

**FOR IMMEDIATE RELEASE**

**The ACTG Immunizes First Subject in Clinical Trial of Profectus Biosciences' Therapeutic HIV DNA Vaccine**

*Study Designed to Establish the Optimal Dose of GENEVAX™ IL-12 Adjuvant in Formulation with the Profectus Multi-Antigen Therapeutic HIV DNA Vaccine when Delivered with the Ichor Medical Systems' TriGrid™ Electroporation Delivery Device*

**Baltimore, MD – May 25, 2011** – Profectus BioSciences, Inc., a leader in the development of therapeutic vaccines against chronic infectious diseases and cancers, announced today that the AIDS Clinical Trials Group (ACTG) has immunized the first subject in a U.S. phase 1 clinical trial of Profectus' multi-antigen HIV plasmid DNA (MAG-pDNA) vaccine administered with various doses of GENEVAX™ interleukin-12 (IL-12) pDNA adjuvant and delivered using the electroporation (EP) based TriGrid™ delivery system (TriGrid) developed by Ichor Medical Systems. This multi-center study is being sponsored by the National Institutes of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The study is being conducted by the NIAID-funded ACTG under a protocol designated A5281.

The phase 1, placebo-controlled, dose-escalation study will enroll 60 HIV-infected subjects on stable anti-retroviral therapy (ART). It will assess the safety and immunogenicity of a fixed dose of the Profectus therapeutic MAG-pDNA vaccine administered alone or with low, intermediate, and high doses of GENEVAX™ IL-12 pDNA adjuvant when delivered with the TriGrid device. Pre-clinical studies conducted by Profectus in a non-human primate (NHP) model of HIV infected humans have demonstrated that vaccination with a combination of MAG-pDNA and IL-12 pDNA delivered with EP can maintain robust cell-mediated immune (CMI) responses during extended ART. It is believed the maintenance of CMI responses in subjects receiving effective ART will help prevent the evolution of drug-resistant virus and contribute to decreasing the virus reservoir in infected individuals. A prior clinical study conducted by the HIV Vaccine Trials Network (HVTN 080) using a fixed quantity of GENEVAX™ IL-12 equivalent to the high dose in the A5281 trial demonstrated that it effectively augmented responses to an experimental HIV pDNA vaccine delivered with EP in HIV-negative volunteers. As previously reported, the interim data from HVTN 080 show GENEVAX™IL-12 significantly increased the proportion of vaccine recipients that mounted antigen-specific CMI responses as compared to HIV pDNA alone.

Dr. John Eldridge, Profectus BioSciences' Chief Scientific Officer, said: "It is quite exciting to initiate the A5281 study in collaboration with the NIH, Ichor and the ACTG. This study will provide important information as to the most adjuvant active dose of GENEVAX™ IL-12, and it will do so in combination

with the Profectus therapeutic vaccine in HIV infected subjects. Improving the length and quality of life for those living with HIV infection is a goal we have been working toward for many years.”

### **About Profectus’ Multi-Antigen Therapeutic HIV pDNA Vaccine and GENEVAX™ IL-12 pDNA**

Profectus’ therapeutic MAG-pDNA vaccine consists of two plasmid vectors designed to induce immune responses against the env, gag, pol, nef, tat, and vif proteins of HIV. GENEVAX™ IL-12 is a proprietary pDNA vector that expresses the immune modulating cytokine human interleukin-12. The pDNA vectors are supplied for clinical use in a proprietary formulation containing the anesthetic bupivacaine. In addition to its anesthetic properties, bupivacaine has been shown to enhance the efficiency of DNA vaccines and to provide a liquid formulation with multi-year stability.

### **About the ACTG**

The AIDS Clinical Trials Group (ACTG) is an international collaboration of scientists and educators with the mission of conducting translational research and therapeutic clinical trials to evaluate novel therapeutic agents and the most effective approaches to treat HIV-1 infection. The ACTG conducts all phases of clinical trials, from evaluating safety through testing for efficacy. Support for the ACTG is provided through a cooperative agreement from the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH). The Network’s HIV Clinical Trial Units are located at leading research institutions in 47 cities on four continents. Internationally recognized HIV researchers lead the units.

### **About Ichor Medical Systems**

Ichor is dedicated to the clinical application and commercialization of electroporation technology for the delivery of DNA drugs and vaccines to treat and prevent debilitating or life threatening diseases. The company’s proprietary TriGrid™ Delivery System enables the efficient delivery of DNA drugs to address unmet medical needs in areas including therapeutic cancer vaccines, therapeutic proteins and vaccines for serious infectious disease.

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

[Profectus BioSciences, Inc.](#) 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 in-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 disease and virus targets include Hepatitis C Virus (HCV), Human Papilloma Virus (HPV), Herpes Simplex Virus type 2 (HSV-2), and Human Immunodeficiency Virus (HIV), and Malaria. The Profectus HIV DNA

### Profectus BioSciences 3

vaccine program has been supported through the award of a \$32 M HIV Vaccine Design and Development Teams (HVDDT) contract (HHSN272200800062C) from the NIH that has 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.

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**Contact:**

Jeffrey N. Meshulam

Vice President, COO

Profectus BioSciences, Inc.

443-743-1100

[Meshulam@profectusbiosciences.com](mailto:Meshulam@profectusbiosciences.com)