Vaxcyte Announces FDA Clearance of Investigational New Drug Application for VAX-31 for the Prevention of Invasive Pneumococcal Disease in Adults

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-- Company Expects to Initiate VAX-31 Phase 1/2 Study in Healthy Adults This Quarter--

-- Topline Safety, Tolerability and Immunogenicity Results from VAX-31 Phase 1/2 Study Expected in the Second Half of 2024 --

-- VAX-31 is a 31-Valent Pneumococcal Conjugate Vaccine Designed to Provide Coverage for Approximately 95% of Disease Currently Circulating in the U.S. Adult Population --

SAN CARLOS, Calif., Oct. 19, 2023 (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 Company's adult Investigational New Drug (IND) application for VAX-31, a 31-valent pneumococcal conjugate vaccine (PCV) candidate designed to prevent invasive pneumococcal disease (IPD). Vaxcyte expects to initiate the VAX-31 Phase 1/2 clinical study in adults in the fourth quarter of this year and announce topline safety, tolerability and immunogenicity results in the second half of 2024.

"The FDA clearance of the VAX-31 IND application represents an important step toward our goal of building a best-in-class PCV franchise, including VAX-31 and VAX-24, the 24-valent PCV for which we achieved positive results in two adult Phase 2 clinical studies," said Grant Pickering, Chief Executive Officer and Co-founder of Vaxcyte. "Given VAX-31, which will be the broadest-spectrum PCV to enter the clinic, leverages the foundation already established with VAX-24, we are very excited about the promise of this vaccine candidate. We expect to advance VAX-31 into the clinic this quarter and announce topline safety, tolerability and immunogenicity results in the second half of 2024."

"The VAX-31 Phase 1/2 study, which will enroll approximately 1,000 adults aged 50 and older, is designed to enable us to understand the clinical potential of VAX-31 to improve upon the standard-of-care for adults by providing a broader-spectrum of protection," said Jim Wassil, Executive Vice President and Chief Operating Officer at Vaxcyte. "With VAX-31, we are leveraging our cell-free platform to develop a PCV candidate with expanded coverage against approximately 95 percent of the serotypes that currently cause IPD in the U.S. adult population. This is important given IPD contributes to high-case fatality rates, antibacterial resistance and meningitis, all of which are particularly concerning in the older adult population."

About the VAX-31 Phase 1/2 Study
The VAX-31 Phase 1/2 clinical study is a randomized, observer-blind, active-controlled, dose-finding clinical study designed to evaluate the safety, tolerability and immunogenicity of VAX-31 compared to Prevnar 20® (PCV20) in approximately 1,000 healthy adults aged 50 and above. The Phase 1 portion of the study will evaluate the safety and tolerability of a single injection of VAX-31 at three dose levels (low, middle and high) administered to approximately 64 healthy adults 50 to 64 years of age before the study progresses to Phase 2. Phase 1 participants will also be evaluated for immunogenicity, and the Phase 1 safety, tolerability and immunogenicity data will be pooled with the participants in the Phase 2 portion of the study. The Phase 2 portion of the study will evaluate the safety, tolerability and immunogenicity of a single injection of VAX-31 at the same three dose levels compared to that of PCV20 in approximately 936 healthy adults 50 years of age and older.

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 VAX-31
VAX-31, an investigational 31-valent PCV candidate, is designed to prevent IPD, which is especially serious in 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. Both VAX-31 and VAX-24, Vaxcyte's 24-valent PCV candidate entering late-stage clinical development, are designed to improve upon the standard-of-care PCV vaccines for both children and adults by covering the serotypes that are responsible for a significant portion of IPD currently in circulation and are associated with high case-fatality rates, antibiotic resistance and meningitis. VAX-31 was designed to provide coverage for approximately 95% of the IPD currently circulating in the U.S. adult population. Vaxcyte aims to efficiently create and deliver high-fidelity, broad-spectrum vaccines by using modern synthetic techniques, including advanced chemistry and the XpressCF™ cell-free protein synthesis platform. With VAX-31 and 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, carrier-sparing PCV being developed for the prevention of IPD and is poised to move into late-stage development. VAX-31, which will be the broadest-spectrum PCV candidate to enter the clinic, is a follow-on candidate to VAX-24 and part of

the Company's PCV franchise.

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 program 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-31 and VAX-24, including breadth of coverage and clinical potential, the ability to deliver potentially best-in-class profiles and the improvement upon the standard-of-care; the design, process and timing of anticipated future development of VAX-31 and VAX-24, including the timing of the VAX-31 Phase 1/2 clinical study in adults and announcement of topline safety, tolerability and immunogenicity results; the potential of VAX-31 to serve as a follow-on candidate to VAX-24; 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 Quarterly Report on Form 10-Q filed with the SEC on August 8, 2023 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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