



## **IAVI and Partners Initiate AIDS Vaccine Trial in Africa**

NEW YORK, NY, December 19, 2011—The International AIDS Vaccine Initiative (IAVI), Profectus BioSciences Inc. and Ichor Medical Systems announce today the start of a multi-center Phase I trial in Africa to evaluate the safety and immunogenicity of a preventive AIDS vaccine candidate. The trial is sponsored by IAVI and will be conducted in collaboration with Profectus, Ichor and three clinical research partners in Africa.

Known as B004, the study will evaluate the combination of two vaccine components in a prime-boost regimen. The first component, supplied by Profectus, is DNA that has been engineered to encode multiple HIV proteins. It is co-delivered with GENEVAX™ IL-12 DNA in an effort to enhance the immune response to the encoded proteins. The second component is a vector, Ad35, containing several HIV genes. The trial is the first to test this particular combination of vaccine components in humans, though each of the individual components has been, or is being, evaluated in other clinical trials. The DNA vaccine components will be delivered using Ichor Medical Systems' proprietary TriGrid™ Delivery System.

Vaccinations in the trial have commenced at Projet San Francisco, Emory University's research center in Kigali, Rwanda, and are expected to begin at research centers in Uganda and Kenya in early 2012, pending approvals. In total, the trial aims to enroll approximately 75 healthy volunteers aged 18 to 50.

"The clinical evaluation of this AIDS vaccine candidate is an example of how product-development partnerships can drive novel scientific concepts into the clinic," said IAVI's Chief Scientific Officer Dr. Wayne Koff. "IAVI and Profectus each brings to this project a promising vaccine component that has generated excellent safety and immunogenicity data in previous studies. These vaccine components will be evaluated in combination at African research centers that have, with IAVI's support, built a reputation for the competent and ethical conduct of vaccine trials."

Dr. John Eldridge, Chief Scientific Officer of Profectus, said, "After a decade of pre-clinical and clinical development, this partnership provides the first opportunity to clinically evaluate our IL-12 optimized DNA vaccine with a heterologous vectored boost. Based on data from animal models, we anticipate this will be a safe and highly immunogenic combination. This partnership also represents the first time a Profectus vaccine will be tested in Africa, an area profoundly affected by the HIV pandemic."

This trial follows the recent publication of data<sup>1</sup> showing that an analogous approach can prevent infection or progression to disease from a virus similar to HIV in an animal model. The current, Phase I trial will evaluate whether these vaccine regimens are both safe and tolerable in humans, and whether they provoke vigorous immune responses. If they prove to be safe and immunogenic, subsequent studies will evaluate their potential as vaccine candidates in larger cohorts of volunteers.

<sup>1</sup> *J Virol.* 2011 Sep; 85(18):9578-87. Epub 2011 Jul 6.)

### **About the International AIDS Vaccine Initiative (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, IAVI works with partners in 25 countries to research, design and develop AIDS vaccine candidates. In addition, IAVI conducts policy analyses and serves as an advocate for the AIDS vaccine field. IAVI supports a comprehensive approach to addressing HIV and AIDS that balances the expansion and strengthening of existing HIV-prevention and treatment programs with targeted investments in the design and development of new tools to prevent HIV. IAVI is dedicated to ensuring that a future AIDS vaccine will be available and accessible to all who need it. IAVI relies on the generous donations from governments, private individuals, corporations and foundations to carry out its mission. For more information, see [www.iavi.org](http://www.iavi.org).

### **About Profectus BioSciences, Inc.**

[Profectus BioSciences, Inc.](http://www.ProfectusBioSciences.com) is a technology based vaccine company devoted to the treatment and prevention of chronic viral diseases with the goal of reducing morbidity and mortality. Since its inception in 2003, the Company's strategic intent has been to develop and acquire the technologies needed to deliver on that mission within high value markets. The Company has licensed a group of vaccine-based technologies from Wyeth Vaccines (now part of Pfizer, Inc.) that greatly accelerate its ability to deliver highly effective therapeutic vaccines based on a "prime-boost" strategy. This strategy uses the delivery of a best-in-class plasmid DNA (pDNA) vaccine to "prime" the immune system, followed by a first-in-class "boost" using a recombinant Vesicular Stomatitis Virus (rVSV) vector. Current targets include Hepatitis C Virus (HCV), Human Papilloma Virus (HPV), Herpes Simplex Virus type 2 (HSV-2), Human Immunodeficiency Virus (HIV), Malaria and Ebola and Marburg viruses. The Profectus HIV vaccine program has been supported through the award of two HIV Vaccine Design and Development Teams (HVDDT) contracts (HHSN272200800062C and HHSN272200800061C) from the NIH that have supported 60% of the research, development, and manufacturing costs of the multi-antigen HIV vaccine and GENEVAX™ IL-12 programs, while the remainder of the cost has been provided through a contribution-in-kind. For more information, see [www.ProfectusBioSciences.com](http://www.ProfectusBioSciences.com).

### **About Ichor Medical Systems**

Ichor Medical Systems' TriGrid™ Delivery System (TriGrid) is the first integrated and fully automated device for electroporation-mediated DNA administration in humans. Ichor, a privately-held biotech company based in San Diego, CA, is collaborating with partners to provide its enabling TriGrid platform as a means for delivery of DNA drugs and vaccines in disease indications such as melanoma, malaria, hepatitis B virus (HBV) infection, human immunodeficiency virus (HIV) infection, melanoma, Alzheimer's disease, and others. For further information, visit [www.ichorms.com](http://www.ichorms.com).

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