Vaxcyte Advances to Second Stage of Ongoing Phase 2 Study Evaluating VAX-24 for the Prevention of Invasive Pneumococcal Disease in Infants

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-- Initiation of Stage 2 Approved by Independent Data Safety Monitoring Board Following Review of Stage 1 Safety and Tolerability Data --

-- The Stage 2 Portion of VAX-24 Infant Study Will Include Prevnar 20® (PCV20) as Study Comparator --

-- Company Expects to Announce Topline Data from Primary Immunization Series by 2025, Followed by Topline Data from Booster Dose Approximately Nine Months Later --

SAN CARLOS, Calif., July 11, 2023 (GLOBE NEWSWIRE) -- Vaxcyte, Inc. (Nasdaq: PCVX), a clinical-stage vaccine innovation company engineering high-fidelity vaccines to protect humankind from the consequences of bacterial diseases, today announced that the ongoing Phase 2 study of VAX-24 in healthy infants is advancing to the second and final stage of the study. The independent Data Safety Monitoring Board approved advancing to the second stage of the study following the review of the safety and tolerability results from the first stage. The Phase 2 study is evaluating the safety, tolerability and immunogenicity of VAX-24, the Company's lead, broad-spectrum 24-valent pneumococcal conjugate vaccine (PCV) candidate designed to prevent invasive pneumococcal disease (IPD). Vaxcyte expects to share topline data from the primary three-dose immunization series of the study by 2025, followed by topline data from the booster dose approximately nine months later.

"Today's news illustrates the steady momentum of our VAX-24 infant clinical program and underscores our commitment to progressing the evaluation of VAX-24 relative to the broadest-spectrum standard-of-care PCV available for this vulnerable population," said Grant Pickering, Chief Executive Officer and Co-Founder of Vaxcyte. "We designed VAX-24 to deliver broader coverage and improved immune responses and we look forward to sharing topline data from the primary three-dose immunization series by 2025."

Vaxcyte's Phase 2 infant study is being conducted in two stages and compares VAX-24 to the broadest-spectrum standard-of-care PCVs currently available. Stage 1 of the study evaluated the safety and tolerability of a single injection of VAX-24 at three dose levels in a dose-escalation approach compared to VAXNEUVANCE™ (PCV15) in 48 infants. The Stage 2 portion is evaluating the safety, tolerability and immunogenicity of VAX-24 at the same three dose levels compared to PCV20 in approximately 750 infants. Participants from Stage 1 will continue the standard dosing regimen as part of Stage 2. The Company anticipates dosing new subjects in Stage 2 by the end of July. In agreement with the U.S. Food and Drug Administration (FDA), Vaxcyte amended the study protocol for Stage 2 and changed the study comparator to PCV20, which is currently the broadest-spectrum PCV recommended by the Advisory Committee on Immunization Practices (ACIP).

"The public health community has continued to affirm the need for broader-spectrum PCVs given the burden of disease in the pediatric population, and VAX-24 includes serotypes that cover a significant portion of IPD currently in circulation that are associated with high case-fatality rates, antibiotic resistance and meningitis," said Jim Wassil, Executive Vice President and Chief Operating Officer. "We believe the findings from our Phase 2 infant study will provide valuable insights into the potential utility of VAX-24, the broadest-spectrum PCV in U.S. clinics today."

About the VAX-24 Phase 2 Infant Study
This Phase 2, randomized, observer-blind, dose-finding two-stage clinical study is evaluating the safety, tolerability and immunogenicity of VAX-24 in healthy infants. The Stage 1 portion of the study evaluated the safety and tolerability of a single injection of VAX-24 at three dose levels (low dose/1.1mcg, middle dose/2.2mcg, mixed dose/2.2mcg or 4.4mcg) and compared to PCV15 in 48 infants in a dose-escalation approach. The Stage 2 portion is evaluating the safety, tolerability and immunogenicity of VAX-24 at the same three dose levels and compared to PCV20, currently the broadest-spectrum PCV recommended by the ACIP, in approximately 750 infants.

In line with recommendations from the ACIP, the study design includes a primary immunization series consisting of three doses given at two months, four months and six months of age, followed by a subsequent booster dose at 12-15 months of age, in conjunction with the routinely recommended vaccines. The key prespecified immunogenicity study endpoints include an assessment of immune responses for all three VAX-24 doses and compared to PCV20 on the shared serotypes measured at 30 days post-dose three (PD3) and post-dose four (PD4). Immune responses will be assessed based on anti-pneumococcal polysaccharide serotype-specific immunoglobulin G (IgG) responses (proportion of participants achieving the accepted IgG threshold value of ≥0.35mcg/ml) at 30 days PD3 and IgG geometric mean titer ratios at 30 days PD4, among other immunogenicity endpoints. All participants in the study will be evaluated for safety through six months following the booster dose. The study is being conducted at approximately 30 sites in the United States. Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT05844423.

About VAX-24
VAX-24 is an investigational 24-valent PCV candidate designed to prevent IPD, which can be most serious for infants, young children, older adults and those with immune deficiencies or certain chronic health conditions. The public health community continues to affirm the need for vaccines that offer broader protection to prevent IPD. VAX-24 is intended to improve upon the standard-of-care PCVs for both children and adults by covering the serotypes that are responsible for most of the pneumococcal disease currently in circulation. Vaxcyte aims to efficiently create and deliver high-fidelity, broad-spectrum vaccines, such as VAX-24, by using modern synthetic techniques, including advanced chemistry and the XpressCF™ cell-free protein synthesis platform. Vaxcyte is deploying this approach with VAX-24 in order to add more pneumococcal strains without compromising the overall immune response.

About Pneumococcal Disease
Pneumococcal disease (PD) is an infection caused by *Streptococcus pneumoniae* (pneumococcus) bacteria. It can result in IPD, including meningitis and bacteremia, and non-invasive PD, including pneumonia, otitis media and sinusitis. In the United States, approximately 320,000 people get pneumococcal pneumonia each year, which is estimated to result in approximately 150,000 hospitalizations and 5,000 deaths. Pneumococci also cause over 50% of all cases of bacterial meningitis in the United States. Antibiotics are used to treat PD, but some strains of the bacteria have developed resistance to treatments. The morbidity and mortality due to PD are significant, particularly for young children and older adults, underscoring the need for a more broad-spectrum vaccine.

About Vaxcyte
Vaxcyte is a vaccine innovation company engineering high-fidelity vaccines to protect humankind from the consequences of bacterial diseases. The Company is developing broad-spectrum conjugate and novel protein vaccines to prevent or treat bacterial infectious diseases. Vaxcyte's lead candidate, VAX-24, is a 24-valent, broad-spectrum, carrier-sparing PCV being developed for the prevention of IPD. Vaxcyte is re-engineering the way highly complex vaccines are made through modern synthetic techniques, including advanced chemistry and the XpressCF™ 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 efficiently create and deliver high-fidelity vaccines with enhanced immunological benefits. Vaxcyte's pipeline also includes VAX-31, a 31-valent PCV candidate; VAX-A1, a prophylactic vaccine candidate designed to prevent Group A Strep infections; VAX-PG, a therapeutic vaccine candidate designed to slow or stop the progression of periodontal disease; and VAX-GI, a vaccine program designed to prevent Shigella. Vaxcyte is driven to eradicate or treat invasive bacterial infections, which have serious and costly health consequences when left unchecked. 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 VAX-24, including breadth of coverage, the ability to deliver potentially better immune responses and the improvement upon the standard-of-care; the anticipated timing of dosing new subjects in Stage 2 of the Phase 2 study; the process and timing of anticipated future development of Vaxcyte's vaccine candidates; the timing and availability of data for the VAX-24 Phase 2 infant study and related regulatory interactions; the continued need for broader-spectrum PCVs; the ability to add more pneumococcal strains to VAX-24 without compromising the overall immune response; and other statements that are not historical fact. The words "anticipate," "believe," "could," "expect," "intend," "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, without limitation, its Quarterly Report on Form 10-Q filed with the SEC on May 8, 2023 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. Readers should not rely upon the information in this press release as current or accurate after its publication date.

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