DEVELOPMENT OF A BI-VALENT LYOPHILIZED VESICULOVAX™ VECTORED VACCINE FOR THE PROPHYLAXIS OF CHIKUNGUNYA (CHIKV) AND ZIKA (ZIKV) VIRUS INFECTION

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Chikungunya virus (ChikV) and Zika virus (ZikV) are transmitted to humans via the bite of an infected mosquito from the Aedes genus. 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. Symptomatic ChikV disease is characterized by sudden onset of high fever and joint pain. Joint symptoms are often severe and can be debilitating and persistent. ZikV infection is associated with serious neurological complications such as Guillain-Barré syndrome and with pediatric microcephaly that have been reported to overlap with ZikV endemicity in South America. The ideal prophylactic vaccine would rapidly confer protection against both ChikV and ZikV infection with a single administration, would not require cold storage and would find application with medical personnel and close contacts during outbreaks in endemic areas of sub-Saharan Africa, South America, the Caribbean. Profectus BioSciences has begun to develop and evaluate a bi-valent VesiculoVax™ vectored vaccine for the prevention of ChikV and ZikV infection.

To test the immunogenicity of the bi-valent VesiculoVax™ vectored ChikV/ZikV vaccine candidate, Balb/c mice were vaccinated IM at study weeks 0 and 4 with $2 \times 10^7$ PFU of the bi-valent ChikV/ZikV vaccine. Over the course of the study, serum was collected and ChikV- and ZikV-specific antibody responses were measured by ELISA. Importantly, immunization with the bi-valent VesiculoVax™ vectored ChikV/ZikV vaccine elicited both ChikV- and ZikV-specific ELISA responses in all immunized mice after a single dose. Booster immunization with the bi-valent VesiculoVax™ vectored ChikV/ZikV vaccine increased both ChikV- and ZikV-specific ELISA responses by ~1-log. To test the efficacy of the bi-valent VesiculoVax™ vectored ChikV/ZikV vaccine candidate, A129 mice were vaccinated IM at study day 0 with $2 \times 10^7$ PFU of the bi-valent ChikV/ZikV vaccine. On study day 28, immunized mice will be challenged with 1,000 PFU CHIKV (LaReunion strain) or 1x10^5 pfu ZikV (Cambodian strain FSS13025).

The pre-clinical immunogenicity and efficacy of this novel bivalent VesiculoVax™ vectored ZikV/ChikV vaccine will be discussed. In addition, progress on the development of a lyophilized bi-valent ZikV/ChikV vaccine, advancement of the vaccine through manufacturing process development will also be discussed.