



## FOR IMMEDIATE RELEASE

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## **Profectus BioSciences Receives \$8.6 Million HHS Contract to Accelerate Ebola Vaccine into Human Clinical Studies**

- Studies will accelerate IND-enabling development of VesiculoVax™ Ebola vaccine —
- rVSV-based VesiculoVax™ Ebola vaccine demonstrated single-dose protection of monkeys against lethal challenge with Ebola Zaire virus —

*BALTIMORE, Md., October 22, 2014* – Profectus BioSciences, Inc. announced today that the company has received a contract from the U.S. Department of Health and Human Services (HHS) Office of the Assistant Secretary for Preparedness and Response (ASPR) aimed at accelerating the advancement of the company’s candidate Ebola vaccine into human clinical studies. In previous preclinical studies conducted in collaboration with the National Institutes of Health (NIH) and Department of Defense (DoD) in non-human primates, a single dose of the Profectus vaccine has been shown to provide 100% protection against Ebola Zaire.

The one-year contract with the ASPR’s Biomedical Advanced Research and Development Authority (BARDA) will provide \$5.8 million in funding to conduct toxicology studies to evaluate the safety of the company’s novel VesiculoVax™ Ebola vaccine candidate and to manufacture the vaccine for use in Phase 1 clinical studies. The contract can be extended to a total of 13 months and \$8.6 million. Upon successful completion of these initiatives, Profectus will apply to the U.S. Food and Drug Administration for an Investigational New Drug (IND) designation that would allow initiation of human clinical trials to evaluate the vaccine’s safety and immunogenicity in humans.

With this most recent funding, Profectus has secured a total of \$27.9 million to develop the VesiculoVax™ Ebola vaccine, including:

- HHS, October 2014: \$8.6 million
- DoD, October 2014: \$8.5 million
- NIAID, March 2014: \$5.4 million
- NIAID, May 2012: \$5.4 million

“We are grateful that the Department of Health and Human Services has recognized the potential of Profectus’ VesiculoVax™ Ebola vaccine, which offers promise for preventing as well as treating individuals from infection with the Zaire variant of Ebola that is responsible for the current outbreak in West Africa,” said John Eldridge, Ph.D., Chief Scientific Officer of Profectus. “Advancing this vaccine into human studies is a top priority for Profectus, and we remain committed to moving this program into clinical evaluation as rapidly as possible.”

### **About the VesiculoVax™ Prophylactic Vaccine for Ebola**

Profectus has developed the highly immunogenic VesiculoVax™ vaccine delivery system for 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 disease (VEE, EEE, WEE); and arthralgic disease (Chikungunya). VesiculoVax™ vaccines are based on replication-competent recombinant vesiculoviruses that have been genetically attenuated so as not to cause illness in animals or humans.

The company’s VesiculoVax™ vaccine for pre- and post-exposure protection against the Ebola virus is based on a form of vesicular stomatitis virus (rVSV) engineered to express the surface protein from the Zaire variant of the Ebola virus responsible for the 2014 Ebola outbreak. 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 Department of Defense (DoD), a single dose of the Profectus VesiculoVax™-vectored Ebola vaccine provided 100% protection of non-human primates against challenge with 1,000 times the lethal dose of low-passage (i.e., highly virulent) Ebola Zaire virus. In addition, preclinical studies conducted with investigators from the Galveston National Laboratory (GNL) at the University of Texas Medical Branch (UTMB) at Galveston and the National Institutes of Health (NIH) have shown that a single dose of the VesiculoVax™ Ebola vaccine is able to protect non-human primates against lethal challenge with the highly pathogenic, low-passage isolates of the Zaire and Sudan species of Ebola virus, and that a single dose of the VesiculoVax™ Marburg vaccine is able to protect non-human primates against lethal challenge with a highly pathogenic, low-passage isolate of the Angola species of Marburg virus. A trivalent VesiculoVax™-vectored vaccine to protect against all filoviruses has entered non-human primate testing with financial support from the NIAID and DoD.

Profectus has demonstrated the safety and immunogenicity of its VesiculoVax™ rVSV-based vaccines against HIV in humans.

### **About the Ebola Virus**

Ebola virus is a filovirus that causes periodic outbreaks of a highly contagious and lethal human infectious disease marked by severe hemorrhagic fever, with a mortality rate that ranges between 50% and 90%. The infection typically affects multiple organs in the body and is often accompanied by severe bleeding (hemorrhage). The virus is transmitted to people from wild animals and spreads in the human population through human-to-human transmission. At present, there are no FDA-approved pre- or post-exposure interventions available in the event of natural outbreak, laboratory accident, or deliberate misuse. The Ebola virus is classified as a Category A

Priority Pathogen by the Centers for Disease Control and Prevention (CDC). This designation prescribes an accelerated development pathway for FDA approval that determines efficacy based on two different validated animal studies followed by clinical evaluation in Phase 1 and Phase 2 trials to establish safety and immunogenicity for use in humans.

### **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™), which enable the tailoring of immune responses 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 using VesiculoVax™ vectors without the need for GeneVax® priming 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. For more information, please visit [www.profectusbiosciences.net](http://www.profectusbiosciences.net).

### **About the U.S. Department of Health and Human Services (HHS)**

HHS is the principal federal agency for protecting the health of all Americans and providing essential human services, especially for those who are least able to help themselves. The Office of the Assistant Secretary for Preparedness and Response (ASPR) leads HHS in preparing the nation to respond to and recover from adverse health effects of emergencies, supporting communities' ability to withstand adversity, strengthening health and response systems, and enhancing national health security.

Within ASPR, BARDA develops and procures medical countermeasures—vaccines, medicines, diagnostics and medical equipment—that address the public health and medical consequences of chemical, biological, radiological, and nuclear (CBRN) accidents, incidents and attacks, pandemic influenza, and emerging infectious diseases. For more information about advanced research and development of medical countermeasures, visit [www.medicalcountermeasures.gov](http://www.medicalcountermeasures.gov). Contract opportunities and awards are announced at [www.fbo.gov](http://www.fbo.gov).

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