# Vaxcyte Advances Adult and Infant Programs for VAX-31, a Potential Best-in-Class, Next-Generation Pneumococcal Conjugate Vaccine

January 22, 2026

***VAX-31 Adult Indication: Vaxcyte Doses First Participants in Phase 3 Study Evaluating Concomitant Administration of VAX-31 and Seasonal Influenza Vaccine (OPUS-2) and Expects to Initiate Phase 3 Study in Adults Previously Vaccinated with Pneumococcal Vaccines (OPUS-3) in First Quarter of 2026***

***Company Expects to Report Topline Safety, Tolerability and Immunogenicity Data from Both OPUS-2 and OPUS-3 Phase 3 Studies in First Half of 2027, Supporting Planned BLA Submission***

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

***VAX-31 Adult Phase 3 Clinical Studies Designed in Consultation and Alignment with U.S. Food and Drug Administration***

***VAX-31 Infant Indication: Vaxcyte Completes Enrollment of Phase 2 Dose-Finding Study Evaluating VAX-31 for the Prevention of Invasive Pneumococcal Disease, Expects to Announce Topline Data from Primary Immunization Series and Booster Dose Either Sequentially or Together by End of First Half of 2027***

***Company Expects to Initiate Buildout of Custom Fill-Finish Line in First Quarter of 2026 in Connection with Previously Announced Long-Term Commitment of up to $1 Billion in U.S. Manufacturing and Services and Has Established Dedicated North Carolina Presence***

SAN CARLOS, Calif., Jan. 22, 2026 (GLOBE NEWSWIRE) -- Vaxcyte, Inc. (Nasdaq: PCVX), a clinical-stage vaccine innovation company, today provided updates on the continued advancement of VAX-31, the Company's next-generation 31-valent pneumococcal conjugate vaccine (PCV) candidate, across its adult and infant clinical programs.

For the VAX-31 adult indication, the first participants have been dosed in a Phase 3 trial evaluating VAX-31 when administered concomitantly with a licensed seasonal influenza vaccine in pneumococcal-naïve[1] adults aged 50 years and older (OPUS-2 trial). Additionally, Vaxcyte plans to initiate a separate Phase 3 trial in the first quarter of 2026 evaluating VAX-31 in adults who have previously received a pneumococcal vaccine (OPUS-3 trial). For the VAX-31 infant indication, the Company has completed enrollment in its Phase 2 dose-finding study evaluating VAX-31 in healthy infants.

"The continued advancement of VAX-31 in adults reflects disciplined execution across our Phase 3 clinical program, which was finalized in consultation and alignment with the U.S. Food and Drug Administration (FDA), as we work toward delivering a best-in-class, next-generation pneumococcal conjugate vaccine with the potential to set a new standard-of-care for adults and children," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "In adults, evaluating VAX-31 in settings that reflect real-world vaccination practice, including coadministration with a seasonal influenza vaccine and in individuals with prior pneumococcal vaccination, will provide important insights into how VAX-31 is expected to perform across the adult population. We expect to announce topline data from the ongoing OPUS-1 Phase 3 pivotal, noninferiority trial in the fourth quarter of 2026 and results from these additional Phase 3 adult studies in the first half of 2027, keeping us on track toward a planned Biologics License Application (BLA) submission."

"Completing enrollment in the VAX-31 infant dose-finding study with more than 900 healthy infants represents an important step in advancing the broadest PCV candidate currently in the clinic for this vulnerable population," said Jim Wassil, Executive Vice President and Chief Operating Officer of Vaxcyte. "VAX-31 has the potential to significantly reduce the burden of disease in infants by expanding coverage against currently and historically circulating strains while maintaining robust immune responses. We expect to announce the topline safety, tolerability and immunogenicity data from both the primary three-dose immunization series and booster dose either sequentially or together by the end of the first half of 2027."

**VAX-31 Franchise Key Updates**

**VAX-31 Adult Indication:**

Vaxcyte is advancing a comprehensive Phase 3 adult clinical program for VAX-31 to support a planned BLA submission. The announced Phase 3 clinical studies, which were finalized in consultation and alignment with the 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 adults (OPUS-2, enrolling); and a trial in adults who have previously received a pneumococcal vaccine (OPUS-3, not yet 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 for a manufacturing consistency study (e.g., a lot-to-lot study).

***About OPUS-2, the Adult Phase 3 Trial of VAX-31 Concomitantly Administered with a Seasonal Influenza Vaccine (n~1,300)***
This Phase 3 study is a randomized, double-blind, placebo-controlled clinical trial designed to evaluate the safety, tolerability and immunogenicity of VAX-31 when administered either concomitantly with or one month following administration of a licensed seasonal influenza vaccine in pneumococcal-naïve, healthy U.S. adults aged 50 years and older. The study is expected to enroll approximately 1,300 participants at approximately 25 sites in the United States. The results of this descriptive study are intended to inform the design of a potential post-licensure outcomes study that further evaluates

VAX-31 in concomitant use with an influenza vaccine and to provide supportive evidence as part of the broader Phase 3 dataset.

**Participant Overview**
Participants will be randomized 1:1 into one of two groups:

- **Concomitant Administration Group (n~650):** Participants receive a seasonal influenza vaccine administered open-label and concomitantly with VAX-31 administered blinded on Day 1, followed by a blinded placebo injection at Month 1.
- **Sequential Administration Group (n~650):** Participants receive a seasonal influenza vaccine administered open-label with a blinded placebo injection on Day 1, followed by VAX-31 administered blinded at Month 1. This sequential dosing approach allows for evaluation of immune responses to VAX-31 when administered alone, while preserving blinding and controlling for vaccination timing.

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

**Immunogenicity Analyses**
*Primary immunogenicity objectives:*

- **Month 1: Assessing 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 pneumococcal-naïve adults aged 50 years and older.
- **Month 2: Comparing strain-specific immune responses** (hemagglutination inhibition (HAI) GMTs) elicited by a seasonal influenza vaccine when co-administered with VAX-31 to those elicited by a seasonal influenza vaccine alone.

*Secondary immunogenicity objective:*

- **Comparing immunoglobulin G (IgG) antibody responses** (IgG geometric mean concentrations (GMCs)) elicited by VAX-31 across all 31 serotypes and serotype 20B when VAX-31 is co-administered with a seasonal influenza vaccine to those elicited by VAX-31 alone.

***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 will be 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: Assessing serotype-specific immune responses** (OPA GMTs and 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:*

- **Describing serotype-specific IgG antibody responses** (IgG GMCs and GMFRs) elicited by VAX-31 across all 31 serotypes and serotype 20B.

**VAX-31 Infant Indication:**

Vaxcyte announced the completion of enrollment (n=905) in its Phase 2 dose-finding study evaluating the safety, tolerability and immunogenicity of VAX-31 compared to PCV20 in healthy infants. The study design includes a primary immunization series with doses given at two, four and six months of age, followed by a booster dose at 12-15 months of age. With the completion of enrollment, all participants have received at least their first dose at two months of age. VAX-31 is designed to substantially expand coverage in the pediatric population relative to today's standard-of-care, PCV20, by adding 11 incremental serotypes. VAX-31 has the potential to increase protection against IPD from approximately 69% to approximately 92% of disease circulating in children under five years of age in the U.S. and increase protection against acute otitis media from approximately 61% to approximately 96% in U.S. children five years of age or under. Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT06720038.

**Commercial Supply Chain:**

Building on its September 2025 update outlining plans to expand U.S.-based fill-finish manufacturing capacity for its PCVs in North Carolina, representing a long-term commitment of up to $1 billion in manufacturing and services, Vaxcyte announced the establishment of a dedicated local presence, comprising full-time employees focused on chemistry, manufacturing and controls (CMC) activities. As the Company advances its long-term domestic manufacturing strategy, it is recruiting experienced scientific and manufacturing professionals in one of the country's most established vaccine-development hubs. In parallel, Vaxcyte expects the buildout of its custom PCV fill-finish line at the North Carolina facility to begin in the first quarter of 2026.

**Anticipated Key PCV Program Milestones**
Vaxcyte is advancing the clinical development of its PCV programs with several anticipated key upcoming milestones:

**VAX-31 Adult Indication**

- Initiate the OPUS-3 Phase 3 trial in the first quarter of 2026 evaluating VAX-31 in adults who have previously received pneumococcal vaccination.
- Announce topline safety, tolerability and immunogenicity data for the OPUS-1 Phase 3 pivotal, noninferiority trial in the fourth quarter of 2026.
- Announce topline safety, tolerability and immunogenicity data for the OPUS-2 and OPUS-3 Phase 3 trials in the first half of 2027.

**VAX-31 Infant Indication**

- Announce topline safety, tolerability and immunogenicity data for the VAX-31 infant Phase 2 randomized, dose-finding study from both the primary three-dose immunization series and booster dose either sequentially or together by the end of the first half of 2027.

**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.

**Contacts:**

Patrick Ryan, Executive Director, Corporate Affairs
Vaxcyte, Inc.
415-606-5135
media@vaxcyte.com

Jeff Macdonald, Executive Director, Investor Relations
Vaxcyte, Inc.
917-371-0940
investors@vaxcyte.com

---

[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.