



Vaxxinity's Cholesterol Vaccine Candidate Successfully Lowers LDL-C: Preclinical Data Published

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Preclinical data published in the Journal of Lipid Research indicate VXX-401 is well-tolerated, with no safety signals observed, and robustly reduces LDL-C in cynomolgus monkeys.

A Phase 1 trial of VXX-401 is ongoing, with topline results expected mid-2024.

CAPE CANAVERAL, Fla., Feb. 15, 2024 (GLOBE NEWSWIRE) -- Vaxxinity, Inc. (Nasdaq: [VAXX](#)), a U.S. company pioneering the development of a new class of medicines, today announced the [publication](#) of data from multiple non-human primate studies demonstrating that VXX-401 reproducibly lowers low-density lipoprotein cholesterol (LDL-C) in non-human primates. The results, which support the continued clinical development of VXX-401 as a candidate for the treatment of hypercholesterolemia and prevention of atherosclerotic cardiovascular disease, were published in the *Journal of Lipid Research* (Volume 65, Issue 2, 100497, February 2024).

VXX-401 is a synthetic peptide vaccine designed to stimulate the immune system to produce antibodies targeting proprotein convertase subtilisin/kexin type 9 (PCSK9), which reduce circulating LDL-C by inhibiting the breakdown of low density lipoprotein receptor (LDLR). High LDL-C is a major risk factor for coronary heart disease, heart attack, and stroke, and atherosclerosis is the leading cause of disease burden globally.ⁱ Previous studies have demonstrated that blocking PCSK9 yields lower LDL-C levels and reduces the risk of adverse cardiovascular events.^{ii iii}

Across three separate preclinical studies in cynomolgus monkeys, VXX-401 induced a strong and durable antibody response against PCSK9, and robust, sustained reduction of LDL-C over time. Prolonged exposure with VXX-401 resulted in an average of 44% LDL-C reduction. VXX-401 was well tolerated and did not induce any toxicity nor pathology beyond mild injection site reactions. These results suggest that VXX-401 could be a safe and effective anti-PCSK9 immunotherapy.

"Vaxxinity is committed to providing scalable, accessible, game-changing solution for worldwide heart health," said Mei Mei Hu, CEO of Vaxxinity. "Despite multiple approved medications for LDL-C reduction, heart disease remains the number one killer in the world. A cholesterol vaccine like VXX-401 may provide a cost-effective and widely deployable solution that could potentially benefit hundreds of millions of people at risk. A well tolerated intervention that people can start early in life, and remain on for many years, lowering the cholesterol 'area under the curve,' has the potential to help us win the fight against heart disease."

VXX-401 is currently in a Phase 1 clinical trial for safety and tolerability. Vaxxinity is on track to report initial topline data in mid-2024. More information about the trial is available at clinicaltrials.gov using Identifier [NCT05762276](#).

About VXX-401

VXX-401 was designed using Vaxxinity's proprietary synthetic peptide vaccine platform and is being developed for the treatment of hypercholesterolemia. The platform is designed to harness the immune system to convert the body into its own natural "drug factory," stimulating the production of antibodies. VXX-401 is designed to induce robust, long-acting antibodies against PCSK9 and lower LDL cholesterol to prevent or treat coronary heart disease.

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 medicines 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 synthetic peptide immunotherapy candidates designed to bring the efficiency of vaccines to the treatment of chronic diseases, including Alzheimer's disease, Parkinson's disease, 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 Statements

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," "will" and similar expressions, are intended to identify forward-looking statements. Forward-looking statements include statements, other than statements of historical fact, regarding, among other things: the plans for, or progress, scope, initiation, duration, enrollment, results or timing for availability of results of, development of any of Vaxxinity's product candidates or programs; the target indication(s) for development or approval, the size, design, population, location, conduct, cost, objective, enrollment, duration or endpoints of any clinical trial, or the timing for initiation or completion of or availability or reporting of results from any clinical trial; the potential future regulatory authorization or approval and commercialization of Vaxxinity's product candidates; the potential benefits or competitive position of any Vaxxinity product candidate or program or the commercial opportunity in any target indication; and Vaxxinity's plans, expectations or future operations, financial position, revenues, costs or expenses. 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, including, but not limited to: whether UB-311, UB-312, UB-313, VXX-401, UB-612 or any other current or future product candidate of Vaxxinity will be approved or authorized by any regulatory agency for the indications that Vaxxinity targets; any potential negative impacts of the COVID-19 pandemic, including on manufacturing, supply, conduct or initiation

of clinical trials, or other aspects of Vaxxinity's business; Vaxxinity's product candidates may not be successful or clinical development may take longer and be more costly than anticipated; product candidates that appeared promising in earlier research and clinical trials may not demonstrate safety or efficacy in larger-scale or later clinical trials or in clinical trials for other indications; the timing for initiation or completion of, or for availability of data from, clinical trials for UB-311, UB-312, UB-313, VXX-401 or UB-612, and the outcomes of such trials; Vaxxinity's reliance on collaborative partners and other third parties for development of its product candidates; Vaxxinity's ability to obtain coverage, pricing or reimbursement for any approved products and acceptance from patients and physicians for any approved indications; delays or other challenges in the recruitment of patients for, or the conduct of, Vaxxinity's clinical trials; challenges associated with supply and manufacturing activities; and Vaxxinity's accounting policies. These and other important factors to be considered in connection with forward-looking statements are described in the "Risk Factors" section of Vaxxinity's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on March 27, 2023. 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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ⁱ World Health Organization. (2021, July). Cardiovascular diseases (CVDs). [https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-\(cvds\)](https://www.who.int/news-room/fact-sheets/detail/cardiovascular-diseases-(cvds))

ⁱⁱ Sabatine MS, Giugliano RP, Keech AC, et al. Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease. *N Engl J Med.* 2017;376(18):1713-1722. doi:10.1056/NEJMoa1615664

ⁱⁱⁱ Schwartz GG, Steg PG, Szarek M, et al. Alirocumab and Cardiovascular Outcomes after Acute Coronary Syndrome. *N Engl J Med.* 2018;379(22):2097-2107. doi:10.1056/NEJMoa1801174