SARS Vaccine Achieves Neutralizing Responses in First U.S. Human Trial

SAN DIEGO, Dec 09, 2008 /PRNewswire-FirstCall via COMTEX News Network/ --

Vical Incorporated (Nasdaq: VICL) today announced that results from a Phase I clinical trial of a DNA vaccine for severe acute respiratory syndrome (SARS), conducted by the National Institutes of Health (NIH) and published in the November 25 issue of Vaccine(1), demonstrated that the vaccine was well-tolerated, and induced neutralizing antibody responses in 80% of the vaccinees and T-cell immune responses in all vaccinees. The Phase I trial was initiated with unprecedented speed, within 19 months of the publication of the SARS coronavirus genetic sequence from which the vaccine was derived, and was the first SARS vaccine human clinical trial conducted in the United States.

The DNA vaccine was developed by the Vaccine Research Center (VRC), National Institute of Allergy and Infectious Diseases (NIAID), NIH, and manufactured by Vical. Three doses of 4 mg each were delivered on Days 0, 28 and 56 with the Biojector(R) 2000 needle-free injection system (Bioject Medical Technologies Inc., OTC Bulletin Board: BJCT). In the article, authors from the VRC detailed safety and immunogenicity results, and concluded, "This vaccine also demonstrates the feasibility of rapid manufacturing and regulatory review and provides additional safety and immunogenicity data to support the concept of DNA vaccination as a potential vaccine platform for future emerging infectious diseases."

After completion of the NIH Phase I clinical trial, NIAID transferred the Investigational New Drug application (IND) for the vaccine to Vical, and the company has evaluated its options to continue development of the vaccine when a medical need arises. "Like many emerging infectious diseases, SARS is suspected of having origins in an animal reservoir and is therefore likely to re-emerge at some point in the future," said Vijay Samant, Vical's President and Chief Executive Officer. "With the data from this successful Phase I trial and control of the IND, we are prepared to advance this vaccine quickly in the event of another outbreak. In the meantime, we can look to the model established with this program in addressing other emerging infectious diseases."

Side effects in the Phase I trial were typically mild, and no serious adverse events were reported. SARS-specific neutralizing antibody responses were detected in 8 of 10 subjects. SARS-specific CD4+ T-cell responses were detected in all 10 subjects, and CD8+ T-cell responses were detected in 2 of 10 subjects. Neutralizing antibody responses are important in preventing infection. CD4+ T cells help direct the appropriate immune resources against specific pathogens. CD8+ T cells find and kill infected cells and are important in clearing virus after infection.

About SARS

Following the initial cases of SARS, identified in the Guangdong Province of China in late 2002, the disease spread rapidly through the summer of 2003 and reached epidemic status, affecting more than 8,000 and killed more than 900 people in 25 countries before it was contained. SARS affects the respiratory system and gastrointestinal tract as well as other internal organs, with particular risk to the elderly and immunocompromised. Healthy adults may become infected and spread the disease without exhibiting any symptoms.

About DNA Vaccines

DNA vaccines may offer both technical and economic advantages compared with conventional vaccine approaches. DNA vaccines encode certain proteins associated with a target pathogen, rather than using any part of the pathogen itself, and can prime the immune system as well as induce antibody and T-cell immune responses. DNA vaccines contain no viral particles, are non-infectious, and can be administered on a repeat basis without unwanted immune responses. Additionally, DNA vaccines have the potential to achieve proof of concept more quickly and cost-effectively than conventional vaccines, and can be manufactured using uniform methods of fermentation and purification, allowing significantly faster development and production.

About Vical

Vical researches and develops biopharmaceutical products based on its patented DNA delivery technologies for the prevention and treatment of serious or life-threatening diseases. Potential applications of the company's DNA delivery technology include DNA vaccines for infectious diseases or cancer, in which the expressed protein is an immunogen; cancer immunotherapeutics, in which the expressed protein is an immune system stimulant; and cardiovascular therapies, in which the expressed protein is an angiogenic growth factor. The company is developing certain infectious disease vaccines and cancer therapeutics internally. In addition, the company collaborates with major pharmaceutical companies and biotechnology companies that give it access to complementary technologies or greater resources. These strategic partnerships provide the company with mutually
beneficial opportunities to expand its product pipeline and address significant unmet medical needs. Additional information on Vical is available at http://www.vical.com.

This press release contains forward-looking statements subject to risks and uncertainties that could cause actual results to differ materially from those projected, including: whether Vical or others will continue development of the SARS DNA vaccine; whether SARS will re-emerge, and if so, whether the DNA vaccine will be effective in protecting against SARS infection or disease; whether DNA vaccines will be successfully developed for other emerging infectious diseases; whether the SARS vaccine or any other product candidates will be shown to be safe and effective in clinical trials; the timing, nature and cost of clinical trials; the availability of future funding to support the cost of continued development; whether Vical or its collaborative partners will seek or gain approval to market the measles vaccine or any other product candidates; whether Vical or its collaborative partners will succeed in marketing the SARS vaccine or any other product candidates; and additional risks set forth in the company's filings with the Securities and Exchange Commission. These forward-looking statements represent the company's judgment as of the date of this release. The company disclaims, however, any intent or obligation to update these forward-looking statements.


Contact: Alan R. Engbring

(858) 646-1127
Website: http://www.vical.com

SOURCE Vical Incorporated

http://www.vical.com

Copyright (C) 2008 PR Newswire. All rights reserved

News Provided by COMTEX