Vaxcyte Initiates Phase 2 Study Evaluating VAX-31 for the Prevention of Invasive Pneumococcal Disease in Infants

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-- Company Expects to Announce VAX-31 Infant Study Topline Safety, Tolerability and Immunogenicity Data from Primary Immunization Series in Mid-2026, Followed by Topline Data from the Booster Dose Approximately Nine Months Later --

-- VAX-31 is Designed to Cover Approximately 94% of Invasive Pneumococcal Disease and Approximately 93% of Acute Otitis Media in U.S. Children Under Five --

-- VAX-31 Offers Potential to Protect Vulnerable Population by Providing Greater Coverage Against Both Currently Circulating and Historically Prevalent Strains Relative to Standard-Of-Care Pneumococcal Conjugate Vaccines --

-- Company Remains on Track to Announce VAX-24 Phase 2 Infant Study Topline Data from Primary Immunization Series by End of First Quarter of 2025 --

SAN CARLOS, Calif., Dec. 03, 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 initiation of the Phase 2 study of VAX-31 in healthy infants and that the first study participants have been dosed. This study is evaluating the safety, tolerability and immunogenicity of VAX-31, a 31-valent pneumococcal conjugate vaccine (PCV) candidate designed to prevent invasive pneumococcal disease (IPD). The Company expects to share topline data from the primary three-dose immunization series of the study in mid-2026, followed by topline data from the booster dose approximately nine months later.

“The initiation of the VAX-31 Phase 2 infant study marks a significant milestone as we continue advancing our PCV clinical programs, which also include the fully enrolled, ongoing VAX-24 Phase 2 infant study,” said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. “PCVs are vital to combating *Streptococcus pneumoniae*, a serious public health threat exacerbated by increasing antimicrobial resistance. As the broadest-spectrum PCV candidate in the clinic today, VAX-31 has the potential to expand coverage and provide protection against both currently circulating and historically prevalent serotypes. We look forward to sharing topline data for safety, tolerability and immunogenicity from the VAX-31 Phase 2 infant study’s primary immunization series in mid-2026, and from the booster dose approximately nine months later.”

“Despite the effectiveness of current vaccines, *Streptococcus pneumoniae* is the leading cause of vaccine-preventable deaths globally in children under five and IPD, including meningitis and bacteremia, remains persistent in the first years of life,” said Jim Wassil, Executive Vice President and Chief Operating Officer of Vaxcyte. “It has been clearly signaled by the public health community that a pneumococcal vaccine with a broader spectrum of coverage is needed to provide greater protection against this disease. VAX-31 is designed to cover approximately 94% of IPD and approximately 93% of acute otitis media in U.S. children under five, with the potential to offer much greater coverage relative to the standard-of-care PCVs.”

About the VAX-31 Phase 2 Infant Study
The VAX-31 Phase 2 infant study is a randomized, double-blind, active controlled, dose-finding, two-stage clinical study evaluating the safety, tolerability and immunogenicity of VAX-31 compared to Prevnar 20 (PCV20) in healthy infants.

- Stage 1 of the study is evaluating the safety and tolerability of VAX-31 at three dose levels (low, middle and high) and compared to PCV20 in approximately 48 infants in a dose-escalation approach. In the low, middle and high doses, all serotypes were dosed at 1.1mcg, 2.2mcg and 3.3mcg, respectively, except serotypes 1, 5 and 22F, which were dosed at 1.65mcg, 3.3mcg, and 4.4mcg, respectively. Participants who receive VAX-31 in Stage 1 will continue the standard dosing regimen as part of Stage 2 and will be included in the safety, tolerability and immunogenicity analysis of the study.
- Stage 2 of the study will evaluate the safety, tolerability and immunogenicity of VAX-31 at the same three dose levels and compared to PCV20 in approximately 750 infants.
- In line with recommendations from the Advisory Committee on Immunization Practices (ACIP), the study design includes a primary immunization series consisting of three doses given at two months, four months and six months of age, followed by a subsequent booster dose at 12-15 months of age.
- The key prespecified immunogenicity study endpoints include an assessment of immune responses for each of the VAX-31 dose levels in comparison with PCV20 for the 20 common and 11 unique serotypes in VAX-31. Post-primary series (post-dose 3 or PD3) immune responses will be assessed based on serotype-specific immunoglobulin G (IgG) seroresponse rates (proportion of participants achieving the accepted IgG threshold value of ≥0.35mcg/mL) at 30 days PD3. IgG geometric mean titers will be assessed at 30 days PD3 and post-dose 4 (PD4), along with other key immunogenicity endpoints.
- All participants in the study will be evaluated for safety through six months following the booster dose.
- The study is being conducted at approximately 50 sites in the United States.

About Pneumococcal Disease
Pneumococcal disease (PD) is an infection caused by *Streptococcus pneumoniae* bacteria. It can result in invasive pneumococcal disease (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 150,000 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 advancing to a Phase 3 adult clinical program and currently being evaluated in a Phase 2 infant clinical program, is designed to prevent IPD, which is especially serious in infants, young children, older adults and those with immune deficiencies or certain chronic health conditions. IPD is associated with high case-fatality rates, antibiotic resistance and meningitis. VAX-31 is the broadest-spectrum PCV in the clinic and has the potential to provide protection against both currently circulating and historically prevalent serotypes. VAX-31 was designed to increase coverage, in a single vaccine, to more than 95% of IPD circulating in adults in the United States aged 50 and older, with the potential to provide an incremental 12-40% of coverage over current standard-of-care adult PCVs. In infants, it was designed to cover approximately 94% of IPD and approximately 93% of acute otitis media due to *Streptococcus pneumoniae* in children under five years of age in the United States.

In November 2024, Vaxcyte announced that the FDA granted Breakthrough Therapy designation to VAX-31 for the prevention of IPD in adults. The Breakthrough Therapy designation process is designed to expedite the development and review of drugs that are intended to treat a serious or life-threatening condition.

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. VAX-31 is a 31-valent, carrier-sparing PCV being developed for the prevention of IPD in adults and infants and is the broadest-spectrum PCV candidate in the clinic today. VAX-24, the Company's 24-valent PCV candidate, is designed to cover more serotypes than any infant PCV on-market and is currently being evaluated in a Phase 2 infant study. Both VAX-31 and VAX-24 are designed to improve upon the standard-of-care PCVs by covering the serotypes in circulation that are responsible for a significant portion of IPD 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 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 candidate 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-24 and VAX-31, including breadth of coverage, and the ability to deliver potentially best-in-class PCVs and improve upon the standard-of-care a; the process and timing of anticipated future development of Vaxcyte's vaccine candidates; the design of the VAX-31 infant Phase 2 study, and the timing of its data readouts; 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 5, 2024 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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