



Phase I Study of Preventive HIV Vaccine Shows Improved Immune Responses When the Vaccine is Delivered by Electrical Impulses

First Clinical Study of Electroporation-Enhanced DNA Vaccine Delivery in Healthy Human Volunteers

NEW YORK, NY, and SAN DIEGO, CA, November 30, 2009 – A Phase 1 study of a preventive HIV vaccine testing a novel delivery mechanism known as electroporation – the use of electrical pulses to increase the immune responses elicited by DNA vaccines – was recently completed in New York City. The results show that TriGrid™, a technology developed by Ichor Medical Systems, Inc., helped to enhance the immunogenicity of the vaccine tested. Compared to intramuscular injection, the conventional mode of delivery, electroporation significantly enhanced detectable immune responses to the DNA vaccine, known as ADVAX, which was tested in 40 healthy human volunteers. Initial results were presented at the end of October at the AIDS Vaccine Conference in Paris, France.

Conducted by Drs. Sandhya Vasan and David Ho of the Aaron Diamond AIDS Research Center (ADARC) at the Rockefeller University Hospital in New York City, with technical support from the International AIDS Vaccine Initiative (IAVI), this randomized, placebo-controlled trial is the first systematic evaluation of an HIV DNA vaccine delivered with electroporation ever conducted in healthy human volunteers. In addition to evaluating the safety and tolerability of the vaccine candidate, the clinical trial also assessed the frequency, magnitude and breadth of human immune responses to ADVAX, a DNA-based AIDS vaccine candidate.

“We are pleased to have worked with such prestigious collaborators to complete this important clinical study,” says Ichor’s CEO Robert Bernard, “and are hopeful that the results will prove to be an important step forward in the field of HIV vaccine development and for DNA vaccines more broadly.”

The experimental vaccine tested consists of circles of DNA, which carry genes for proteins that are found in HIV. The vaccine is intended to teach the immune system to recognize and destroy cells that have been infected with HIV. Years of research in animal models have shown that DNA injected directly into muscle is not efficiently taken up by cells, but electroporation – the formation of small pores in cell membranes in response to pulses of electricity – with the TriGrid™ technology enhances the vaccine uptake between 100 and 1000 times. Getting the vaccine efficiently into cells, where it can start producing the proteins it encodes, is a step of critical importance to their mechanism of action. Ichor’s technology helps to do just this.

“We are excited by these results. They have shown that we must pay close attention to how we are delivering DNA vaccine candidates, to ensure they have the maximum impact possible,” said Dr. Pat Fast, IAVI’s Chief Medical Officer.

A total of 40 subjects were enrolled in the study, which was designed to compare the safety, tolerability, and immune responses to ADVAX following administration via either the TriGrid™ delivery device or conventional intramuscular injection. A total of 24 volunteers received ADVAX at one of three dosage levels (0.2 mg, 1.0 mg or 4.0 mg) by electroporation, another eight by conventional intramuscular injection at the 4.0 mg dose level, and another eight were given a placebo via the TriGrid™ device.

All volunteers have now completed their scheduled vaccinations and follow-up visits to the clinic, and the accumulated data suggest that TriGrid™-mediated ADVAX delivery has a good safety profile, is well-tolerated and acceptable to healthy non-HIV-infected human volunteers. Moreover, immunological analyses performed on blood samples taken from the volunteers reveal that electroporation improved the frequency, magnitude, breadth and duration of the cellular immune responses to HIV antigens encoded by the vaccine.

Specifically, in the TriGrid™ arm of the study, cellular immune responses were detected after two immunizations in 37.5% (3/8) of subjects in the 0.2 mg dosage group, 87.5% (7/8) of subjects in the 1.0 mg dosage group, and 75% (6/8) of subjects in the 4.0 mg dosage group. Notably, a third immunization given to the 4.0 mg dosage cohort by electroporation improved the response rate to 100% (8/8 subjects). By contrast, none of the subjects who received ADVAX intramuscularly generated detectable cellular immune responses.

Increasing the dosage of ADVAX delivered using electroporation also enhanced the breadth of the response. Among the responders in the 0.2 mg dosage group, immune responses were detected against one of the four HIV antigens encoded by the DNA vaccine. In the 1.0 and 4.0 mg cohorts, responses were detected against three of four and four of four of the antigens, respectively. Additional analyses are underway to further characterize the immunological responses.

"This is the first study of electroporation in healthy human volunteers. In broad brushstrokes, these results confirm the enhanced immunogenicity of DNA vaccines delivered by electroporation over standard intramuscular immunization that has been seen in animals. This is a step forward in DNA vaccine development," said Dr. David D. Ho, CEO of ADARC and Irene Diamond Professor at the Rockefeller University, and the Principal Investigator of the trial.

About Aaron Diamond AIDS Research Center (ADARC)

The Aaron Diamond AIDS Research Center is a large non-profit HIV/AIDS research center in New York City, affiliated with the Rockefeller University. Founded in 1991, ADARC focuses both on basic research efforts to increase understanding of the structure and function of HIV and to define the mechanism by which it destroys the immune system, and on translational efforts to develop novel therapies to treat and prevent HIV. In recent years, development of novel vaccines to prevent HIV infection has been a substantial focus of research at ADARC.

About Ichor Medical Systems

Ichor Medical Systems' TriGrid™ Delivery System is the first integrated and fully automated system for electroporation-mediated DNA administration in humans. Ichor, a privately-held biotech company based in San Diego, CA, is collaborating with partners on three continents in a wide range of studies to test the TriGrid as an enabling platform for delivery of DNA drugs and vaccines to treat diseases such as pandemic flu, hepatitis B, HIV, melanoma, Alzheimer's

disease, and others. The TriGrid™ device is also being tested by the U.S. military as an efficient means of delivering biodefense countermeasures. Ichor's current research partners also include Delphi Genetics, FIT Biotech, Genexine, INSERM, the Johns Hopkins Bloomberg School of Public Health, Leiden University Medical Center, Memorial Sloan-Kettering Cancer Center, the Pasteur Institute, ScanCell, The Scripps Research Institute, the U.S. Army Medical Research Institute of Infectious Diseases (USAMRIID), the Naval Medical Research Center (NMRC), the University of Georgia, University of Constance and the Vaccine and Infectious Disease Organization (VIDO). For further information, visit www.ichorms.com. For additional inquiries, please contact: May de las Alas, Ph.D. at mdelasalas@ichorms.com.

About IAVI

The International AIDS Vaccine Initiative (IAVI) is a global not-for-profit organization whose mission is to ensure the development of safe, effective, accessible, preventive HIV vaccines for use throughout the world. Founded in 1996 and operational in 25 countries, IAVI and its network of collaborators research and develop vaccine candidates. IAVI was founded with the generous support of the Alfred P. Sloan Foundation, The Rockefeller Foundation, The Starr Foundation, and Until There's A Cure Foundation. Other major supporters include the Bill & Melinda Gates Foundation, the Foundation for the National Institutes of Health, The John D. Evans Foundation, The New York Community Trust, the James B. Pendleton Charitable Trust; the Governments of Canada, Denmark, India, Ireland, The Netherlands, Norway, Spain, Sweden, the United Kingdom, and the United States, the Basque Autonomous Government, the European Union as well as The City of New York, Economic Development Corporation; multilateral organizations such as The World Bank; corporate donors including BD (Becton, Dickinson & Co.), Bristol-Myers Squibb, Continental Airlines, Google Inc., Henry Schein, Inc., Pfizer Inc, and Thermo Fisher Scientific Inc.; leading AIDS charities such as Broadway Cares/Equity Fights AIDS; other private donors such as The Haas Trusts; and many generous individuals from around the world. For more information, see www.iavi.org.

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