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**Profectus BioSciences Bivalent Vaccine Protects Animals from Infection and Death After Exposure to Chikungunya or Zika Virus**

– Vaccine based on the company’s highly attenuated Isfahan virus (ISF) vector –

*BALTIMORE, Md., January 9, 2017* —Profectus BioSciences, Inc., a clinical-stage company developing novel vaccines for the prevention and treatment of infectious diseases and the treatment of cancer, and the University of Texas Medical Branch (UTMB), announced today the results of a preclinical study demonstrating that its bivalent VesiculoVax™-vectored Chikungunya/Zika virus vaccine protected animals after exposure to Chikungunya virus (ChikV) or Zika virus (ZikV). In this study a single dose of the bivalent VesiculoVax™-vectored ChikV/ZikV vaccine protected 100% of A129 IFN $\alpha$ R<sup>-/-</sup> mice from lethal chikungunya virus infection after exposure to the virus. In addition, a single dose of the bivalent VesiculoVax™-vectored ChikV/ZikV vaccine protected these same mice from disease and weight loss after exposure to the Zika virus.

The bivalent VesiculoVax™-vectored ChikV/ZikV vaccine is a mixture of the company’s and UTMB’s patented Isfahan virus (ISFV) vectors that have been engineered for safe use in humans. One ISFV vector in the mixture expresses the E2-E1 surface protein of ChikV, and the second vector expresses the prM/E gene of ZikV.

“Profectus is pleased to announce these results, which are an important step in the development of a prophylactic vaccine that will rapidly confer protection against ChikV and ZikV infection with a single administration,” said John H. Eldridge, PhD, Chief Scientific Officer of Profectus. “With the recent demonstration that the mosquito host can simultaneously carry both viruses, it is clear that a single vaccine to protect against both diseases provides a significant advantage in cost and efficiency of administration. This study demonstrates the preclinical efficacy of our attenuated VesiculoVax™-vectored ChikV/ZikV vaccine in a highly sensitive animal model. We have initiated the first steps in the manufacture and release of our VesiculoVax™-vectored ChikV/ZikV vaccine and are planning rapid clinical evaluation.”

**About the Chikungunya Virus**

In the December 2015 WHO Workshop on Prioritization of Pathogens, ChikV was designated as “serious,” requiring action by WHO to promote R&D as soon as possible. ChikV is a single-stranded, positive-sense RNA virus that belongs to the family *Togaviridae*, genus *Alphavirus*. ChikV is transmitted to humans via the bite of an infected mosquito from the *Aedes* genus; predominantly *Aedes aegypti* and *Aedes albopictus*. Nonhuman primates (NHP) and humans are likely the main virus reservoirs, and anthroponotic (human-to-vector-to-human) transmission occurs during outbreaks of the disease. ChikV often causes large outbreaks with high attack rates,

affecting one-third to three-quarters of the population in areas where the virus is circulating. Outbreaks of ChikV disease have occurred in Africa, Asia, Europe, and islands in the Indian and Pacific Oceans. In late 2013, the first locally acquired cases of ChikV were reported in the Americas on islands in the Caribbean. Since that time, ChikV has continued to spread in the Americas, with cases reported throughout the Caribbean and in several North, Central, and South American countries. Clinically, 3%–28% of people infected with ChikV will remain asymptomatic. For people who develop symptomatic illness, the incubation period is typically 3-7 days (range, 1–12 days). Disease is most often characterized by sudden onset of high fever [temperature typically >102°F (39°C)] and joint pain. Other symptoms may include headache, myalgia, arthritis, conjunctivitis, nausea, vomiting, or a maculopapular rash. Fevers typically last from several days up to one week and can be biphasic. Joint symptoms are often severe involving multiple joints with bilateral symmetry and can result in debilitating disease lasting for months. Currently, no specific antiviral treatment, preventative drug, or vaccine is available to combat ChikV infection and disease progression.

### **About the Zika Virus**

ZikV is a member of the Flavivirus family that was first isolated from a febrile sentinel rhesus monkey in Uganda in 1947. Like ChikV, ZikV is also transmitted to humans via the bite of an infected mosquito from the *Aedes* genus; predominantly *Aedes aegypti* and *Aedes albopictus*. In January 2016, the United States Centers for Disease Control and Prevention (CDC) issued travel guidance on affected countries, including the use of enhanced precautions and guidelines for pregnant women, including considering postponing travel. Primary ZikV infection is often mild in adults, with only a small percentage of those infected presenting as clinically symptomatic. Diagnosis is complicated by clinical similarity and geographic overlap with dengue and chikungunya infection. However, ZikV infection is associated with serious neurological complications. Adults may present with Guillain-Barré syndrome, and children born to mothers infected during pregnancy may suffer from severe underdevelopment of the brain (pediatric microcephaly). ZikV can be transmitted from men and women to their sexual partners.

### **About Profectus VesiculoVax™ Vaccines**

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 (Ebola, Marburg, and Lassa); encephalitic disease (Venezuelan, Eastern, and Western equine encephalitis); arthralgic disease (ChikV); and neurologic disease (ZikV). The Profectus VesiculoVax™ vaccine delivery technology is based on seminal discoveries made in the laboratory of Dr. John Rose and patented by Yale University. Building on these discoveries, Profectus scientists introduced multiple non-reversible genetic modifications into the prototype that synergistically attenuate the virus and provide vectors that are safe for human use. To extend the VesiculoVax™ platform, Profectus is conducting collaborative studies with scientists at the University of Texas Medical Branch (UTMB) that have identified additional vesiculoviruses with utility as vaccine vectors. The resulting VesiculoVax™ platform consists of a family of non-cross reactive vaccine vectors that are constructed and attenuated so they do not cause illness in animal or humans using methods exemplified with rVSV. Profectus has demonstrated the safety and immunogenicity of its VesiculoVax™-vectored vaccines against HIV and Ebola in multiple human clinical trials.

### **About UTMB Health**

Texas' first academic health center opened its doors in 1891 and today has three campuses, four health sciences schools, three institutes for advanced study, a research enterprise that includes one of only two national laboratories dedicated to the safe study of infectious threats to human health, a Level 1 Trauma Center and a health system offering a full range of primary and specialized medical services throughout Galveston County and the Texas Gulf Coast region. UTMB Health is a

part of the University of Texas System and a member of the Texas Medical Center. For more information, please visit [www.utmb.edu](http://www.utmb.edu).

### **About Profectus BioSciences**

Profectus BioSciences is a clinical-stage company developing preventive and therapeutic vaccines for infectious diseases and oncolytic vaccines for cancer immunotherapy. Profectus vaccines are based on the company's proprietary VesiculoVax™ and DNA vaccine delivery platforms. Used alone, 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 pDNA vaccines, VesiculoVax™-vectored vaccines lead to the expansion of primed T cells into effector cells that are uniquely suited to killing virally infected cells and cancers.

Current programs using the 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 Vyriad, 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 [www.profectusbiosciences.com](http://www.profectusbiosciences.com).

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