Vaxcyte Completes Enrollment of Phase 1/2 Study Evaluating VAX-31 for the Prevention of Invasive Pneumococcal Disease (IPD) in Adults Aged 50 and Older

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-- Topline Safety, Tolerability and Immunogenicity Data from VAX-31 Phase 1/2 Study (n=1,015) Expected in Third Quarter of 2024 --

-- VAX-31 is Designed to Provide Coverage for Approximately 95% of IPD Circulating in the U.S. Adult Population --

-- Company's Potential Best-in-Class Pneumococcal Conjugate Vaccine (PCV) Franchise, VAX-24 and VAX-31, Intended to Deliver the Broadest-Spectrum of Coverage Against IPD --

SAN CARLOS, Calif., Jan. 29, 2024 (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 its Phase 1/2 clinical study evaluating VAX-31, a 31-valent pneumococcal conjugate vaccine (PCV) candidate designed to prevent invasive pneumococcal disease (IPD), in healthy adults aged 50 and older. Vaxcyte expects to announce topline safety, tolerability and immunogenicity data from the Phase 1/2 study in the third quarter of 2024.

"Completing the enrollment of the VAX-31 study with more than one thousand adults 50 years and older is a significant step for our PCV franchise and we look forward to announcing topline safety, tolerability and immunogenicity data in the third quarter of this year," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "VAX-31, the broadest-spectrum PCV in the clinic, has the potential to address a significant public health need by covering approximately 95% of IPD circulating in the U.S. adult population while maintaining coverage of previously circulating strains that are currently contained via ongoing vaccination."

Mr. Pickering continued, "Given the significant progress across our PCV franchise, comprising VAX-24 and VAX-31, we intend to deliver multiple anticipated Phase 3 data readouts over the next few years as we conduct Phase 3 studies and, if those studies are successful, prepare a Biologics License Application submission for either the VAX-24 or VAX-31 adult program."

About the VAX-31 Phase 1/2 Study
The VAX-31 Phase 1/2 clinical study, which is now fully enrolled, is a randomized, observer-blind, active-controlled, dose-finding clinical study designed to evaluate the safety, tolerability and immunogenicity of VAX-31 at three dose levels (low, middle and high) and compared to Prevnar 20® (PCV20) in 1,015 healthy adults aged 50 and older.

- The Phase 1 portion of the study evaluated the safety and tolerability of a single injection of VAX-31 at three dose levels and compared to PCV20 in 64 healthy adults 50 to 64 years of age. An independent Data Monitoring Committee conducted an assessment of the Phase 1 safety and tolerability results and recommended that the study proceed as planned to Phase 2. Phase 1 participants will also be evaluated for immunogenicity, and the data will be pooled with the participants in the Phase 2 portion of the study.
- The Phase 2 portion of the study will evaluate the safety, tolerability and immunogenicity of a single injection of VAX-31 at the same three dose levels and compared to PCV20 in 951 healthy adults 50 years of age and older.
- The immunogenicity objectives 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-31 doses and compared to PCV20 for the 20 serotypes in common, as well as for the additional 11 serotypes contained in VAX-31, but not in PCV20.
- Participants in the study are being evaluated for safety through six months after vaccination. The study is being conducted in approximately 25 sites in the United States.
- Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT06151288.

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's PCV Franchise: VAX-24 and VAX-31
Vaxcyte's carrier-sparing PCV franchise candidates, including VAX-24, a Phase 3-ready 24-valent PCV, and VAX-31, the Company's next-generation 31-valent PCV currently in an ongoing Phase 1/2 study, are being studied for the prevention of IPD. The public health community continues to affirm the need for vaccines that offer broader protection to prevent IPD, which can be most serious for infants, young children, older adults and those with immune deficiencies or certain chronic health conditions.

Both VAX-24 and VAX-31 are designed to improve upon the standard-of-care PCVs for both children and adults by covering the serotypes that are responsible for a significant portion of IPD in circulation and are associated with high case-fatality rates, antibiotic resistance and meningitis, while maintaining coverage of previously circulating strains that are currently contained through continued vaccination practice. Vaxcyte aims to efficiently create and deliver high-fidelity, broad-spectrum carrier-sparing conjugate vaccines in order to add coverage without compromising overall immune responses by using modern synthetic techniques, including advanced chemistry and the XpressCF™ cell-free protein synthesis platform. Vaxcyte is deploying this approach with VAX-24 and VAX-31, the latter of which has the potential to provide the broadest coverage of any PCV to reach the clinic with approximately 95 percent coverage of circulating IPD strains in the U.S. adult population.

In January 2023, Vaxcyte announced that the U.S. Food and Drug Administration granted Breakthrough Therapy designation to VAX-24 for the prevention of IPD in adults based on positive topline results from the Phase 1/2 proof-of-concept study, which evaluated the safety, tolerability and immunogenicity of VAX-24 in adults 18 to 64 years of age. The Breakthrough Therapy designation process is designed to expedite the development and review of drugs and biologics that are intended to treat a serious or life-threatening condition, where preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

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 Phase 3-ready 24-valent, broad-spectrum, carrier-sparing PCV being developed for the prevention of IPD. VAX-31, the Company's next-generation 31-valent PCV, is the broadest-spectrum PCV candidate in the clinic today.

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-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-31 and VAX-24, including breadth of coverage and clinical potential, the ability to deliver potentially best-in-class profiles and the improvement upon the standard-of-care; the design, process and timing of anticipated future developments and milestones of VAX-31 and VAX-24, including the design of the VAX-31 Phase 1/2 clinical study in adults and the timing of announcement of topline safety, tolerability and immunogenicity results; the timing of the potential VAX-24 or VAX-31 Phase 3 clinical studies in adults, as well as the timing of data readouts from such studies; the timing of a potential Biologics License Application submission for VAX-24 or VAX-31; and other statements that are not historical fact. The words "anticipate," "believe," "could," "expect," "intend," "look forward," "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; 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 November 6, 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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