



## FOR IMMEDIATE RELEASE

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## **Profectus BioSciences Receives Department of the Army Funding for Studies Directed Toward the Development of a VesiculoVax™ rVSV-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 Rapidly Confer Protection Against Ebola and Marburg Viruses —

*BALTIMORE, Md., October 22, 2014* – Profectus BioSciences, Inc., a clinical-stage vaccine company developing novel vaccines for the treatment and prevention of infectious diseases, announced today that Profectus and the Galveston National Laboratory (GNL) at the University of Texas Medical Branch at Galveston (UTMB) have received a three-year \$8.5M grant from the Department of the Army, U.S. Army Contracting Command, Aberdeen Proving Ground, Natick Contracting Division, Ft Detrick MD. The grant will support studies directed at early steps of the ongoing development of a vaccine to provide pre- and post-exposure protection against exposure with all major strains of Ebola and Marburg viruses.

“In light of the current outbreak of Ebola in Western Africa, we are grateful that the Department of the Army has recognized the potential of Profectus’ VesiculoVax™ rVSV-vectored filovirus vaccine to counter biowarfare threats, and Profectus BioSciences is confident it will also have application with regard to protecting civilians and military personnel against highly lethal emerging infectious diseases,” said John Eldridge, PhD, Chief Scientific Officer of Profectus. “In studies conducted by the National Institutes of Health in non-human primates, the Profectus vaccine has been shown to provide rapid protection against hemorrhagic fever viruses such as Ebola and Marburg, and is the only vaccine to have demonstrated single-dose protection of monkeys against lethal challenge with low-passage Ebola and Marburg viruses. We remain committed to finding the means to move these treatment options into clinical evaluation as rapidly as possible.”

The new Department of the Army funding will build on Profectus and GNL’s extensive ongoing Ebola and Marburg vaccine development effort, including:

- In March 2014, UTMB, Profectus Biosciences, Tekmira Pharmaceuticals, and the Vanderbilt University Medical Center were awarded \$26 million by the National Institutes of Health (NIH) to advance combination treatments for Ebola and Marburg infection.
- In December 2012, Profectus BioSciences, Inc., and the HIV Vaccine Trials Network announced that a clinical Phase 1 study has demonstrated the safety and immunogenicity of its VesiculoVax™ vaccine vector platform. The VesiculoVax™ vectored HIV vaccine was found to be safe at all dose levels tested and to induce a vaccine-specific cell-mediated immune response in 62.5% of vaccine recipients.
- In 2012, Profectus BioSciences and GNL received a five-year \$5.4 M grant from the National Institute of Allergy and Infectious Diseases (NIAID) supporting the development of a trivalent vaccine to protect against systemic exposure with all major strains of Ebola and Marburg viruses.

"We are very grateful for the opportunity to work with Profectus BioSciences and are both humbled and gratified that this important work has the support of our government and the Department of Defense. The work we're doing can make a difference in the lives of people all over the world. Funding like this is the key to ensuring that research and development moves forward to address the biowarfare threat, which also has application in the mitigation of the public health threat of highly contagious and dangerous viruses like Ebola," stated Tom Geisbert, Professor, Microbiology & Immunology at the Galveston National Labs.

### **About Profectus VesiculoVax™ Vaccines for Ebola and Marburg Viruses**

Profectus has developed the highly immunogenic VesiculoVax™ vaccine delivery system to address emerging infectious disease indications where the rapid induction of neutralizing antibodies is needed to protect against the viruses that cause hemorrhagic fevers such as Ebola, Marburg, and Lassa; encephalitic diseases such as Venezuelan, Eastern, and Western Equine Encephalitis viruses (EEVs); and arthralgic disease caused by infection with Chikungunya virus. VesiculoVax™ vaccines are based on replication-competent recombinant vesiculoviruses that have been attenuated so as not to cause illness in animals or humans.

The VesiculoVax™ vaccine for both pre- and post-exposure protection against the hemorrhagic diseases caused by Ebola and Marburg viruses are based on the use of vesicular stomatitis virus (rVSV) as a vehicle. The Profectus rVSV-based vectors are engineered to express the surface glycoproteins that the Ebola and Marburg viruses use to recognize a host cell, bind to it, and infect. Thus, the vaccine triggers the body to generate an immune response that blocks the Ebola and Marburg viruses from being able to infect. Importantly, the Profectus VesiculoVax™ vaccine platform has been tested in multiple Phase I clinical studies and been shown to be safe and immunogenic.

The Profectus VesiculoVax™ rVSV-vectored vaccine for Ebola and Marburg viruses has completed preclinical studies and is positioned for human clinical trials. Key findings from preclinical studies include:

- Preclinical studies conducted with investigators from the Galveston National Laboratory (GNL) at the University of Texas Medical Branch at Galveston, and the National Institutes of Health (NIH) have shown that a single dose of the VesiculoVax™ rVSV-vectored Ebola

vaccine is able to protect guinea pigs and non-human primates against lethal challenge with the Zaire species of Ebola virus.

- In multiple studies conducted by a team from the National Institute for Allergy and Infectious Diseases (NIAID), the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and the U.S. Department of Defense (DoD), a single dose of the Profectus VesiculoVax™rVSV-vectored Ebola vaccine provided 100% protection of non-human primates against challenge with 1,000 times the lethal dose of highly pathogenic low passage Ebola virus Zaire. In addition, a single dose of the Profectus VesiculoVax™rVSV-vectored Marburg vaccine provided 100% protection against challenge with 1,000 times the lethal dose of low passage Marburg virus Angola.

This most recent grant award from the Department of the Army, U.S. Army Contracting Command, Aberdeen Proving Ground, Natick Contracting Division, Fort Detrick, MD, supports studies directed toward the development of a lyophilized trivalent formulation of VesiculoVax™-vectored filovirus vaccines. The lyophilized trivalent Ebola/Marburg vaccine will be tested in both pre-exposure and post-exposure studies to confirm protection of non-human primates from exposure to Ebola and Marburg viruses.

### **About the Ebola and Marburg Viruses**

Ebola and Marburg viruses are related filoviruses that are highly contagious and cause periodic outbreaks of severe hemorrhagic fever with mortality rates that range between 50% and 90%. The infection typically affects multiple organs and is often accompanied by severe bleeding (hemorrhage). The viruses are believed to be transmitted to people from bats and then spread in the human population through human-to-human transmission of blood and bodily fluids. At present, there are no FDA-approved 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. The ongoing widespread Ebola outbreak in West Africa has highlighted concern regarding these viruses. The development pathway for FDA approval of a filovirus vaccine will consist of clinical evaluation in Phase 1 and Phase 2 trials to establish safety and immunogenicity in humans and the demonstration of efficacy in validated animal challenge studies.

### **About The Galveston National Laboratory**

The Galveston National Laboratory (GNL) 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.

### **About Profectus Biosciences**

Profectus BioSciences is a clinical-stage vaccine platform company developing novel vaccines for the prevention and treatment of infectious diseases and related cancers. Profectus vaccines are based on the company's proprietary Prime/Boost System of Vaccines (PBS Vax™) system, which enables the tailoring of immune response to a specific disease target to achieve greatly enhanced immunogenicity of prophylactic and therapeutic vaccines. The PBX Vax™ platform comprises priming with GeneVax® DNA vaccines enhanced by the co-administration of GeneVax IL-12® and electroporation delivery, followed by boosting with VesiculoVax™ vaccines vectored with replication-competent vesiculoviruses. Clinical studies of PBS Vax have demonstrated a favorable safety profile and that the platform enhances immune responses in novel ways. Profectus is using the PBS Vax discovery engine to create a pipeline of differentiated new vaccines that have the potential to be first-in-class or best-in-class products to treat and prevent disease. The company's biodefense vaccine franchise for the Ebola and Marburg viruses is in late-stage preclinical development and was shown to provide 100 percent protection in non-human primates against lethal challenge with these agents when tested by the U.S. government. The company's lead product candidate, a therapeutic and prophylactic vaccine for HIV, is in human clinical studies and is currently being used in the clinic as part of the National Institutes of Health's HIV "Cure Agenda." For more information, please visit [www.profectusbiosciences.net](http://www.profectusbiosciences.net).

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