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**Profectus BioSciences Initiates Ebola Vaccine Phase 1 Clinical Trial**

- Phase 1 trial will evaluate the safety and immunogenicity of Profectus’ Ebola virus vaccine administered at various dose levels –
- Vaccine based on the company’s highly attenuated vesicular stomatitis virus (VSV) vector –
- Filovirus vaccine program supported by the DOD Medical Countermeasures Systems - Joint Vaccine Acquisition Program (MCS-JVAP) both directly and through contracts with Battelle, the Biomedical Advanced Research and Development Authority (BARDA), and the National Institutes of Health (NIH) –

*BALTIMORE, Md., January 19, 2016*— Profectus BioSciences, Inc., a clinical-stage vaccine company developing novel vaccines for the prevention and treatment of infectious diseases and the treatment of cancer, announced today the initiation of a Phase 1 clinical study of Profectus’ VesiculoVax™-vectored Ebola virus vaccine. The vaccine is a version of the company’s patented VSV vector that has been engineered for safe use in humans and to express the surface protein of Ebola virus. In preclinical studies, a single dose of this vaccine completely protected monkeys against the strain of Ebola virus responsible for the recent outbreak in West Africa<sup>1</sup>.

The Phase 1, placebo-controlled, dose-escalation study will enroll 39 subjects into three groups that will receive progressively higher doses of the vaccine by intramuscular injection. The trial is designed to establish the safety and immunogenicity of the vaccine at dose levels that span the dose shown to protect monkeys.

The Profectus Ebola vaccine programs are supported by the U.S. Department of Defense Medical Countermeasures Systems–Joint Vaccine Acquisition Program (MCS-JVAP) both directly and through contracts with Battelle, the Biomedical Advanced Research and Development Authority (BARDA), and the National Institutes of Health (NIH).

“Profectus is pleased to announce initiation of the first step in a systematic clinical evaluation of our filovirus vaccine,” said John H. Eldridge, PhD, Chief Scientific Officer of Profectus. “This first study is designed to quickly establish the safety and immunogenicity of our attenuated VSV-vectored Ebola vaccine. The next step, anticipated for mid-next year, will be a trial of our trivalent vaccine to protect against all species of Ebola and Marburg viruses. That will be followed by the testing of a freeze-dried formulation that will allow field use without refrigerated storage. We want

to acknowledge the continuing financial and technical support provided by MCS-JVAP and especially for providing the funding for the execution of this Phase 1 clinical trial.”

### **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).

### **About Profectus VesiculoVax™ Vaccines**

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). The Profectus VesiculoVax™ vaccine delivery technology is based on seminal discoveries made in the laboratory of Dr. John Rose and patented by Yale University. Building on these discoveries, Profectus scientists introduced multiple non-reversible genetic modifications into the prototype that synergistically attenuate the virus and provide vectors that are safe for human use. To extend the VesiculoVax™ platform, Profectus is conducting collaborative studies with scientists at the University of Texas Medical Branch (UTMB) that have identified additional vesiculoviruses with utility as vaccine vectors. The resulting VesiculoVax™ platform consists of a family of non-cross reactive vaccine vectors that are constructed and attenuated so they do not cause illness in animal or humans using methods exemplified with rVSV. Profectus has demonstrated the safety and immunogenicity of its VesiculoVax™ rVSV-based vaccines against HIV in human clinical trials.

### **About MCS-JVAP**

Medical Countermeasure Systems’ Joint Vaccine Acquisition Program (MCS-JVAP) is a Department of Defense (DoD) program under the Joint Program Executive Office for Chemical and Biological Defense (JPEO-CBD). Its mission is to develop, produce, and field FDA licensed vaccine systems to protect the Warfighter from biological agents. MCS-JVAP’s Filovirus Vaccine Program has been leading the vaccine development effort that will protect against intramuscular (IM) and aerosolized exposure to Ebola Zaire, Ebola Sudan, and Marburg viruses in a single vaccine formulation since 2010.

### **About Battelle**

Every day, the people of Battelle apply science and technology to solving what matters most. At major technology centers and national laboratories around the world, Battelle conducts research and development, designs and manufactures products, and delivers critical services for government and commercial customers. Headquartered in Columbus, Ohio since its founding in 1929, Battelle serves the national security, health and life sciences, and energy and environmental industries. For more information, visit [www.battelle.org](http://www.battelle.org).

## **About Profectus BioSciences**

Profectus BioSciences is a clinical-stage vaccine company developing innovative vaccines for the prevention and treatment of infectious diseases and the treatment of cancer. Profectus vaccines are based on the company's proprietary VesiculoVax™ and DNA vaccine delivery platforms. Used alone, the first-in-class VesiculoVax™-vectored vaccines lead to rapid expansion of B cells to provide protection against emerging infectious diseases of public health and biodefense importance such as Ebola, Marburg, Chikungunya, and the Equine Encephalitis viruses. When used as a boost after priming the immune system with best-in-class pDNA vaccines, VesiculoVax™-vectored vaccines lead to the expansion of primed T cells into effector cells that are uniquely suited to killing virally infected cells and cancers. Current programs using the Prime/Boost System of Vaccines (PBS Vax™) strategy include hepatitis B virus (HBV), human papilloma virus (HPV), herpes simplex virus type 2 (HSV-2), and human immunodeficiency virus (HIV). Partners and collaborators include the Galveston National Laboratory at UTMB, 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 HIV Vaccines Trials Network, and the AIDS Clinical Trials Group. Profectus has been funded by Cross Atlantic Capital Partners ("XACP") of Radnor, Pennsylvania. XACP's primary investor is the Pennsylvania Public School Employees' Retirement System (PSERS). For more information, please visit [www.profectusbiosciences.com](http://www.profectusbiosciences.com).

*Any opinions, findings, and conclusions or recommendations expressed in this material are those of the author(s) and do not necessarily reflect the position or policy of the Government and no official endorsement should be inferred.*

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<sup>1</sup>Mire et al. "Single-Dose Attenuated VesiculoVax Vaccines Protect Primates Against Ebola Makona Virus." *Nature* 520:688-691, 2015.

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