Vaxxinity Completes Enrollment in Pivotal Phase 3 Clinical Trial of UB-612 COVID-19 Vaccine Heterologous Booster Candidate and Initiates Rolling Submission for Provisional Approval in Australia

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UB-612 Phase 3 topline data readout expected in 4Q22

DALLAS, Oct. 24, 2022 (GLOBE NEWSWIRE) -- Vaxxinity, Inc. (Nasdaq: VAXX), a U.S. company pioneering the development of a new class of immunotherapeutic vaccines, today announced that enrollment is complete for its global Phase 3 pivotal trial evaluating UB-612 as a heterologous booster vaccine to mRNA, adeno-vectored, and inactivated primary series vaccinations. The company remains on track to report topline data in the fourth quarter of 2022. In addition, the company has initiated a rolling submission to the Therapeutic Goods Administration (TGA) in Australia for provisional approval of its UB-612 COVID-19 vaccine as a heterologous boost after being granted provisional determination from the TGA in September 2022.

“Completing enrollment in a pivotal COVID-19 vaccine trial is a tremendous accomplishment in today’s environment and we are extremely grateful to all the participants, investigators, and CRO partners involved in this milestone. We look forward to announcing topline immunogenicity data that will serve as the basis for future authorization applications,” said Mei Mei Hu, CEO of Vaxxinity. “Our regulatory progress continues with the initiation of a rolling submission to the TGA in Australia, following the previously announced initiation of the rolling submission to MHRA in the UK. The review and potential approval by these two regulatory agencies will allow us to pursue our mission of democratizing health by bringing UB-612 to the countries that are most in need of next generation COVID-19 vaccines.”

The Phase 3 clinical trial of UB-612 was designed to compare the safety and immunogenicity of a booster dose of UB-612 in patients who have received a primary immunization with mRNA, adenovirus vector, or inactivated virus vaccines to a booster dose with the same vaccine used in the primary series vaccination. UB-612 is a vaccine booster candidate designed to boost COVID-19 immunity against the original strain and multiple variants of concern including Omicron in people aged 16 years or older. More information about the Phase 3 study with UB-612 is available at clinicaltrials.gov (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 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 "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 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 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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