Vaxcyte Doses First Participant in Phase 1 Study Evaluating VAX-A1 for the Prevention of Disease Caused by Group A Streptococcus in Healthy Adults

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First-in-Human Study Evaluating VAX-A1, a Potential Best-in-Class Vaccine Candidate Designed to Provide Broad Protection Against Disease Caused by Group A Streptococcus

Two-Stage, Dose-Escalation Study Designed with Primary Objective to Evaluate Safety and Tolerability and Secondary Objective to Assess Antigen-Specific Immune Responses

Group A Strep Is Responsible for Approximately 800 Million New Cases of Illness and More Than 600,000 Deaths Annually Worldwide, with No Approved Vaccine and Significant Public Health Burden

SAN CARLOS, Calif., June 02, 2026 (GLOBE NEWSWIRE) -- Vaxcyte, Inc. (Nasdaq: PCVX), a clinical-stage vaccine innovation company engineering high-fidelity vaccines to protect humankind from bacterial diseases, today announced that the first participant was dosed in the Phase 1, first-in-human study evaluating VAX-A1, the Company's investigational prophylactic vaccine candidate for the prevention of disease caused by Group A Streptococcus (Group A Strep), in healthy adults aged 18 to 40 years. The Company expects to announce topline data from the study in the second half of 2027.

The primary objective of this randomized, double-blind, placebo-controlled, dose-escalation, two-stage study is assessing the safety and tolerability of VAX-A1, along with a secondary objective of evaluating initial immunogenicity data, to support potential further advancement. The Stage 1 portion of the study is evaluating three dose levels (Low, Mid and High) compared to placebo in approximately 12 adults in a controlled, staged enrollment and dose-escalation approach. Following completion of the Stage 1 Month 1 visit, an independent Data Safety Monitoring Board (DSMB) will review unblinded safety and tolerability data. Upon DSMB approval, the Stage 2 portion of the study is expected to proceed and evaluate the same three dose levels compared to placebo in approximately 68 adults. All participants in the study will be evaluated for safety through six months following the second dose.

"Initiation of our VAX-A1 adult study represents an important milestone as we advance a novel approach to addressing disease caused by Group A Strep, a significant global public health challenge with no approved vaccine," said Grant Pickering, Chief Executive Officer and Co-Founder of Vaxcyte. "VAX-A1 is designed to leverage our platform to target conserved elements of the pathogen and disarm its defense mechanisms to provide broad protective immune responses across Group A Strep subtypes. We believe this program has the potential to advance a meaningful preventative approach and look forward to generating initial clinical data to provide a foundation for evaluating next steps in the development of VAX-A1."

"Group A Strep is responsible for a wide spectrum of disease ranging from strep throat to severe invasive infections and immune-mediated conditions such as acute rheumatic fever, rheumatic heart disease and post-streptococcal glomerulonephritis," said Jim Wassil, Executive Vice President and Chief Operating Officer of Vaxcyte. "The burden of disease affects both adults and children globally and contributes to substantial healthcare costs and antibiotic use. In the U.S., serious Group A Strep infections have risen over the past decade and reached a 20-year high in 2023, while antibiotic resistance has also increased, reinforcing the need for preventative approaches such as vaccination to help improve outcomes."

About the VAX-A1 Adult Phase 1 Study
This randomized, double-blind, placebo-controlled, two-stage, dose-escalation clinical study is evaluating VAX-A1 in approximately 80 healthy adults aged 18 to 40 years. Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT07616934.

Stage 1 of the study will enroll approximately 12 participants to evaluate VAX-A1 at three dose levels (Low, Mid and High), in a controlled, staged enrollment and dose-escalation approach. Dose escalation for each cohort in Stage 1 will be based on a review of blinded safety and tolerability data by the Company's Internal Safety Team prior to proceeding with enrolling the next cohort. Following completion of the Stage 1 Month 1 visit, an independent DSMB will review unblinded safety and tolerability data. Upon DSMB approval, Stage 2 is expected to proceed and enroll approximately 68 participants to further evaluate VAX-A1 across the same three dose levels.

The study is being conducted at an investigative site in Australia, where Group A Strep has been especially problematic and where there are experienced investigator networks with expertise in Group A Strep.

Participant Overview

- **Stage 1 (n=12):** Participants will be randomized 3:1 to receive VAX-A1 or placebo across three dose levels (Low, Mid and High).
- **Stage 2 (n=68):** Participants will be randomized 1:1:1:1 to receive VAX-A1 at one of the three dose levels or placebo.

All participants are expected to receive two doses administered approximately two months apart.

Safety and Immunogenicity Assessments

- Primary objectives include evaluation of safety and tolerability, including assessment of solicited and unsolicited adverse events, serious adverse events and adverse events of special interest.
- Secondary objectives include evaluation of antigen-specific immune responses to Group A Strep antigens, including serum immunoglobulin G (IgG) responses to C5a peptidase (ScpA), streptolysin O (SLO), S. pyogenes adhesion and division protein (SpyAD) and a universal polysaccharide (modified Group A carbohydrate or GAC^{PR}).

Safety and tolerability will be assessed for approximately six months following the second and final vaccination.

About Group A Strep
Group A Strep is one of the leading causes of bacterial infections worldwide, responsible for a broad spectrum of disease ranging from common illnesses such as strep throat and skin infections to severe invasive disease, including necrotizing fasciitis and streptococcal toxic shock syndrome, as well as immune-mediated sequelae such as acute rheumatic fever, rheumatic heart disease and post-streptococcal glomerulonephritis, a form of kidney inflammation. With an estimated 800 million new cases of illness and more than 600,000 deaths annually worldwide, Group A Strep remains a major clinical burden. The economic impact is substantial, exceeding an estimated $6 billion annually in the U.S. alone.

The public health challenge associated with Group A Strep is compounded by evolving epidemiology, including increasing rates of invasive disease and the re-emergence of certain manifestations in markets with historically lower disease burden. Group A Strep also drives significant antibiotic use, especially among children, contributing to rising resistance to multiple antibiotic classes. As a result, Group A Strep contributes to the global threat of antimicrobial resistance (AMR), reinforcing the need for preventative approaches such as vaccination.

About VAX-A1
VAX-A1 is a prophylactic vaccine candidate designed to provide broad protection against Group A Strep by targeting conserved antigens associated with immune evasion and virulence. The candidate incorporates three protein antigens, including C5a peptidase (ScpA), streptolysin O (SLO) and S. pyogenes adhesion and division protein (SpyAD), as well as a modified Group A carbohydrate (GAC^{PR}) designed to remove potentially cross-reactive epitopes historically associated with autoimmune complications. VAX-A1 is being developed using Vaxcyte's cell-free protein synthesis platform, which enables precise antigen design and site-specific conjugation intended to preserve immunogenicity while avoiding problematic regions.

The vaccine is designed to induce functional immune responses against conserved structures of the pathogen and disarm its defense mechanisms, providing broad, strain-independent protection. This approach is intended to address limitations of prior vaccine strategies, including antigen variability and concerns regarding autoimmune cross-reactivity.

About Vaxcyte
Vaxcyte is a vaccine innovation company engineering high-fidelity vaccines to protect humankind from the consequences of bacterial diseases. VAX-31, a 31-valent PCV candidate being evaluated in the OPUS Phase 3 adult clinical program and in a Phase 2 infant clinical program, is being developed for the prevention of IPD and is the broadest-spectrum PCV candidate in the clinic today. VAX-24, a 24-valent PCV candidate, is designed to cover more serotypes than any infant PCV on-market. VAX-31 and VAX-24 are designed to improve upon standard-of-care PCVs by covering the serotypes in circulation that cause a significant portion of IPD and are associated with high case-fatality rates, antibiotic resistance and meningitis, while maintaining coverage of previously circulating strains. VAX-XL, in earlier-stage development, also leverages the Company's carrier-sparing, site-specific conjugation technology with the aim of further expanding coverage to deliver the broadest-spectrum candidate in the Company's PCV franchise.

VAX-A1 is a prophylactic vaccine candidate designed to provide broad, strain-independent protection against disease caused by Group A Strep and is currently being evaluated in a Phase 1 clinical study in adults. Group A Strep remains a significant global cause of morbidity and mortality across both adult and pediatric populations and is a leading driver of antibiotic use, underscoring the substantial public health burden.

Vaxcyte is re-engineering the way highly complex vaccines are made through XpressCF®, its cell-free protein synthesis platform exclusively licensed from Sutro Biopharma, Inc. Unlike conventional cell-based approaches, the Company's system for producing difficult-to-make proteins and antigens is intended to accelerate its ability to develop high-fidelity vaccines with enhanced immunological benefits. Vaxcyte's pipeline also includes VAX-GI, a vaccine candidate designed to prevent Shigella. For more information, visit www.vaxcyte.com.

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements related to the potential benefits of Vaxcyte's carrier-sparing platform and vaccine candidates, including, but not limited to, breadth of coverage, the ability to deliver potentially best-in-class vaccines, the ability to improve upon the standard-of-care, and the ability to significantly reduce the burden of disease; the expected timing of the announcement of topline data from the VAX-A1 Phase 1 study; the demand for Vaxcyte's vaccine candidates; and other statements that are not historical fact. The words "anticipate," "believe," "could," "expect," "intend," "may," "on track," "potential," "should," "would" and similar expressions (as well as other words or expressions referencing future events, conditions or circumstances) convey uncertainty of future events or outcomes and are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements are based on Vaxcyte's current expectations and actual results and timing of events could differ materially from those anticipated in such forward-looking statements as a result of risks and uncertainties, including, without limitation, risks related to Vaxcyte's product development programs, including development timelines, success and timing of chemistry, manufacturing and controls and related manufacturing activities, potential delays or inability to obtain and maintain required regulatory approvals for its vaccine candidates, and the risks and uncertainties inherent with preclinical and clinical development processes; the success, cost and timing of all development activities and clinical trials; and sufficiency of cash and other funding to support Vaxcyte's development programs and other operating expenses. These and other risks are described more fully in Vaxcyte's filings with the Securities and Exchange Commission (SEC), including its Quarterly Report on Form 10-Q filed with the SEC on May 6, 2026, or in other documents Vaxcyte subsequently files with or furnishes to the SEC. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date, and readers should not rely upon the information in this press release as current or accurate after its publication date. Vaxcyte undertakes no duty or obligation to update any forward-looking statements contained in this release as a result of new information, future events or changes in its expectations.

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