



Vaxcyte Announces FDA Clearance of Investigational New Drug Application for VAX-24 for the Prevention of Invasive Pneumococcal Disease

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

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

SAN CARLOS, Calif., Jan. 06, 2022 (GLOBE NEWSWIRE) -- Vaxcyte, Inc. (Nasdaq: PCVX), a vaccine innovation company engineering high-fidelity vaccines to protect humankind from the consequences of bacterial diseases, announced today that the U.S. Food and Drug Administration (FDA) has cleared the Investigational New Drug (IND) application for VAX-24, its lead, 24-valent pneumococcal conjugate vaccine (PCV) candidate designed to prevent invasive pneumococcal disease. Vaxcyte expects to initiate the VAX-24 Phase 1/2 clinical proof-of-concept study in adults in the first quarter of 2022 and announce topline immunogenicity results by the end of the year.

"Clearance of our first IND is an important milestone as we transition to being a clinical-stage company with VAX-24, our lead, broad-spectrum PCV candidate, as it advances into the clinic to generate proof-of-concept data in adults," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "We currently expect to deliver topline results from our VAX-24 Phase 1/2 clinical study by the end of 2022, while also continuing to advance the rest of our pipeline including VAX-XP, our PCV candidate with an expanded breadth of coverage of greater than 30 strains."

"The global impact of pneumococcal disease in children and adults remains significant, and the public health community continues to advocate for vaccines that can offer broader protection to prevent pneumococcal disease," added Jim Wassil, Chief Operating Officer and Head of Clinical Development at Vaxcyte. "Our PCV franchise, consisting of VAX-24 and VAX-XP, is designed specifically to address this need and has the potential to deliver the broadest protection for this very serious disease."

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 administered to 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 compared to that of Prevnar 20™ in approximately 800 healthy adults 50 to 64 years of age.

About Pneumococcal Disease

Pneumococcal disease (PD) is an infection caused by *Streptococcus pneumoniae* (pneumococcus) bacteria. It can result in invasive PD (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, 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 pneumococcal disease. 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. Vaxcyte is re-engineering the way highly complex immunizations 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, including the initiation of the VAX-24 Phase 1/2 clinical proof-of-concept study and the development of VAX-XP; the timing and availability of topline data for VAX-24, including the impact of COVID-19; 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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