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Profectus BioSciences Announces Initiation of Phase I Clinical Trial to Evaluate Safety and Immunogenicity of a Vesicular Stomatitis Virus-vector HIV-1 Vaccine

Baltimore, MD – May 25, 2011 – Profectus BioSciences, Inc., a leader in the development of therapeutic and preventive vaccines against infectious diseases, and the HIV Vaccine Trials Network (HVTN) announced today the initiation of a phase 1 HIV vaccine study involving a recombinant vesicular stomatitis virus (rVSV). VSV, a type of arbovirus that can infect insects and mammals, is commonly used in laboratory settings to study viral evolution. The recombinant version used in this new vaccine study has been weakened, or attenuated, so as not to cause illness in animals or humans.

The new multi-center study, which is testing a novel rVSV vector, or carrier, expressing HIV-1 gag protein, is being sponsored by the National Institutes of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health (NIH). The study is being conducted by the NIAID-funded HVTN under a protocol designated HVTN 090.

The phase 1, placebo-controlled, dose-escalation study will enroll 60 HIV-uninfected adults. It will assess the safety and immunogenicity of increasing doses of the rVSV_{IN} HIV-1 gag vaccine administered by intramuscular injection. The vaccine was found to be safe and immunogenic in non-human primates and is the first vaccine based on an rVSV platform to be tested in humans.

Dr. John Eldridge, Chief Scientific Officer, said: "Profectus is very pleased to collaborate with the NIH and the HVTN in the development of the rVSV_{IN} HIV-1 gag vector as a prophylactic vaccine with the potential to block HIV infection. We are very excited about the future of the rVSV vector platform, because of its potential to induce long-lived immune responses in mucosal tissues, the portals of HIV-1 entry. This clinical study should provide a pathway for improved immunogenicity and efficacy in combination with our proprietary plasmid DNA vectors. "

About the rVSV_{IN} HIV-1 gag vaccine

The rVSV_{IN} HIV-1 gag vaccine consists of an attenuated replication competent form of the Indiana serotype of rVSV that expresses the HIV-1 gag protein. The vaccine was designed to elicit a robust cell mediated immune response to the HIV-1 gag protein, and will be supplied in frozen formulation to this proof-of-concept study. Ongoing studies are examining the potential to develop a freeze-dried formulation that will replace the frozen form, and greatly simplify distribution of vaccine to the developing world.

About the HVTN

The HIV Vaccine Trials Network (HVTN) is an international collaboration of scientists and educators searching for an effective and safe HIV vaccine. The HVTN's mission is to facilitate the process of testing preventive vaccines against HIV/AIDS. The HVTN conducts all phases of clinical trials, from evaluating experimental vaccines for safety and the ability to stimulate immune responses, to testing vaccine efficacy. Support for the HVTN is provided through a cooperative agreement from the National Institute of Allergy and Infectious Diseases (NIAID), part of the U.S. National Institutes of Health (NIH). The Network's HIV Vaccine Trial Units are located at leading research institutions in 27 cities on four continents. Internationally renowned HIV vaccine and prevention researchers lead the units.

About Profectus BioSciences, Inc.

[Profectus BioSciences, Inc.](#) 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), and malaria. The Profectus rVSV HIV-1 vaccine program has been supported through the award of a \$22.5M HIV Vaccine Design and Development Teams (HVDDT) contract HHSN272200800061C from the NIH that has supported the research, development, and manufacturing costs of the rVSV_{IN} HIV-1 gag vaccine.

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