Profectus BioSciences, Inc.

FINAL

Profectus BioSciences Announces Initiation of Clinical Trial Evaluating pDNA Prime/rVSV Boost Regimen to Prevent HIV Infection

NIAID-funded Phase 1 Study Will Assess the Safety and Immunogenicity of the Profectus Multi-Antigen HIV DNA Vaccine in Formulation with Various Doses of GENEVAX™ IL-12 Adjuvant when Delivered with the Ichor Medical Systems TriGrid™ Electroporation Delivery Device to prime the immune response followed by booster immunization with the Profectus Vesicular Stomatitis Virus-Vectored HIV Vaccine in Normal Healthy Adults

Baltimore, MD – August 14, 2012– Profectus BioSciences, Inc., a leader in the development of therapeutic and preventive vaccines against infectious diseases and cancers, and the HIV Vaccine Trials Network (HVTN) announced today the initiation of a phase 1 study of the Profectus multi-antigen HIV plasmid DNA (MAg-pDNA: *env*, *gag*, *pol*, *nef*, *tat*, and *vif*) vaccine administered with various doses of GENEVAX™ interleukin-12 (IL-12) pDNA adjuvant and delivered using the TriGrid™ electroporation (EP) delivery system (TriGrid) developed by Ichor Medical Systems in a prime-boost vaccination regimen with the Profectus recombinant vesicular stomatitis virus (rVSV)-vectored HIV vaccine in normal healthy adult volunteers. 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 HVTN under a protocol designated HVTN-087.

HVTN-087 is a phase 1, placebo-controlled, dose-escalation study that will enroll 100 HIV-uninfected adults. It will assess the safety and immunogenicity of a fixed dose of the Profectus MAg-HIV pDNA vaccine administered with escalating doses of GENEVAX™ IL-12 pDNA adjuvant when delivered with the TriGrid™ device as a priming vaccine. Subjects will then receive a booster immunization with the Profectus rVSV-vectored HIV-1 gag vaccine delivered by intramuscular injection. Pre-clinical studies conducted by Profectus have demonstrated that the prime-boost delivery of the HIV pDNA and HIV rVSV vaccines results in an HIV-specific cell-mediated immune (CMI) response of significantly increased magnitude and functionality as compared to delivery of the HIV pDNA or HIV rVSV vaccines alone.

The HVTN-087 study will build upon promising results seen in other clinical trials of the Profectus MAg-HIV pDNA and HIV rVSV vaccine candidates:

- In HVTN-080, a fixed dose level of GENEVAX™ IL-12 pDNA was evaluated for its ability to augment immune responses to an experimental HIV pDNA vaccine delivered with EP in HIV-negative volunteers. The final data from that study show that GENEVAX™ IL-12 pDNA delivered with EP is safe and significantly increases the percentage of vaccine recipients that mount a CMI response as compared to the HIV pDNA alone. In addition to improving the response rate, the inclusion of IL-12 DNA was also observed to lessen injection site discomfort.

- In ACTG-5281, a fixed dose of the Profectus HIV MAg-DNA vaccine with low, intermediate, or high doses of GENEVAX™ IL-12 pDNA adjuvant delivered with the TriGrid™ device is being evaluated in HIV-infected subjects on stable anti-retroviral therapy. This placebo-controlled, dose-escalation study is being conducted by the NIAID-funded AIDS Clinical Trials Group at 14 sites in the US and has fully enrolled 60/60 subjects. No safety issues have been noted and immunologic assessment of the groups receiving the no and low doses of GENEVAX™ IL-12 have confirmed CMI responses in a subset of the subjects.
- In IAVI-B004, a fixed priming dose of the Profectus HIV MAg-pDNA vaccine with various dose levels of GENEVAX™ IL-12 pDNA adjuvant delivered with the TriGrid™ device, followed by booster immunization with a recombinant serotype 35 adenovirus delivering HIV *gag*, *rt*, *int*, and *env* (rAd35 GRIN/ENV) is being evaluated in HIV-negative volunteers. This placebo-controlled study is being sponsored by the International AIDS Vaccine Initiative (IAVI) and conducted in collaboration with three clinical research partners in Africa and has fully enrolled 75/75 subjects. No safety issues have been noted at this time and data on the immunogenicity of this prime/boost combination is anticipated in early 2013. For more information about the International AIDS Vaccine Initiative, please visit www.iavi.org.
- In HVTN-090, 5 dose levels of the Profectus rVSV-vectored HIV vaccine delivered by intramuscular injection are being tested for safety and immunogenicity in HIV-negative volunteers. This placebo-controlled study has fully enrolled 60/60 subjects at 4 clinical sites. No dose-limiting toxicities have been seen and the immunogenicity data needed for selection of the boosting dose to be tested in the HVTN 087 pDNA prime/rVSV boost trial are anticipated in late September.

Dr. John Eldridge, Profectus BioSciences' Chief Scientific Officer, said: "Everyone at Profectus is very pleased to extend our long-standing collaboration with the NIH and the HVTN in the development of a vaccine to prevent HIV infection. With the help of the NIH, HVTN, ACTG, Ichor, and IAVI we are systematically evaluating the safety and immunogenicity of our pDNA prime/rVSV boost vaccine platform technology. The absence of pre-existing immunity to VSV in the general population, combined with the recent clinical results validating the adjuvant activity of GENEVAX™ IL-12 provide a level of confidence that significantly improved immunogenicity will be obtained relative to prime-boost vaccines tested to date."

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

The Profectus multi-antigen HIV 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 dual-promoter 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 rVSV HIV-1 gag vaccine

The rVSV HIV-1 gag vaccine consists of an attenuated replication competent form of the Indiana serotype of rVSV that expresses the HIV-1 gag protein. The vaccine was designed to elicit a robust cell mediated immune response to the HIV-1 gag protein, and is being supplied in frozen formulation to this proof-of-concept study. Ongoing studies are examining the potential to develop a lyophilized formulation that will replace the frozen form, and greatly simplify distribution of vaccine to the developing world.

About NIAID

NIAID conducts and supports research—at NIH, throughout the United States, and worldwide—to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. News releases, fact sheets and other NIAID-related materials are available on the NIAID Web site at http://www.niaid.nih.gov/.

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 infectious disease and related cancers, with the goal of reducing morbidity and mortality. Since its inception in 2003, the Company's strategic intent has been to acquire and develop the technologies needed to achieve this goal. The Company has licensed a group of vaccine-based technologies from Wyeth Vaccines (now Pfizer, Inc.) that greatly enhance the immunogenicity of prophylactic and therapeutic vaccines based on a "prime-boost" strategy. This strategy uses the delivery of a best-in-class pDNA vaccine to "prime" the immune system, followed by a first-in-class "boost" with an rVSV vector. Current disease and virus targets include hepatitis C virus (HCV), human papilloma virus (HPV), herpes simplex virus type 2 (HSV-2), human immunodeficiency virus (HIV), Ebola and Marburg viruses, 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. Partners and collaborators include Ichor Medical Systems, the Galveston National Laboratory, Yale University, the Institute of Human Virology, the Center for HIV/AIDS Vaccine Immunology, the National Cancer Institute, the NIH Division of AIDS, the Bill and Melinda Gates Foundation, the International AIDS Vaccine Initiative, the

PATH Malaria Vaccine Initiative, the HIV Vaccines Trials Network, and the AIDS Clinical Trials Group. More information is available at www.ProfectusBioSciences.com.

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