VBI VACCINES

IMMUNO-ONCOLOGY SUMMIT

eVLP DELIVERY OF NOVEL FOREIGN ANTIGENS ELICITS POLYVALENT ANTI-TUMOR IMMUNITY

NASDAQ: VBIV
TSX: VBV

AUGUST 2016

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Leading Vaccine & Immunology Innovation in Significant Markets with High Unmet Need

TECHNOLOGY PLATFORMS

- **Enveloped Virus-Like Particle ("eVLP")** platform closely mimics viruses and induces potent and durable immune responses
- **Thermostable Lipid Particle Vaccine ("LPV™")** platform enables thermostable delivery, and increased access, safety, and efficacy

PIPELINE

- **Hepatitis B Vaccine:** 3rd generation vaccine targeting non-responders to Standard of Care
- **Congenital CMV Vaccine:** Target young women to prevent a leading cause of birth defects
- **GBM Therapeutic:** Therapeutic vaccine for most common brain tumor type
- **Zika Vaccine:** Prevent birth defects caused by congenital Zika infection

LPV™ COLLABORATIONS

- Broad research collaborations to confer thermostability and enhance stability of key vaccine programs with:
  - Sanofi Pasteur
  - GSK

MANAGEMENT

- **World-class leadership:** Dr. Steve Gillis, Steve Rubin, Jeff Baxter, Dr. Michel De Wilde, and Dr. David Anderson
- **Scientific Advisory Board:** Dr. Florian Schödel and Dr. Stanley Plotkin

About VBI Vaccines

FINANCIAL OVERVIEW (as at close 8/18/2016)

- Traded on Nasdaq (VBIV) and TSX (VBV.TO)
- Current Nasdaq share price: $3.88
- Market Cap: $140MM
- 3 Month Average Volume: 71,714 shares

HEADQUARTERS – CAMBRIDGE, MA

- CEO, CSO, CTO, CFO + 4 FTEs
- Central location in biotechnology hub

RESEARCH OPERATIONS – OTTAWA, CANADA

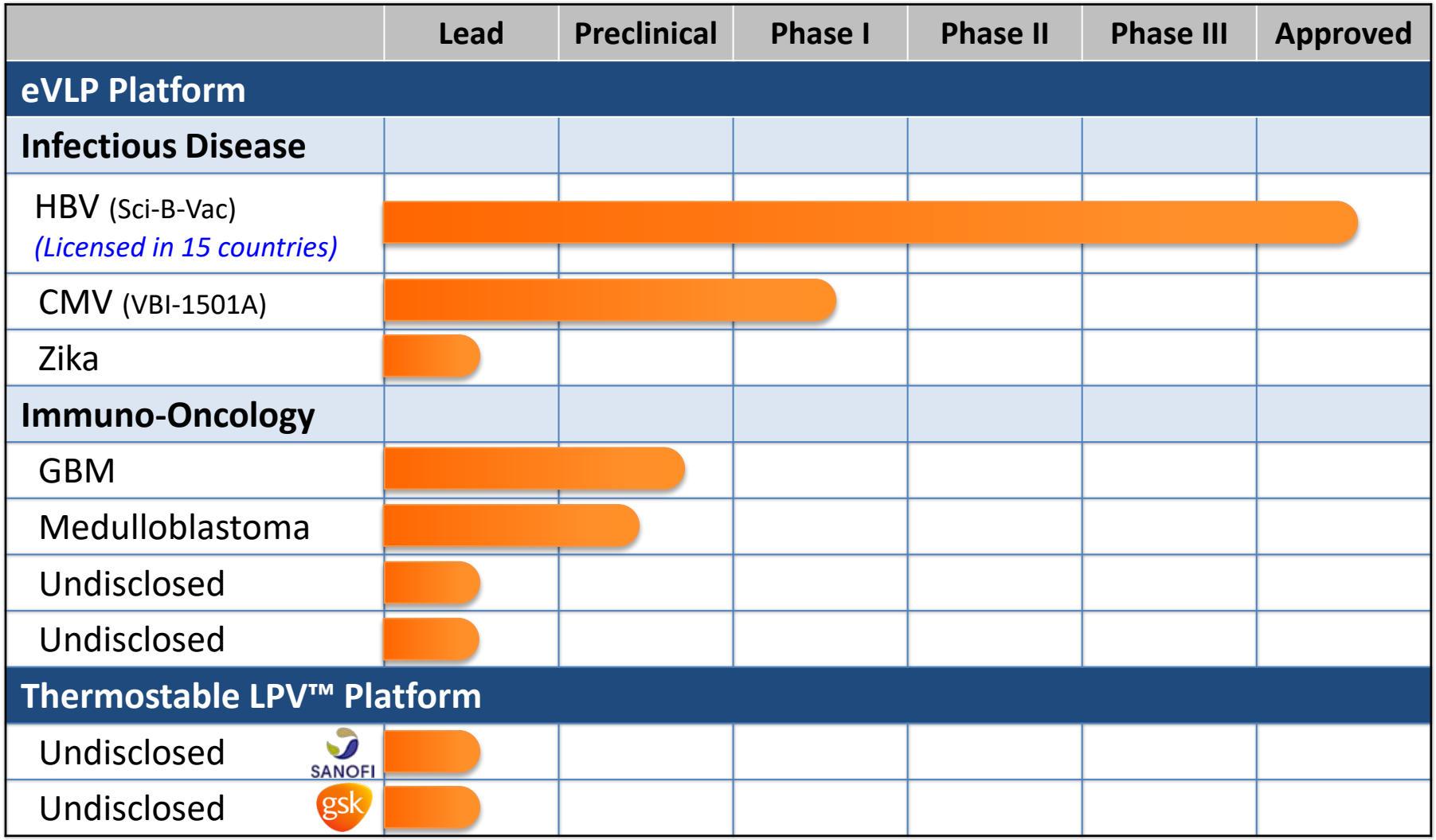
- CMO + ~25 FTEs
- World-class R&D team and facility

MANUFACTURING FACILITY – REHOVOT, ISRAEL

- ~50 FTEs
- GMP manufacturing facility for the production of Sci-B-Vac™ and for contract services

VBI Vaccines Pipeline

Multiple Opportunities in Infectious Disease and Oncology



Overview

VBI-1901 provides an off-the-shelf, highly potent, immuno-oncology vaccine capable of addressing multiple solid tumors

- Breakthrough immuno-oncology therapy depends on appropriate antigen selection
  - Past cancer vaccines focused on weakly immunogenic “self” antigens (TAA)
  - Success of PD-1/PD-L1 therapy is built on a tapestry of “not-quite-self” neoantigens
  - Like neo-antigens, foreign viral antigens are inherently more immunogenic than TAA
- CMV provides ideal target antigens suitable for multiple solid tumors:
  - CMV is highly immunogenic
  - CMV is expressed on over 95% of glioblastomas, breast cancer & medulloblastoma tumors
- Presentation matters, eVLP technology allows:
  - Customized presentation of multiple antigens in a highly potent virus like particle
  - eVLP particles recruit & activate dendritic cells
- VBI-1901 utilizes highly potent CMV antigens for an “off-the-shelf” cancer vaccine
  - Currently in late stage preclinical development, with pre-IND meeting completed
  - Builds on VBI’s lead prophylactic CMV vaccine (VBI-1501a), now in Ph I development

Antigen Selection:

Breakthrough Immunotherapy Depends on Appropriate Antigens to Target Anti-Tumor Immunity

The Immuno-Oncology Renaissance Depends on an Ability to Direct Anti-Tumor Immunity via Appropriate Antigen Selection

Historic Context of Cancer Vaccines

- Historically, cancer vaccines have consisted of weakly immunogenic "self" tumor associated antigens (TAA)
  - Central tolerance naturally opposes potent responses to "self" TAA
- Recently, PD-1 & CTLA-4 success explained by mutation frequency – "NeoAntigens"
  - Occur in frequently mutating/inflamed/"hot" tumors
  - Lead to potent "vaccine-like" immunity in the context of PD-1 or CTLA-4
  - Must be personalized, time consuming, cancer doesn't wait
- Foreign viral antigens are inherently "hot"
  - Our body has vigorous anti-viral immunity
  - Opportunity for off the shelf therapy
- ***Tumor-associated viral antigens ("TAVA") make an ideal antigenic target***

Nature Review Article on "NeoAntigens":
Schumacher & Schrieber, Science, April 2015

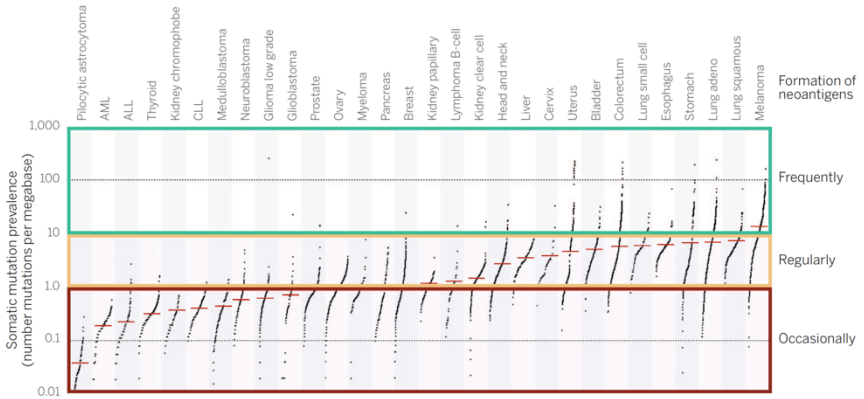
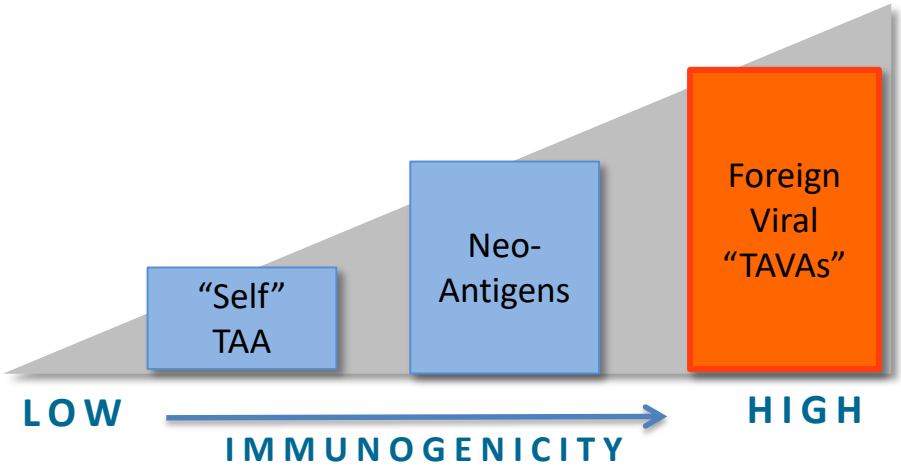


Fig. 2. Estimate of the neoantigen repertoire in human cancer. Data depict the number of somatic mutations in individual tumors. Categories on the right indicate current estimates of the likelihood of neoantigen formation in different tumor types. Adapted from (*50*). It is possible that the immune system in melanoma patients picks up on only a fraction of the available neoantigen repertoire, in which case the current analysis will be an underestimate. A value of 10 somatic mutations per Mb of coding DNA corresponds to ~150 nonsynonymous mutations within expressed genes.



Ideal Features of CMV as a "TAVA" in GBM & Beyond

CMV is Highly Immunogenic

- CMV stimulates powerful immunity – 1-2% of circulating T-cells in infected individuals[1]
- CMV – gB: Predominant antibody & CD4+ T-cell target on CMV
- CMV – pp65: Highly immunogenic CD8+ T-cell target

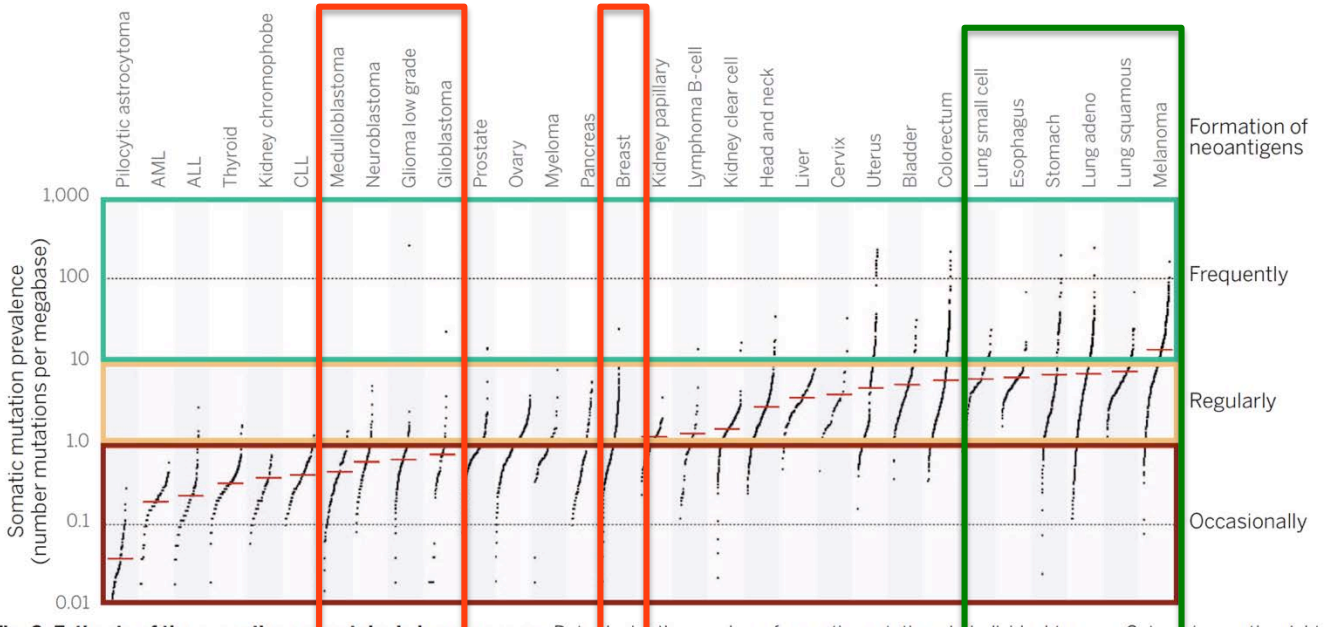
CMV is Highly Expressed in Multiple Solid Tumors

- CMV is highly expressed (> 90%) on multiple solid tumors:
  - Glioblastoma (GBM)[2]:
  - Medulloblastoma[3,4]
  - Meningioma[4]
  - Neuroblastoma[5]
  - Breast cancer[6,7]

Sources: 1) Sylwester AW (2005) J Exp. Med. 202, 673-685 ; 2) Cobbs CS(2013) Curr Opin Oncol 25, 682; 3) Baryawno N(2011) J Clin Invest 121, 4043-4055; 4) Libard S(2014) PLoS ONE 9, e108861; 5) Wolmer-Solberg (2013), Int J Cancer 133, 2351-61 6_ Taher C(2013) J Clin Virol 54, 240; 7) Harkins LE (2010) Herpesviridae 1, 8

Leveraging CMV Tumor Associated Viral Antigens Provides Opportunity to Attack Tumors NOT Predicted to be Susceptible to PD-1/CTLA-4 Alone

PD-1/CTLA-4 Success Rate is Dependent on Availability of Suitable Antigens



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>90% CMV Positive[1,2,3,4,5]:
Great potential for VBI-1901

Success with PD-1

1) Wolmer-Solberg N, et al.Int. J Cancer. Nov 15;133(10):2351-61, 2) Libard, et al. PLoS ONE 9, e108861

3) Cobbs CS(2013) Curr Opin Oncol 25, 682; 4) Baryawno N(2011) J Clin Invest 121, 4043-4055; 6) Taher C(2013) J Clin Virol 54, 240; 7) Harkins LE (2010) Herpesviridae 1, 8

VBI-1901:

Unmet Medical Need & Construct Design

VBI – 1901: Addresses Multiple Unmet Medical Needs

Glioblastoma (GBM)

- GBM is the most aggressive form of brain cancer
- Median overall survival is 14.6 months, only 30% will live two years[1]
- Standard of care is Temodar + surgery
- ~90% of patients will experience recurrent GBM[2]
- Market is predicted to grow to $623M by 2020[2]

Multiple Brain Cancers[3]

- Medullo-blastoma is a common pediatric brain cancer, representing 18% of all diagnosis[3]
- Meningioma: represent one third of all primary brain tumors
- Neuroblastoma: accounts for 6% of all cancers in children[4]

Breast Cancer

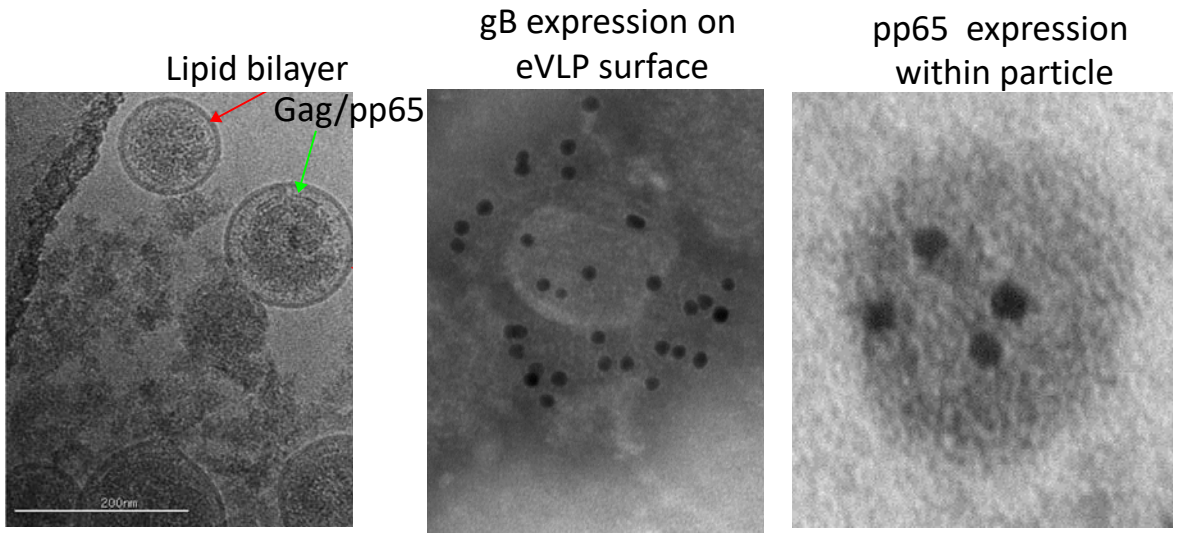
- 12% of women will experience breast cancer, with an incidence of 71.2/100,000[5]
- Despite advances in therapeutics, metastatic breast cancer still carries a 24.3% 5 year survival[6]
- Market (7MM) is predicted to grow to $13.1 billion by 2020[7]

1. http://www.abta.org/brain-tumor-information/types-of-tumors/glioblastoma.html
2. GBI Research: Glioblastoma Multiforme Therapeutics in Major Developed Markets to 2020
3. http://www.abta.org/brain-tumor-information/types-of-tumors/medulloblastoma.html
4. http://www.cancer.org/cancer/neuroblastoma/
5. Youlden et al., 2012
6. National Cancer Institute Report, 2013
7. GBI Research: Breast Cancer Therapeutics Maj Mkts to 2020

VBI-1901: A Rationally Designed Therapeutic CMV Vaccine

Highly potent antigens delivered in a next-generation VLP

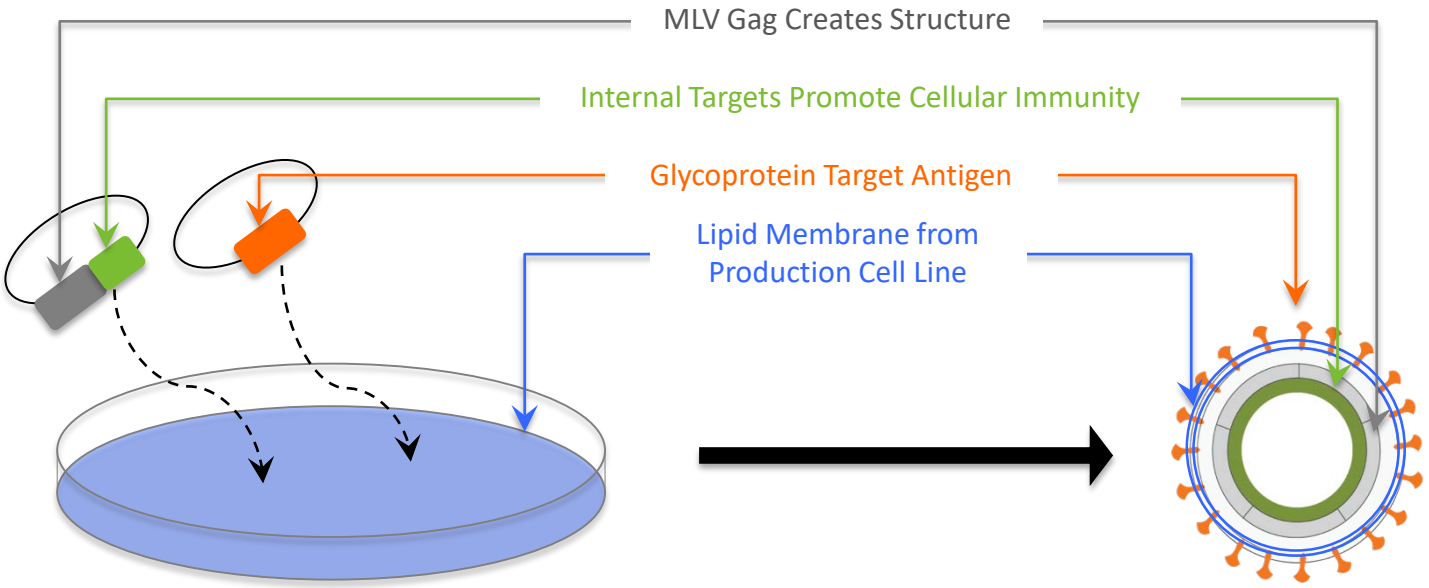
Vaccine Component	Immune Response	Scientific Support
CMV gB	Anti-gB Antibodies Anti-gB CD4+ T-helper cells	• #1 Antibody target for CMV (to stimulate ADCC) • gB binding is known to potentiate tumor growth[1] • #1 CD4+ T-helper cell target
CMV pp65	Polyvalent CD8+ T-cell Responses	• #1 CD8+ T-cell target • Multivalent/multi-epitope design avoids tumor escape • Clinical evidence of pp65-mediated survival[2]
eVLP formulation with GM-CSF	Stimulation of IFN-g and CCL3	• IFN-g and CCL3 are key biomarkers of efficacious tumor immunity [2, 3]



1. Cobbs C et al, 2014
2. Mitchell, et al, 2015
3. Galon J et al, 2006

Enveloped Virus Like Particle (eVLP) Enables Potent Delivery of Vaccine Antigens in an Effective Viral Mimic

Flexible, Customized Antigen Delivery in a Biologically Relevant Construct



- "e" VLP Key Attributes
  - MLV capsid protein creates "enveloped" virus like structure (*unique*)
  - Envelope glycoproteins presented in lipid membrane as in nature (*unique*)
  - T-cell antigens can be delivered internally to promote cellular immunity (*unique*)
  - Particle structure & size promotes dendritic cell update and activation (*unique*)

Cancer Immunity Cycle:

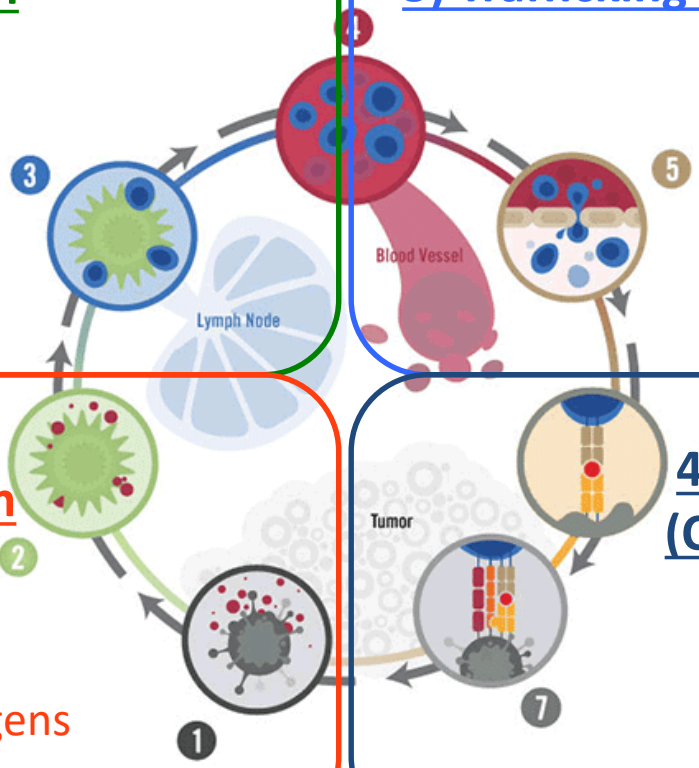
Potent, "Foreign" Antigen Presentation is Critical to the Solution

2) Priming & Activation (or GAS)

Examples:
Positive: GM-CSF, STING
Negative: CTLA-4

3) Trafficking & Immunosuppressive Microenvironment

Examples:
Positive: TILs
Negative: T-Regs, MDSC



1) Antigen Presentation (or Steering)

Examples:
Positive: Viral & Neo-antigens
Negative: "self" TAAs

4) Recognition & Killing (Checkpoints = Brakes):

Examples:
Positive: IFN-γ
Negative: PD1

Image: Chen & Mellman (2013), Immunity v39 pp1-10 (image adapted at Gene.com)

VBI-1901 Therapeutic Concept for Glioblastoma:

Direct Activity on Three Quadrants of Effective Tumor Immunity

2) Priming & Activation (or GAS)

2) Priming & Activation

Examples:

Positive: GM-CSF, IFN-α

Negative: CTLA-4

GM-CSF

3) Immunosuppressive Microenvironment

3) Trafficking & Immunosuppressive Microenvironment

Relief via Tumor "Debulking" Surgery

Examples:

Positive: TILs

Negative: T-Regs, MDSC

1) Antigen Presentation (or Steering)

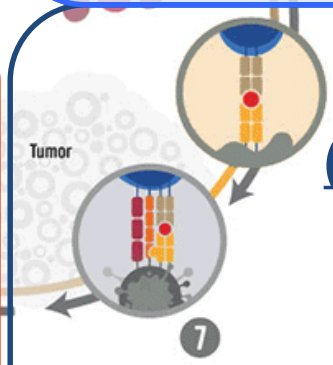
1) Antigen Presentation

CMV gB & pp65 in an eVLP

Examples:

Positive: Viral & Neo-antigens

Negative: "self" TAAs



4) Recognition & Killing (Checkpoints = Brakes):

Examples:

Positive: IFN-γ

Negative: PD1

Image: Chen & Mellman (2013), Immunity v39 pp1-10 (image adapted at Gene.com)

VBI-1901:

Proof of Concept Data

Rationale for VBI-1901 in GBM

VBI-1901 Builds on Data in the Field – Designed to Stimulate Balanced Anti-CMV Immunity for Therapeutic Benefit

1. Recent Clinical Evidence: CMV DC Vaccination Extends Survival[1]
   - DC priming + CMV DC vaccination increased OS of GBM patients
   - Overall survival (>36.6 months) vs. control cohort with median OS of 18.5 months
   - ***Survival was correlated with increased levels of CCL3***

2. Evidence Supporting the Need for Balanced Anti-Tumor Immunity
   A. Cellular Immunity: CD8 Role Appreciated, but CD4+ responses play a critical role
      - CD4 T-cell responses are critical for sustained CD8+ T-cell activity[3]
      - CD4 T-cell based CAR-T provides clinical responses in solid tumors[2]

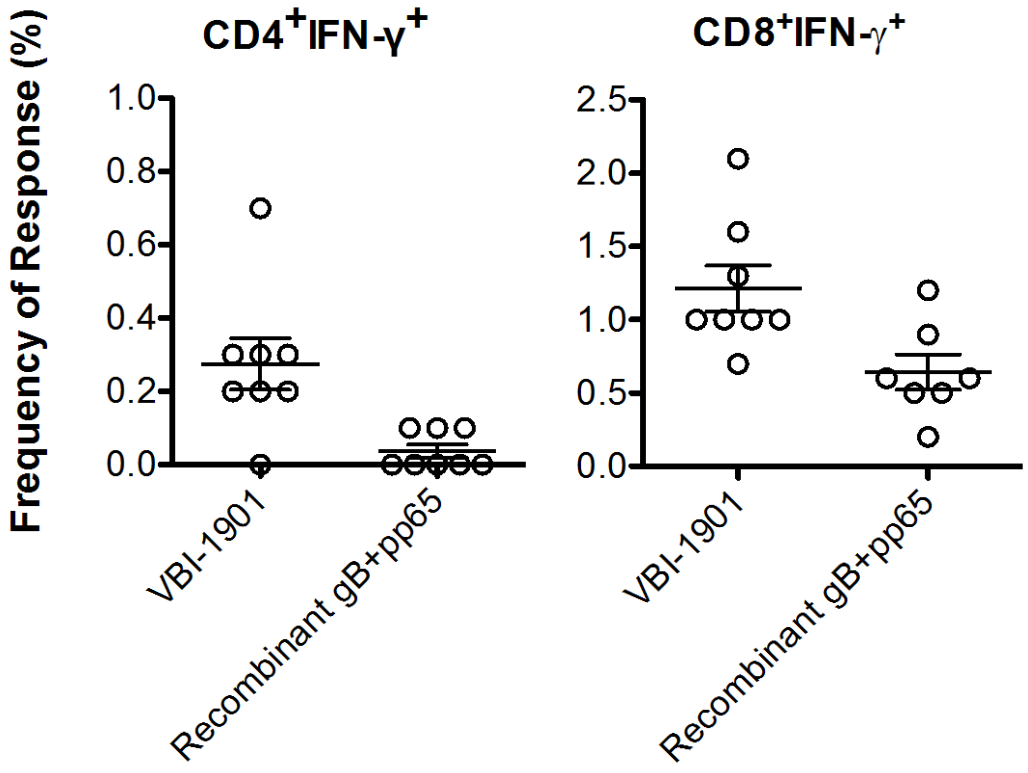
   B. Humoral Immunity
      - mAbs against EGFRvIII mutants on GBM can stimulate potent ADCC activity[4]
      - B-cells are critical to tumor regression in murine model of GBM[5]
      - Approved mAbs (Herceptin, Rituximab) elicit activity through antibody (FcR) mediated cytotoxicity[6]

1. Mitchell DA(2015) Nature 519, 366-369
2. http://www.medscape.com/viewarticle/862095
3. Muranski, Curr Opin Immunol, v21, April 2009
4. Fukai J, et al. Cancer Sci, v99, Oct 2008
5. Candolfi, et al. Neoplasia v13, Oct 2011
6. Clynes RA, Nature Medicine, v6, April 2000

VBI-1901: Re-stimulates CD4+ and CD8+ T-cell Responses in CMV-positive Human Subjects *Ex Vivo*

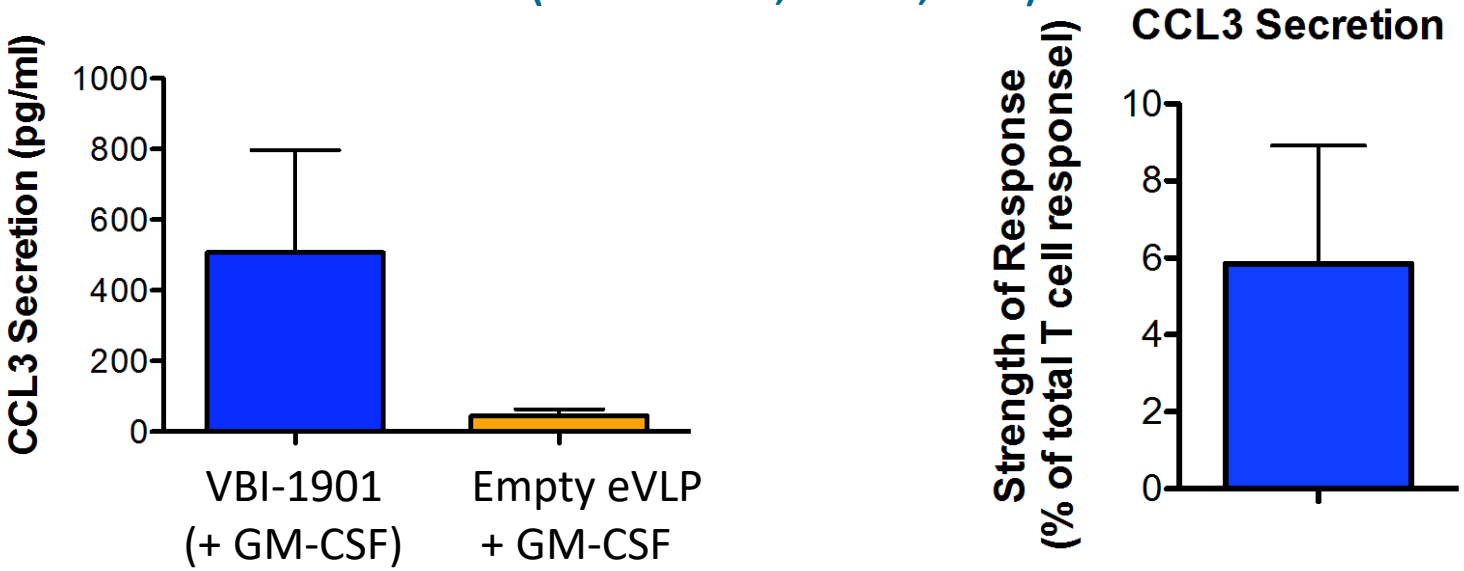
- Fresh PBMCs stimulated with VBI-1901 vs recombinant antigens
- eVLPs rapidly restimulate both CD4+ & CD8+ T-cell responses
- eVLP presentation enhances stimulation relative to matched recombinant antigen

Restimulation of CD4+ & CD8+ T-cells in Ex Vivo Human Samples



VBI-1901: Specific *Ex-Vivo* Re-stimulation of CCL3 (biomarker of clinical success) in CMV-positive GBM Patient Samples

Stimulation of CCL3 Biomarker, Predictive of Clinical Efficacy of Analogous DC Vaccine (Mitchell et al, Nature, 2015)

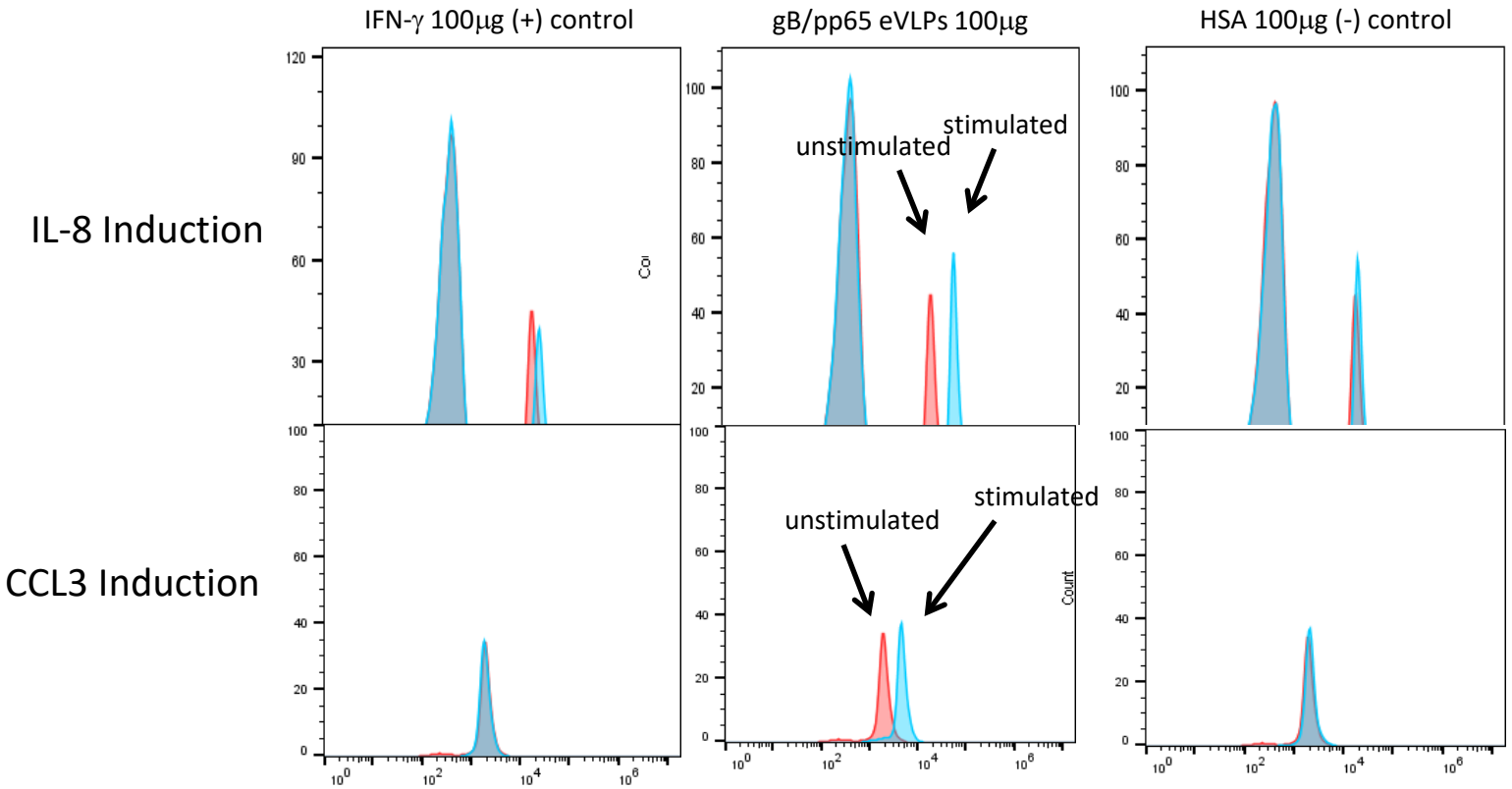


VBI-1901 Provides an Opportunity for an Off-the-Shelf Glioblastoma Immunotherapy with Excellent Clinical Promise

- PBMCs (n=4) from GBM patients were stimulated for 36 hours with the indicated eVLPs, at which time CCL3 production was measured
- gB/pp65 eVLP-induced responses were compared to stimulation of all T cells (PHA stimulation) to estimate the strength of the vaccine-induced response

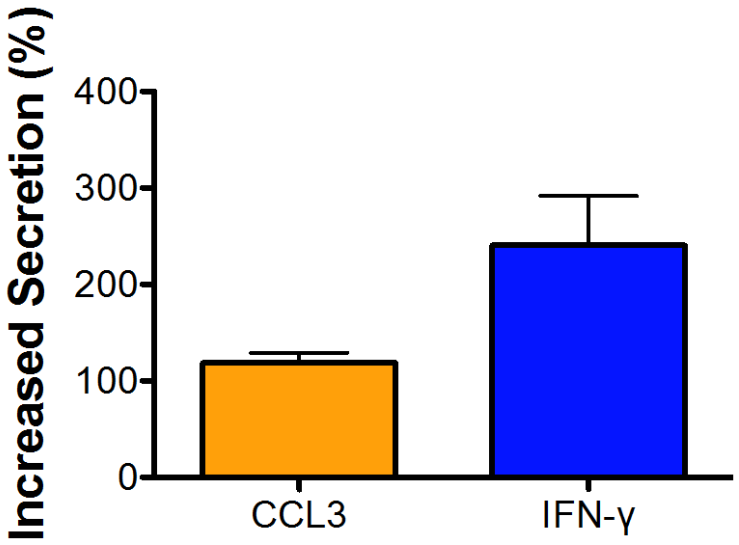
VBI-1901 eVLPs recruit (CCL3) and Activate (IL-8) Dendritic Cells

VBI-1901: An "Off-the-Shelf" Dendritic Cell Vaccine



- Immature DCs generated by culture of MUTZ-3 myeloid cell line for 6 days in GM-CSF
- DCs exposed to IFN-g, eVLPs, or control recombinant protein (HSA) for 48 hours
- Induction of proinflammatory IL-8 cytokine and CCL3 chemokine determined by CBA assay

Checkpoint Inhibitor (anti-PD-1 mAb) Blockade Enhances CMV eVLP-induced IFN-γ



Increases in CCL3 and IFN-γ secretion are based on 5 healthy CMV+ subjects, comparing gB/pp65 eVLP stimulation in the presence or absence of anti-PD-1 mAb (Opdivo).

VBI-1901

Summary

VBI-1901: Targeting Solid Tumors Through Innovative Use of Foreign Viral Antigens

Next Generation Cancer Vaccines Leverages Natural Anti-Viral Immunity

- Tumor Associated Viral Antigens represent a unique “off the shelf” vaccination opportunity relevant to multiple solid tumors

- CMV is highly immunogenic and expressed by over 90% of:
  - Glioblastomas (GBM)
  - Brain Cancers
  - Breast Cancer

- VBI-1901 benefits from rational design & potent antigen delivery platform
  - eVLP presentation natively stimulates all arms of immunity (Antibody, T-helper & CTL)
  - eVLP particulate structure directly stimulates dendritic cell recruitment & activation

- ***VBI is advancing VBI-1901 into Ph I clinical development & is exploring options for synergistic combinations in other cancers, including breast***

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