Profectus BioSciences, Inc.

First Human Volunteer Immunized in Clinical Trial of Profectus BioSciences' Vesicular Stomatitis Virus-vectored HIV-1 Vaccine

NIAID-funded Study Designed to Establish the Optimal Dose of Vesicular Stomatitis Virus-Vectored Prophylactic HIV Vaccine in Normal Healthy Adults

Baltimore, MD – January 4, 2012 – Profectus BioSciences, Inc., a leader in the development of therapeutic and preventive vaccines against infectious diseases, announced that a phase 1 study to test the safety and immunogenicity of a recombinant vesicular stomatitis virus (rVSV)-vectored HIV vaccine initiated on October 26th and, as of December 27th, 20 volunteers have been immunized. 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 new vaccine 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, is being evaluated in a trial sponsored by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The study is being conducted by the NIAID-funded HIV Vaccine Trials Network (HVTN) under a protocol designated HVTN 090.

The phase 1, placebo-controlled, dose-escalation study will enroll 60 HIV-uninfected adults. It will assess the safety and immunogenicity of increasing doses of the rVSV HIV-1 gag vaccine administered by intramuscular injection. Assays conducted by the HVTN Central Immunology Laboratories will measure the ability of the vaccine to induce both antibody and cell-mediated immune responses to the HIV gag protein. The vaccine was found to be safe and immunogenic in non-human primates, and is the first vaccine based on an rVSV platform to be tested in humans.

Dr. John Eldridge, Chief Scientific Officer, said: "Profectus is very pleased to announce the first clinical evaluation of the rVSV HIV-1 vaccine. This replication competent delivery vector provides both unique immunogenicity and the high manufacturing yields needed for an HIV vaccine intended for worldwide use."

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 will be 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 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 the units.

About Profectus BioSciences, Inc.

Profectus BioSciences, Inc. is a technology based vaccine company devoted to the treatment and prevention of infectious disease and related cancer, 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, 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 manufacturing costs of the $rVSV_{IN}$ HIV-1 gag vaccine.

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