Vaxcyte Provides Positive Regulatory Updates for VAX-24 Adult and Pediatric Programs

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-- Company Receives FDA Fast Track Designation for VAX-24 in Adults --

-- Vaxcyte Completes Successful Pre-IND Meeting with FDA Regarding VAX-24 Pediatric Program, Supporting Path to Proceed Directly into Infants --

-- VAX-24 is 24-Valent Pneumococcal Conjugate Vaccine Designed to Deliver Broad-Spectrum Protection to Prevent Invasive Pneumococcal Disease --

SAN CARLOS, Calif., Aug. 04, 2022 (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 that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to VAX-24, the Company's 24-valent pneumococcal conjugate vaccine (PCV) candidate designed to prevent invasive pneumococcal disease (IPD), in adults ages 18 and older. The Fast Track designation is an FDA process that has been designed to facilitate the development and expedite the review of drugs, including vaccines, that treat or prevent serious conditions and fill an unmet medical need.

The Company also completed a successful pre-Investigational New Drug (IND) meeting with the FDA regarding the VAX-24 pediatric program. Vaxcyte received positive written feedback from the FDA supporting the initiation of a pediatric study that proceeds directly into infants, contingent on satisfactory topline safety, tolerability and immunogenicity results from the ongoing VAX-24 Phase 1/2 clinical proof-of-concept study in adults 18 to 64 years of age. This approach provides the Company with an accelerated clinical path to deliver a potentially best-in-class PCV, VAX-24, to the pediatric population, which represents the largest portion of the pneumococcal vaccine market in the United States.

"We are very pleased with the FDA's feedback, which we believe provides an expedited path to deliver VAX-24 to adults and children, while also underscoring the need for a PCV that provides broader protection to prevent this serious disease," said Grant Pickering, Chief Executive Officer and Co-Founder of Vaxcyte. "By leveraging our site-specific technology, the XpressCF™ cell-free protein synthesis platform, VAX-24 is designed to improve upon the standard-of-care PCVs and surpass the coverage of those currently available without compromising overall immune response."

"Despite high vaccination rates, a broader spectrum PCV remains an important public health need, especially in vulnerable populations such as infants and older adults, due to substantial disease driven by emerging serotypes not covered by currently available vaccines," said Jim Wassil, Executive Vice President and Chief Operating Officer of Vaxcyte. "With multiple milestones anticipated over the next 12 months for VAX-24, we expect strong, continued momentum."

About VAX-24 and the Ongoing Adult Clinical Program
VAX-24 is an investigational 24-valent PCV candidate designed to prevent IPD, which can be most serious for infants, young children, older adults and those with immune deficiencies or certain chronic health conditions.

VAX-24 is intended to improve upon the standard-of-care PCVs for both children and adults by covering the serotypes that are responsible for most of the pneumococcal disease currently in circulation. Vaxcyte aims to efficiently create and deliver high-fidelity, broad-spectrum vaccines, such as VAX-24, by using modern synthetic techniques, including advanced chemistry and the XpressCF™ cell-free protein synthesis platform. Vaxcyte is deploying this approach with VAX-24 in order to add more pneumococcal strains without compromising the overall immune response.

VAX-24 is currently being evaluated in two clinical studies in adults:

- **A Phase 1/2 Clinical Proof-of-Concept Study in Adults Aged 18-64:** The Phase 1/2 clinical proof-of-concept study is now fully enrolled and the Company expects to announce topline safety and tolerability results from the Phase 1 portion of the study and safety, tolerability and immunogenicity results from the Phase 2 portion of the study in October or November 2022.
    - The VAX-24 Phase 1/2 clinical proof-of-concept study (VAX-24 Study 101, NCT05266456) is a randomized, observer-blind, dose-finding, controlled study designed to evaluate the safety, tolerability and immunogenicity of VAX-24 in healthy adults 18-64 years of age.
    - The Phase 1 portion of the study is evaluating safety and tolerability of a single injection of VAX-24 at three dose levels and compared to Prevnar 20™ in 64 healthy adults 18 to 49 years of age.
    - The Phase 2 portion is evaluating the safety, tolerability and immunogenicity of a single injection of VAX-24 at three dose levels and compared to a single injection of Prevnar 20™ in approximately 800 healthy adults 50 to 64 years of age.

- **A Separate Phase 2 Clinical Study in Adults Aged 65 and Older:** Vaxcyte announced the dosing of the first participants in a separate Phase 2 study in adults 65 years of age and older in July 2022. Topline safety, tolerability and

immunogenicity results from this study are expected in the first half of 2023, further building upon the body of clinical evidence to support the potential of VAX-24 as the broadest-spectrum PCV.

- This VAX-24 Phase 2 clinical study (VAX-24 Study 102, NCT05297578) is a randomized, observer-blind, dose-finding, controlled study designed to evaluate the safety, tolerability and immunogenicity of VAX-24 in approximately 200 healthy adults 65 years of age and older.
- The study is evaluating the safety, tolerability and immunogenicity of a single injection of VAX-24 at three dose levels and compared to a single injection of Prevnar 20™.

About the FDA's Fast Track Program
The Fast Track designation is an FDA process that has been designed to facilitate the development and expedite the review of drugs, including vaccines, that treat or prevent serious conditions and fill an unmet medical need. Aimed at getting important medications to patients earlier, the Fast Track process addresses a broad range of serious conditions. Companies with products receiving Fast Track designation are eligible for more frequent meetings with the FDA to discuss the drug's development plan and ensure collection of data needed to support drug approval and more frequent written communication from the FDA about things such as the design of proposed clinical trials. Finally, these companies may also be eligible for Accelerated Approval and Priority Review, if relevant criteria are met

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. Despite universal vaccination for PD in infants and in many adults in the United States, the overall incidence of PD is substantial and is driven by emerging serotypes not covered by currently available vaccines. In the United States, approximately 900,000 people get pneumococcal pneumonia each year, which is estimated to result in approximately 400,000 hospitalizations and 28,000 deaths. Pneumococci also cause over 50% of all cases of bacterial meningitis in the United States. Antibiotics are used to treat pneumococcal disease, but some strains of the bacteria have developed resistance to treatments. The morbidity and mortality due to pneumococcal disease are highly significant, particularly for young children and older adults, underscoring the need for a more broad-spectrum vaccine.

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 24-valent, broad-spectrum pneumococcal conjugate vaccine being developed for the prevention of IPD. 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-XP, a PCV with an expanded breadth of coverage of greater than 30 strains; VAX-A1, a prophylactic vaccine candidate designed to prevent Group A Strep infections; and VAX-PG, a therapeutic vaccine candidate designed to slow or stop the progression of periodontal disease. 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, including breadth of coverage, the improvement upon the standard-of-care, the ability to deliver a potentially best-in-class PCV and the achievement of clinical proof-of-concept; the process and timing of anticipated future development, milestones and momentum of Vaxcyte's vaccine candidates; the timing, availability and outcome of topline data for the VAX-24 Phase 1/2 clinical proof-of-concept study and Phase 2 clinical study; the demand for Vaxcyte's vaccine candidates; and other statements that are not historical fact. The words "believe," "could," "expect," "may," "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; impacts of COVID-19; 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, without limitation, its Quarterly Report on Form 10-Q filed with the SEC on May 9, 2022 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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