Vaxfectin(R)-formulated Measles DNA Vaccine Could Address Unmet Need for Infants

SAN DIEGO, Aug. 21 /PRNewswire-FirstCall/ -- Vical Incorporated (Nasdaq: VICL) today announced that results from nonhuman primate studies of a Vaxfectin®-formulated DNA vaccine for measles, published in the August issue of Clinical and Vaccine Immunology(1), offer a promising approach to the development of a measles vaccine to address an unmet need for human infants. Vical recently reported breakthrough preliminary Phase 1 trial results for the company's H5N1 pandemic influenza DNA vaccines formulated with the same Vaxfectin® adjuvant.

In the article, authors from the Johns Hopkins Bloomberg School of Public Health, the Johns Hopkins School of Medicine, and Vical detailed results from studies in juvenile and infant nonhuman primates demonstrating that the vaccine induced rapid, durable, high-avidity, neutralizing antibody responses; measles-specific memory T-cells; and long-term protection against measles challenge. The article concluded, "A Vaxfectin®-formulated DNA vaccine is a promising approach for the development of a new measles vaccine for young children." The ability to induce broad-based and lasting immune responses, confirmed by long-term protection, adds further evidence supporting the potential for Vaxfectin®-formulated DNA vaccines.

The measles studies were conducted in collaboration with Diane E. Griffin, M.D., Ph.D., Alfred and Jill Sommer Professor and Chair of Molecular Microbiology and Immunology, Johns Hopkins Bloomberg School of Public Health, under a grant from the Bill and Melinda Gates Foundation. "Although a safe and effective live attenuated commercial measles vaccine is available, measles continues to be a major cause of infant mortality," said Dr. Griffin. "The immaturity of the immune system, coupled with circulating maternal antibodies that interfere with the live attenuated vaccine, severely limits vaccine effectiveness during an infant's first year. The juvenile and infant nonhuman primate studies provide encouragement that Vaxfectin®-formulated DNA vaccination may be able to overcome these obstacles, and may provide a viable alternative for infant immunization."

In May 2007, Vical announced that a measles DNA vaccine formulated with the company's Vaxfectin® adjuvant elicited protective levels of neutralizing antibodies in juvenile (1 - 2 year old) rhesus macaques confirmed by complete protection following challenge more than one year after vaccination. In October 2007, the company announced similar neutralizing antibody and protection results in infant (6 - 10 weeks old) rhesus macaques.

Vaxfectin®-formulated Measles DNA Vaccine

The study in juvenile macaques tested a bivalent DNA vaccine encoding measles hemagglutinin and fusion glycoproteins formulated with Vical's patented Vaxfectin® adjuvant. Vaccine was delivered by intradermal injection of two 0.5 mg doses or by intramuscular injection of two 1.0 mg doses at four-week intervals. The study in infant macaques tested only intradermal delivery of two 0.5 mg doses. The vaccines were well-tolerated in all animals. In both studies, animals were challenged by intratracheal inoculation at least one year after initial vaccination.

Within one month of initial vaccination, all immunized juvenile macaques developed protective levels of neutralizing antibody that were similar to those previously reported for rhesus macaques after immunization with the currently marketed live attenuated measles vaccine. Neutralizing antibody levels exceeded the accepted protection threshold prior to the second injection at Week 4, peaked at Week 5, and remained well above the accepted protection threshold for more than one year, with no difference noted between intramuscular or intradermal routes of administration. In the infant macaques, neutralizing antibody levels exceeded the accepted protection threshold prior to the second injection at Week 4, peaked at Week 8, and remained above the threshold at least through the 20-week follow-up period.

Measles-specific T-cell responses peaked at Week 2 in vaccinated juvenile and infant macaques, and remained detectable for more than one year. Following challenge, all vaccinated animals demonstrated rapidly rising measles-specific T-cell responses, indicating that vaccination had induced memory responses. Vaxfectin®-formulated DNA vaccines have now demonstrated significant and durable antibody responses, durable T-cell responses after vaccination and rapidly rising T-cell responses after subsequent challenge.

All vaccinated juvenile and infant animals were completely protected against challenge with live measles virus. None of the vaccinated animals developed symptoms or had culturable levels of measles virus at any time point tested, in contrast to negative control animals which all developed rashes and had detectable virus.

About Measles
Routine vaccination with a live attenuated measles vaccine has largely eliminated the disease among children in most developed countries, however, it remains among the top ten infectious disease causes of deaths among young children worldwide because of poor vaccine acceptance in some countries, poor vaccine availability in others, and lack of effectiveness in young infants. Measles causes approximately one of every five deaths from vaccine-preventable diseases in children under age five. The disease is particularly prevalent in infants less than one year old in developing countries, and is most severe among those who are malnourished. One complicating factor is the immaturity of the immune system in young infants, preventing their immune systems from developing complete and appropriate immune responses. Another factor is that young infants typically have circulating maternal antibodies against measles which can interfere with the live attenuated 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 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 evaluation of the Vaxfectin®-formulated measles DNA vaccine; whether the vaccine will be effective in protecting juvenile or infant humans against measles infection or disease; whether the measles 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 measles vaccine or any other product candidates; whether the company's issued patents will be challenged and whether such challenges will have an adverse effect on the scope of the patents; whether the company will enforce its issued patents or will be successful in any enforcement efforts; 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.


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