Vaxcyte Completes Enrollment of Phase 2 Study Evaluating VAX-24 for the Prevention of Invasive Pneumococcal Disease (IPD) in Infants

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-- Company Expects to Announce Topline Safety, Tolerability and Immunogenicity Data from Primary Immunization Series by the End of the First Quarter of 2025, Followed by Topline Data from Booster Dose by the End of 2025 --

-- VAX-24, a 24-Valent Pneumococcal Conjugate Vaccine (PCV), is Designed to Cover More Serotypes Than Any Infant Pneumococcal Vaccine On-Market or in U.S. Clinics Today --

-- Company's Potential Best-in-Class, Carrier-Sparing PCV Programs, VAX-24 and VAX-31, Intended to Deliver the Broadest-Spectrum of Coverage Against IPD --

SAN CARLOS, Calif., March 04, 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 completion of enrollment in its Phase 2 study evaluating VAX-24, a broad-spectrum, carrier-sparing 24-valent pneumococcal conjugate vaccine (PCV) candidate designed to prevent invasive pneumococcal disease (IPD), in healthy infants. Vaxcyte expects to announce topline safety, tolerability and immunogenicity data from the Phase 2 study primary three-dose immunization series by the end of the first quarter of 2025, followed by topline data from the booster dose by the end of 2025.

"Completing enrollment of the VAX-24 study with more than 800 healthy infants demonstrates yet another significant milestone in the development of our VAX-24 and VAX-31 PCV candidates," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "We believe VAX-24 has a potential best-in-class profile for this vital population and is designed to cover more serotypes than any infant pneumococcal vaccine on-market or in U.S. clinics today. We look forward to announcing the expected topline safety, tolerability and immunogenicity data from the primary immunization series by the end of the first quarter of 2025, which will follow participants receiving all three doses in this series, as well as the serology and data analsysis."

"Despite the effectiveness of current vaccines, IPD, which includes meningitis and bacteremia, remains persistent in the first years of life and is a leading cause of invasive disease in children two years of age and under," said Jim Wassil, Executive Vice President and Chief Operating Officer of Vaxcyte. "Given the significant burden of disease in young children, there remains a need for broader-spectrum vaccines like VAX-24 and VAX-31, our next-generation 31-valent PCV candidate, that are designed to provide greater protection than the current standard-of-care."

About the VAX-24 Infant Phase 2 Study
The VAX-24 infant Phase 2 clinical study, which is now fully enrolled with 802 healthy infants, is a randomized, observer-blind, dose-finding two-stage clinical study evaluating the safety, tolerability and immunogenicity of VAX-24.

- The Stage 1 portion of the study evaluated the safety and tolerability of a single injection of VAX-24 at three dose levels (low dose/1.1mcg, middle dose/2.2mcg, mixed dose/2.2mcg or 4.4mcg) and compared to VAXNEUVANCE™ (PCV15), which was the broadest-spectrum PCV at the time of study initiation, in 48 infants.
- The Stage 2 portion is evaluating the safety, tolerability and immunogenicity of VAX-24 at the same three dose levels and compared to Prevnar 20® (PCV20), currently the broadest-spectrum PCV recommended by the Advisory Committee on Immunization Practices (ACIP), in 754 infants. Participants who received VAX-24 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.
- In line with recommendations from the 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, in conjunction with the other routinely recommended non-PCV vaccines on the infant immunization schedule.
- The key prespecified immunogenicity study endpoints include an assessment of immune responses for all three VAX-24 doses and compared to PCV20 on the shared serotypes measured at 30 days post-dose three (PD3) and post-dose four (PD4). Immune responses will be assessed based on anti-pneumococcal polysaccharide serotype-specific immunoglobulin G (IgG) responses (proportion of participants achieving the accepted IgG threshold value of ≥0.35mcg/mL) at 30 days PD3 and IgG geometric mean titer ratios at 30 days PD4, among other 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 32 sites in the United States.
- Additional information about the study can be found at www.clinicaltrials.gov under the identifier NCT05844423.

About Pneumococcal Disease
Pneumococcal disease (PD) is an infection caused by *Streptococcus pneumoniae* (pneumococcus) bacteria. It can result in IPD, including meningitis and bacteremia, and non-invasive PD, including pneumonia, otitis media and sinusitis. In the United States, approximately 320,000 people get

pneumococcal pneumonia each year, which is estimated to result in approximately 150,000 hospitalizations and 5,000 deaths. 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 more broad-spectrum vaccine.

About Vaxcyte's PCV Franchise Candidates: VAX-24 and VAX-31
Vaxcyte's carrier-sparing PCV franchise candidates, including VAX-24, a Phase 3-ready 24-valent PCV, and VAX-31, the Company's next-generation 31-valent PCV currently being evaluated in a Phase 1/2 study, are being studied for the prevention of IPD. The public health community continues to affirm the need for vaccines that offer broader protection to prevent IPD, which can be most serious for infants, young children, older adults and those with immune deficiencies or certain chronic health conditions.

Both VAX-24 and VAX-31 are designed to improve upon the standard-of-care PCVs for both children and adults by covering the serotypes that are responsible for a significant portion of IPD in circulation 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 aims to efficiently create and deliver high-fidelity, broad-spectrum carrier-sparing conjugate vaccines in order to add coverage without compromising overall immune responses by using modern synthetic techniques, including advanced chemistry and the XpressCF™ cell-free protein synthesis platform. Vaxcyte is deploying this approach with VAX-24 and VAX-31, the latter of which has the potential to provide the broadest coverage of any PCV to reach the clinic with approximately 95 percent coverage of circulating IPD strains in the U.S. adult population.

In January 2023, Vaxcyte announced that the U.S. Food and Drug Administration granted Breakthrough Therapy designation to VAX-24 for the prevention of IPD in adults based on positive topline results from the Phase 1/2 proof-of-concept study, which evaluated the safety, tolerability and immunogenicity of VAX-24 in adults 18 to 64 years of age. The Breakthrough Therapy designation process is designed to expedite the development and review of drugs and biologics that are intended to treat a serious or life-threatening condition, where preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints.

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. Vaxcyte's lead candidate, VAX-24, is a Phase 3-ready 24-valent, broad-spectrum, carrier-sparing PCV being developed for the prevention of IPD. VAX-31, the Company's next-generation 31-valent PCV, is the broadest-spectrum PCV candidate in the clinic today.

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, the ability to deliver a potentially best-in-class PCV franchise and the improvement upon the standard-of-care; the timing and availability of data for the VAX-24 infant Phase 2 study; the demand for Vaxcyte's vaccine candidates; the potential benefits and opportunities available as a result of the Breakthrough Therapy designation for VAX-24 in adults; 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 27, 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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