



Positive VAX-31 Phase 1/2 Adult Data Published in The Lancet Infectious Diseases Highlight Best-in-Class Potential of Vaxcyte's 31-Valent Pneumococcal Conjugate Vaccine (PCV) Candidate

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Based on the Strength of Unprecedented Results from the Positive Phase 1/2 Study in Adults Aged 50 and Older, Vaxcyte Advanced VAX-31 High Dose into Comprehensive Phase 3 Adult Program; Topline Data from the OPUS-1 Pivotal Noninferiority Trial Expected in the Fourth Quarter of 2026

At All Doses Studied, VAX-31 Demonstrated Robust Opsonophagocytic Activity and Immunoglobulin G Immune Responses for All 31 Serotypes and Was Observed to be Well Tolerated with a Safety Profile Similar to Prevnar 20®

Results Further Validate Potential of Vaxcyte's Carrier-Sparing Platform to Deliver Broadest-Spectrum PCV Candidates that Provide Protection Against Both Currently Circulating and Historically Prevalent Serotypes

VAX-31 is Designed to Cover ~95% of Invasive Pneumococcal Disease (IPD) and ~88% of Pneumococcal Pneumonia in U.S. Adults Aged 50 and Older, 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., March 18, 2026 (GLOBE NEWSWIRE) -- Vaxcyte, Inc. (Nasdaq: PCVX), a clinical-stage vaccine innovation company, today announced the publication of results from the positive VAX-31 adult Phase 1/2 clinical study in the journal [The Lancet Infectious Diseases](#). The study evaluated the safety, tolerability and immunogenicity of VAX-31, the Company's next-generation 31-valent pneumococcal conjugate vaccine (PCV) candidate, for the prevention of invasive pneumococcal disease (IPD) and pneumonia compared to one of the current standard-of-care vaccines, Prevnar 20® (PCV20), in healthy adults aged 50 years and older. Based on the positive results of this Phase 1/2 study, VAX-31 is currently being evaluated in the OPUS Phase 3 adult program.

The study results showed that VAX-31 was observed to be well tolerated and demonstrated a safety profile similar to PCV20 through the full six-month evaluation period at all doses studied. At all doses studied, VAX-31 demonstrated robust opsonophagocytic activity (OPA) and immunoglobulin G (IgG) immune responses, with high geometric mean concentrations (GMCs) across all 31 serotypes. The VAX-31 High Dose, which is currently being evaluated in the OPUS Phase 3 program, met or exceeded the OPA response non-inferiority criteria¹ for all 20 serotypes common with PCV20 and met the superiority criteria² for the 11 incremental serotypes unique to VAX-31 and not in PCV20. The VAX-31 High Dose average OPA immune responses were greater for 18 of 20 serotypes compared to PCV20 (geometric mean ratio (GMR) greater than 1.0), with seven of these serotypes achieving statistically higher immune responses³ compared to PCV20.

"The publication of these data, including both the OPA and IgG results, in *The Lancet Infectious Diseases* further affirms the potential of our site-specific, carrier-sparing platform to deliver the broadest-spectrum PCVs to provide protection against both currently circulating and historically prevalent serotypes," said Grant Pickering, Chief Executive Officer and Co-Founder of Vaxcyte. "Based on the strength of the unprecedented results from this study, we advanced VAX-31 into a comprehensive Phase 3 adult program and believe we are uniquely positioned to set a new standard by which future adult pneumococcal vaccines will be measured. Through the OPUS Phase 3 trials, we are aiming to expand the breadth of disease and serotype coverage while ensuring immunogenicity levels remain high to ensure durable protection and deliver a next-generation PCV with a best-in-class profile."

"The published results provide validation of VAX-31's safety profile and robust immune responses across all 31 serotypes," said Jim Wassil, Executive Vice President and Chief Operating Officer of Vaxcyte. "These data directly informed the design of our comprehensive OPUS Phase 3 program, including the decision to advance the VAX-31 High Dose and the structure of our pivotal, noninferiority trial that includes head-to-head comparisons of VAX-31 to both PCV20 and Capvaxive® (PCV21). This OPUS Phase 3 program is intended to support a planned Biologics License Application, subject to study outcomes."

About the VAX-31 Phase 1/2 Adult Study

The VAX-31 Phase 1/2 clinical study was a randomized, observer-blind, active-controlled, dose-finding study that evaluated the safety, tolerability and immunogenicity of a single injection of VAX-31 at three dose levels (Low, Middle and High) compared to PCV20 in 1,015 healthy adults aged 50 years and older. The High Dose is currently being evaluated in the comprehensive OPUS Phase 3 adult clinical program.

Safety and Tolerability Findings:

- VAX-31 was observed to be well tolerated and demonstrated a safety profile similar to PCV20 at all doses studied.
- Frequently reported local and systemic reactions were generally mild-to-moderate, resolving within several days of vaccination, with no meaningful differences observed across the cohorts. No serious adverse events were considered to be related to study vaccines.

Immunogenicity Findings:

- VAX-31 demonstrated robust OPA immune responses for all 31 serotypes at all doses studied, and all three doses were considered advanceable to Phase 3.
- At the High and Middle Doses, VAX-31 met or exceeded regulatory immunogenicity criteria for all 31 serotypes and, at the Low Dose, for 29 of 31 serotypes.
- For the 20 serotypes common with PCV20 (1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, 33F):
 - High Dose: All 20 serotypes met OPA response non-inferiority criteria; 18 of 20 serotypes had a GMR greater than 1.0 and seven serotypes achieved statistically higher immune responses compared to PCV20.
 - Middle Dose: All 20 serotypes met OPA response non-inferiority criteria; 13 of 20 serotypes had a GMR greater than 1.0 and five serotypes achieved statistically higher immune responses compared to PCV20.
 - Low Dose: 18 of 20 serotypes met OPA response non-inferiority criteria; eight of 20 serotypes had a GMR greater than 1.0 and three serotypes achieved statistically higher immune responses compared to PCV20.
- For all 11 additional serotypes unique to VAX-31 (2, 7C, 9N, 15A, 16F, 17F, 20B, 23A, 23B, 31, 35B), and not in PCV20, all three doses met superiority criteria.
- At all doses studied, VAX-31 demonstrated high IgG GMCs across all 31 serotypes, and IgG GMC responses were consistent with the immune response profile observed in the OPA analyses.

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 the OPUS 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 IPD⁴ and approximately 96% of acute otitis media⁵ 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.

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 the OPUS 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 Annual Report on Form 10-K filed with the SEC on February 24, 2026 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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¹Lower bound of the 2-sided 95% confidence interval of the OPA geometric mean ratio is greater than 0.5.

²Lower 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.

³Lower bound of the 2-sided 95% confidence interval of the OPA geometric mean ratio is greater than 1.0.

⁴In U.S. children under five years of age: *CDC 2023 Active Bacterial Core (ABC) Surveillance data*.

⁵In 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).