Vaxcyte Completes Enrollment of Phase 2 Study Evaluating Safety, Tolerability and Immunogenicity of VAX-24 in Adults 65 Years and Older

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-- Company Expects to Announce Topline Data from Study in Adults 65 Years and Older in the First Half of 2023 --

-- Vaxcyte Remains on Track to Announce Topline Data from the Phase 1 and Phase 2 Portions of the VAX-24 Proof-of-Concept Study in Adults Aged 18-64 in October or November 2022 --

-- VAX-24 is a 24-Valent Pneumococcal Conjugate Vaccine Designed to Deliver Broad-Spectrum Protection to Prevent Invasive Pneumococcal Disease --

SAN CARLOS, Calif., Sept. 06, 2022 (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 the completion of enrollment in the Phase 2 study evaluating VAX-24 in healthy adults 65 years of age and older. VAX-24 is the Company's lead, 24-valent pneumococcal conjugate vaccine (PCV) candidate designed to prevent invasive pneumococcal disease (IPD).

This Phase 2 clinical study, which is now fully enrolled with approximately 200 participants, is a randomized, observer-blind, dose-finding study designed to evaluate the safety, tolerability and immunogenicity of VAX-24 in adults 65 years of age and older. Vaxcyte expects to announce topline safety, tolerability and immunogenicity results from this Phase 2 study in the first half of 2023.

"Completing the enrollment of the VAX-24 study in adults 65 years and older is a significant step toward understanding the full clinical potential of our lead vaccine candidate in adults," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "We are very pleased with the progress made to advance the VAX-24 clinical program and we remain on track to announce the topline data from the VAX-24 Phase 1/2 study in adults 18-64 years of age in October or November of this year, as well as the topline data from the study in adults 65 and older in the first half of 2023."

"VAX-24 was granted Fast Track designation in adults by the FDA, which we believe provides an expedited path to deliver VAX-24 to adults and underscores the need for a PCV that provides broader protection to prevent this serious disease," said Jim Wassil, Executive Vice President and Chief Operating Officer of Vaxcyte. "Older adults are at increased risk for pneumococcal disease and severe complications, making the need for a broad-spectrum PCV even more important to protect against infection in this population."

Despite nearly universal vaccination for pneumococcal disease (PD) in infants and in many adults in the United States, the overall incidence of PD is substantial and is driven by emerging serotypes not covered by currently available vaccines. The public health community continues to affirm the need for vaccines that offer broader protection to prevent invasive PD. VAX-24 is intended to improve upon the standard-of-care PCVs by covering the serotypes that are responsible for most of the residual PD currently in circulation.

About the VAX-24 Clinical Program

- **VAX-24 Phase 1/2 Clinical Proof-of-Concept Study in Adults Aged 18-64 (VAX-24 Study 101, NCT05266456):**
  - This is a randomized, observer-blind, dose-finding, controlled study designed to evaluate the safety, tolerability and immunogenicity of VAX-24 in healthy adults 18-64 years of age.
  - The Phase 1 portion of the study is evaluating safety and tolerability of a single injection of VAX-24 at three dose levels and compared to Prevnar 20™ in 64 healthy adults 18 to 49 years of age.
  - The Phase 2 portion is evaluating the safety, tolerability and immunogenicity of a single injection of VAX-24 at three dose levels and compared to a single injection of Prevnar 20™ in approximately 800 healthy adults 50 to 64 years of age. The prespecified immunogenicity endpoints of the Phase 2 portion of the study include an assessment of the induction of antibody responses, using opsonophagocytic activity (OPA) and immunoglobulin G (IgG), at each of the three VAX-24 doses and compared to Prevnar 20™ and, for the additional four serotypes contained in VAX-24 and Pneumovax® 23, but not in Prevnar 20™, the percentage of subjects that experience a four-fold rise in antibody titers.
  - Participants in the study will be evaluated for safety through six months after vaccination.
  - The study enrolled subjects from 13 sites in the United States.

- **VAX-24 Phase 2 Clinical Study in Adults Aged 65 and Older (VAX-24 Study 102, NCT05297578):**
  - This is a randomized, observer-blind, dose-finding, controlled study designed to evaluate the safety, tolerability and immunogenicity of VAX-24 in healthy adults 65 years of age and older.
  - The study is evaluating the safety, tolerability and immunogenicity of a single injection of VAX-24 at three dose levels and compared to a single injection of Prevnar 20™ in approximately 200 healthy adults. The prespecified

immunogenicity endpoints of the study include an assessment of the induction of antibody responses, using OPA and IgG, at each of the three VAX-24 doses and compared to Prevnar 20™ and, for the additional four serotypes contained in VAX-24 and Pneumovax® 23, but not in Prevnar 20™, the percentage of subjects that experience a four-fold rise in antibody titers.
- Participants in the study will be evaluated for safety through six months after vaccination.
- The study enrolled subjects from 19 sites in the United States.

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 900,000 people get pneumococcal pneumonia each year, which is estimated to result in approximately 400,000 hospitalizations and 28,000 deaths. Pneumococci also cause over 50% of all cases of bacterial meningitis in the United States. Antibiotics are used to treat pneumococcal disease, but some strains of the bacteria have developed resistance to treatments. The morbidity and mortality due to pneumococcal disease are highly significant, particularly for young children and older adults, underscoring the need for a more broad-spectrum vaccine.

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 residual 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.

In August 2022, the U.S. Food and Drug Administration (FDA) granted Fast Track Designation to VAX-24 for the adult indication. The Fast Track designation is an FDA process that has been designed to facilitate the development and expedite the review of drugs, including vaccines, that treat or prevent serious conditions and fill an unmet medical need.

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 pneumococcal conjugate vaccine 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^{TM} 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-XP, a PCV with an expanded breadth of coverage of greater than 30 strains; VAX-A1, a prophylactic vaccine candidate designed to prevent Group A Strep infections; and VAX-PG, a therapeutic vaccine candidate designed to slow or stop the progression of periodontal disease. 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 improvement upon the standard-of-care and the achievement of clinical proof-of-concept; the process and timing of anticipated future development of Vaxcyte's vaccine candidates; the timing, availability and outcome of topline data for the VAX-24 Phase 1/2 clinical proof-of-concept study and Phase 2 clinical study; the demand for Vaxcyte's vaccine candidates; and other statements that are not historical fact. The words "believe," "could," "expect," "may," "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 August 8, 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.

Contacts:
Andrew Guggenhime, President and Chief Financial Officer
Vaxcyte, Inc.
650-837-0111
investors@vaxcyte.com

Janet Graesser, Vice President, Corporate Communications and Investor Relations
Vaxcyte, Inc.
917-685-8799
media@vaxcyte.com