

FILOVIRUS VACCINES AND DIAGNOSTICS BASED ON GLYCOPROTEIN-FC FUSION PROTEINS

Technology Summary

Ebola virus is a member of the Filoviridae, a family of viruses classified as "Category A" bioterrorism agents that cause severe hemorrhagic fever in humans and nonhuman primates with high morbidity and mortality rates up to 90%.

Researchers at FDA developed an efficacious Filovirus subunit vaccine based on a recombinant protein consisting of the extracellular domain of the Filovirus glycoprotein fused to an Fc Fragment of human immunoglobulin (FiloGP-Fc). Vaccination with FiloGP-Fc elicited humoral and cellular immunity against Filoviruses. The FiloGP-Fc vaccine induced antibodies that bound and neutralized replication-competent recombinant G-deleted Vesicular Stomatitis Virus containing the Filovirus GP (rVSV-FiloGP), and protected animals against Filovirus lethal challenge. Also available are cellular and humoral immunity tests, as well as rVSV-FiloGP neutralization tests to evaluate anti-Filovirus immune responses in individuals.

Potential Commercial Applications

- Vaccines for protection against infections by Ebola Virus and other Filoviruses.
- Diagnostic tests for cellular and humoral immunity based on FiloGP-Fc and rVSV-FiloGP to evaluate anti-Filovirus immune responses in vaccinated and infected animals and individuals.
- Ideal substrates to evaluate immune responses in animals and vaccinees.

Competitive Advantages

- Although Filovirus vaccine candidates based on virus-like particles and virus vectors are currently under development by others, efficacious subunit vaccines have not yet been developed.
- The FiloGP-Fc fusion protein resembles the native glycoprotein expressed at the surface of cells and viral particles.

Development Stage: preclinical animal studies

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Publications:

"Ebola virus glycoprotein Fc fusion protein confers protection against lethal challenge in vaccinated mice" *Vaccine* 2011 Apr. 5;29(16):2968-77 PMID: <u>21329775</u>

Intellectual Property:

United States patent: US <u>9,347,951</u> B2, issued 05.24.2016 China patent: ZL201180063188.9, issued 09.07.2016 Germany, France, United Kingdom patent application: pending-allowed India patent application: 3983/CHENP/2013, filed 10.28.2011

Product Area: biologics

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