Vaxxinity Receives FDA Fast Track Designation for UB-311 for Treatment of Alzheimer's Disease

May 2, 2022

DALLAS, May 02, 2022 (GLOBE NEWSWIRE) -- Vaxxinity, Inc. (Nasdaq: VAXX), a company pioneering the development of a new class of immunotherapeutic vaccines, today announced that UB-311, an anti-amyloid beta immunotherapeutic vaccine, has been granted Fast Track designation by the U.S. Food and Drug Administration (FDA) for the treatment of Alzheimer's disease.

"We are excited that the FDA has granted UB-311 Fast Track Designation, as it recognizes the evidence demonstrating the potential for UB-311 to address a serious unmet medical need for patients with Alzheimer's disease," said Mei Mei Hu, Chief Executive Officer of Vaxxinity. "We are on an encouraging clinical path for UB-311 and look forward to collaborating with the FDA and other global regulatory agencies to bring UB-311 expeditiously to the global market. Because our vaccine approach allows for more convenient administration and broad access, UB-311 is positioned to potentially lead a paradigm shift in the treatment, and even prevention, of Alzheimer's."

The Fast Track program is designed to facilitate the development and expedite the review of new drugs intended to treat serious or life-threatening conditions, with evidence demonstrating the potential to address an unmet medical need. A Fast Track designation allows for more frequent engagement with the FDA to discuss development plans and the design of proposed clinical trials to ensure appropriate data collection to support drug approval processes.

About Alzheimer's Disease
Alzheimer's disease (AD), the most common form of dementia, is a progressive neurodegenerative disorder that slowly destroys memory and cognitive skills and eventually the ability to carry out simple tasks. Its symptoms include cognitive dysfunction, memory abnormalities, progressive impairment in activities of daily living and a host of other behavioral and neuropsychiatric symptoms. The exact cause of AD is unknown, but genetic and environmental factors are established contributors. Accumulation of the amyloid beta peptide is a key component of AD pathophysiology with current evidence supporting the hypothesis that amyloid beta deposits in the brain contribute to disease progression. AD affects more than six million people in the United States and 44 million worldwide. The economic burden of AD is expected to surpass $2.8 trillion by 2030.

About UB-311
UB-311 is an immunotherapeutic vaccine candidate targeting toxic forms of aggregated amyloid beta in the brain to treat Alzheimer's disease. Phase 1, Phase 2a, and Phase 2a Long Term Extension trials have shown UB-311 to be well tolerated in mild-to-moderate AD patients over three years of repeat dosing, with a safety profile comparable to placebo and no cases of amyloid-related imaging abnormalities-edema ("ARIA-E") in the main study. UB-311 also elicited robust and durable anti-amyloid beta antibody responses in patients. A Phase 2b trial is expected to be initiated in late 2022.

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.

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," "aim," "strive," "intend," "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, the potential outcome and findings of clinical trials for UB-311 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.

Investor Contact
Claudia Styslinger
vaxxinity@argotpartners.com

Press Contact
Karen Chase
karen.chase@westwicke.com