

FOR IMMEDIATE RELEASE

Profectus BioSciences Announces Initiation of Clinical Trial of IL-12 Enhanced Therapeutic HIV DNA Vaccine Delivered Using Electroporation

Phase 1 Trial Will Assess the Safety and Immunogenicity of Profectus' Multi-Antigen HIV DNA Vaccine in Formulation with Various Doses of GENEVAX™ IL-12 Adjuvant when Delivered with Ichor Medical Systems' TriGrid™ Electroporation Delivery Device

Baltimore, MD – January 05, 2011 – Profectus BioSciences, Inc., a leader in the development of therapeutic and preventive vaccines against infectious diseases and cancers, and the AIDS Clinical Trials Group (ACTG) announced today the initiation of a phase 1 study of Profectus' multi-antigen HIV plasmid DNA (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. The 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. It will assess the safety and immunogenicity of a fixed dose of the Profectus therapeutic multi-antigen HIV pDNA vaccine administered with escalating doses of GENEVAX™ IL-12 pDNA adjuvant and delivered with the TriGrid device. Non-human primate studies conducted by Profectus have demonstrated that the combination of IL-12 pDNA adjuvant plus EP delivery significantly increases the immunogenicity of pDNA vaccines compared to delivery with either EP alone or IL-12 alone. In a separate clinical study (HVTN 080), a fixed dose level of GENEVAX™ IL-12 is currently being evaluated for its ability to augment immune responses to an experimental HIV pDNA vaccine delivered with EP in HIV-negative volunteers. As previously reported, the interim data from that study indicate GENEVAX™ IL-12 significantly increased the percentage of vaccine recipients that mounted antigen-specific T-cell responses as compared to HIV pDNA alone. In addition to improving response rates, the inclusion of GENEVAX™ IL-12 was also observed to significantly lessen injection site discomfort.

Dr. John Eldridge, Profectus BioSciences' Chief Scientific Officer, said: "Profectus is very pleased to collaborate with the NIH and the ACTG in the development of a therapeutic vaccine with the potential to improve viral control and clinical outcome in subjects battling HIV infection. The recent clinical results that validate the adjuvant activity of GENEVAX™ IL-12 in normal healthy volunteers provide a level of confidence that a significant improvement in immunogenicity will be obtained relative to the therapeutic HIV vaccines tested to date."

About Profectus' Multi-Antigen Therapeutic HIV pDNA Vaccine and GENEVAX™ IL-12 pDNA

Profectus' multi-antigen therapeutic 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 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