Vaxcyte Announces Publication of Preclinical Data Supporting the Potential of VAX-24 for the Prevention of Invasive Pneumococcal Disease

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VAX-24 is a 24-Valent Broad-Spectrum Pneumococcal Conjugate Vaccine Leveraging Vaxcyte's Technology Platform

FOSTER CITY, Calif., May 10, 2021 (GLOBE NEWSWIRE) -- Vaxcyte, Inc. (Nasdaq: PCVX), a next-generation vaccine company seeking to improve global health by developing superior and novel vaccines designed to prevent or treat some of the most common and deadly infectious diseases worldwide, today announced the publication of preclinical data supporting the potential of VAX-24, its lead vaccine candidate, in the journal *Vaccine*. VAX-24 is an investigational 24-valent pneumococcal conjugate vaccine (PCV) designed to prevent invasive pneumococcal disease, which can be most serious for infants, young children, older adults and those with immune deficiencies or certain chronic health conditions.

Today, despite widespread PCV vaccination in infants and older adults, there continues to be considerable impact from disease-causing pneumococcal serotypes, or strains, not covered by the currently available 13-valent PCV. This is largely due to the inherent genetic diversity of *Streptococcus pneumoniae*, and is further exacerbated by the phenomenon of serotype replacement. High rates of morbidity and mortality due to pneumococcal disease underscore the need for a more broad-spectrum vaccine.

The paper, "Non-clinical Immunological Comparison of a Next-Generation 24-Valent Pneumococcal Conjugate Vaccine (VAX-24) Using Site-Specific Carrier Protein Conjugation to the Current Standard of Care (PCV13 and PPV23)," which includes previously disclosed data, uses a rabbit model to evaluate the immune response of Vaxcyte's 24-valent PCV candidate compared to Prevnar13 ® (PCV13) and Pneumovax®23 (PPV23). In this study, all serotype conjugates in VAX-24 met the primary objective to elicit immune responses that were more robust compared to PPV23 and at least comparable to PCV13.

"Despite widespread, global use of pneumococcal conjugate vaccines, the prevalence of invasive pneumococcal disease remains high, and there is a significant unmet need for a vaccine that provides safe, effective and broader protection," said Jim Wassil, Chief Operating Officer, Vaxcyte. "These preclinical data add to the growing body of evidence supporting the potential for VAX-24, using Vaxcyte's proprietary cell-free protein synthesis platform, to become the broadest-spectrum PCV. We continue to advance VAX-24 in preparation for the anticipated submission of the Investigational New Drug Application to the U.S. Food and Drug Administration in order to generate clinical proof of concept in a Phase 1/2 study."

Highlights of Study Design and Findings:

- In this study, VAX-24, PCV13 and PPV23 were administered to New Zealand White rabbits to compare the resulting opsonophagocytic, or neutralizing antibody, activity (OPA) and anti-capsular IgG antibodies generated that specifically bind to all the individual serotypes included in each respective vaccine.
- The rabbits were dosed at either 0.11µg or 1.1µg of VAX-24 at the start of the study and a booster was given 21 days later. Immunogenicity was measured 14 days after both the initial and booster doses and compared to the 13 serotypes contained in PCV13 and the incremental 11 serotypes contained in PPV23.
- In the study, VAX-24 showed conjugate-like immune responses to all 24 serotypes based on comparable OPA and IgG responses to PCV13 and higher responses than PPV23.
- This study demonstrated the utility of Vaxcyte's site-specific conjugation technology in a preclinical setting and the potential for a PCV with broader serotype coverage.

Vaccine Paper Details and Access
"Non-clinical Immunological Comparison of a Next-Generation 24-Valent Pneumococcal Conjugate Vaccine (VAX-24) Using Site-Specific Carrier Protein Conjugation to the Current Standard of Care (PCV13 and PPV23)," by Jeff Fairman, Paresh Agarwal, Sandrine Barbanel, Christopher Behrens, Aym Berges, John Burky, Peter Davey, Phil Fernsten, Chris Grainger, Sherry Guo, Sam Iki, Mark Iverson, Martin Kane, Neeraj Kapoor, Olivier Marcq, Thi-Sau Migone, Paul Sauer, and James Wassil. DOI: 10.1016/j.vaccine.2021.03.070. The paper is in press in *Vaccine*, Vol. 39, issue 23 (2021) published by Elsevier. The paper is available online: https://www.sciencedirect.com/science/article/pii/S0264410X21003741.

About Pneumococcal Disease
Pneumococcal disease is an infection caused by *Streptococcus pneumoniae* bacteria. This infection can lead to a wide range of serious invasive infections including pneumonia, meningitis and blood stream infections, as well as less severe, non-invasive ear and sinus infections, and can also cause secondary infections due to other respiratory pathogens. In the U.S. alone, approximately 900,000 people get pneumococcal pneumonia each year, including as many as 400,000 requiring hospitalization and approximately 28,000 deaths. 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, which underscores the need for a more broad-spectrum vaccine.

About VAX-24
VAX-24 is designed to improve upon the standard-of-care PCV vaccine by covering the additional strains that are responsible for the majority of residual pneumococcal disease currently in circulation. Vaxcyte's cell-free protein synthesis platform, which is comprised of the XpressCF ^{TM} platform exclusively licensed from Sutro Biopharma, and its proprietary know-how, offer several advantages over conventional cell-based protein expression methods, which Vaxcyte believes enables it to generate a more broad-spectrum PCV. Vaxcyte's approach is focused on expanding coverage by adding more antigenic strains without compromising the overall immune response. Vaxcyte achieved preclinical proof of concept for VAX-24 by demonstrating that VAX-24 has the potential to protect against the pneumococcal strains collectively covered by PCV13 and PPV23 and showed the durable, boostable immune response of a conjugate vaccine. The incremental 11 strains covered by VAX-24 and not covered by PCV13 are responsible for the majority of circulating invasive pneumococcal disease in both the United States and European Union and are associated with high case-fatality rates, antibiotic resistance and/or serious invasive infections.

About *Vaccine*
Vaccine is the pre-eminent journal for those interested in vaccines and vaccination. It is the official journal of The Edward Jenner Society and The Japanese Society for Vaccinology and is published by Elsevier www.elsevier.com/locate/vaccine.

About Vaxcyte
Vaxcyte is a next-generation vaccine company seeking to improve global health by developing superior and novel vaccines designed to prevent or treat some of the most common and deadly infectious diseases worldwide. The Company's cell-free protein synthesis platform, comprising the XpressCF^{TM} platform, exclusively licensed from Sutro Biopharma, Inc., together with Vaxcyte's proprietary know-how, enables the design and production of protein carriers and antigens, the critical building blocks of vaccines, in ways that the Company believes conventional vaccine technologies currently cannot. Vaxcyte's lead vaccine candidate, VAX-24, is a preclinical, 24-valent broad-spectrum pneumococcal conjugate vaccine (PCV) being developed for the prevention of invasive pneumococcal disease. Vaxcyte's pipeline also includes VAX-XP, a PCV with an expanded breadth of coverage of at least 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 by targeting the keystone pathogen responsible for this chronic, oral inflammatory disease. 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 preventative benefit of VAX-24; the attributes or advantages of the XpressCF^{TM} platform; Vaxcyte's business opportunities; the process and timing of anticipated future development of Vaxcyte's vaccine candidates; whether preclinical data support further development of VAX-24; and the potential success of the VAX-24 program. 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; 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 Annual Report on Form 10-K filed with the SEC on March 29, 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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