



Vaxxinity Announces First Subjects Dosed in Phase 1 Clinical Trial of VXX-401, Investigational Anti-PCSK9 Vaccine to Treat Hypercholesterolemia

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CAPE CANAVERAL, Fla., March 20, 2023 (GLOBE NEWSWIRE) -- Vaxxinity, Inc. (Nasdaq: [VAXX](#)), a U.S. company pioneering the development of a new class of immunotherapeutic vaccines, today announced that the first subjects have been dosed in a randomized, double-blind, placebo-controlled Phase 1 clinical trial of VXX-401, an investigational vaccine designed to lower low-density lipoprotein (LDL) cholesterol, a known factor contributing to heart disease, by targeting proprotein convertase subtilisin/kexin type 9 serine protease (PCSK9). Heart disease remains the leading cause of death globally, claiming over 18 million lives per year, despite the existence of approved treatments that lower LDL.

"This is an exciting milestone for VXX-401 and Vaxxinity in our pursuit to vaccinate the world against heart disease with a preventative option that is convenient and accessible, addressing an unmet need to combat the leading global cause of death," said Mei Mei Hu, Chief Executive Officer of Vaxxinity. "PCSK9 antibody therapies are well-tolerated and effective, but huge unmet patient need remains. In order to solve the problem of heart disease, the world needs a scalable, accessible technology that can reach the hundreds of millions, if not billions of people at risk. With an LDL-lowering vaccine we can potentially offer an option that's cost-effective, safe, convenient, long-acting, and deployable."

The multicenter Phase 1 dose-escalation trial aims to enroll 48 subjects aged 18 to 75 years, with LDL cholesterol between 2.59 and 4.89 mmol/L. The objectives of the trial are to evaluate safety, tolerability and immunogenicity (as measured by serum anti-PCSK9 antibody titers). Pharmacodynamics of the immune response will be measured by LDL cholesterol levels, an established model of PCSK9 inhibition in hypercholesterolemia.

"We're excited to get this first-in-human trial of VXX-401 started. The concept of a vaccine for cholesterol could be a game-changer in cardiovascular health due to its potentially very broad reach and impact on human health," said Professor Stephen Nicholls of Monash University and Victorian Heart Hospital in Australia. "Targeting PCSK9 with a monoclonal antibody is a proven and effective approach for lowering cholesterol and reducing the risk of heart attack and stroke. Despite the availability of statins and the approval of PCSK9-targeting medicines, there is still a need for new therapies. VXX-401 has the potential to extend the use of PCSK9 inhibition to the full population who could benefit."

Earlier this month, Vaxxinity presented pre-clinical data at the American College of Cardiology/World Congress of Cardiology Annual Scientific Session demonstrating that VXX-401 induced robust anti-PCSK9 antibodies and durable LDL cholesterol lowering without affecting high-density lipoprotein (HDL) cholesterol levels, indicating that VXX-401 has the potential to be a safe and effective LDL lowering therapy. Data in non-human primate studies show that VXX-401 was well tolerated and provided durable and significant LDL reduction of 30% to 50% change from baseline. The data also demonstrate VXX-401's immunogenicity: purified antibodies from immunized animals bound to human PCSK9 with high affinity, and exhibited a dose-dependent functional inhibition of PCSK9 in vitro. Additionally, Peripheral Blood Mononuclear Cells (PBMCs) collected prior to immunization did not release cytokines upon stimulation with various components of the vaccine, suggesting that VXX-401 may safely overcome immune tolerance.

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 in order to lower LDL cholesterol.

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.

Investor Contact

Mark Joinnides
ir@vaxxinity.com

Press Contact

Jon Yu
media@vaxxinity.com