Vaxcyte Doses First Participants in Phase 2 Study Evaluating VAX-24 for the Prevention of Invasive Pneumococcal Disease in Infants

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-- Company Expects to Announce Topline Safety, Tolerability and Immunogenicity Data from Primary Immunization Series by 2025 --

-- The Nine Incremental Serotypes in VAX-24 Cover an Additional 20-25 Percent of Strains Causing Invasive Pneumococcal Disease Over the Current Standard-of-Care PCV in Infants --

SAN CARLOS, Calif., March 30, 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 first participants were dosed in the Phase 2 study of VAX-24 in healthy infants. This study will evaluate 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). The Company expects to share topline data from the primary three-dose immunization series of the Phase 2 study by 2025.

Vaxcyte's Phase 2 infant study is being conducted in two stages and compares VAX-24 to the broadest standard-of-care PCV, which is currently PCV15. Stage 1 of the study, which is now currently underway, is evaluating the safety and tolerability of a single injection of VAX-24 at three dose levels and compared to PCV15 in approximately 48 infants in a dose-escalation approach. The Stage 2 portion will evaluate the safety, tolerability and immunogenicity of VAX-24 at the same three dose levels and compared to PCV15 in approximately 750 infants. The study design includes a primary immunization series consisting of three doses followed by a subsequent booster dose.

"The initiation of our Phase 2 clinical study in infants is a significant advancement for VAX-24, which we believe has the potential to deliver a best-in-class profile with broader coverage and better immune responses relative to the standard-of-care today," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "We look forward to sharing the topline safety, tolerability and immunogenicity results from the primary immunization series by 2025, as well as the opportunity to gain additional insights from the full data set into the clinical potential of VAX-24, including the optimal design and powering of a Phase 3 program, in this population."

"Despite the effectiveness of current vaccines, IPD, including meningitis and bacteremia, remains persistent in the first years of life and is a leading cause of invasive disease in children two years of age and under," said Jim Wassil, Executive Vice President and Chief Operating Officer of Vaxcyte. "VAX-24 has the potential to help address the burden of disease in young children by covering an additional 20-25 percent of strains causing IPD over the current 15-valent standard-of-care PCV."

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 and compared to the broadest standard-of-care PCV, which is currently VAXNEUVANCE™ (PCV15) in healthy infants. The Stage 1 portion of the study, which is now underway, is evaluating 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 approximately 48 infants in a dose-escalation approach. The Stage 2 portion will evaluate the safety, tolerability and immunogenicity of VAX-24 at the same three dose levels and compared to PCV15 in approximately 750 infants.

In line with recommendations from the Advisory Committee on Immunization Practices (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 PCV15 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.

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 a potentially best-in-class PCV and the improvement upon the standard-of-care; 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 and Phase 3 studies and related regulatory interactions; the timing and submission of an IND application for the VAX-24 Phase 2 infant study and the availability of Phase 2 topline results; the timing and submission of an IND application for the VAX-31 (formerly called VAX-XP) adult program and the timing and availability of the Phase 1/2 topline data for such program; the potential for VAX-31 to become the broadest-spectrum PCV; the timing of guidance for an IND application for VAX-A1; the timing of a nomination of a final vaccine candidate for VAX-PG; the demand for Vaxcyte's vaccine candidates; 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; impacts of COVID-19; 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 November 7, 2022 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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