Profectus BioSciences, Inc.

Profectus BioSciences' Vesicular Stomatitis Virus-Vectored HIV-1 Vaccine Safe and Immunogenic in Government Sponsored Phase 1 Trial

NIAID-funded Study Establishes the Safety and Immunogenicity of Vesicular Stomatitis Virus-Vectored Prophylactic HIV Vaccine in Normal Healthy Adults

Baltimore, MD – December 4, 2012 – Profectus BioSciences, Inc., a leader in the development of therapeutic and preventive vaccines against infectious diseases, announced that a phase 1 study has demonstrated the safety and immunogenicity of its recombinant vesicular stomatitis virus (rVSV)-vectored HIV vaccine. VSV is a type of RNA virus that can infect both insects and mammals. It is commonly used in laboratory settings as a gene delivery vector without the potential for integration, a characteristic that provides a safety advantage in vaccine applications. The first studies to demonstrate the potential of rVSV as an HIV vaccine vector were performed in the laboratories of Dr. John K. Rose at Yale University more than a decade ago. The recombinant version used in this clinical study is able to replicate in human cells, but has been attenuated (weakened) so as not to cause illness in animals or humans.

The novel rVSV vector, expressing the HIV-1 gag protein, was evaluated in a clinical trial sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The study was conducted by the NIAID-funded HIV Vaccine Trials Network (HVTN) under a protocol designated HVTN 090.

The phase 1, placebo-controlled, dose-escalation study enrolled 60 HIV-uninfected adults at HVTN clinical sites located in Nashville TN, Philadelphia PA, Decatur GA, and San Francisco CA. It assessed the safety and immunogenicity of increasing doses (10^4, 10^5, 10^6, 10^7, and 10^8 plaque-forming units) of the rVSV HIV-1 gag vaccine administered by intramuscular injection. The vaccine was found to be safe at all dose levels, and the 10^8 PFU dose has been selected for evaluation in a follow-on clinical trial (HVTN 087). Assays conducted by Profectus confirmed that 0/60 (0.0%) subjects had pre-existing immunity to VSV, that there was a vaccine "take" in 50/50 (100.0%) vaccine recipients across all dose levels, and that no rVSV entered the blood stream or was shed in saliva or urine. Assays conducted by the HVTN Central Immunology Laboratories demonstrated the 10^8 PFU dose level induced a gag-specific cell-mediated immune (CMI) response in 5/8 (62.5%) of vaccine recipients.

Dr. John Eldridge, Chief Scientific Officer, said: "The demonstration that our rVSV vaccine delivery platform is safe and immunogenic in healthy adult volunteers is a milestone that allows Profectus to advance not only its HIV vaccine program, but also vaccines for multiple infectious disease indications. The response rate observed in this clinical trial is absolutely consistent with our data in non-human primates. Those data show that although not all macaques immunized with rVSV vaccine alone mount a demonstrable CMI response, 100% of animals primed with DNA vaccine prior to boosting with rVSV vectored vaccine will mount a synergistic and sustained effector memory CMI response. The pDNA prime/rVSV boost vaccination strategy is currently being tested in HVTN trial 087, which to date has enrolled 41/100 subjects. I look forward to the results from that trial, which I am confident will show the Profectus prime/boost platform to be the industry leader for inducing CMI responses."

About the Profectus rVSV-vectored HIV-1 vaccines

The rVSV HIV-1 gag vaccine consists of an attenuated replication competent form of the Indiana serotype of $rVSV_{IN}$ that expresses the HIV-1 gag protein. The vaccine is designed to elicit a robust cell mediated immune response to the HIV-1 gag protein when used as a booster for the Profectus interleukin-12 enhanced pDNA gag/pol vaccine. With NIAID funding, Profectus is currently manufacturing an $rVSV_{IN}$-vectored vaccine that expresses a secreted form of env glycoprotein from HIV-1 clade C strain 1086.C. Pre-clinical studies have shown this vaccine to induce high antibody responses when used as a booster for an IL-12 enhanced pDNA env1086.C vaccine. Profectus has also been funded by the NIAID to develop a lyophilized form of rVSV vaccines that will 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 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 preventive 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 these units.

About Profectus BioSciences, Inc.

Profectus BioSciences, Inc. is a technology based vaccine company devoted to the treatment and prevention of infectious diseases 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 virus, Marburg Virus, the arenaviruses and malaria. The Profectus rVSV HIV-1 vaccine program has been supported through the award of a $22.5M HIV Vaccine Design and Development Teams (HVDDT) contract HHSN272200800061C from the NIH that has supported the research, development, and manufacture of the $rVSV_{IN}$ HIV-1 gag and $rVSV_{IN}$ HIV-1 env1086.C vaccines. 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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