

Zika Synthetic DNA (SD)-prME Vaccine

Nonclinical Protection and Clinical Immunogenicity

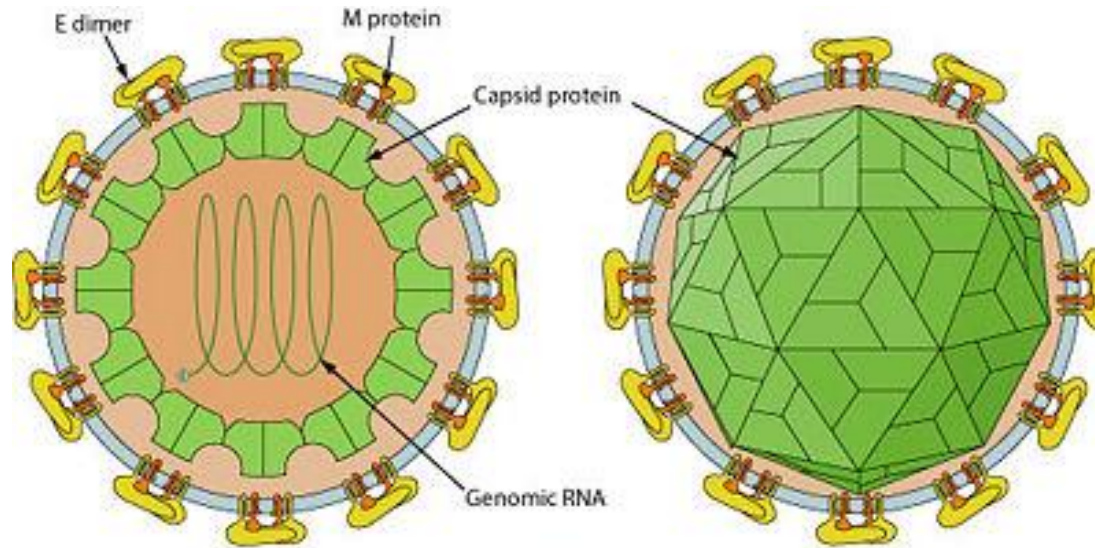
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VP Clinical Development



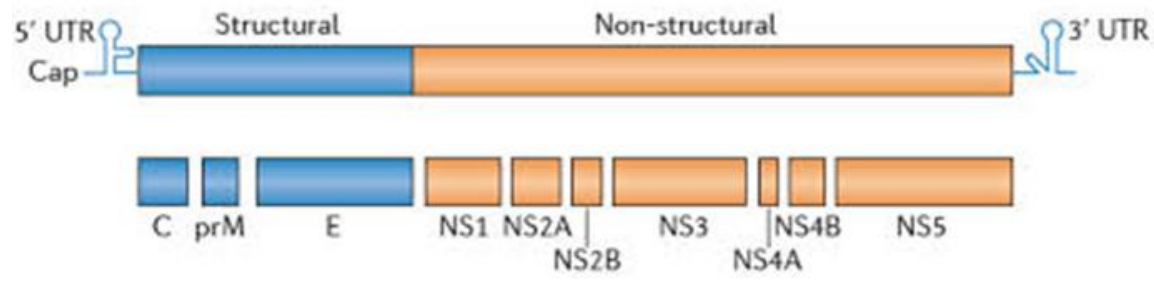
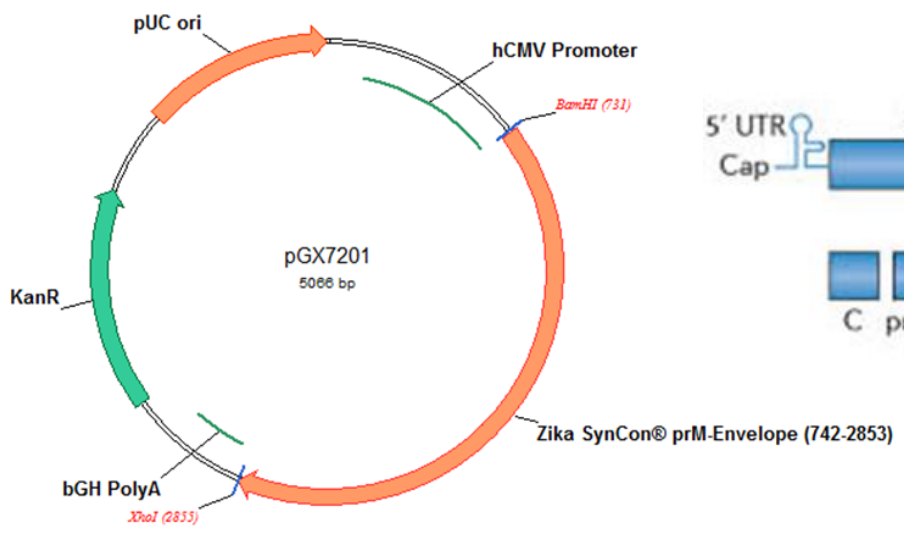
진원생명과학(주)
GeneOne Life Science



Zika Virus Structure and Vaccine Antigen

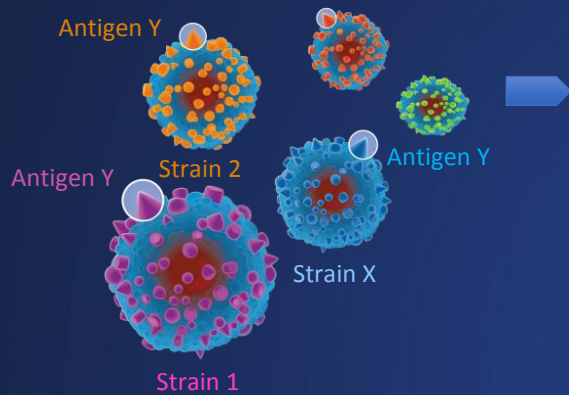


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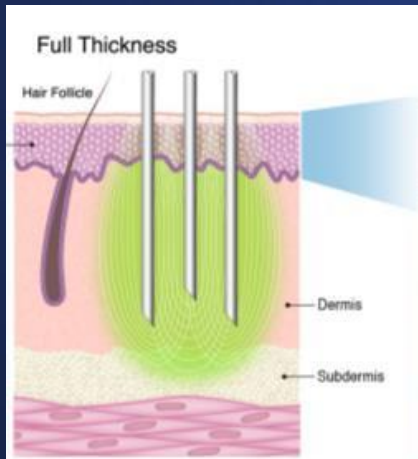
Immune Responses by Design: Antigen-Specific, Optimized, Best-in-Class



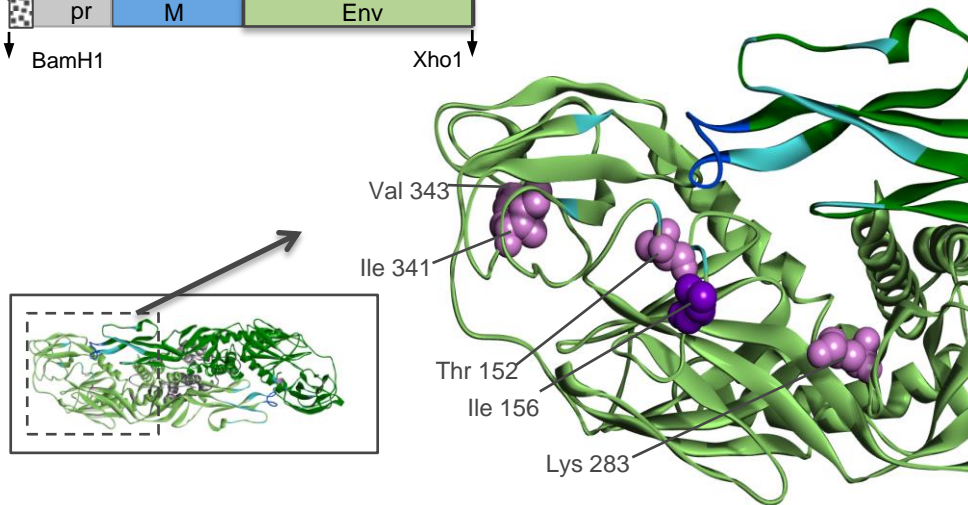
Identify gene sequence of selected antigen(s) from chosen strains/variants of the virus/cancer

Virus/cancer strain: synthetic Antigen gene sequence: consensus AMEKIVILLFAIV...SL

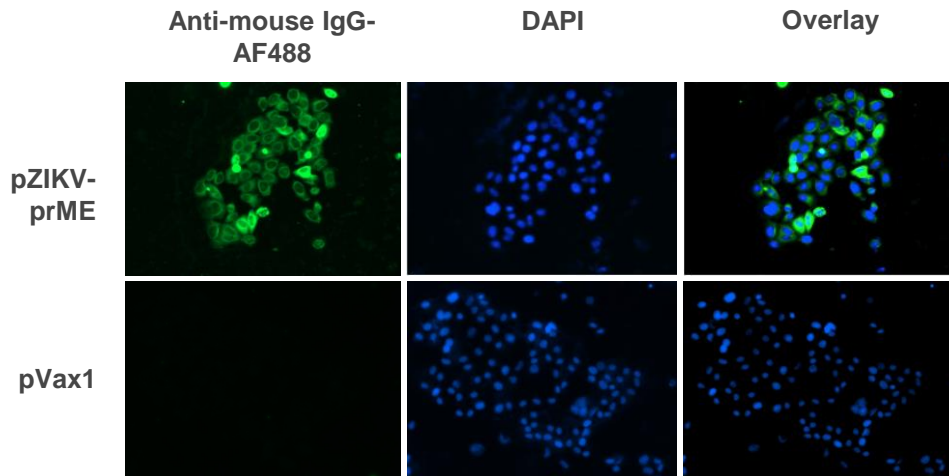
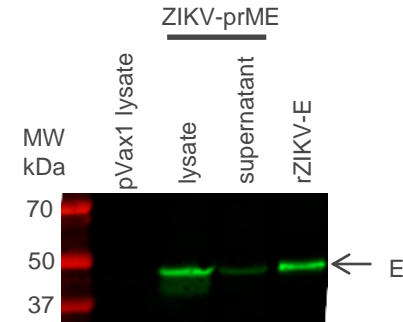
Synthetically create optimal consensus gene sequence for the selected antigen



ZIKA Virus SD-prME vaccine



- E Subunits
- Epitope
- Fusion Loop
- SynCon-prME
- Epitope + SynCon-prME

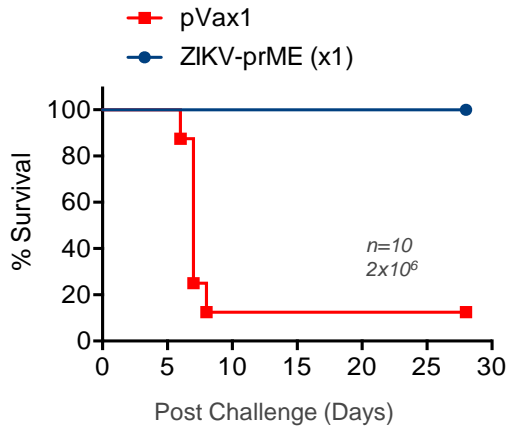


Novel, synthetic, DNA vaccine targeting the pre-membrane + envelope proteins of ZIKV expresses well and reacts with relevant antibodies to Zika E antigen domains

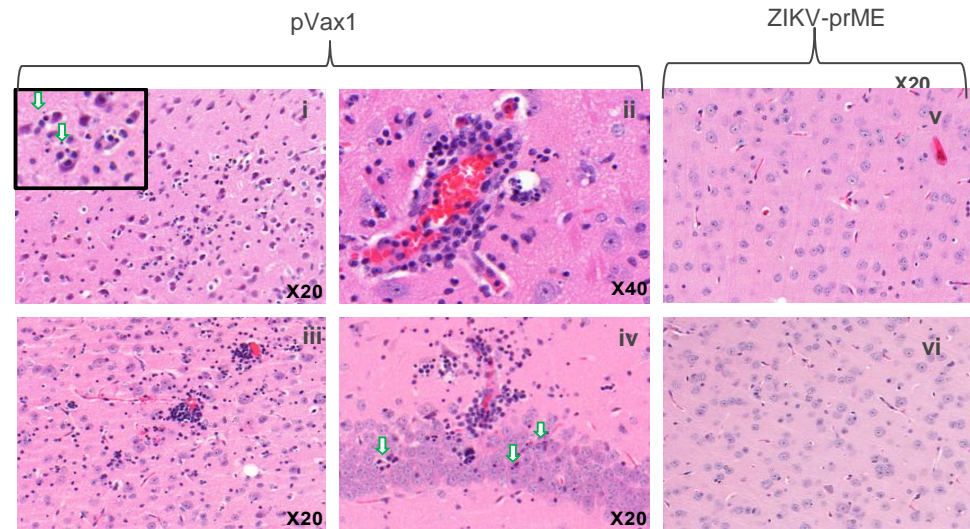
Single Dose SD-prME vaccination protects against Zika challenge induced VL & pathogenesis in brain, testes & death in INFAR -/- model



Vaccine protects from lethality



Vaccine is protective in brain



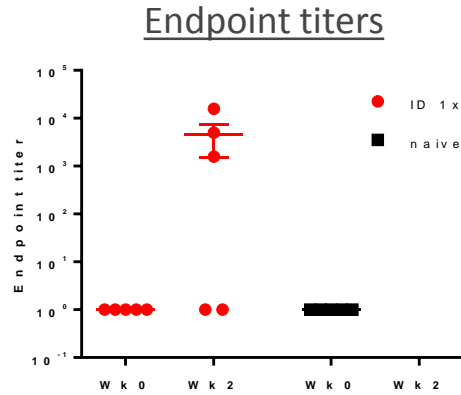
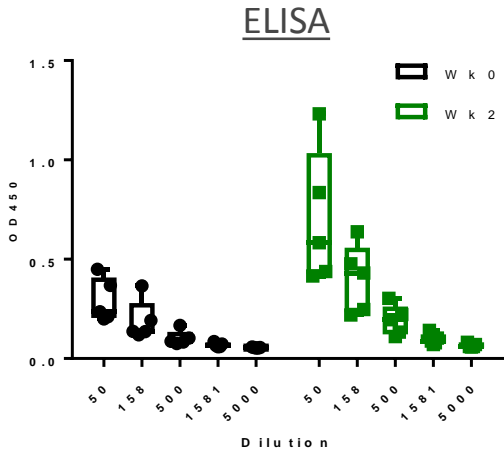
Vaccine is protective in testes



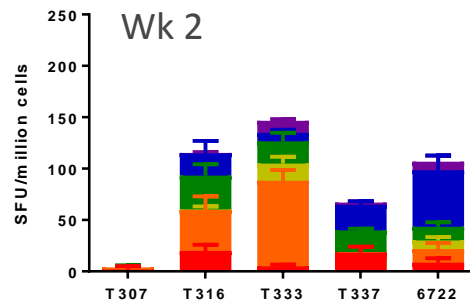
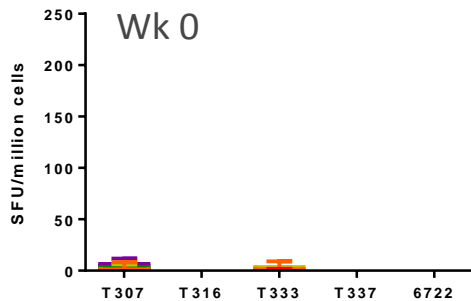
- ZIKV infection causes severe brain and testis pathology
- **Single immunization** with SD prME vaccine lowers viral load, preserves brain and testicular tissue and protects from death



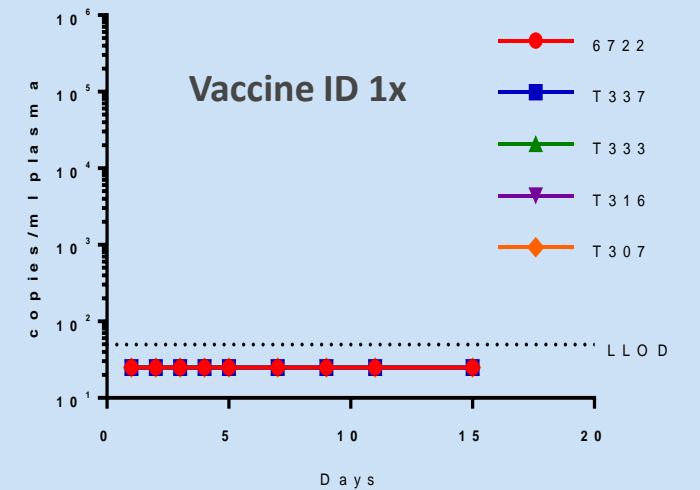
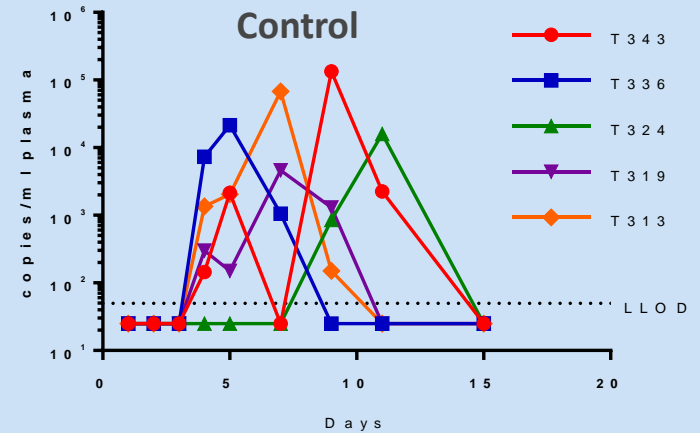
Intradermal Single Dose SD-prME Protects Against Viremia



IFN γ ELISPOT



Challenge Week 4



Note: If viral load was undetectable (<50 copies), it was assigned a value of 25 for graphing purposes

FDA approves first human trial for Zika vaccine

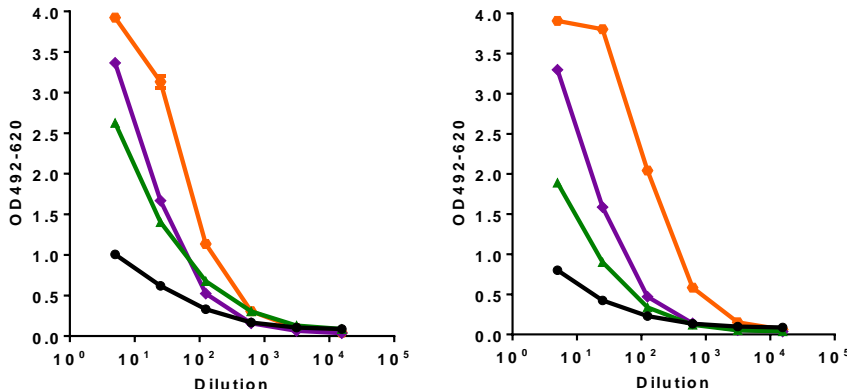


A phase I, open-label, dose-ranging study with 40 healthy subjects evaluating the safety, tolerability and immunogenicity of vaccine administered by the ID/EP route- this vaccine showed it was tolerable and immunogenic in this study.

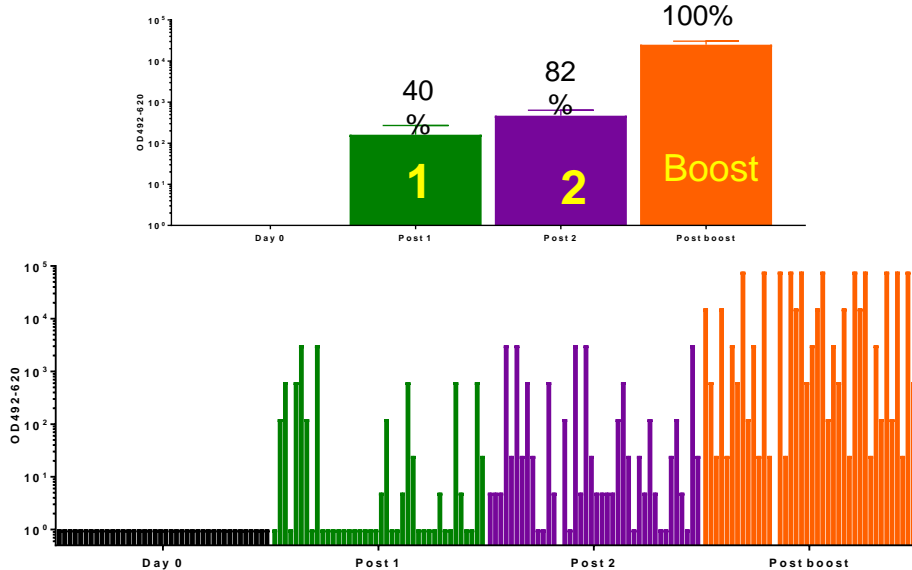
A second study opened in Puerto Rico and will enroll 160 adult patients. Half of the patients will receive the Zika vaccine and the other half will receive placebo.

Interim Analysis: Clinical Responses to SD-prME Zika Vaccine

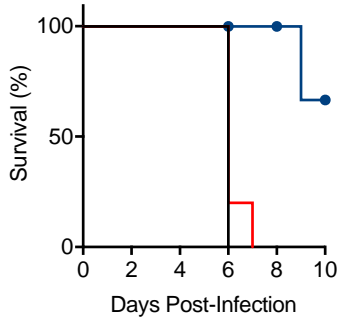
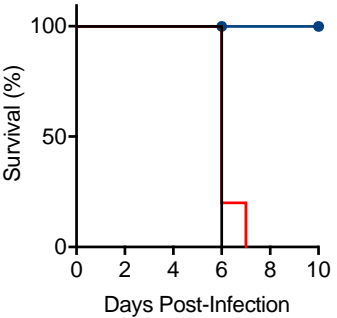
Binding ELISA



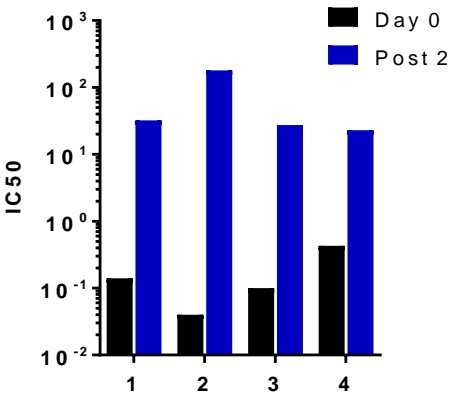
Characterization % Binding responders:



Passive Transfer & Protection



Neutralization Post Dose 2



Summary

- Synthetic DNA prME vaccines generate protective immunity against Zika Virus
 - Rapid seroconversion & neutralizing activity
 - Robust T cell responses recognizing multiple epitopes in Zika prME
- Single vaccination induces 100% protection from pathogenesis (including neuronal & testicular disease), and death & suppression of VL in INFAR^{-/-} murine model
- Single ID prME immunization 100% protective in NHP Zika challenge
- Ab responses from immunized NHP are protective in serum transfer experiments
- ID delivered SD prME in Phase I appears well tolerated and immunogenic

Acknowledgements

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