



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

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-- Infant Phase 2 Study Initiation Expected in the Second Quarter of 2023, with Initial Topline Safety, Tolerability and Immunogenicity Data by 2025 --

-- Based on Positive Topline VAX-24 Phase 1/2 Proof-of-Concept Study Results in Adults, FDA Supported Initiation of Pediatric Program in Infants --

SAN CARLOS, Calif., Feb. 21, 2023 (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 U.S. Food and Drug Administration (FDA) has cleared the Company's infant Investigational New Drug (IND) application for VAX-24, its lead, 24-valent pneumococcal conjugate vaccine (PCV) candidate designed to prevent invasive pneumococcal disease (IPD). Vaxcyte plans to initiate the infant Phase 2 study in the second quarter of 2023, with topline safety, tolerability and immunogenicity data following the primary three-dose immunization series expected by 2025. The study design will include a primary immunization series consisting of three doses followed by a subsequent booster dose.

Based on the positive topline results from the VAX-24 Phase 1/2 proof-of-concept study, which evaluated the safety, tolerability and immunogenicity of VAX-24 in adults 18-64 years of age, the FDA supported the initiation of a pediatric study in healthy infants. 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. The burden of disease in the pediatric population underscores the need for a broader-spectrum vaccine.

"The clearance of the VAX-24 infant IND application marks an important step in expanding the development of our lead, broad-spectrum PCV candidate in this important and vulnerable population," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "Based on the positive data from our Phase 1/2 proof-of-concept study in adults, we believe VAX-24 has the potential to deliver a best-in-class profile with broader coverage and better immune responses relative to the standard-of-care for both the adult and pediatric populations. We remain focused on advancing our VAX-24 clinical programs and look forward to the anticipated initiation of the infant study and announcement of the topline results from our Phase 2 study in adults aged 65 and older in the second quarter of this year."

Jim Wassil, Executive Vice President and Chief Operating Officer of Vaxcyte, added, "The 24 serotypes included in VAX-24 cover a significant portion of the IPD currently in circulation that are associated with high case-fatality rates, antibiotic resistance and meningitis. Importantly, the nine incremental serotypes in VAX-24 cover an additional 20-25 percent of strains causing IPD over the current 15-valent standard-of-care PCV in infants. Given the significant burden of disease in young children, there remains a need for broader-spectrum vaccines like VAX-24 and VAX-31, our 31-valent PCV candidate, that are designed to provide greater protection."

About the VAX-24 Phase 2 Infant Study

This Phase 2, randomized, observer-blind, dose-finding two-stage clinical study will evaluate the safety, tolerability and immunogenicity 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) in healthy infants. The Stage 1 portion of the study will evaluate the safety and tolerability of a single injection of VAX-24 at three dose levels compared to PCV15 in approximately 48 infants in a dose-escalation approach. The Stage 2 portion will evaluate the safety, tolerability and immunogenicity of VAX-24 at three dose levels and compared to PCV15 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 all three VAX-24 doses and compared to PCV15 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 ≥ 0.35 mcg/ml) at 30 days PD3 and IgG geometric mean titer ratios at 30 days PD4. All participants in the study will be evaluated for safety through six months following the booster dose.

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 IPD. 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.

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

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, carrier-sparing PCV 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-31, a 31-valent PCV candidate; 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.

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 ability to deliver a potentially best-in-class PCV and the improvement upon the standard-of-care; the VAX-24 Phase 2 infant study design; the process and timing of anticipated future development of Vaxcyte's vaccine candidates; the timing and availability of data for the VAX-24 Phase 2 studies and related regulatory interactions; the potential for VAX-31 to provide broader protection; the demand for Vaxcyte's vaccine candidates; and other statements that are not historical fact. The words "anticipate," "believe," "could," "expect," "intend," "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 November 7, 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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