



Profectus BioSciences Announces Initiation of Clinical Trial Evaluating its Therapeutic HIV Vaccine in Support of the “Cure Agenda”

An NIAID-conducted Phase 1 Study Will Assess the Safety and Immunogenicity of the Profectus Multi-Antigen HIV DNA Vaccine in Formulation with Profectus’ GENEVAX™ IL-12 Adjuvant when Delivered by Electroporation to prime the immune response followed by booster immunization with the Profectus recombinant Vesicular Stomatitis Virus (rVSV)-Vectored HIV Vaccine in HIV-infected Adults on Antiretroviral Therapy. In addition, the ability of the “prime boost” vaccination regimen to address the goals of the HIV cure agenda by targeting the latent reservoir and eradicating HIV will be evaluated.

Baltimore, MD – September 16, 2013— Profectus BioSciences, Inc., a developer of the next generation of vaccines addressing high-value unmet indications in biodefense, infectious and emerging diseases, announced today the initiation of a phase 1 study evaluating the safety and immunogenicity of a therapeutic HIV vaccine strategy. HIV-infected adults on stable antiretroviral therapy (ART) will receive the Profectus multi-antigen HIV plasmid DNA (MAg-pDNA: *env, gag, pol, nef, tat* and *vif*) vaccine administered with the Profectus GENEVAX™ interleukin-12 (IL-12) pDNA adjuvant, delivered using the TriGrid™ electroporation (EP) delivery system licensed from Ichor Medical Systems, as a priming vaccine. This will be followed by booster immunization with the Profectus recombinant vesicular stomatitis virus (rVSV)-vectored HIV vaccine delivered by intramuscular injection. The randomized, double-blind, placebo-controlled study is in support of the HIV Cure Agenda and is being sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. The study, which will enroll 30 HIV-infected adults, is being conducted by NIAID’s Dr. Michael Sneller under a protocol designated Theravax 13-I-0141.

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. To address the goals of the HIV Cure Agenda the effect of vaccination on the rate of decay of the HIV-infected, CD4+ T-cell reservoir and the effect on rebound viremia following analytical treatment interruption will also be tested.

Dr. John Eldridge, Profectus BioSciences’ Chief Scientific Officer, said: "Everyone at Profectus is very pleased to continue our collaboration with NIAID in the development of a vaccine to treat HIV infection. While current antiretroviral therapy is wonderfully effective at controlling HIV, unfortunately, we know that stopping antiretroviral therapy results in a rapid return of high level HIV into the bloodstream. Therefore, Profectus Biosciences is committed to the development of therapeutic strategies aimed at destroying persistently infected cells with the ultimate goal of eradicating HIV in infected individuals

receiving ART. As a first step toward “the cure,” in this clinical trial we will investigate the effect of our prime-boost therapeutic vaccination strategy on the decay of the persistent HIV reservoir in infected individuals who initiated ART during the early/acute phase of HIV infection. This trial represents an early step towards the ultimate goal of eradication or drug-free control of HIV infection.”

The Theravax 13-I-0141 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 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 also lessened 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 participants.
- 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) was evaluated in HIV-negative volunteers. This placebo-controlled study was sponsored by the International AIDS Vaccine Initiative (IAVI) and conducted in collaboration with three clinical research partners in Africa enrolling 75 subjects. No safety issues have been noted. For more information about IAVI, please visit www.iavi.org.
- In **HVTN-090**, five dose levels of the Profectus rVSV-vectored HIV vaccine delivered by intramuscular injection were tested for safety and immunogenicity in HIV-negative volunteers. This placebo-controlled study has fully enrolled 60/60 subjects at four clinical sites. Results from this study confirm that the rVSV vectored vaccine is safe and well-tolerated at all dose levels. Furthermore, 63% of vaccinated volunteers at the highest dose level tested demonstrated significant HIV gag-specific CMI responses.
- In **HVTN-087**, 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 the Profectus rVSV-vectored HIV vaccine delivered by intramuscular injection, is being evaluated in HIV-negative volunteers. This placebo-controlled study has fully enrolled 100/100 subjects at 6 clinical sites. No dose-limiting toxicities have been seen, and the immunogenicity data are anticipated in early 2014.

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

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. It is designed to elicit a robust cell mediated immune response to the HIV-1 gag protein when used to boost following pDNA priming, 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., enabled by an experienced development team and two propriety platform technologies in-licensed from Wyeth Vaccines (now Pfizer, Inc.), is developing the next generation of vaccines for high value unaddressed targets in biodefense, infectious and emerging diseases.

The two in-licensed platforms greatly enhance the immunogenicity of prophylactic and therapeutic vaccines. They consist of first-in-class vaccines vectored with vesiculoviruses such as vesicular stomatitis virus (VSV), and best-in-class pDNA vaccines enhanced by the co-administration of GENEVAX IL-12™ and delivery with electroporation. Depending on the disease target, the pDNA and vesiculovirus-vectored

vaccines are used singly or in prime/boost combination. As part of the in-licensing transaction, two NIAID contracts initially totaling more than \$65 M were Novated from Wyeth to Profectus. These funds have advanced the pDNA and vesiculovirus vector programs through phase 1 safety and immunogenicity testing, both individually and in prime/boost combination.

Profectus' two lead programs, heavily supported by non-dilutive funding, consist of a therapeutic HIV vaccine in clinical evaluation to address the HIV "Cure Agenda" and a VSV-vectored vaccine for single dose pre- and post-exposure protection against the Category A threat agents Ebola and Marburg viruses. The company's rVSV-vectored Ebola and Marburg vaccines have provided 100% protection of monkeys against lethal challenge with these agents when tested by the US Government.

Additional programs in development include vaccines against Lassa and Chikungunya viruses utilizing the vesiculovirus platform, and vaccines against human papilloma viruses (HPV), hepatitis C virus (HCV) and herpes simplex virus type-2 (HSV-2) using the pDNA prime/vesiculovirus vectored boost platform.

The Profectus HIV pDNA 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. The Profectus HIV rVSV vaccine program has been supported through the award of an \$8.5 M HVDDT contract (HHSN272200800061C) from the NIH. 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 HIV Vaccines Trials Network, and the AIDS Clinical Trials Group. More information is available at www.ProfectusBioSciences.com.

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