

Vical TransVax(tm) CMV Vaccine Achieves Promising Interim Clinical ...

SAN DIEGO, July 8, 2009 (GLOBE NEWSWIRE) -- Vical Incorporated (Nasdaq:VICL) announced today that its TransVax(tm) therapeutic DNA cytomegalovirus (CMV) vaccine provided promising results compared with placebo across a broad range of clinical efficacy endpoints at the four-month interim analysis in an ongoing Phase 2 trial. The trial is evaluating the potential for TransVax(tm) to prevent CMV reactivation in immunosuppressed CMV-seropositive hematopoietic stem cell transplant (HCT) recipients, which could reduce antiviral usage and CMV-associated disease. The interim efficacy data for evaluable subjects, unblinded by treatment groups, also reinforced encouraging immunogenicity data from an initial group of HCT recipients in the trial reported previously in the fourth quarter of 2008. The company expects the trial to be completed in the fourth quarter of 2009, and to have final data available in the first half of 2010.

"These interim results demonstrating efficacy for a DNA vaccine in a highly immunocompromised patient population are excellent news for our technology platform," said Vijay B. Samant, Vical's President and Chief Executive Officer. "This latest development, coupled with the significant progress in our ongoing programs including our Phase 3 Allovectin-7(r) immunotherapy for metastatic melanoma, our Phase 3 angiogenesis programs partnered with sanofi-aventis and AnGes MG, and our successful Phase 1 pandemic influenza vaccine trial, we believe our technology is 'ready for prime time.' While we await final results following completion of this endpoint-defining Phase 2 trial, we can now begin working with CMV and transplant experts on Phase 3 trial design."

Viral load endpoints in the trial were based on central laboratory (Mayo Clinic) analyses of samples provided from multiple U.S. trial sites. At the four-month analysis, the TransVax(tm) vaccine demonstrated a clear reduction compared with placebo in the percentage of recipients experiencing CMV reactivation. TransVax(tm) vaccine also showed a decrease in recurrence of CMV reactivation, a delay in time to initial detectable viremia, a decrease in duration of viremia, and decreases in peak and cumulative viral loads. TransVax(tm) vaccine also provided an overall increase in cellular immune responses compared with placebo.

As defined in the trial protocol, where site-specific differences in medical practices would affect the endpoints, comparisons between vaccine and placebo were conducted on a site-by-site basis. Consolidated results of site-specific analyses favored vaccine over placebo for a clear majority of sites for several endpoints, including a decrease in the occurrence of initiating antiviral therapy, and a decrease in the duration of antiviral therapy.

The Phase 2 trial of TransVax(tm) included two arms. In one arm, vaccine or placebo was administered to both the donors and recipients undergoing stem cell transplants (the donor-recipient arm). In the other arm, vaccine or placebo was administered only to the stem cell transplant recipients (the recipient-only arm). The recipient-only arm of the trial achieved full enrollment of 80 subjects in the fourth quarter of 2008. Preliminary analysis of the immunogenicity data for the initial subjects in the recipient-only arm of the study showed enhancement of CMV-specific T-cell responses in vaccinated subjects after transplant. Based on the results of the interim immunogenicity analysis, the company determined that there was no need to continue enrollment in the donor-recipient arm.

Conference Call/Webcast

Vical will conduct an audio-only conference call and audio/slide webcast at 11 a.m. Eastern Time today to discuss details of the results with invited analysts and institutional investors. CMV and organ transplant expert Mark D. Pescovitz, M.D., Professor of Surgery and Microbiology & Immunology, and Vice Chair of Research in Surgery at the Indiana University School of Medicine, is scheduled to join Vical management on the call.

The call is open on a listen-only basis to any interested parties. The webcast audio and slides also will be available live and archived through the Events page of the company's website at www.vical.com. To listen to the conference call, dial (877) 857-6177, or (719) 325-4838 for international participants. A replay of the call will be available for 48 hours beginning about two hours after the call. To listen to the replay, dial (888) 203-1112, or (719) 457-0820 for international participants, and enter conference identification number 4682239. For further information, contact Vical's Investor Relations department by phone at (858) 646-1127 or by e-mail at info@vical.com.

About TransVax(tm)

TransVax(tm) is a bivalent DNA vaccine containing plasmids (closed loops of DNA) encoding CMV phosphoprotein 65 (pp65) and glycoprotein B (gB) for induction of cellular and humoral immune responses. TransVax(tm) is formulated with a proprietary poloxamer-based delivery system. TransVax(tm) has received orphan drug designation for HCT and solid organ transplant patients.

About CMV

CMV is a herpes virus that infects more than half of all adults in the United States by age 40, and is even more widespread in developing countries. While a healthy immune system typically protects an infected person against CMV disease, it rarely succeeds in eliminating the infection, and those whose immune systems are not fully functional are at high risk of CMV flare-up, potentially leading to severe illness or death. These include transplant patients who take immunosuppressive drugs, and fetuses and newborns of mothers who first become infected during pregnancy.

CMV infection affects 30 to 60 percent of the patients undergoing various transplant procedures, causing transplant rejection, serious illness and even death if untreated. Expensive and toxic antiviral drug therapy is used to control the disease, but does not clear the latent virus. Congenital CMV infection affects one out of every hundred infants, and causes severe consequences in about 3,600 infants and death in about 400 each year in the United States.

There is no approved vaccine against CMV. Vaccine approaches that predominantly result in antibody responses to CMV have not proven highly effective in transplant patients. Vaccine approaches using live, attenuated viruses can induce both antibody and cellular immune responses, but pose a potential safety concern, particularly for immunocompromised patients, of causing the disease they are intended to prevent. Vical's novel DNA vaccine approach is designed to induce both antibody and cellular immune responses against specific features of the CMV virus without the risk of causing CMV disease.

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.

About the Author

Herpes simplex virus infection, congenital

Birth-Acquired Herpes - Symptoms, Diagnosis, Treatment of Birth

Congenital hemolytic jaundice - Hutchinson encyclopedia article

Health Library

Genital herpes and pregnancy - Health - redOrbit

Birth-acquired herpes Information on Healthline

HowStuffWorks "Birth-acquired Herpes - Medical Dictionary"

Congenital herpes infection: placental and umbilical cord findings

Source: <http://productsherbal.com>