



Vaxcyte Reports Positive Topline Data from OPUS-1, the Pivotal Adult Phase 3 Trial of VAX-31, the Company's 31-Valent Pneumococcal Conjugate Vaccine Candidate

October 5, 2026

VAX-31 Met All Prespecified Primary Endpoints Across Age Groups Studied Compared to Prevnar 20® (PCV20) and/or Capvaxine® (PCV21)

Prespecified Co-Primary Immunogenicity Endpoints: In Adults 50 and Older, All 28 VAX-31 Serotypes Shared with PCV20 and/or PCV21 Met Noninferiority Criterion at >0.667 Threshold; All Three Serotypes Unique to VAX-31 and Cross-Reactive Serotype 20B Met Superiority Criterion

Prespecified Primary Immunobridging Endpoint: Across All 32¹ Serotype Comparisons, VAX-31 Met Noninferiority Criterion at >0.667 Threshold in Adults Aged 18-49 Compared with Adults Aged 50-64

Prespecified Primary Safety Endpoint: VAX-31 Was Well Tolerated and Demonstrated a Safety Profile Similar to PCV20 and PCV21 Across All Ages Studied

Prespecified Individual Comparator Results: VAX-31 Met Noninferiority Criterion at >0.667 Threshold for 20 of 20 Serotypes Shared with PCV20 and 17 of 19 Shared with PCV21, and at Historical >0.5 Threshold, VAX-31 Met Noninferiority Criterion for 19 of 19 Shared with PCV21²

Company Expects to Report Results from OPUS-2 and OPUS-3 Adult Phase 3 Trials in First Half of 2027, Supporting Planned Biologics License Application Submission in First Half of 2028

Topline Results Further Validate Potential of Vaxcyte's Carrier-Sparing Platform to Deliver Broader Coverage While Maintaining Magnitude of Immune Responses

Company to Host Webcast/Conference Call Today at 8:00 a.m. ET/5:00 a.m. PT

SAN CARLOS, Calif., Oct. 05, 2026 (GLOBE NEWSWIRE) -- Vaxcyte, Inc. (Nasdaq: PCVX), a clinical-stage vaccine innovation company, today announced positive topline results from the OPUS-1 pivotal adult Phase 3 trial evaluating 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 pneumococcal pneumonia. The results of OPUS-1 will serve as the cornerstone of a planned filing of a Biologics License Application (BLA), which will be subject to U.S. Food and Drug Administration (FDA) review.

In the OPUS-1 trial, VAX-31 met all prespecified co-primary immunogenicity endpoints in adults 50 and older:

- All 28 VAX-31 serotypes shared with PCV20 and/or PCV21 met the prespecified noninferiority criteria (lower bound of the 95% confidence interval (LBCI) >0.667).³
 - For the 11 serotypes shared by VAX-31, PCV20 and PCV21, VAX-31 met all 11 primary noninferiority assessments based on opsonophagocytic activity (OPA) geometric mean ratios (GMRs). For each serotype, the prespecified analysis required noninferiority against one or both comparators, using an OPA GMR noninferiority criterion of LBCI >0.667 with prespecified multiplicity adjustment.³
 - For the nine serotypes only in VAX-31 and PCV20, all nine met the prespecified OPA GMR noninferiority criterion (LBCI >0.667).⁴
 - For the eight serotypes only in VAX-31 and PCV21, all eight met the prespecified OPA GMR noninferiority criterion (LBCI >0.667).⁴
- The three serotypes unique to VAX-31 and cross-reactive serotype 20B met the OPA GMR superiority criterion (LBCI >2.0) with prespecified multiplicity adjustment.³

For the prespecified primary immunobridging endpoint, VAX-31 met the noninferiority criterion (LBCI >0.667) for all 32¹ serotype OPA GMR comparisons in adults aged 18-49 compared to adults aged 50-64.

In the study, VAX-31 was well tolerated and demonstrated a safety profile similar to PCV20 and PCV21 at all ages studied.

In the prespecified individual comparator analyses, VAX-31 met the noninferiority criterion (LBCI >0.667) for 20 of 20 serotypes shared with PCV20 and 17 of 19 shared with PCV21. Compared to PCV21, serotypes 3 and 12F missed the LBCI >0.667 noninferiority criterion and met the historical LBCI >0.5 threshold.²

"We believe these positive OPUS-1 results provide clinical validation of our site-specific, carrier-sparing platform's potential to deliver broader-

spectrum pneumococcal vaccines while maintaining the magnitude of immune responses,” said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. “VAX-31 met all prespecified primary immunogenicity endpoints across all age groups studied in this pivotal Phase 3 trial, providing the clinical cornerstone for our planned Biologics License Application. We believe VAX-31’s combination of broader coverage and robust immune responses, demonstrated in a trial inaugurating a more stringent noninferiority standard, sets a new benchmark for the class and gives us confidence in its potential for approval. We look forward to announcing results from OPUS-2 and OPUS-3 in the first half of 2027, to be followed by a manufacturing consistency study, as we work toward making this vaccine broadly available to help protect adults from the consequences of pneumococcal disease.”

“These OPUS-1 results strengthen our confidence in VAX-31’s potential to provide broader protection against invasive pneumococcal disease and pneumococcal pneumonia,” said James Wassil, Chief Scientific Officer and Chief Operating Officer of Vaxcyte. “Given current U.S. epidemiology, with the serotypes unique to PCV21 accounting for a larger share of adult disease, we expect the comparison of VAX-31 to PCV21 to be a particular focus of FDA review. PCV20 remains an important immunogenicity comparator for VAX-31, including for serotypes 4 and 19F, which are not contained in PCV21. We want to extend our gratitude to everyone involved in this program, especially the study participants, trial investigators and sites.”

“Important gaps remain in adult pneumococcal disease coverage, and OPUS-1 highlights VAX-31’s potential to address them,” said Luis Jodar, Ph.D., Chief Medical Officer of Vaxcyte. “Today’s adult PCVs differ in the serotypes they cover, requiring tradeoffs between coverage of currently circulating disease-causing serotypes and preserving coverage of historically important serotypes. VAX-31 is designed to bring both into a single 31-valent vaccine, with the potential to provide incremental coverage of 13-36% of invasive pneumococcal disease⁵ and 19-31% of pneumococcal pneumonia⁶ compared with currently available adult PCVs.”

About OPUS-1, the VAX-31 Adult Pivotal Phase 3 Trial

OPUS-1 is a randomized, double-blind, active-controlled Phase 3 trial evaluating the safety, tolerability and immunogenicity of the VAX-31 High Dose, the adult formulation being evaluated in the OPUS Phase 3 program, in healthy, pneumococcal-naïve⁷ U.S. adults aged 50 years and older (n=3,572), with a separate cohort of adults aged 18-49 years (n=475). In the High Dose formulation, all serotypes are dosed at 3.3 mcg, except serotypes 1, 5 and 22F, which are dosed at 4.4 mcg. The trial dosed 4,047 participants at approximately 30 sites across the United States. Participants aged 50 years and older were randomized 1:1:1 to receive a single dose of VAX-31, PCV20 or PCV21 on Day 1. Participants aged 18-49 years were randomized 3:1 to receive a single dose of VAX-31 or PCV20 on Day 1, with PCV20 serving as the safety comparator. Immune responses were assessed one month after vaccination. Safety and tolerability are assessed for six months following vaccination. Additional information about the study can be found at www.clinicaltrials.gov under the identifier [NCT07284654](https://clinicaltrials.gov/ct2/show/study?term=NCT07284654).

Key Topline Study Results

Safety and Tolerability Findings:

- VAX-31 was well tolerated and demonstrated a safety profile similar to PCV20 and PCV21 across all ages studied.
- Frequently reported solicited local and systemic reactions, assessed from Day 1 through Day 7, were generally mild-to-moderate, with the majority resolving within 48 hours of vaccination, and with no meaningful differences observed across the cohorts.
- No serious adverse events were considered to be related to study vaccines, and there were no study discontinuations due to adverse events.

Immunogenicity Findings:

Prespecified co-primary immunogenicity endpoints in adults 50 and older:

- For the 11 serotypes in common with PCV20 and PCV21, VAX-31 met 11 of 11 serotype OPA GMR comparisons per the prespecified noninferiority criterion⁴ (LBCI >0.667) compared to PCV20 and/or PCV21.³
- For the nine serotypes in common with PCV20 only, VAX-31 met 9 of 9 serotype OPA GMR comparisons per the prespecified noninferiority criterion⁴ (LBCI >0.667).
- For the eight serotypes in common with PCV21 only, VAX-31 met 8 of 8 serotype OPA GMR comparisons per the prespecified noninferiority criterion⁴ (LBCI >0.667).
- For the three unique serotypes and cross-reactive serotype 20B, VAX-31 met 4 of 4 serotype OPA GMR comparisons per the prespecified superiority criterion⁸ (LBCI >2.0) compared to PCV20 and/or PCV21.³

Prespecified primary immunobridging in adults aged 18-49:

- For all 32¹ serotype OPA GMR comparisons, VAX-31 met the noninferiority criterion (LBCI >0.667) in adults aged 18-49 compared to adults aged 50-64.

Prespecified individual noninferiority comparisons to PCV20 and PCV21:

- Compared to PCV20: VAX-31 OPA GMRs met the prespecified noninferiority criterion (LBCI >0.667)⁴ for 20 of 20 serotypes in common.
- Compared to PCV21: VAX-31 OPA GMRs met the prespecified noninferiority criterion (LBCI >0.667)⁴ for 17 of 19 serotypes in common. Serotypes 3 and 12F missed the LBCI >0.667 noninferiority criterion and met the historical LBCI >0.5 threshold.²

Key Anticipated PCV Franchise Milestones

Vaxcyte is advancing the clinical development of its PCV programs with several anticipated key milestones, including:

VAX-31 Adult Indication

- Announce safety, tolerability and immunogenicity data from 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 from 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.

Conference Call and Webcast

Vaxcyte will hold a webcast and conference call today, October 5, 2026, at 8:00 a.m. ET / 5:00 a.m. PT to discuss the results from OPUS-1. To participate in the conference call, please dial 800-445-7795 (domestic) or 785-424-1699 (international) and refer to conference ID PCVX1005. A live webcast of the conference call will also be available on the investor relations page of the Vaxcyte corporate website at www.vaxcyte.com. After the live webcast, the event will remain archived on the Vaxcyte website for 30 days.

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 IPD⁵ and approximately 88% of pneumococcal pneumonia⁶ 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 13-36% 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, VAX-31 is designed to cover approximately 91% of IPD⁹ and approximately 96% of acute otitis media¹⁰ due to *Streptococcus pneumoniae*. This disease coverage has the potential to result in VAX-31 providing an incremental 27-47% 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.

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, has generated positive Phase 2 clinical results in both adults and infants and is designed to cover more serotypes than any 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.

VAX-A1 is a prophylactic vaccine candidate designed to provide broad, strain-independent protection against disease caused by Group A Strep and is currently being evaluated in a Phase 1 clinical study in adults. Group A Strep remains a significant global cause of morbidity and mortality across both adult and pediatric populations and is a leading driver of antibiotic use, underscoring the substantial public health burden.

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 develop and deliver high-fidelity vaccines with enhanced immunological benefits. Vaxcyte's pipeline also includes 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 vaccine candidates, including breadth of coverage, the ability to deliver potentially best-in-class vaccines and improve upon the standard-of-care; the design, timing of initiation, progress and expected results of Vaxcyte's clinical trials and regulatory plans along with the standards for review and licensure of vaccines and regulators accepting our study as designed; and other statements that are not historical fact. The words "anticipate," "believe," "could," "expect," "intend," "plan," "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 August 5, 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.

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¹ 31 vaccine serotypes plus cross-reactive serotype 20B.

² In the prespecified individual comparator-specific noninferiority assessments of VAX-31 vs PCV21, the lower bounds of the 95% confidence intervals for the OPA GMRs for serotypes 3 and 12F exceeded >0.5 but did not meet the prespecified individual noninferiority criterion of LBCI >0.667. The historical LBCI >0.5 noninferiority comparison was a prespecified key secondary endpoint.

³ Under the prespecified Hochberg multiplicity adjustment, each of the 11 shared-serotype noninferiority assessments and each of the four primary superiority assessments succeeds against PCV20 and/or PCV21 if the one-sided adjusted p-value is <0.025 against at least one comparator. The OPA GMR margin for primary endpoints is >0.667 for noninferiority and 2.0 for superiority.

⁴ For individual comparator-specific noninferiority assessments and the primary immunobridging assessment, the lower bound of the 95% confidence interval (LBCI) for the opsonophagocytic activity (OPA) geometric mean ratio (GMR) must exceed 0.667 to establish noninferiority.

⁵ Vaxcyte estimates using CDC 2022–2024 Active Bacterial Core surveillance data for U.S. adults aged 50 years and older. Cases with missing serotype data were excluded; non-typeable cases were included in the denominator. The estimates assume cross-protection between serotypes 6A/6C and 15B/15C. <https://data.cdc.gov/d/qvzb-qs6p>.

⁶ King LM, et al. Pneumococcal Serotype Distribution and Coverage of Existing and Pipeline Pneumococcal Vaccines. *J Infect Dis.* 2025;232(4):e609–e620. <https://doi.org/10.1093/infdis/jiaf376>. Vaxcyte estimates use a weighted average of inpatient pneumonia cases in adults aged 50–64 and ≥65 years and assume cross-protection between serotypes 6A/6C and 15B/15C.

⁷ Pneumococcal-naïve means no known history of invasive pneumococcal disease, pneumococcal pneumonia or receipt of a licensed or investigational pneumococcal vaccine.

⁸ LBCI >2.0 for individual comparator-specific superiority assessments. See footnote 3 for the multiplicity-adjusted primary superiority analysis.

⁹ Vaxcyte estimate using CDC 2022–2024 Active Bacterial Core surveillance data for U.S. children under five years of age. Cases with missing serotype data were excluded; non-typeable cases were included in the denominator. The estimate assumes cross-protection between serotypes 6A/6C and 15B/15C. <https://data.cdc.gov/d/qvzb-qs6p>.

¹⁰ Vaxcyte estimate based on 2017–2021 serotype data for U.S. children five years of age or younger in Supplemental Table 1 of Grant LR, et al. Characterization of *Streptococcus pneumoniae* isolates obtained from the middle ear fluid of US children, 2011–2021. *Front Pediatr.* 2024;12:1383748. <https://doi.org/10.3389/fped.2024.1383748>. The estimate assumes cross-protection between serotypes 6A/6C and 15B/15C.