

## **Profectus BioSciences Receives NCI Small Business Innovative Research Grant to Develop Therapeutic HCV Vaccine**

*Funding to Support a Non-Human Primate Study of the Profectus pDNA Prime/rVSV Boost Therapeutic HCV Vaccine Administered as an Adjunct to Various Anti-HCV Drug Regimens*

**Baltimore, MD – April, 2012** – Profectus BioSciences, Inc., a leader in the development of therapeutic and preventive vaccines against infectious diseases, announced today that it has received a Small Business Innovative Research (SBIR) Grant from the National Cancer Institute to support the development of its proprietary “prime/boost” vaccination strategy to treat chronic infection with Hepatitis C Virus (HCV). The vaccine employs DNA plasmids (pDNA) encoding HCV components and the regulatory cytokine interleukin-12 (IL-12) delivered with electroporation (EP) to “prime” the immune system. This is followed by a “boost” immunization with the HCV components delivered by a replication competent recombinant vesicular stomatitis virus (rVSV) vector. Using recombinant genetic techniques Profectus scientists have made the rVSV vector safe for human use by introducing multiple attenuating modifications to its genome. The prime/boost HCV vaccine strategy is designed to induce a potent cell-mediated immune (CMI) response that is resistant to the immunologic tolerance that characterizes chronic HCV infection.

### **About HCV Infection**

HCV is the infectious agent responsible for most transfusion-associated non-A, non-B hepatitis, and it is the most common chronic blood-borne infection of humans. The World Health Organization estimates more than 170 million individuals worldwide, and more than 4 million in the US, are chronically infected. HCV accounts for 40% to 60% of chronic liver disease in the US, and chronic liver disease is currently the tenth leading cause of death among adults. HCV is the most frequent indication for liver transplantation in US; the number of patients on transplant waiting lists has doubled in the past 5 years, and about half of these patients die while awaiting an organ. There are multi-drug regimens that can clear HCV infection in some patients when administered for 24 to 48 weeks, but all the effective combinations include interferon-alpha (INF). The side effects of IFN treatment are so debilitating that it cannot be used in approximately 50% of those in need of treatment. The Profectus pDNA prime/rVSV boost vaccine is designed to replace INF in the drug regimens.

### **About the Profectus HCV Vaccine**

Individuals that successfully clear HCV infection exhibit a CMI response directed against conserved portions of the HCV non-structural (NS) proteins. The Profectus pDNA prime/rVSV boost vaccine targets the subset of HCV NS proteins most highly conserved across HCV genotypes to provide a universal vaccine for world-wide use. In individuals that become chronically infected with HCV the immune

response is aborted because of the tolerance-inducing environment in the infected liver. IL-12 is included in the Profectus HCV vaccine because it is both a powerful enhancer of immunity and because it is a potent inhibitor of tolerance induction. The studies funded under this SBIR grant will address the timing of the prime/boost vaccination in relation to the course of anti-HCV drugs. This information is intended to help in the design of a clinical trial under active planning.

Dr. John Eldridge, Chief Scientific Officer, said: "Profectus currently has three HIV vaccine clinical trials in progress and a fourth that will initiate within 10 days. We are systematically validating the safety and immunogenicity of our pDNA and rVSV vaccine platforms, both individually and in prime/boost combination. The clinical data gained over the next 6 months, along with the IND-supporting non-human primate study performed under this grant effort will allow us to quickly and efficiently test our therapeutic HCV vaccine in the clinic."

**About Profectus BioSciences, Inc.**

[Profectus BioSciences, Inc.](http://www.ProfectusBioSciences.com) is a technology based vaccine company devoted to the treatment and prevention of infectious disease and related cancer, with the goal of reducing morbidity and mortality. Since its inception in 2003, the Company's strategic intent has been to acquire and develop the technologies needed to achieve this goal. The Company has licensed a group of vaccine-based technologies from Wyeth Vaccines (now Pfizer, Inc.) that greatly enhance the immunogenicity of prophylactic and therapeutic vaccines based on a "prime-boost" strategy. This strategy uses the delivery of a best-in-class pDNA vaccine to "prime" the immune system, followed by a first-in-class "boost" with an rVSV vector. Current disease and virus targets include hepatitis C virus (HCV), human papilloma virus (HPV), herpes simplex virus type 2 (HSV-2), human immunodeficiency virus (HIV), Ebola and Marburg viruses, and malaria. 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 PATH Malaria Vaccine Initiative, the HIV Vaccines Trials Network, and the AIDS Clinical Trials Group. More information is available at [www.ProfectusBioSciences.com](http://www.ProfectusBioSciences.com).

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