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Data from Vaxin's First Flu Vaccine Clinical Trial Reported in Journal "Vaccine"
– Safety and Immunogenicity Established for Cell-Culture Manufactured Influenza Vaccine –

Birmingham, AL – January 11, 2005 – Vaxin Inc., a privately-held biotechnology company, has demonstrated, in a Phase I human clinical study, that the company's recombinant influenza vaccine provides a potential alternative to traditional flu vaccines. Published in the January 11, 2005 issue of the journal *Vaccine* (volume 23, issue 8, pages 1029-1036), the paper is entitled "Safety and immunogenicity of adenovirus-vectored nasal and epicutaneous influenza vaccines in humans." The authors conclude that Vaxin's novel flu vaccine, which is produced in cell culture, was immunogenic and well tolerated by human volunteers.

"To our knowledge, this represents the first report of a recombinant influenza vaccine using a non-replicating adenovirus vector delivered either nasally or epicutaneously (to the surface of the skin)," said De-chu C. Tang, Ph.D., corresponding author and Vice President and Chief Technical Officer of Vaxin.

The study was designed to determine whether humans can be immunized by a recombinant influenza vaccine, using the hemagglutinin (HA) gene from the PR8 (H1N1) influenza strain, contained within a non-replicating adenovirus vector. There were 24 study participants (healthy adults, age 20-31), in 4 groups. Groups 1, 2 and 3 received increasing doses delivered to the skin, respectively. Group 4 received the dose intra-nasally.

At a dose approximately 1000-fold lower (10^8 vs. 10^{11} virus particles) the nasal vaccine elicited a stronger immune response as compared to the vaccine delivered to the skin. 67% of the nasal vaccine recipients developed a 4-fold antibody rise after one dose, which increased to 83% after a second dose. Immune response is a function of serum antibody level, and a 4-fold or better rise in serum antibody level is considered "protective."

There was no correlation between pre-existing levels of antibody to adenovirus, and the ability to achieve a four-fold rise in antibody to the influenza antigen. This finding indicates that the recombinant influenza vaccine may not be affected by pre-existing antibodies to the adenovirus vector when delivery is intranasal.

"We are very pleased to report these encouraging findings from our proof-of-principle human clinical trial," commented Frank Cano, Ph.D., Chairman and Chief Executive Officer of Vaxin. "These results are impressive given the low dose administered to the nose, especially since the PR8 strain is known to be inherently poorly immunogenic. The results support further study of intranasal administration, using increased dose levels and other influenza strains."

“Furthermore, we believe our nasal vaccine will be at least as protective as the existing licensed influenza vaccines, and will be appropriate for children, adults and the elderly. Our clinical plans were discussed with the Food and Drug Administration (FDA) last fall and we are now planning for an expanded Phase I monovalent study this year, followed by a trivalent study,” Dr. Cano concluded.

Vaxin is Addressing the Need for Alternative Influenza Vaccines

The manufacturing method being used by Vaxin for its influenza vaccine has several important advantages. Currently, all FDA-approved flu vaccines are produced in chicken eggs. Vaxin, however, produces its vaccine in cell culture. Among the many benefits to this manufacturing process is that the product availability is not dependent on the long lead times required to secure chicken eggs every year, which may be important especially in the event of a pandemic. Cells for manufacturing Vaxin’s vaccine are stored in the freezer and are available the moment that manufacturing is required. In addition, the use of cell culture manufacturing eliminates the possibility of contamination with the avian flu virus, a risk inherent in egg-based production. Furthermore, the Vaxin process provides higher yields, greater quantities in a faster timeframe, and more reliable manufacturing than the egg-based process. Also, the Vaxin manufacturing process is not dependent on how well (if at all) a particular strain grows in eggs. Finally, because the Vaxin process does not need to be adapted to grow in eggs to achieve higher yields, the Vaxin vaccine is “truer” to the strains picked by the regulatory agencies.

About Vaxin

Vaxin Inc. is an emerging biotechnology company developing vaccines and other biological products utilizing its proprietary technology for non-invasive delivery to the nasal passages and skin. The company’s products use non-replicating recombinant adenovirus or inactivated bacterial vectors to deliver vaccine antigens where they stimulate a protective immune response. This method has been tested in proof-of-principle animal studies as well as a Phase I human clinical trial. Initial product development is targeted towards an improved influenza vaccine manufactured in cell culture, and vaccines for anthrax, RSV and tetanus/diphtheria. Earlier stage programs include therapeutic vaccines to address disease targets such as Alzheimer’s and cancer. The company has raised more than \$15 million in venture capital and government grants.

For more information about Vaxin, please visit our web site www.vaxin.com.