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Profectus Biosciences' GENEVAX™ IL-12 Adjuvant Significantly Improves pDNA Vaccine Performance in Phase I Human Trial

A significant increase in the number of volunteers making a vaccine-specific T-cell immune response demonstrates the potential of the GENEVAX™ IL-12 vaccine adjuvant

Baltimore, MD – December 14, 2010 – Profectus Biosciences, Inc., a leader in the development of therapeutic and preventive vaccines against infectious diseases and cancers, announced today that its GENEVAX™ IL-12 pDNA adjuvant has significantly improved the vaccine-induced response rate in a Phase I clinical study of an experimental DNA vaccine for the prevention of HIV infection. The response rates and magnitude of responses achieved in this study are significantly higher than those seen previously with other DNA vaccine trials. Dr. Spyros Kalamis, principal investigator for the study and Immunology Director of the Vanderbilt Center for AIDS Research at Vanderbilt University Medical Center, presented the interim immune response and safety data at the annual HIV Vaccine Trials Network (HVTN) Conference held November 15-17 in Seattle, WA.

This study, designated HVTN-080, involved the vaccination of 48 healthy, HIV-negative volunteers to assess safety and levels of immune responses generated by an experimental HIV DNA vaccine (PENNVAX™-B, provided by Inovio Pharmaceuticals, Inc.) delivered using in vivo electroporation (EP) with or without Profectus BioSciences' GENEVAX™ IL-12 plasmid. GENEVAX™ IL-12 is a proprietary formulation of a plasmid DNA vector that expresses the p40 and p35 subunits of the human cytokine Interleukin-12 plus the anesthetic bupivacaine. In addition to its anesthetic properties, bupivacaine has been shown to significantly stabilize and enhance the efficiency of DNA vaccines. This randomized, double-blind, multi-center study is being sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), an agency of the National Institutes of Health, and conducted by the NIAID-funded HVTN, at several clinical sites.

Non-human primate studies conducted by Profectus have shown that IL-12 pDNA adjuvant plus EP delivery significantly increases the immunogenicity of DNA vaccines compared to delivery with EP alone. The GENEVAX™IL-12 used in HVTN-080 was manufactured under an HIV Vaccine Design and Development Teams (HVDDT) contract from NIAID that is held by Profectus. Of the 48 total volunteers in HVTN-080, eight subjects received a placebo, 10 subjects received PENNVAX™-B vaccine alone, and 30 subjects received PENNVAX™-B along with GENEVAX™IL-12 DNA. All volunteers received vaccine or placebo administered with EP at months 0, 1, and 3. The DNA vaccine in combination with GENEVAX™ IL-12 delivered by in vivo EP was generally safe and well tolerated and there were no GENEVAX™ IL-12 related serious adverse events. Reported adverse events and injection site reactions were mild to moderate and required no treatment. Vaccine-specific T-cell immune responses were detected using a

validated flow cytometry-based intracellular cytokine staining (ICS) assay at the HVTN core immunology laboratory at the Fred Hutchinson Cancer Research Center (Seattle, WA).

Preliminary data reported at the meeting included safety data from all trial participants (48) and immunogenicity data from 38 out of 40 vaccine recipients post-second-dose and from 31 out of 40 vaccine recipients post-third-dose. The interim data indicate that GENEVAX™IL-12 significantly increased the percentage of vaccine recipients that mounted either a CD4+ or CD8+ or both T-cell responses to at least one of the vaccine antigens.

- After two vaccinations: 30.0% (3 out of 10) of evaluated subjects receiving PENNVAX-B and 71.4% (20 out of 28) receiving PENNVAX-B™ plus GENEVAX™ IL-12 mounted an antigen-specific T-cell response ($p=.03$).
- After three vaccinations: 66.7% (6 out of 9) of evaluated subjects receiving PENNVAX-B and 90.9 % (20 out of 22) receiving PENNVAX-B™ plus GENEVAX™ IL-12 mounted an antigen-specific T-cell response ($p=.13$).

In addition to improving response rates, inclusion of GENEVAX™ IL-12 was observed to significantly lessen injection site discomfort at all injections.

Dr. John Eldridge, Profectus Biosciences' Chief Scientific Officer, said: "Profectus is very pleased to see clinical validation of the GENEVAX IL-12 adjuvant platform. This was only made possible by a broad collaboration between industry, academia, and the US government. We thank NIAID for supporting the clinical trials through the HVTN, and for the award of the \$32 M HVDDT contract that has supported 60% of the research, development, and manufacturing costs of the Profectus HIV DNA vaccine and GENEVAX™ IL-12 program, while the remainder of the cost has been provided through a contribution-in-kind. This investment has not only benefitted our fight against HIV, but has advanced our understanding of how to produce vaccines against many chronic viral infections. Finally, I would like to thank the HVTN-080 trial subjects, who have made this advance possible."

In addition to the interim ICS results presented at the meeting, end-of-study safety data (including additional antibody and T-cell results based on ELISpot assays) are expected in 2Q 2011.

About the HVTN

The HIV Vaccine Trials Network (HVTN) is an international collaboration of scientists and educators searching for an effective and safe HIV vaccine. The HVTN's mission is to facilitate the process of testing preventative vaccines against HIV/AIDS. The HVTN conducts all phases of clinical trials, from evaluating experimental vaccines for safety and the ability to stimulate immune responses, to testing vaccine efficacy. Support for the HVTN 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 Vaccine Trial Units are located at leading research institutions in 27 cities on four continents. Internationally renowned HIV vaccine and prevention researchers lead the units.

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 foundation of Profectus BioSciences' approach is the premise that effective management of inflammation and immunity can dramatically improve clinical outcomes. The Company has in-licensed a group of vaccine-based technologies from Wyeth Vaccines 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 contract (HHSN272200800062C) from the NIH.

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