Vaxcyte's VAX-24 Granted FDA Breakthrough Therapy Designation for the Prevention of Invasive Pneumococcal Disease in Adults

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-- Breakthrough Therapy Designation for 24-Valent Investigational Pneumococcal Conjugate Vaccine Candidate Based on Positive Topline Proof-of-Concept Data Results in Adults Aged 18-64 That Suggest Potential Best-in-Class Profile --

-- Topline Safety, Tolerability and Immunogenicity Data from VAX-24 Phase 2 Study in Adults 65 and Older Expected in Q2 2023 --

-- Company Continues to Advance PCV Franchise, Including VAX-24 and VAX-31, While Progressing Early-Stage Vaccine Programs --

SAN CARLOS, Calif., Jan. 05, 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) granted Breakthrough Therapy designation for VAX-24, the Company's investigational 24-valent pneumococcal conjugate vaccine (PCV) candidate for the prevention of invasive pneumococcal disease (IPD), in adults. The FDA's decision was based on positive topline results from the Phase 1/2 proof-of-concept study, which evaluated the safety, tolerability and immunogenicity of VAX-24 in adults 18-64 years of age.

In the Phase 1/2 clinical study, VAX-24 met the primary safety and tolerability objectives, demonstrating a safety profile similar to Prevnar 20™ (PCV20) for all doses studied. The study also demonstrated that VAX-24 met or exceeded the established regulatory immunogenicity standards for all 24 serotypes at the conventional 2.2mcg dose, which the Company intends to move forward into a pivotal Phase 3 program. At this dose, VAX-24 met the standard opsonophagocytic activity response non-inferiority criteria for all 20 serotypes common with PCV20, of which 16 achieved higher immune responses.

"The FDA's Breakthrough Therapy designation supports further acceleration of the VAX-24 development program in adults, while also providing validation of the potential of VAX-24 to deliver broader coverage and better immune responses relative to the standard of care," said Grant Pickering, Chief Executive Officer and Co-Founder of Vaxcyte. "Our focus remains on advancing our VAX-24 clinical programs in both adults and infants and we anticipate announcing the topline data from the Phase 2 study in adults 65 and older in the second quarter of 2023."

The FDA's Breakthrough Therapy process is designed to expedite the development and review of drugs that are intended to treat a serious or life-threatening condition. The designation is based upon preliminary clinical evidence indicating that the drug or vaccine may demonstrate substantial improvement over available therapies on one or more clinically significant endpoints. With Breakthrough Therapy designation, Vaxcyte will have access to all of the elements of the FDA's Fast Track program, as well as the ability to receive guidance and support from the FDA on an efficient drug development program and an organizational commitment from senior managers within the FDA.

"We are pleased to have received this important designation for VAX-24, which we believe underscores the public health need for broader protection from IPD, as well as the importance of innovative technology platforms in vaccine development, such as our cell-free, carrier-sparing approach," said Jim Wassil, Executive Vice President and Chief Operating Officer of Vaxcyte. "In addition to our PCV franchise, comprising VAX-24 and VAX-31, our PCV candidate with 31 strains (formerly VAX-XP), we are also leveraging the XpressCF™ cell-free platform to develop earlier-stage vaccines, including VAX-A1 and VAX-PG, that are designed to prevent or treat bacterial infectious diseases and further demonstrate the full potential of our platform."

Anticipated Key Milestones
Vaxcyte is advancing the clinical development of its PCV and early-stage programs with several anticipated key milestones, including:

VAX-24 Adult Program

- Topline safety, tolerability and immunogenicity data from the Phase 2 study in adults 65 and older are anticipated in the second quarter of 2023.
- Final results with the 6-month safety data from the two Phase 2 adult studies are anticipated in the first half of 2023.
- Following the receipt of the final safety reports from the two adult Phase 2 studies, regulatory interactions to inform the Phase 3 program are anticipated in the second half of 2023.
- Topline safety, tolerability and immunogenicity data from the pivotal Phase 3 non-inferiority study in adults are expected in 2025.

VAX-24 Pediatric Program

- The infant Investigational New Drug (IND) application submission and the Phase 2 study initiation are both anticipated in first half of 2023.
- Topline safety, tolerability and immunogenicity data from the infant Phase 2 study following the primary 3-dose immunization series are expected by 2025. The study design will include a primary immunization series consisting of three

doses followed by a subsequent booster dose.

VAX-31 (Formerly VAX-XP) Adult Program

- The IND application submission for VAX-31 is anticipated in the second half of 2023.
- Topline safety, tolerability and immunogenicity data from a Phase 1/2 study in adults 18 years of age and older are expected in 2024.

VAX-A1

- Vaxcyte continues to advance the development of VAX-A1, a novel conjugate vaccine designed to prevent infections caused by Group A Strep bacteria, and further information about the anticipated timing of an IND application will be provided as the program progresses.

VAX-PG

- Vaxcyte nominated a final vaccine candidate for VAX-PG, its novel therapeutic vaccine designed to treat periodontal disease, in the fourth quarter of 2022 and continues to progress the program.

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 900,000 people get pneumococcal pneumonia each year, which is estimated to result in approximately 150,000 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, 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 PCV with coverage of 31 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.

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 process and timing of anticipated future development of Vaxcyte's vaccine candidates; the timing and availability of data for the VAX-24 Phase 2 and Phase 3 studies and related regulatory interactions; the timing and submission of an IND application for the VAX-24 Phase 2 infant study and the availability of Phase 2 topline results; the timing and submission of an IND application for the VAX-31 adult program and the timing and availability of the Phase 1/2 topline data for such program; the timing of guidance for an IND application for VAX-A1; the demand for Vaxcyte's vaccine candidates; the potential benefits and opportunities available as a result of the Breakthrough Therapy designation; 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.

Contacts:

Andrew Guggenhime, President and Chief Financial Officer
Vaxcyte, Inc.
650-837-0111
investors@vaxcyte.com

Janet Graesser, Vice President, Corporate Communications and Investor Relations
Vaxcyte, Inc.
917-685-8799
media@vaxcyte.com