

Profectus BioSciences Awarded NIH Contract for up to \$22.25 Million to Develop Multi-Component Vaccine for Ebola, Marburg, and Lassa Viruses

 Supports development of the multi-component VesiculoVax[™]-vectored vaccine through Phase 1 clinical evaluation –

- Vaccine will be developed in a lyophilized presentation to simplify use in endemic areas -

BALTIMORE, Md., October 2, 2017 – Profectus BioSciences, Inc. announced today that the company has received a contract for up to \$22.25 million from the National Institute of Allergy and Infectious Diseases (NIAID), a division of the National Institutes of Health. The base period of the contract, with a value of \$6.96 million, will support a proof-of-concept (POC) study in non-human primates (NHP) and preparations for manufacture under Good Manufacturing Processes (GMP) of a vaccine designed to protect against Zaire ebolavirus, Sudan ebolavirus, Marburgvirus, and Lassa viruses. The contract also includes \$15.29 million in options that may be exercised by the NIAID to support GMP manufacture and clinical evaluation of the multi-component vaccine. The vaccine is being developed in lyophilized form to allow distribution without a cold chain and enable routine mass immunization.

Ebola and Marburg viruses belong to the filovirus family of viruses, which cause periodic outbreaks of a highly contagious and lethal human infectious disease marked by a hemorrhagic fever, with a mortality rate that ranges between 25% 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.

Lassa virus is endemic to West Africa, where it infects up to 300,000 individuals per year, resulting in 60,000 cases of severe multisystem disease and 5,000 deaths. Among those who survive, about one in eight suffer permanent deafness. The main reservoir of this virus is the multimammate rat, which lives in close proximity to humans and sheds the virus in its urine and feces.

At present, there are no FDA-approved pre- or post-exposure interventions available in the event of natural outbreak, laboratory accident, or deliberate misuse of these viruses. The filoviruses and Lassa viruses are classified as Category A Priority Pathogens by the NIAID, Centers for Disease Control (CDC), and U.S. Department of Defense because they can be easily transmitted from person to person and have the potential for major health impact. Working with these viruses requires specialized containment procedures, and the Profectus NHP POC study will be conducted in the biosafety level 4 (BSL-4) containment laboratories at the Galveston National Laboratories of the University of Texas Medical Branch at Galveston.

Preclinical studies have demonstrated that a three-component vaccine using the Profectus VesiculoVax[™] platform provides rapid and durable protection of NHP against lethal disease caused by the Ebola and Marburg viruses. In addition, a Phase 1, placebo-controlled, dose-escalation study of the Ebola Zaire VesiculoVax[™] vaccine demonstrated a low rate of side effects and a 100% response rate in vaccine recipients. The average response magnitude seen at the top dose of vaccine exceeded that associated with complete protection in previously published studies in NHP.

"We are gratified to enter into this co-development contract with the NIAID," said John Eldridge, Ph.D., Chief Scientific Officer of Profectus. "Our Lassa vaccine has shown excellent immunogenicity when combined with the multi-component Ebola/Marburg vaccine. We look forward to the clinical testing of a vaccine designed to prevent the annual burden of Lassa fever and the sporadic, but increasing, severe outbreaks of Ebola and Marburg."

About Profectus VesiculoVax[™] Vaccines

The Profectus VesiculoVax[™] vaccine delivery technology is based on the discovery that replicationcompetent vesiculoviruses are uniquely suited for use as vaccine vectors. This discovery was made in the laboratory 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 vesicular stomatitis virus (VSV) that render it safe for human use. The VesiculoVax[™] platform consists of a growing family of attenuated, non-cross-reactive vaccine vectors.

About NIAID

NIAID conducts and supports research—at the NIH, throughout the United States, and worldwide—to study the causes of infectious and immune-mediated diseases, and to develop better means of preventing, diagnosing and treating these illnesses. Profectus has utilized NIAID's preclinical services program. News releases, fact sheets and other NIAID-related materials are available on the NIAID Web site at http://www.niaid.nih.gov/.

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 cancers. 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, Zika, the equine encephalitis viruses, and respiratory syncytial virus. When used as a boost after priming the immune system with best-in-class pDNA vaccines, VesiculoVaxTM-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 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 <u>www.profectusbiosciences.com</u>

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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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