has initiated a rolling submission to the Medicines and Healthcare products Regulatory Agency (MHRA) in the United Kingdom for conditional marketing authorization of its UB-612 COVID-19 vaccine as a heterologous boost to authorized primary series vaccines. UB-612 is currently being assessed in a Phase 3 pivotal trial as a booster vaccine for subjects who have received primary immunization with mRNA, adenovirus vector, or inactivated virus vaccines. Vaxxinity reiterates its plan to have a topline readout of the Phase 3 trial in the fourth quarter of 2022.

“Authorizations by stringent regulatory authorities such as the MHRA could open the pathway for UB-612 to reach countries with high unmet needs,” said Mei Mei Hu, CEO of Vaxxinity. “Because so many low and middle income (LMIC) countries look to stringent regulators' decisions as a reference, we anticipate that MHRA authorization, if achieved, could ultimately enable Vaxxinity to market UB-612 in a number of LMIC countries across the globe, which is the heart of Vaxxinity’s mission. Additionally, this authorization is a pathway to grant WHO emergency use listing (EUL), which would provide another option for getting UB-612 to countries through the COVAX program.”

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 directed against multiple structural viral antigens. 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 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. UB-612 is now in a pivotal Phase 3 trial. 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 “could,” “anticipate,” “would,” "potentially," and "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 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 and other reports we file with the 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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