



Profectus BioSciences Presents Data at Filovirus Medical Countermeasures Meeting Showing That a Single Dose of VSV-Vectored Vaccine Completely Protects Monkey Against Challenge with Ebola and Marburg Viruses

Profectus recombinant vesicular stomatitis virus (rVSV) vectored vaccine tested in multi-agency supported studies designed to identify the animal model to be used for filovirus vaccine licensure under the "animal rule".

Baltimore, MD – September 24th, 2013– Profectus BioSciences Inc., a leader in developing next generation vaccines for high value targets in biodefense, infectious, and emerging diseases, presented on the development of its rVSV-vectored Ebola and Marburg virus vaccine at the Filovirus Medical Countermeasures (MCM) Workshop held in the National Institutes of Health (NIH) Fishers Lane Conference Center in Rockville, MD. The two day meeting was sponsored by the NIH’s National Institute of Allergy and Infectious Diseases (NIAID), the Food and Drug Administration (FDA), the Department of Defense Joint Vaccine Acquisition Program (DoD-JVAP), the Assistant Secretary for Preparedness and Response (ASPR), and the Biomedical Advanced Research and Development Authority (BARDA).

The meeting was opened with a series of presentations by members of the Filovirus Animal Non-Clinical Group (FANG), a US interdepartmental and interagency group established to support and facilitate the advanced development of filovirus MCM. These presentations outlined progress in developing the animal model, challenge materials, and assays needed for product testing in support of FDA licensure of safe and effective filovirus MCM. The challenge materials group described the selection of highly virulent, low passage viruses isolated from cases of fatal human disease for use in the non-human primate protection studies that together with human safety will form the basis of licensure. The low passage viruses selected for these challenge studies are *Sudan ebolavirus* variant Gulu (S-EboV), *Zaire ebolavirus* variant Kikwit (Z-EboV), and *Marburgvirus* variant Angola (MarV).

In his presentation at the Workshop, Dr. John H. Eldridge, CSO of Profectus, described the tri-valent rVSV vectored Ebola and Marburg virus vaccine being developed by Profectus. The vaccine is based on the live attenuated rVSV_{IN}4CT1 clinical vector, which has successfully completed phase 1 safety and immunogenicity testing as an HIV vaccine candidate (HVTN trial 090). To provide protection against all filoviruses, the Profectus vaccine contains a blend of three rVSVN4CT1 vectors expressing the G proteins from S-EboV, Z-EboV, and MarV. In support of animal model development, Profectus provided the Z-EboV-rVSVN4CT1 and MarV-rVSVN4CT1 vaccines for two FANG-coordinated non-human primate challenge studies conducted under NIAID’s preclinical services program. In the first study, a single IM dose of the Z-EboV-rVSVN4CT1 vaccine completely protected 3 cynomolgus macaques against challenge 28 days later with a lethal dose (1,000 pfu) of low passage Z-EboV, while 3 non-vaccinated macaques succumbed to lethal disease. Twenty eight days after the first challenge, the protected macaques were

then challenged with a lethal dose (1,000 pfu) of low passage S-EboV. Two of three were protected, even though S-EboV is distantly related to Z-EboV. In the second study, a single dose of the MarV-rVSVN4CT1 vaccine completely protected 2 cynomolgus macaques against lethal challenge 28 days later with low passage MarV, while 2 non-vaccinated macaques succumbed.

Dr. Eldridge commented: "Profectus is indebted to the NIH for providing the grant funding that allowed us to bring the tri-valent N4CT1-vectored filovirus vaccine to late stage preclinical development, and to the FANG for including our vaccine in their challenge studies. To my knowledge, Profectus has the only vaccine platform that to date has demonstrated single dose protection against the highly virulent, low passage viruses that will be the standard for licensure. I also wish to acknowledge the contributions made by Drs. Heinz Feldmann of the NIH Rocky Mountain Laboratories and Thomas Geisbert of the Galveston National Laboratory. Without their help and collaboration we would not have obtained the early protection data needed for our investment in this program".

About the Profectus vesiculovirus-vectored vaccine delivery platform

The Profectus rVSV vaccine delivery vector is a replication competent form of the Indiana serotype of VSV that has been genetically attenuated for safe human use (rVSV_{IN}N4CT1). This vector has now been shown to be safe and immunogenic in normal healthy adults and will soon be tested as a therapeutic in HIV infected subjects. Profectus has also identified additional vesiculovirus vectors that are immunologically non-cross reactive with VSV, and that have been attenuated using similar genetic manipulations. This family of vectors has been designed to rapidly induce high level antibody responses specific for the surface glycoproteins of emerging infectious disease and bio-threat agents such as those causing viral hemorrhagic fever (Ebola, Marburg, Lassa), viral encephalitis (VEE, EEE, and WEE), and viral arthralgic disease (Chikungunya).

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 Profectus BioSciences, Inc.

Enabled by an experienced development team and two propriety platform technologies in-licensed from Wyeth Vaccines (now Pfizer, Inc.), Profectus BioSciences Inc. is developing the next generation of vaccines for high value unmet targets in biodefense, infectious and emerging diseases.

The two in-licensed platforms greatly enhance the immunogenicity of prophylactic and therapeutic vaccines. They consist of first-in-class vaccines vectored with vesiculoviruses such as vesicular stomatitis virus (VSV), and best-in-class pDNA vaccines enhanced by the co-administration of GENEVAX IL-12™ and

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delivery with electroporation. Depending on the disease target, the pDNA and vesiculovirus-vectored vaccines are used singly or in prime/boost combination. As part of the in-licensing transaction, two NIAID contracts were novated from Wyeth to Profectus, totaling \$16,591,707. These funds have advanced the pDNA and vesiculovirus vector programs through phase 1 safety and immunogenicity testing, both individually and in prime/boost combination.

Profectus' two lead programs, heavily supported by non-dilutive funding, consist of a therapeutic HIV vaccine in clinical evaluation to address the HIV "Cure Agenda" and a VSV-vectored vaccine for single dose pre- and post-exposure protection against the Category A threat agents Ebola and Marburg viruses. The company's rVSV-vectored Ebola and Marburg vaccines have provided 100% protection of monkeys against lethal challenge with these agents when tested by the US Government.

Additional programs in development include vaccines against Lassa and Chikungunya viruses utilizing the vesiculovirus platform, and vaccines against human papilloma viruses (HPV) and herpes simplex virus type-2 (HSV-2) using the pDNA prime/vesiculovirus vectored boost platform.

The Profectus HIV pDNA vaccine program has been supported through the award of a \$19 M HIV Vaccine Design and Development Teams (HVDDT) contract (HHSN272200800062C), was novated from Wyeth to Profectus, and has supported the research, development, and manufacturing costs of the multi-antigen HIV vaccine and GENEVAX™ IL-12 programs. The Profectus HIV rVSV vaccine program has been supported through the award of an \$8.7 M HVDDT contract (HHSN272200800061C) from the NIH. 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. More information is available at www.ProfectusBioSciences.com.

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Contact:

Jeffrey N. Meshulam
President Profectus BioSciences, Inc.
443-743-1107
Meshulam@profectusbiosciences.com