Vaxcyte Completes Enrollment of Phase 2 Portion of Phase 1/2 Clinical Proof-of-Concept Study Evaluating Safety, Tolerability and Immunogenicity of VAX-24 in Adults

July 12, 2022

-- Company Expects to Announce Topline Results from the Phase 1 and Phase 2 Portions of the Proof-of-Concept Study in October or November 2022 --

-- Vaxcyte Also Dosed First Participants in Separate VAX-24 Phase 2 Clinical Study in Adults 65 Years and Older, With Topline Data Expected in the First Half of 2023 --

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

SAN CARLOS, Calif., July 12, 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 portion of the ongoing Phase 1/2 proof-of-concept study evaluating VAX-24 in healthy adults 50 to 64 years of age. The Company has also dosed the first participants in a separate Phase 2 study of VAX-24 in healthy adults 65 years of age and older. VAX-24 is a 24-valent pneumococcal conjugate vaccine (PCV) candidate designed to prevent invasive pneumococcal disease (IPD) and pneumonia.

VAX-24 Phase 1/2 Study Enrollment Completion

The Phase 1/2 clinical proof-of-concept study, which is now fully enrolled, is a combined Phase 1 and 2 study evaluating the safety and tolerability of VAX-24 in adults aged 18-49 (Phase 1) and the safety, tolerability and immunogenicity of VAX-24 in adults aged 50-64 (Phase 2). The Company expects to announce topline safety and tolerability results from the Phase 1 portion of the study and safety, tolerability and immunogenicity results from the Phase 2 portion of the study in October or November 2022.

“Completing enrollment of the Phase 2 portion of our Phase 1/2 clinical proof-of-concept study is an important milestone underscoring the continued progress with the VAX-24 clinical program,” said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. “We believe these topline data will provide important insights about the safety, tolerability and immunogenicity of VAX-24 and ultimately, the potential of VAX-24 to deliver the broadest-spectrum PCV for adults. We anticipate sharing these study results in October or November of this year and if successful, we intend to advance additional development activities for our PCV franchise, including the pediatric program for VAX-24.”

Separate Phase 2 Study in Adults 65 Years and Older Initiation

Vaxcyte also dosed the first participants in a separate Phase 2 study in adults 65 years of age and older. Topline safety, tolerability and immunogenicity results from this study are expected in the first half of 2023, further building upon the body of clinical evidence to support the potential of VAX-24 as the broadest-spectrum PCV.
“We are also pleased to have initiated a VAX-24 Phase 2 study in adults aged 65 and over as we expand our clinical program into older adults,” said Jim Wassil, Executive Vice President and Chief Operating Officer of Vaxcyte. “Research has shown that the risk of illness from pneumococcal disease is significantly higher in people over the age of 65, making a broader-spectrum PCV important to help prevent this serious disease in the elderly.”

Despite nearly universal vaccination for pneumococcal disease in infants and in many adults in the United States, the overall incidence of pneumococcal disease 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 IPD and pneumonia. VAX-24 is intended to improve upon the standard-of-care PCVs by covering the serotypes that are responsible for most of the residual pneumococcal disease 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 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 is currently being conducted at approximately 20 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. Despite universal vaccination for 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. 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 and pneumonia, 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 and pneumonia. 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.

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 and pneumonia. 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-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 May 9, 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