

Contact:

Mary Moynihan
M2Friend Biocommunications
802-951-9600
mary@m2friend.com

Profectus BioSciences' Ebola Vaccine Shown Effective and Safe in Providing Rapid, Single-Dose Protection Against Current "Makona" Ebola Outbreak Strain in Non-Human Primates

- A single administration of Profectus VesiculoVax™-vectored vaccine rapidly provides complete protection of non-human primates from sickness and death when challenged with lethal dose of Makona strain of Ebola virus responsible for current outbreak in West Africa –
- Studies conducted in collaboration with investigators at University of Texas Medical Branch at Galveston –
 - Results published in *Nature* –

BALTIMORE, Md., April 8, 2015 – Profectus BioSciences, Inc., a clinical-stage vaccine company developing novel vaccines for the treatment and prevention of infectious diseases, announced today the results of a study demonstrating that a single dose of vaccine administered using the company's VesiculoVax™ vector platform protects non-human primates against challenge with the "Makona" strain of Ebola virus (previously referred to as the Ebola Guinea strain) that is responsible for the current Ebola outbreak in West Africa. Results of the study are published in the April 9, 2015 issue of the journal, *Nature*, in an article entitled, "Single-Dose Attenuated VesiculoVax™ Vaccines Protect Primates Against Ebola Makona Virus." The study was authored by researchers at Profectus and the University of Texas Medical Branch (UTMB) at Galveston.

"A key goal in efforts to address the 2014-2015 outbreak of the highly lethal Zaire Ebola virus has been to develop a preventive vaccine that rapidly confers protection in a single administration," said John Eldridge, PhD, Chief Scientific Officer of Profectus. "This is the first demonstration of a vaccine that is able to rapidly confer single-dose protection against the current Makona strain of Zaire Ebola virus that is responsible for more than 10,000 deaths in the ongoing epidemic in West Africa. We are grateful to the Geisbert laboratory at UTMB for its unrestricted collaboration, and we are excited about the potential of our vaccine to combat the current outbreak. We look forward to continued rapid progress to advance this vaccine—along with our trivalent vaccine for protection against all Ebola and Marburg viruses—into human clinical trials."

In this trial, two candidate VesiculoVax™-vectored Ebola vaccines of intermediate and high attenuation were tested, and both were shown to provide complete, single-dose protection of rhesus macaques against illness and death from the Makona strain of Ebola from Guinea, which is responsible for the current outbreak in West Africa. Eight vaccinated and two unvaccinated control macaques were infected with a Makona strain of Ebola virus 28 days after receiving a single

injection of one of the vaccines. None of the monkeys vaccinated with either vaccine showed any severe signs of illness following infection with the virus, whereas the two unvaccinated animals succumbed to the disease on days seven and eight. Profectus' highly attenuated rVSVN4CT1 VesiculoVax™ vector used in this study is also the foundation of the Profectus Ebola and Marburg monovalent and trivalent vaccines in development by Profectus with support from the National Institutes of Health (NIH), the U.S. Department of Health and Human Services (HHS) Biomedical Advanced Research and Development Authority (BARDA), and the Department of Defense (DoD) Joint Vaccine Acquisition Program (JVAP). The VesiculoVax™ platform provides the flexibility to construct vaccine delivery vectors with different levels of attenuation, a capability that enables the identification of vaccines that provide complete protection with the highest level of safety.

“These data validate the Vesiculovax™ platform approach to delivery of immunogens against infectious diseases,” said Jeffrey Meshulam, President of Profectus. “More than 15 years have been invested in developing the genetically attenuated rVSVN4CT1 VesiculoVax™ vaccine delivery platform and demonstrating its safety and immunogenicity in multiple clinical trials. We are excited about its potential to improve the ability to address the current Ebola outbreak as well as other infectious disease outbreaks.”

About Profectus VesiculoVax™ Vaccines 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™ vaccines for pre- and post-exposure protection against the Ebola viruses is based on a form of vesicular stomatitis virus (rVSV) engineered to express the surface protein from the Zaire and Sudan variants of the 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 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 nonhuman 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).

About UTMB

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.

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 the Galveston National Laboratory at the University of Texas Medical Branch (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 investors include Cross Atlantic Capital Partners \(“XACP”\). XACP's primary investor is the Pennsylvania Public School Employees' Retirement System \(“PSERS”\).](#) For more information, please visit www.profectusbiosciences.com.

###