

Profectus BioSciences Receives \$9.5 Million Department of Defense Funding to Manufacture Trivalent VesiculoVax™-Vectored Vaccine to Protect Against all Ebola and Marburg Viruses

- Funding to support GMP manufacture of VesiculoVax™-vectored vaccines for Zaire-Ebola virus, Sudan-Ebola virus, and Angola-Marburg virus that will be blended into a single formulation; rapid follow-up Phase 1 clinical trial planned —
- Phase 1 clinical trial of VesiculoVax™ Zaire-Ebola virus vaccine funded—

BALTIMORE, Md., October 31, 2014 – Profectus BioSciences, Inc., a clinical-stage vaccine company developing novel vaccines for the treatment and prevention of infectious diseases, announced today that the Department of Defense (DoD) through the Medical Countermeasure Systems-Joint Vaccine Acquisition Program (MCS-JVAP), a subordinate command of the Joint Program Executive Office for Chemical and Biological Defense, Edgewood, MD, has contracted the manufacture and IND-enabling preclinical testing of the Profectus trivalent Ebola/Marburg vaccine. In addition, the USACC has contracted for clinical evaluation of the VesiculoVax™ Zaire-Ebola virus vaccine to meet the current outbreak in West Africa. The \$9.5 million award has been made with Battelle Memorial Institute through the Chemical, Biological, Radiological, & Nuclear Defense Information Analysis Center (CBRNIAC) contract, a Defense Technical Information Center (DTIC®) owned, Indefinite Delivery Indefinite Quantity (ID/IQ) contract vehicle for providing comprehensive scientific and technical research and analysis supporting the Department of Defense CBRN and Homeland Defense communities. Battelle has contracted with Profectus for manufacturing and clinical evaluation and with Charles River Laboratories and Biologics Consulting Group for preclinical testing and IND preparation, respectively.

“While the urgent need today is for a vaccine that protects against the current Ebola Zaire outbreak, we are also anticipating the needs for tomorrow. We are continuing to develop a trivalent vaccine that will protect our service members and DoD civilians against the major filovirus threats: Ebola Zaire, Ebola Sudan, and Marburg viruses,” said LTC Victor Suarez, MCS-JVAP Joint Product Manager. “The available evidence suggests that a trivalent vaccine, such as the one under development by Profectus, is the desired end point as it would simultaneously offer protection against the current Ebola Zaire outbreak and also meet the long-term goals of preventing future infections by the Ebola Sudan and Marburg viruses. The DoD is optimistic that its long-term commitment to identifying and supporting safe and effective trivalent filovirus vaccines is coming to fruition and remains supportive to advancing the Profectus BioSciences trivalent Ebola/Marburg vaccine into human clinical trials as rapidly as possible.”

“We are gratified that the Department of the Defense has recognized the potential of Profectus’ VesiculoVax™ Zaire-Ebola virus vaccine to combat the current outbreak in West Africa, and the

potential of our multi-component vaccine to protect civilians and military personnel against all strains of filoviruses, whether from natural outbreak or deliberate misuse.” said John Eldridge, PhD, Chief Scientific Officer of Profectus. “More than 15 years have been invested in developing the genetically attenuated rVSVN4CT1 VesiculoVax™ vaccine delivery platform and demonstrating its safety in multiple clinical trials. To date, it is the only vaccine to demonstrate single-dose protection of monkeys against lethal challenge with highly virulent low-passage Ebola and Marburg viruses.”

About Profectus VesiculoVax™ Vaccines for Ebola and Marburg Viruses

Profectus began development of VesiculoVax™ rVSVN4CT1 vectored Ebola and Marburg vaccines approximately 5 years ago in collaboration with Dr. Thomas Geisbert at the UTMB Galveston National Laboratories (GNL) and Dr. Heinz Feldmann at the NIH Rocky Mountain Laboratories. The initial studies demonstrated that a single dose of the rVSVN4CT1-Z-Ebola vaccine protected guinea pigs and rhesus macaques against morbidity and mortality when challenged with a lethal dose of Zaire-Ebola virus.

Subsequently, Profectus provided rVSVN4CT1 vectored Ebola and Marburg vaccine candidates into studies conducted by the Filovirus Animal Non-clinical Group (FANG). This team includes members 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), and is charged with identifying and filling knowledge gaps in the areas of assays, animal models, challenge material, and human clinical data in support of advanced development licensure studies for Ebola and Marburg vaccines. In the FANG studies a single dose of the Profectus VesiculoVax™ rVSVN4CT1-vectored Ebola vaccine provided 100% protection of non-human primates against challenge with 1,000 times the lethal dose of highly pathogenic low passage Zaire-Ebola virus. In addition, a single dose of the Profectus VesiculoVax™ rVSVN4CT1-vectored Marburg vaccine provided 100% protection against challenge with 1,000 times the lethal dose of low passage Angola-Marburg virus.

Based on these results, Profectus has partnered with the NIAID, the Department of Defense’s Joint Vaccine Acquisition Program (JVAP), and the Biomedical Advanced Research and Development Authority (BARDA) in the development of rVSVN4CT1-vectored Ebola and Marburg vaccines. Currently funded efforts under these partnerships include:

- In April 2012, Profectus BioSciences and the GNL received a five-year \$5.4 M grant from the NIAID supporting development of a trivalent Ebola/Marburg vaccine to protect against systemic exposure with all major strains of Ebola and Marburg viruses.
- In March 2014, the GNL, Profectus Biosciences, Tekmira Pharmaceuticals, and the Vanderbilt University Medical Center were awarded \$26 million by the NIAID to advance combination treatments for Ebola and Marburg infection.
- In July 2014, Profectus BioSciences and the GNL were awarded a 3 year \$8.5M grant from the DOD/JVAP to support development of a lyophilized trivalent VesiculoVax™-vectored vaccine to protect against all major strains of Ebola and Marburg viruses delivered as aerosols. The lyophilized trivalent vaccine is being tested in both pre-exposure and post-

exposure studies to confirm protection of non-human primates from aerosol exposure to Ebola and Marburg viruses.

- In October 2014, Profectus BioSciences was awarded a 1 year \$5.8M contract with BARDA to manufacture the company's novel VesiculoVax™ Zaire-Ebola vaccine candidate for use in Phase 1 clinical studies. The contract can be extended to a total of 13 months and \$8.6 million. 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 of the vaccine's safety and immunogenicity in humans.

This most recent contract award for \$9.5M from the JVAP through Battelle will support manufacture of the trivalent rVSVN4CT-vectored Ebola/Marburg vaccine, and phase 1 clinical evaluation of rVSVN4CT1-Zaire-Ebola virus vaccine for safety and immunogenicity. A rapid follow up trial of the trivalent vaccine is in planning.

About Profectus VesiculoVax™ Vaccines

The Profectus VesiculoVax™ vaccine delivery technology is based upon seminal discoveries made in the laboratories of Dr. John Rose and patented by Yale University. Building on these discoveries, Profectus scientists have introduced multiple non-reversible genetic modifications into the prototype that synergistically attenuate the virus and provide a vector (rVSVN4CT1) that is safe for human use. With support from multiple HIV Vaccine Design and Development Teams contracts awarded by the NIH, a Profectus rVSVN4CT1 HIV vaccine has been manufactured, extensively evaluated in pre-clinical toxicology studies, and shown to be safe and immunogenic in two phase 1 clinical trials involving more than 200 HIV-negative and -positive vaccine recipients. Among the important findings:

- Demonstration that a second dose of vaccine effectively boosts the antibody response, obviating the need for a heterologous prime/boost.
- At 100-times the dose of vaccine required for a 100% response rate, the rVSVN4CT1 vector remained local to the site of injection and did not enter the blood circulation, nor was it shed in external secretions.

To extend the VesiculoVax™ platform, Profectus has conducted collaborative studies with scientists at the University of Texas Medical Branch at Galveston (UTMB) that have identified additional vesiculoviruses with utility as vaccine vectors. Thus, the VesiculoVax™ platform consists of a family of non-cross reactive vaccine vectors that are constructed and attenuated using methods exemplified with rVSVN4CT1.

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 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 VesiculoVax™ and GeneVax® 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 GeneVax® pDNA vaccines, VesiculoVax™-vectored vaccines lead to the expansion of primed T cells into effector cells that are uniquely suited to attacking virally infected cells and cancers. Current programs using this 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 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 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.net.

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