Vaxcyte Doses First Participants in OPUS-3 Phase 3 Trial Evaluating VAX-31 in Adults Previously Vaccinated with Lower-Valency Pneumococcal Vaccines

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Company Expects to Report Topline Data from OPUS-3 Trial and OPUS-2 Phase 3 Trial Evaluating Concomitant Administration of VAX-31 and a Seasonal Influenza Vaccine in First Half of 2027

OPUS-1, VAX-31 Adult Phase 3 Noninferiority Trial, Continues to Enroll Subjects, with Topline Data Expected in Fourth Quarter of 2026

Vaxcyte's VAX-31 Phase 3 Adult Clinical Program – Finalized in Consultation and Alignment with U.S. Food and Drug Administration – to Support Planned BLA Submission

VAX-31 is Designed to Cover ~95% of Invasive Pneumococcal Disease (IPD) and ~88% of Pneumococcal Pneumonia in U.S. Adults Aged 50+, with Potential to Provide an Incremental 14-34% Broader IPD Coverage and 19-31% Broader Pneumonia Coverage than Standard-of-Care Vaccines

SAN CARLOS, Calif., Feb. 11, 2026 (GLOBE NEWSWIRE) -- Vaxcyte, Inc. (Nasdaq: PCVX), a clinical-stage vaccine innovation company, today announced that the first participants were dosed in the OPUS-3 Phase 3 trial evaluating VAX-31, the Company's next-generation 31-valent pneumococcal conjugate vaccine (PCV) candidate, in adults who have previously received pneumococcal vaccination. This trial is evaluating the safety, tolerability and immunogenicity of VAX-31, including whether VAX-31 can boost serotype-specific immune responses, while providing the broadest coverage in a single vaccine in this adult population.

Vaxcyte is advancing a comprehensive Phase 3 adult clinical program for VAX-31 to support a planned Biologics License Application (BLA) submission. The announced Phase 3 clinical studies, which were finalized in consultation and alignment with the U.S. Food and Drug Administration (FDA), include the pivotal, noninferiority trial evaluating VAX-31 for the prevention of invasive pneumococcal disease (IPD) and pneumonia in adults (OPUS-1, enrolling); a trial evaluating VAX-31 when administered concomitantly with a licensed seasonal influenza vaccine in pneumococcal-naïve[1] adults (OPUS-2, enrolling); and a trial in adults who have previously received a pneumococcal vaccine (OPUS-3, enrolling). Across these three studies, approximately 6,000 adults are expected to be enrolled in total, of whom approximately 3,400 will receive VAX-31, with the intent to generate a broad and robust safety, tolerability and immunogenicity dataset. Vaxcyte is also planning to conduct a manufacturing consistency study (e.g., a lot-to-lot study) to support the planned BLA filing.

"The initiation of our Phase 3 study evaluating VAX-31 administered to adults with prior pneumococcal vaccination marks continued progress for the program as we work toward delivering a best-in-class, next-generation PCV with the potential to set a new standard-of-care for adults," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "Given the potential for VAX-31 to significantly expand protection and provide substantial incremental coverage of approximately 19-31% against pneumococcal pneumonia relative to current standard-of-care vaccines, it is important to understand how VAX-31 may boost immune responses in adults who previously received lower-valency pneumococcal vaccines and broaden serotype coverage."

About OPUS-3, the VAX-31 Adult Phase 3 Trial in Subjects Who Have Previously Received a Pneumococcal Vaccine (n~720)
This Phase 3 study is a randomized, double-blind, active-controlled, descriptive clinical trial designed to evaluate the safety, tolerability and immunogenicity of a single dose of VAX-31 in approximately 720 healthy U.S. adults aged 50 years and older with a history of prior pneumococcal vaccination at least six months prior. The study is being conducted at approximately 30 sites in the United States.

Participant Overview
Approximately 720 participants will be assigned to one of three groups (~240 each) based on prior pneumococcal vaccination history, comprising adults who have previously received 1) Pneumovax® 23 (PPSV23), 2) Prevnar 20® (PCV20) or 3) other licensed pneumococcal vaccines, alone or in combination. Participants in each group will be randomized 3:1 to receive VAX-31 or PCV20, the active comparator, on Day 1.

For all participants, safety and tolerability will be assessed for six months following initial vaccination.

Immunogenicity Analyses
Primary immunogenicity objective:

- **Month 1: Assess serotype-specific immune responses** (opsonophagocytic activity (OPA) geometric mean titers (GMTs) and geometric mean fold rises (GMFRs)) elicited by VAX-31 across all 31 serotypes and serotype 20B in adults who have previously received a licensed pneumococcal vaccine or a combination of licensed pneumococcal vaccines.

Secondary immunogenicity objective:

- **Describe serotype-specific immunoglobulin G (IgG) antibody responses** (IgG geometric mean concentrations (GMCs)

and GMFRs) elicited by VAX-31 across all 31 serotypes and serotype 20B.

About Pneumococcal Disease
Pneumococcal disease (PD) is an infection caused by *Streptococcus pneumoniae* bacteria. It can result in IPD, including meningitis and bacteremia, and non-invasive PD, including pneumonia, otitis media and sinusitis. In the United States, pneumococcal pneumonia is estimated to result in approximately 225,000 adult hospitalizations each year. *Streptococcus pneumoniae* is among the World Health Organization's top antibiotic-resistant pathogens to be urgently addressed, and the U.S. CDC lists drug-resistant *Streptococcus pneumoniae* as a "serious threat." In children under five, *Streptococcus pneumoniae* is the leading cause of vaccine-preventable deaths globally. 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 broader-spectrum vaccine.

About VAX-31
VAX-31, a 31-valent PCV candidate being evaluated in a Phase 3 adult clinical program and in a Phase 2 infant clinical program, is designed to prevent serious and sometimes fatal infections caused by *Streptococcus pneumoniae*, including IPD, pneumonia and otitis media. Specifically, IPD is associated with high case-fatality rates, antibiotic resistance and meningitis. VAX-31 is the broadest-spectrum PCV candidate in the clinic today and has the potential to provide protection against both currently circulating and historically prevalent serotypes. VAX-31 is designed to increase coverage, in a single vaccine, to approximately 95% of IPD and approximately 88% of pneumococcal pneumonia circulating in adults in the United States aged 50 and older. This disease coverage has the potential to result in VAX-31 providing an incremental 14-34% of coverage for IPD and an incremental 19-31% of coverage for pneumococcal pneumonia over current standard-of-care adult PCVs. In U.S. children, it is designed to cover approximately 92% of IPD[2] and approximately 96% of acute otitis media[3] due to *Streptococcus pneumoniae*. This disease coverage has the potential to result in VAX-31 providing an incremental 23-44% of coverage for IPD and an incremental 35-62% of coverage for otitis media over current standard-of-care infant PCVs.

In May 2025, the FDA expanded the Breakthrough Therapy designation (BTD) for VAX-31 to include the prevention of pneumonia caused by *Streptococcus pneumoniae* in addition to the prevention of IPD in adults based on the positive topline results from the VAX-31 adult Phase 1/2 study indicating that VAX-31 may demonstrate substantial improvement over existing therapies. In this study, VAX-31 was observed to be well tolerated, demonstrated a safety profile similar to PCV20 and showed robust OPA immune responses for all 31 serotypes. With the VAX-31 High Dose, all 11 incremental serotypes unique to VAX-31, and not in PCV20, met the superiority criteria,[4] and it delivered greater average OPA immune responses for 18 of the 20 serotypes in common with PCV20, and seven of these serotypes achieved statistically higher immune responses.[5]

About Vaxcyte
Vaxcyte is a vaccine innovation company engineering high-fidelity vaccines to protect humankind from the consequences of bacterial diseases. VAX-31, a 31-valent PCV candidate being evaluated in a Phase 3 adult clinical program and in a Phase 2 infant clinical program, is being developed for the prevention of IPD and is the broadest-spectrum PCV candidate in the clinic today. VAX-24, a 24-valent PCV candidate, is designed to cover more serotypes than any infant PCV on-market. VAX-31 and VAX-24 are designed to improve upon standard-of-care PCVs by covering the serotypes in circulation that cause a significant portion of IPD and are associated with high case-fatality rates, antibiotic resistance and meningitis, while maintaining coverage of previously circulating strains. VAX-XL, in earlier-stage development, also leverages the Company's carrier-sparing, site-specific conjugation technology with the aim of further expanding coverage to deliver the broadest-spectrum candidate in the Company's PCV franchise.

Vaxcyte is re-engineering the way highly complex vaccines are made through XpressCF®, its 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 develop 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, and VAX-GI, a vaccine candidate designed to prevent Shigella. 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 Vaxcyte's carrier-sparing platform and PCV candidates, including breadth of coverage, the ability to deliver potentially best-in-class PCVs, the ability to improve upon the standard-of-care, and the ability to significantly reduce the burden of disease by expanding coverage against currently and historically circulating strains while maintaining robust immune response; the design, timing of initiation, progress and expected results of Vaxcyte's clinical trials and regulatory plans; the demand for Vaxcyte's vaccine candidates; and other statements that are not historical fact. The words "anticipate," "believe," "could," "expect," "intend," "may," "on track," "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 4, 2025 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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[1]Pneumococcal-naïve is defined as having no known prior history of IPD, pneumococcal pneumonia, or receipt of any licensed or investigational pneumococcal vaccine.

[2]In U.S. children under five years of age: *CDC 2023 Active Bacterial Core (ABC) Surveillance data. IPD cases with missing serotype data were excluded, non-typeable cases were included in the denominator.*

[3]In U.S. children five years of age or under: *Grant LR et al., FrontPediatr.2024;12:1383748.* Serotype percentages reflect 2017–2021 data (Supplemental Table 1).

[4]Lower bound of the 2-sided 95% confidence interval of the difference in the proportions of participants with a ≥4-fold increase from Day 1 to Month 1 is greater than 10%, and lower bound of the 2-sided 95% confidence interval of the OPA geometric mean ratio is greater than 2.0.

[5]Lower bound of the 2-sided 95% confidence interval of the OPA geometric mean ratio is greater than 1.0.