



Profectus BioSciences Receives NIAID Grant to Develop a Vesicular Stomatitis Virus-vectored Vaccine for Ebola and Marburg Viruses

Funding to Support Profectus and Galveston National Laboratory Investigators in the Development of a Trivalent rVSV-Vectored Vaccine to Protect Against Ebola and Marburg Viruses.

Baltimore, MD – May 2, 2012 – Profectus BioSciences, Inc., a leader in the development of therapeutic and preventive vaccines against infectious diseases, and the Galveston National Laboratory (GNL) at the University of Texas Medical Branch at Galveston announced today that they have received a 5 year \$5.4 M grant from the National Institute of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health (NIH). The grant will support development of a trivalent vaccine to protect against infection with all major strains of Ebola and Marburg viruses, the two members of the filovirus family of hemorrhagic fever viruses. These agents are classified as Category A Priority Pathogens by the NIAID/NIH and CDC, and there are presently no pre- or post-exposure interventions available in the event of natural outbreak, laboratory accident, or deliberate misuse. Public health concern is based on both the emerging infectious disease status of these viruses and their potential use as biological weapons.

Profectus has developed a highly immunogenic vaccine delivery system based on a replication-competent recombinant vesicular stomatitis virus (rVSV) that has been attenuated so as not to cause illness in animals or humans. Using recombinant genetic techniques, rVSV vectors have been created that express the surface glycoproteins from Ebola and Marburg viruses. A series of preclinical studies conducted in collaboration with GNL and NIH investigators have shown that a single injection of the rVSV-Ebola vaccine is able to protect guinea pigs and non-human primates against lethal challenge with the highly pathogenic Zaire species of Ebola virus. The current grant supports development of a blended vaccine composed of three rVSV vectors that will protect against the major filovirus species and that is suitable for eventual human testing. Profectus will be responsible for the design and development of the lyophilized trivalent vaccine, and the GNL will conduct the studies at biosafety level 4 (BSL4) to demonstrate protection against lethal challenge with multiple strains of Ebola and Marburg viruses.

As previously announced, a phase 1, placebo-controlled, dose-escalation study to assess the safety and immunogenicity of a Profectus rVSV-vectored HIV vaccine initiated on October 26, 2011. That trial is currently enrolling at the highest dose level to be tested, and 51/60 subjects have been vaccinated with no safety issues. The rVSV HIV vaccine was found to be safe and immunogenic in non-human primates, and is the first vaccine based on the rVSV platform to be tested in a human clinical trial.

Dr. John Eldridge, Chief Scientific Officer, said: "Profectus is very pleased the NIH and the scientific community have recognized the potential of an rVSV-vectored filovirus vaccine to provide protection

against these bio-threat agents. In addition to providing single-dose protection, this platform provides the high manufacturing yields that allow rapid and economic production.”

GNL investigator and UTMB professor Tom Geisbert said: “Proving the potential of this vaccine would be an amazing step forward in combating these deadly filoviruses. The unique resources of the GNL’s BSL4 lab provide the confines to test the Profectus candidate vaccine safely and effectively and we look forward to carrying out the task that NIH has set for us.”

[The Galveston National Laboratory](#) is an academic research facility at the University of Texas Medical Branch at Galveston. One of the largest and most sophisticated infectious disease research laboratories in the U.S., the GNL utilizes the unique resources of its BSL2, -3 and -4 laboratories, to study the diseases that make the world’s people and animals sick. This research yields better tests, treatments and vaccines for these diseases. The GNL’s renowned scientists work collaboratively, both locally and internationally, to advance knowledge of infectious diseases that affect global health like West Nile virus, Ebola, Marburg, Nipah, plague, influenza and a host of others.

[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 targets in addition to Ebola and Marburg viruses include hepatitis C virus (HCV), human papilloma virus (HPV), herpes simplex virus type 2 (HSV-2), human immunodeficiency virus (HIV), and malaria. 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.

####

Contact:

Jeffrey N. Meshulam

Vice President, COO

Profectus BioSciences, Inc.

443-743-1100

Meshulam@profectusbiosciences.com