Vical's Herpes Simplex Vaccines Protect Against Lethal Challenge and Demonstrate Significant Therapeutic Benefit in Animal Models

SAN DIEGO, July 26, 2010 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) today announced that its prophylactic Vaxfectin®-formulated plasmid DNA (pDNA) vaccine against herpes simplex virus type 2 (HSV-2) protected mice against lethal challenge, provided sterilizing immunity and inhibited viral counts at both the primary and latent infection sites. The Vaxfectin® adjuvant substantially improved vaccine effectiveness. A related vaccine significantly reduced the recurrence of HSV-2 lesions in a therapeutic model using guinea pigs with latent infection. HSV-2 is a sexually transmitted virus which is the leading cause of genital herpes. Approximately one out of every six individuals in the United States and an estimated one out of every four worldwide is infected by HSV-2 before age 50. HSV-2 infection also significantly increases the risk of acquiring HIV-1.

David Koelle, M.D., professor of medicine in the Division of Allergy and Infectious Diseases at the University of Washington School of Medicine, who led this research, said, "The complete protection and high rate of sterilizing immunity observed in our initial mouse studies are quite impressive with such a safe and practical vaccine platform. We are particularly encouraged by the ability of this novel vaccine to address both primary and latent infection sites."

Initial results presented Saturday at the International Herpes Workshop (Salt Lake City, July 24 – 30) demonstrated that an appropriate dose of the prophylactic Vaxfectin®-formulated vaccine, which encoded the HSV-2 glycoprotein D (gD2) antigen:

- Elicited antibody responses in 100% of mice against the encoded antigen;
- Protected 100% of mice against subsequent challenge with a lethal dose of live virus;
- Reduced viral shedding in mice at both the primary and latent infection sites; and
- Elicited sterilizing immunity in 80% of mice as evidenced by no detectable virus after challenge at either the primary (vagina) or latent (dorsal root ganglia) infection sites.

A therapeutic version of the vaccine, which encoded the gD2 antigen as well as the tegument proteins UL46/UL47, significantly reduced recurrence of HSV-2 lesions in guinea pigs with latent infection (p<0.05). Three doses of Vaxfectin®-formulated vaccine were administered after resolution of the primary infection.

The preclinical development is being funded under a two-year, $2.0 million Phase II Small Business Technology Transfer (STTR) grant awarded in 2008 by the U.S. National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH), an agency of the U.S. Department of Health and Human Services. The grant period was recently extended to allow preclinical development to continue for a third year. The $2.0 million Phase II STTR grant supplements the $0.3 million awarded to Vical in 2005 for the HSV-2 vaccine program under a Phase I STTR grant from the NIAID, which partially funded Vical's initial development of the HSV-2 vaccine.

The initial preclinical development activities covered by the $2.0 million grant are being conducted at the University of Washington School of Medicine and the Sealy Center for Vaccine Development, both centers of excellence in herpes virus research. The vaccine is being designed primarily for use in people already infected with HSV-2, with the goal of reducing or eliminating periodic viral flare-ups and the associated viral shedding and transmission.

About HSV-2

HSV-2 is a member of the herpes virus family, and is the leading cause of genital herpes worldwide. In the United States, HSV-2 infects some 1.6 million new people per year, with approximately 500,000 of those suffering from disease symptoms. At least 40 million people in the United States are infected with HSV-2. Even higher infection rates are evident in developing countries, with further complications in people also infected with HIV. All HSV-2 infections are permanent and result in periodic virus shedding.

There is no approved vaccine for HSV-2. Although antiviral regimens have become a standard of care, their inconvenience, cumulative cost and potential for drug resistance further underscore the need for safe, new approaches to reducing HSV-2 lesions, shedding, and transmission. Estimated costs of treating HSV-2 in the United States alone are close to $1 billion, primarily for drugs and outpatient medical care. Additional indirect costs from HSV-2 infection, such as lost work hours, are more than $200 million annually in the United States.

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

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 HSV-2 vaccine; whether all funding under the grant will be received by the company; whether additional funding will be available to support further development; whether the results from animal testing will be predictive of results in humans; whether the development efforts will result in a vaccine that can generate immune responses sufficient to reduce or eliminate periodic viral flare-ups and the associated viral shedding and transmission; whether the Vaxfectin® adjuvant will effectively enhance the performance of the HSV-2 vaccine; whether Vical or its collaborative partners will seek or gain approval to market the HSV-2 vaccine or any other product candidates; whether Vical or its collaborative partners will succeed in marketing the HSV-2 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: Vical Incorporated
Alan R. Engbring
(858) 646-1127
www.vical.com

(C) Copyright 2010 GlobeNewswire, Inc. All rights reserved.