Vical Confirms Advantages of DNA Technology Platform With Vaccine for H1N1 Influenza

SAN DIEGO, Dec. 29, 2009 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) announced today the publication of data documenting the successful pilot lot production and initiation of animal immunogenicity testing of a Vaxfectin(R)-adjuvanted DNA vaccine for H1N1 influenza before conventional vaccine manufacturers even received the seed virus needed to start production.

The U.S. Navy has awarded a contract for $1.25 million to support large-scale cGMP vaccine manufacturing and related clinical and regulatory preparations for a Phase 1 clinical trial of the company's vaccine against H1N1 pandemic influenza. The trial will be conducted in collaboration with the U.S. Naval Medical Research Center (NMRC), a biomedical research organization within the Navy, and is expected to begin within the next few weeks.

"DNA vaccines offer unprecedented speed in development and production," said Larry Smith, Ph.D., Vical's Vice President of Vaccine Research and an author on the paper, "and the 2009 outbreak of H1N1 pandemic influenza provided an opportunity to demonstrate the advantages of our approach. We do not have to handle the pathogen, and derive our vaccine instead from a gene sequence posted on the Internet. We can develop a vaccine quickly and match it exactly to the circulating pathogen, providing the greatest possible vaccine effectiveness. Our manufacturing process does not rely on chicken eggs or other time- and labor-intensive cell culture processes that require vaccine-specific facilities. We produce our vaccines through rapid and reliable bacterial fermentation. The inherent stability of DNA does not require the precise temperature control needed for conventional vaccines, and allows great flexibility in shipping and storage. In short, the DNA vaccine platform is well-suited to addressing emerging infectious disease threats even before they become pandemics."

The article, which outlines the vaccine development process and timeline during the early stages of the emerging pandemic, was published in the newly reinaugurated international journal Gene Therapy and Regulation.[i] A key point of the article is that the DNA vaccine technology uses consistent and predictable methods that could be applied with the same speed in future pandemics. The company has advanced directly to large-scale cGMP manufacturing of the vaccine for human clinical trials after securing external funding for this program.

The company's vaccine against A/H1N1 pandemic influenza (swine flu) produced robust immune responses against the matching strain that were well above the accepted protection threshold in 100% of vaccinated mice and rabbits after a standard two-dose vaccine regimen. At least 75% of vaccinated animals achieved or exceeded the protection threshold after a single dose of vaccine. In further studies, the vaccine demonstrated robust immune responses in 100% of vaccinated animals against non-matching virus strains isolated from recent outbreaks in three distinct geographic locations - California, Texas and Mexico. Vical's vaccine would also be expected to provide similar robust immune responses against other swine-origin A/H1N1 influenza virus subtypes, supporting selection of a single A/H1N1 virus strain as the basis for the vaccine.

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 www.vical.com.

The Vical Incorporated logo is available at http://www.globenewswire.com/newsroom/prs/?pkgid=5768

This press release contains forward-looking statements subject to risks and uncertainties that could cause actual results to differ materially from those projected. Forward-looking statements include statements about U.S. Navy funding, the Vical/NMRC CRADA, Vical's DNA vaccine and Vaxfectin(R) adjuvant technologies and their potential application in a vaccine against H1N1 influenza, potential human clinical testing of such a vaccine, as well as the company's focus, collaborative partners, and product candidates. Risks and uncertainties include whether Vical will receive all, if any, of the committed Navy funding; whether the committed funding will be sufficient to initiate a human clinical trial; whether the Navy will provide additional funding as needed to complete a human clinical trial; whether Vical's technologies will be successfully applied under the CRADA for the development of a Vaxfectin(R)-formulated DNA vaccine against H1N1 influenza; whether Vical, NMRC or others will continue development of any pandemic influenza DNA vaccine candidates; whether Vical and/or NMRC will terminate the CRADA before...
achievement of its objectives; whether the Phase 1 trial of the H1N1 vaccine will begin within the next few weeks, if at all; whether the company's DNA vaccine candidate will be effective in protecting humans against H1N1 strains of influenza; whether any vaccines based on novel technologies will be applied for emergency use or future routine immunizations; whether the influenza vaccine or any other product candidates will be shown to be safe and effective; the timing, nature and cost of clinical trials; whether Vical or its collaborative partners will seek or gain approval to market any product candidates; whether Vical or its collaborative partners will succeed in marketing any 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: Vical Incorporated
Alan R. Engbring
(858) 646-1127
Website: www.vical.com

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