Vaxcyte Doses First Participants in Phase 1/2 Clinical Study Evaluating VAX-24 for the Prevention of Invasive Pneumococcal Disease and Pneumonia in Adults

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-- Company Expects to Announce Topline Results from the Phase 1/2 Study by the End of 2022 --

-- Proof-of-Concept Study Will Evaluate the Safety, Tolerability and Immunogenicity of VAX-24 --

-- VAX-24 is a 24-Valent Pneumococcal Conjugate Vaccine Designed to Deliver Broad-Spectrum Protection --

SAN CARLOS, Calif., Feb. 23, 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, announced today that the first participants were dosed in the Phase 1/2 clinical study of VAX-24. This clinical proof-of-concept study will evaluate the safety, tolerability and immunogenicity of VAX-24, a 24-valent pneumococcal conjugate vaccine (PCV) candidate designed to prevent invasive pneumococcal disease (IPD) and pneumonia in adults. The Company expects to announce topline safety, tolerability and immunogenicity results from the Phase 1/2 study by the end of 2022.

“Initiating the VAX-24 Phase 1/2 clinical study is an important step forward in the development of our lead, broad-spectrum PCV candidate, and for our company,” said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. “We developed VAX-24, using advanced chemistry and our novel XpressCF™ platform, with the intent to deliver the broadest spectrum PCV to effectively prevent pneumococcal disease and we look forward to announcing the topline safety, tolerability and immunogenicity results from this clinical study by the end of the year.”

“The global impact of pneumococcal disease remains significant and underscores the importance of advancing the development of VAX-24 and VAX-XP, our PCV candidate with an expanded breadth of coverage of greater than 30 strains,” said Jim Wassil, Chief Operating Officer of Vaxcyte. “Our PCV franchise is designed to improve upon the standard-of-care pneumococcal vaccines by covering the serotypes that are responsible for most of the residual pneumococcal disease currently in circulation.”

The VAX-24 Phase 1/2 clinical proof-of-concept study is a randomized, observer-blind, dose-finding, controlled study designed to evaluate the safety, tolerability and immunogenicity of VAX-24 in healthy adults. The Phase 1 portion of the study will evaluate the safety and tolerability of a single injection of VAX-24 at three dose levels and compared to Prevnar 20™ in approximately 64 healthy adults 18 to 49 years of age. The Phase 2 portion will evaluate the safety, tolerability and immunogenicity of a single injection of VAX-24 at three dose levels and compared to Prevnar 20™ in approximately 800 healthy adults 50 to 64 years of age. The prespecified immunogenicity endpoints of the Phase 2 portion of the study include an assessment of the induction of antibody responses, using immunoglobulin G (IgG) and opsonophagocytic activity (OPA), at each of the three VAX-24 doses and compared to Prevnar 20™ and, for the additional four serotypes contained in VAX-24 and Pneumovax® 23 but not in Prevnar 20™, the four-fold rise in antibody titers. The study will be conducted at approximately 13 sites in the United States.

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. The global incidence of PD 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 VAX-24
VAX-24 is an investigational 24-valent PCV candidate designed to prevent IPD and pneumonia, which can be most serious for infants, young children, older adults and those with immune deficiencies or certain chronic health conditions. The public health community continues to affirm the need for vaccines that offer broader protection to prevent IPD and pneumonia. VAX-24 is intended to improve upon the standard-of-care PCV vaccines for both children and adults by covering the serotypes that are responsible for most of the residual 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. With VAX-24, Vaxcyte is deploying this approach with the intent of adding more pneumococcal strains without compromising the overall immune response.

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 and pneumonia. 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 benefit of Vaxcyte's vaccine candidates, including breadth of coverage; the process and timing of anticipated future development 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; 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 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 its Quarterly Report on Form 10-Q filed with the SEC on November 10, 2021 or in other documents Vaxcyte subsequently files with or furnishes to the SEC. 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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