VBI VACCINES

A Prophylactic Human Cytomegalovirus (HCMV) Vaccine Designed to Prevent Congenital Infection Using Enveloped Virus-Like-Particles (eVLPs) by Inducing Potent Immunity Greater Than Natural Infection

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Introduction

Virus-like particle (VLP) vaccines have evolved considerably since their introduction in the early 1990s.

1ST GENERATION

- Design: Antigens are produced and self-assemble
- Key Advantage: Simple structures and repetitive pattern of antigenic epitopes
- Key Limitation: Only a very limited number of antigens spontaneously form orderly VLP structures; cannot be applied to all enveloped viruses
- Examples: Gardasil®, Cervarix®, Engerix-B®, and Recombivax HB®

2ND GENERATION

- Design: Antigens of interest are covalently attached to the surface of a backbone protein
- Key Advantage: Can be applied to multiple different target antigens; VLP structure is not limited to the properties of the antigen
- Key Limitation: Antigen of interest is artificially bound to the structural protein and not represented in a natural configuration
- Example: Qb VLP Platform

3RD GENERATION – VBI

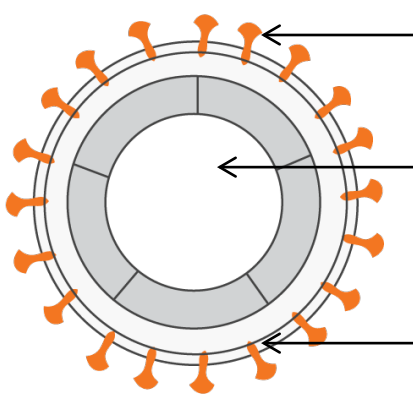
- Design: Common protein backbone and a lipid membrane in which the antigen of interest can be expressed
- Key Advantage: Enables a more natural presentation of the target antigen within a membrane that more closely mimics a virus; can be used to express multiple target antigens in a single VLP
- Limitation: More effort required in purification to meet FDA/EMA standards
- eVLP Ideal Candidates: CMV, HCV, Dengue, RSV, and West Nile

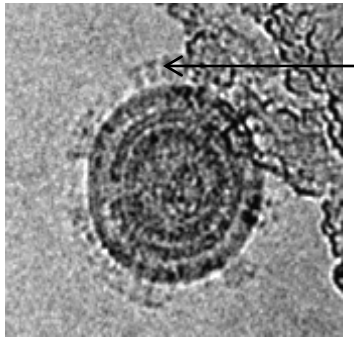
eVLP Platform

eVLPs are a third-generation class of synthetic vaccines that closely resemble the structure of the virus they mimic.

eVLP PLATFORM HIGHLIGHTS

- Same size and structure as enveloped viruses
- Present antigens in their natural state (lipid bilayer) to provoke an optimal immune response
- In animal research, demonstrated ability to trigger strong, broadly neutralizing antibodies in multiple preclinical models (CMV, HCV, and Flu)
- Suitable to a wide array of viruses including CMV, HCV, Dengue, RSV, and West Nile
- Strong intellectual property estate





Top: eVLP Diagram – the foundation of the eVLP technology is a stable, protein-based core on which additional vaccine antigens of interest can be added; Bottom: Electron microscopy image of VBI's CMV eVLP captured by NanoImaging Services.

Medical Need

Cytomegalovirus (CMV) is a common virus that can cause serious, life-threatening complications in persons with weakened immune systems.

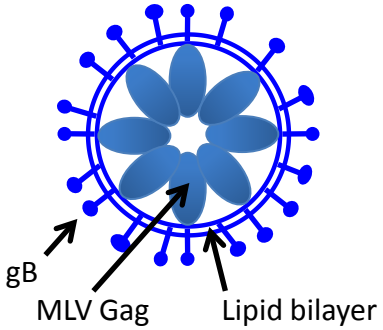
PERSONS LIKELY TO DEVELOP CMV COMPLICATIONS

- **Congenital CMV:** Unborn babies whose mothers become infected with CMV during pregnancy are at high risk
  - Congenital CMV infection causes more long-term problems and childhood deaths than Down Syndrome or Fetal Alcohol Syndrome
  - In the U.S., congenital CMV causes one child to become disabled every hour
- **Immunocompromised:** A primary CMV infection can cause serious disease in organ and bone marrow transplant recipients, cancer patients, and patients receiving immunosuppressive drugs

Overview of eVLP Design and Production

- eVLPs are produced after transient transfection of cells (e.g. HEK 293, CHO, Vero) with plasmids encoding:
  - MLV Gag
  - Extracellular domain of gB protein fused with transmembrane (TM) domain of vesicular stomatitis virus G protein (VSV-G)
- Presence of VSV TM domain enhances targeting to cell membrane and optimal protein conformation (greater induction of neutralizing antibodies)
- MLV Gag expression induces “budding” of particles from lipid raft domain of transfected cells, with CMV gB protein incorporated into the final eVLP structures
- Formulation of eVLPs with alum phosphate (VBI-1501A) provides product stability *in vitro* and enhanced durability of immunity *in vivo*

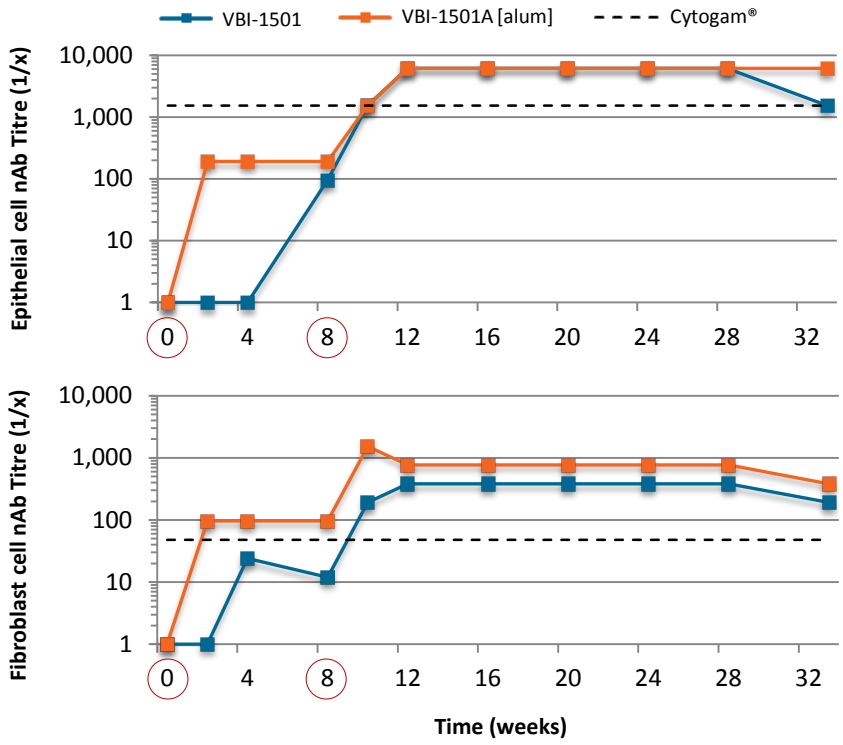
Monovalent gB-G eVLP Vaccine Candidate (VBI-1501)



VBI-1501A: Rapid, Potent, and Durable Immunity

- VBI-1501/A were produced using a GMP compliant HEK 293 cell line and purified to meet FDA standards
- Pooled sera from vaccinated mice (n=8) were tested for the ability to neutralize CMV infection in both Fibroblast and Epithelial cells, two clinically relevant cell types susceptible to CMV infection

VBI-1501A elicits rapid, potent, and durable neutralizing antibody titers, which exceed naturally acquired levels of immunity (Cytogam®) after two immunizations (weeks 0 and 8) in mice.



Successful Optimization of Yield at GMP Manufacturer

- Optimization study improved gB yield ~4X while maintaining optimal gB/Gag ratio

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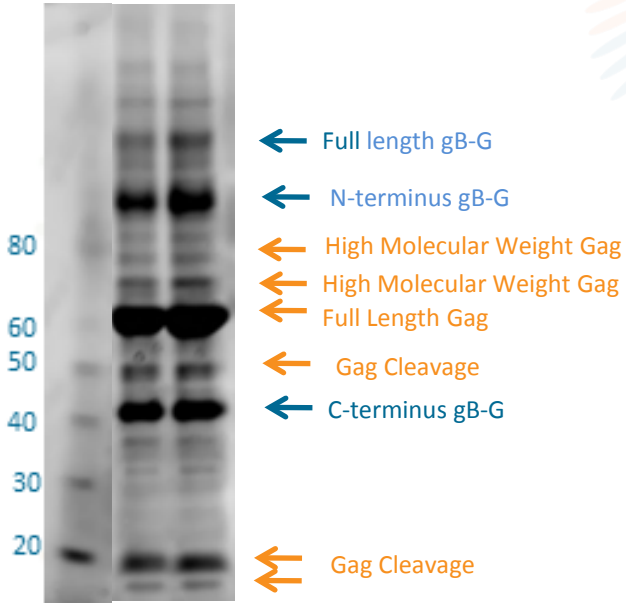
Regulatory Compliant Purity Achieved

eVLP Purification Scheme

- **Centrifuge** — Remove cells/debris
- **Tangential flow filtration** — Purify eVLPs from soluble proteins
- **Benzonase/βPL Tx & diafiltration** — Inactivate/remove residual DNA
- **Ultracentrifugation** — Purify eVLPs from residual host cell proteins
- **Sterilize (filter)**

SDS-PAGE of VBI 1501



CMV Program Summary

- Rapid, potent and durable immunity demonstrated with both drug substance (VBI-1501) and drug product (VBI-1501A)
- Pilot scale(10L) production of VBI-1501 meets Phase I release criteria
  - gB to Gag Ratio a key determinant of potency
  - Purity:
    - Residual DNA: Target <10ng/dose Actual: 5.8ng/dose
    - Residual HCP: Target <500ng Actual: 5ng/dose
- Stability:
  - Confirmed in vivo stability of drug substance (VBI-1501) after 6 mo @ -20°C
- **Planned IND submission / Phase I start in Q4 2015**

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