



## **Key Opinion Leader Lunch**

# **Advances in Vaccination Against Hepatitis B**

*Hosted by VBI Vaccines*  
*(NASDAQ: VBIV | TSX: VBV)*

**June 13 2016**

# Agenda

- **Introduction** ..... *LifeSci Advisors*
- **Significant Unmet Need for an Enhanced Hepatitis B Vaccine** ..... *Dr. Florian Schödel*
- **Sci-B-Vac™ : a 3<sup>rd</sup> Generation Hepatitis B Vaccine with Enhanced Immunogenicity** ..... *Dr. Daniel Shouval*
- **Overview of VBI Vaccines** ..... *Jeff Baxter*  
*VBI Vaccines Inc. CEO*
- **Q&A** .....

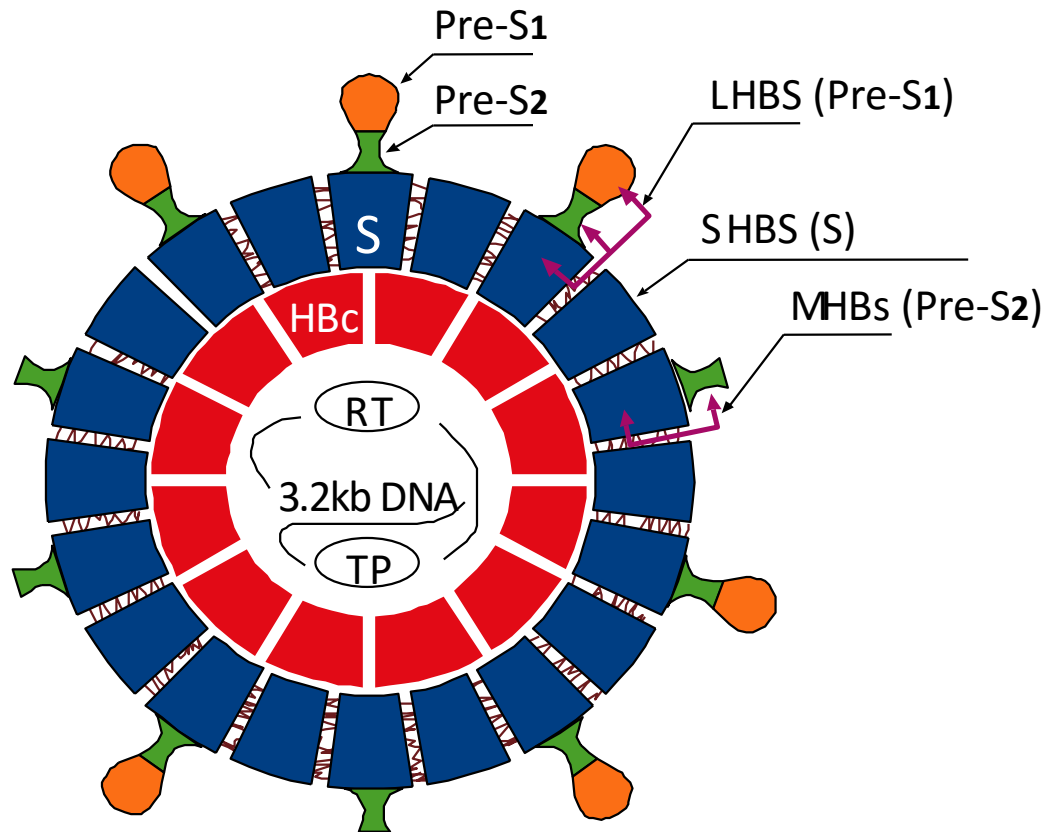
# **Significant Unmet Need for an Enhanced Hepatitis B Vaccine**

Florian Schödel

Independent Consultant

Prev. VP of Vaccines Clinical Research, Merck

# Hepatitis B Virus

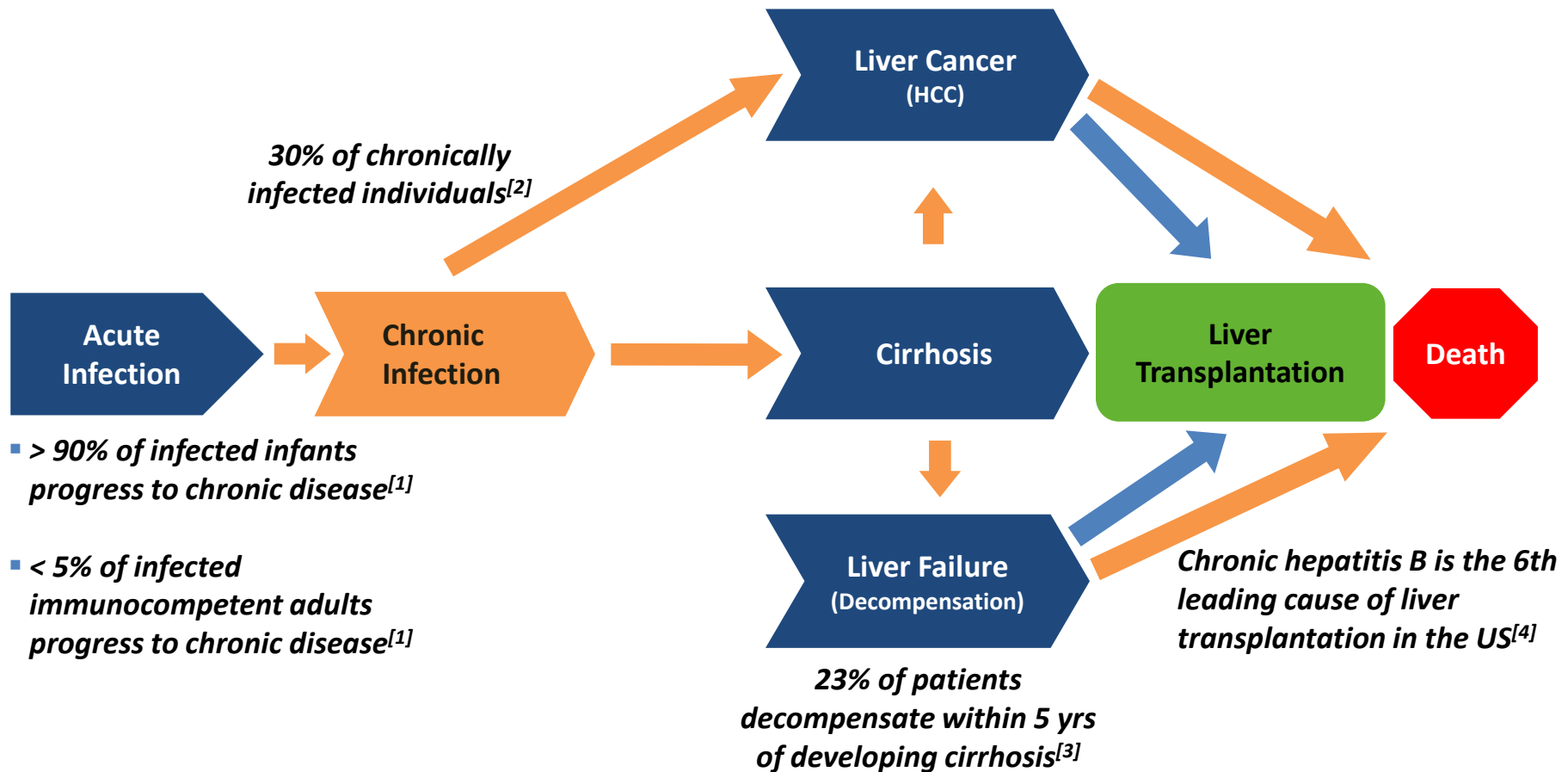


42nm

**HBsAg** – marker of infectivity

**Anti-HBs antibodies** – marker of protection (induced by vaccination or following recovery from HBV)

# Hepatitis B Disease Progression

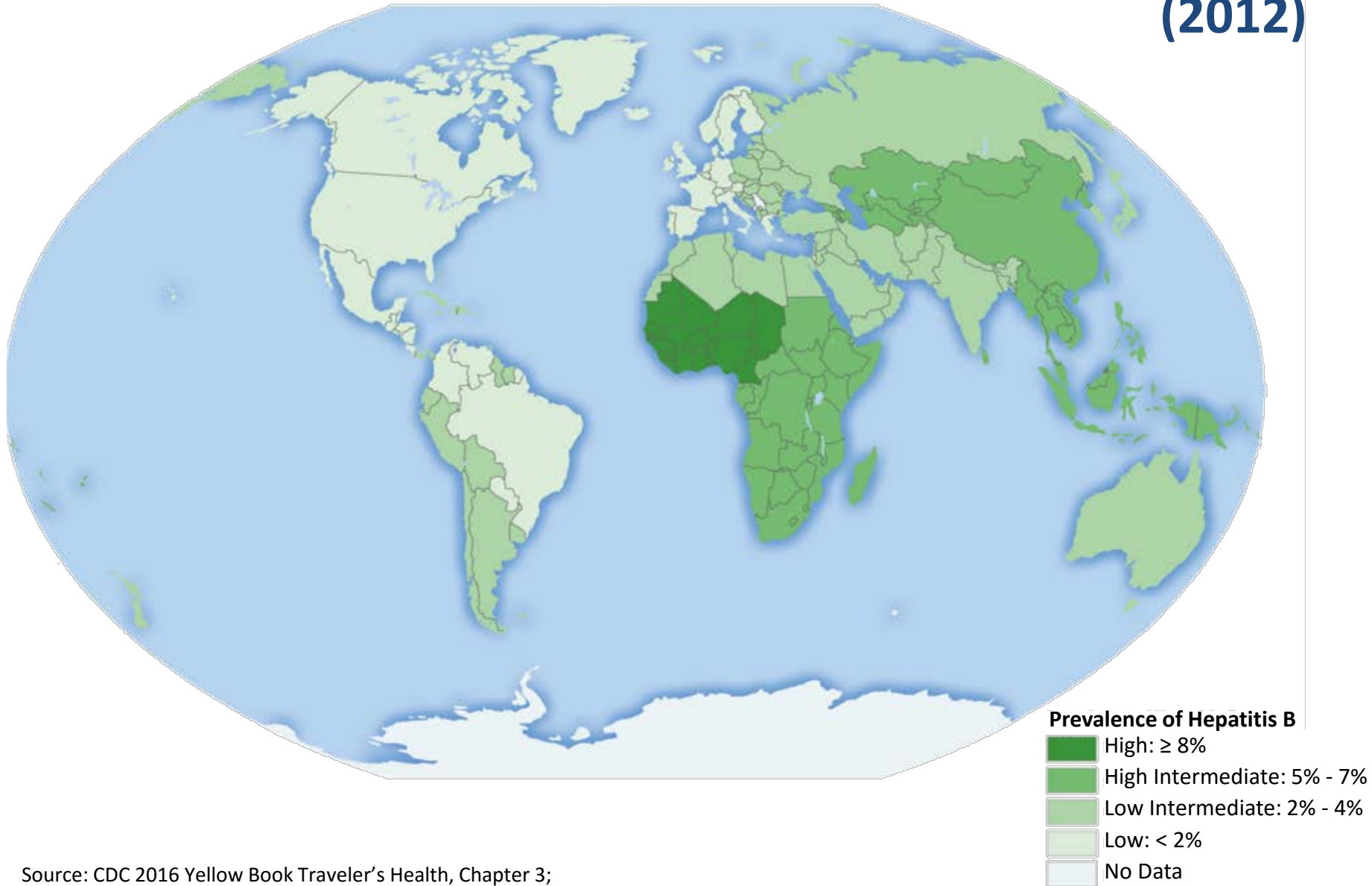


1. CDC. HBV FAQs for health professionals. 2. Torresi J, et al. Gastroenterology. 2000;118(2 suppl 1):S83-S103. 3. Fattovich G, et al. Hepatology. 1995;21:77-82. 4. Seaberg EC, et al. Clin Transpl. 1998:17-37.

# Worldwide HBV Infection

- *More than 2 billion people infected during lifetime*
- *Up to 2 million die each year from HBV infection*
- *Worldwide there are ~350-400 million HBsAg carriers*
- *Persistent HBV is considered a significant risk factor for development of primary liver cancer*
- *<50% liver cancer patients have been infected with HBV*

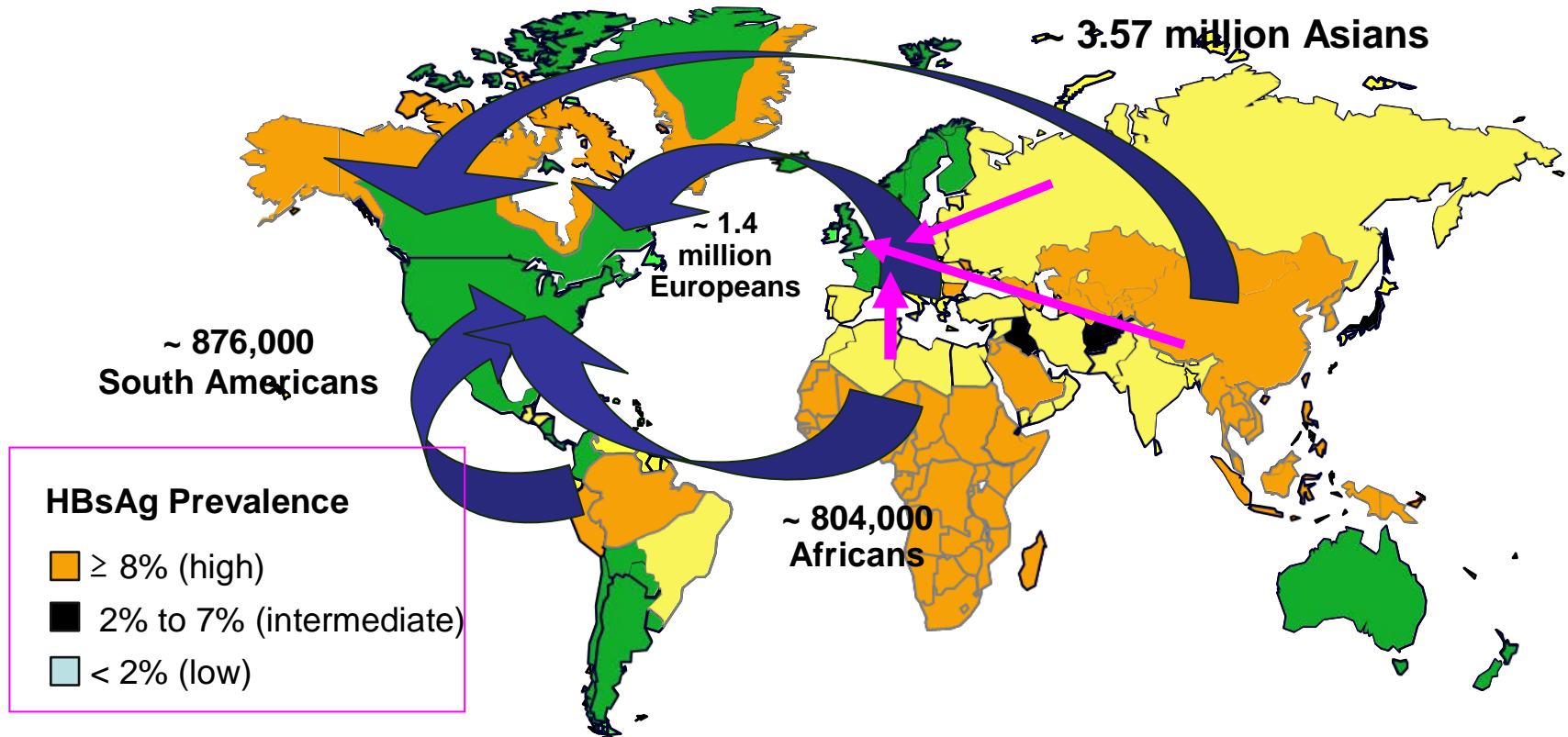
# Prevalence of Chronic Adult Hepatitis B Infection (2012)



Source: CDC 2016 Yellow Book Traveler's Health, Chapter 3;  
<http://wwwnc.cdc.gov/travel/yellowbook/2016/infectious-diseases-related-to-travel/hepatitis-b>

# Immigration Trends to Europe and the US

## Immigration by continent: 2000-2009



. Modified after CDC health information for international travel 2010. <http://wwwnc.cdc.gov/travel/yellowbook/2010/chapter-2/hepatitis-b.aspx#849> ;US Dept of Homeland Security. Yearbook of Immigration Statistics: 2009: U.S. Department of Homeland Security, Office of Immigration Statistics, 2010. [http://www.dhs.gov/xlibrary/assets/statistics/yearbook/2009/ois\\_yb\\_2009.pdf](http://www.dhs.gov/xlibrary/assets/statistics/yearbook/2009/ois_yb_2009.pdf).



# EU Refugee Crisis Increasing Need for Superior HBV Vaccines

**A STUDY PRESENTED AT THE INTERNATIONAL LIVER CONGRESS™ 2016 IN BARCELONA TESTED 793 REFUGEES FOR SEROLOGICAL MARKERS OF HBV INFECTION IN NORTHERN GERMANY:**

- The presence of Hepatitis B, was found in:
  - 2.3% of patients - measured by HBsAg
  - 14% of patients - measured by anti-HBc
  - Higher levels of HBV infection than in German controls
- Highest levels of HBsAg and anti-HBc were found amongst older patients (3.1% and 38% respectively)
- 62% of patients had no immunity to Hepatitis B altogether
- 18.6% of patients had been vaccinated against the disease

# Estimated HBV Prevalence Among Foreign-Born Americans

Foreign-Born Population	HBV Prevalence, %	HBV Prevalence, n
All regions	3.7	1,522,798
Asia	7.9	862,779
Central America	1.3	208,804
Caribbean	2.3	82,000
South America	1.6	46,614
Africa	11.8	196,338
Europe	2.2	114,174
Oceania	5.4	9,424
North America	0.3	2,665

# Chronic Hepatitis B in the US: Undiagnosed & Undertreated

**~ 2 million people have chronic hepatitis B**



**400,000-600,000 diagnosed**



**200,000-300,000 entered  
into care**



**< 50,000 are receiving  
antiviral treatment**

# Evolution of Strategies for Global Prevention of Hepatitis B Virus Infection

- **Immunization of risk groups**
  - ✓ HCW –Healthcare workers
  - ✓ Spouses and contacts of HBsAg carriers
  - ✓ Patients on haemodialysis
  - ✓ People who inject drugs
  - ✓ Institutionalized individuals
  - ✓ MEM –men who have sex with men
  - ✓ Babies born to HBV infected mothers
  - ✓ Immune suppressed patients (i.e HIV)
- ***Universal mass vaccination (UMV)***

# WHO Position on Hepatitis B Vaccine

- **NEWBORNS** should receive their first dose of hepatitis B vaccine as soon as possible after birth, preferably within 24 hours
- **BIRTH DOSE** should be followed by 2 or 3 doses to complete the primary series
- **CATCH-UP VACCINATION** should be considered for cohorts of children with low coverage
- **RECOMMENDED NATIONAL STRATEGIES** to prevent perinatal transmission should include:
  - Providing hepatitis B vaccine at birth, and
  - Ensuring high coverage of the birth dose through (1) strengthened maternal and infant care at birth with skilled health workers present to administer the vaccine , and (2) innovative outreach to provide vaccine for children born at home
- **EXCELLENT SAFETY PROFILE** is confirmed by worldwide experience

# Despite Significant Achievements, There Remains a High Unmet Need

- > one billion doses of HB vaccine have been administered worldwide with an excellent record of safety and efficacy
- Seroprotection rates to anti-HBs are close to 100% in children and up to 95% in healthy young adults
- Most vaccinated individuals have a preserved immune memory and show a strong anamnestic response (“boosterability”) >20 years after primary immunization

***However, an increasing number of booster failures has been reported***

**People who are elderly, obese, heavy smokers, on haemodialysis or immuno-compromised, have suboptimal responses**

# Adult Hepatitis B Vaccination Coverage Remains Inadequate

Reported US Hepatitis B Vaccination Coverage - 2014	
<b>Otherwise Healthy</b>	
Adults aged $\geq 19$ years	24.5%
Adults aged 19-49 years	32.2%
Adults age $\geq 50$ years	15.7%
<b>High-Risk</b>	
Chronic Liver Conditions	29.8%
Diabetics – Age 19-59 years	23.5%
Diabetics – Age $\geq 60$ years	13.5%
Healthcare Providers $\geq 19$ years	60.7%

# Seroconversion Rates in Patient Subgroups

**SEROCONVERSION RATES WITH CURRENT VACCINES FALL DRAMATICALLY WITHIN THE ELDERLY AND HIGH-RISK PATIENT**

Anti-HBs Seroconversion Rates After Hepatitis B Vaccination	
Neonates	> 95%
Age 2 - 19	~99%
Age 20 - 29	~95%
Age 30 - 39	~90%
Age 40 - 49	~85%
Age 50 - 59	~70%
Age 59+	~50%
Renal failure, HIV infection, other immunosuppression	50-70%
Liver Disease	60-70%



# The Unmet Need: High-Risk Populations of Non-Responders & Low Responders to Conventional HBV Vaccination

## SEROCONVERSION RATES:

- Cancer patients (children) ..... ~57%
- Patients with chronic liver disease ..... ~50%
- Chronic renal failure & dialysis ..... 34-81%
- Acute lymphocytic leukemia ..... ~10%
- Bone marrow /stem cell transplant recipients ..... 15-68%
- Pre-transplantation candidates ..... 28-36%
- Post-transplantation patients ..... ~10%
- HIV (children & adolescents) ..... ~30%
- Miscellaneous (i.e. older healthcare workers engaged in exposure prone procedures; genetically determined non-responders, celiac disease, IBD)

# Current Approaches to Vaccination of Non- or Low Responders to Conventional HBV Vaccination

## Means for improving immunogenicity of HBV vaccines

- Increase dose and/or add more injections
- **Use PreS/S HBV vaccine expressed in mammalian cells**
- Add a more immunogenic adjuvant than alum-hydroxide
- Intra-dermal injection instead of intra-muscular injection
- HBsAg or non-HBsAg based novel vaccines

# Selected Monovalent HBV Vaccines

Brand Name	Source/ Expression in	Envelope Protein(s)	Manufacturer	Country
<b>Engerix B<sup>R</sup></b>	Yeast	S	GSK	Belgium
<b>Recombivax<sup>R</sup></b>	Yeast	S	MSD	US
<b>Heberbiovac</b>	Yeast	S	Centro D.I.G Biotecnologia	Cuba
<b>GenHevac B</b>	CHO	S/Pre-S2*	Pasteur-M	France
<b>Hepelisav</b>	Yeast	S	Dynavax	<i>Pending</i>
<b>Sci B Vac<sup>TM</sup></b>	CHO	S/PreS-1/PreS-2*	SciVac/VBI	Israel

*\*Glycosylated*

# Sci B Vac™

## A Third Generation Hepatitis B Vaccine with Enhanced Immunogenicity

Daniel Shouval

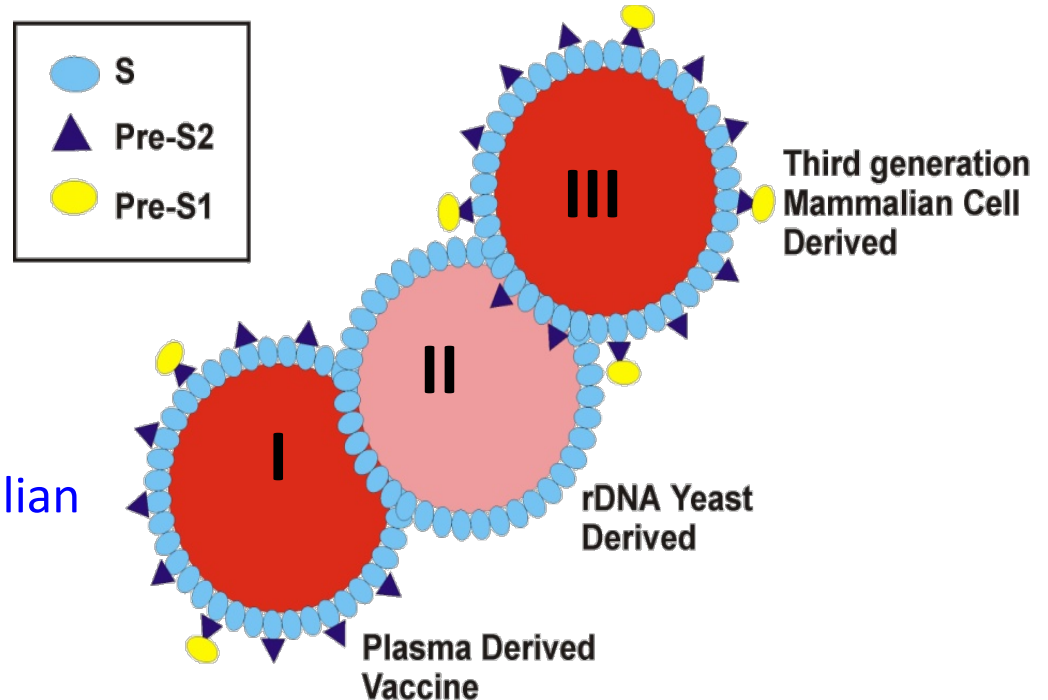
Liver Unit

Hadassah-Hebrew University Hospital

Jerusalem, Israel

# History of 3 generations of HBV vaccines\*

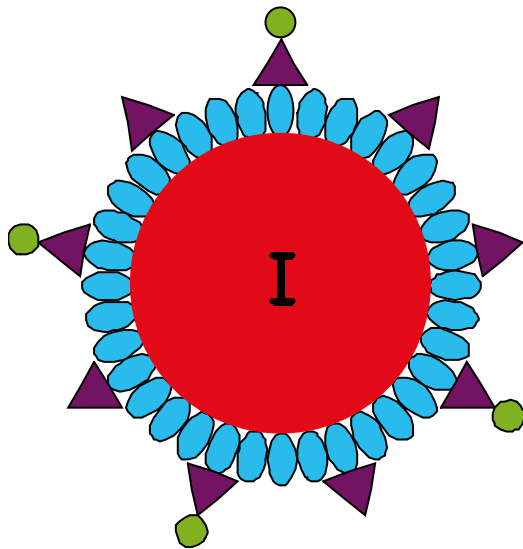
- I. 1981 - 1982: Plasma derived vaccines
- II. 1986 : Recombinant HBV DNA vaccine expressed in yeasts
- III. 1990s : Recombinant pre-S/S vaccines expressed in mammalian cells



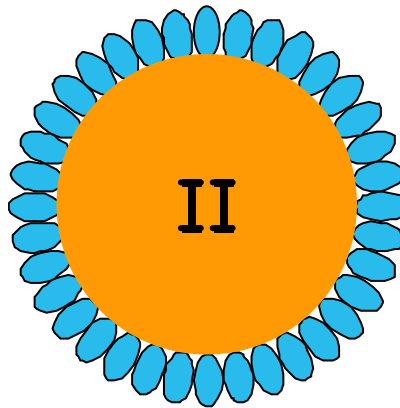
- 1991: WHO recommendation on integration of HBV vaccination into national immunization programs in countries with HBsAg carrier rates  $\geq 8\%$
- 1995: WHO recommendation for global immunization of infants “regardless” of HBsAg rates

# 3 Generations of HBV Vaccines

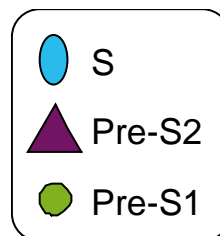
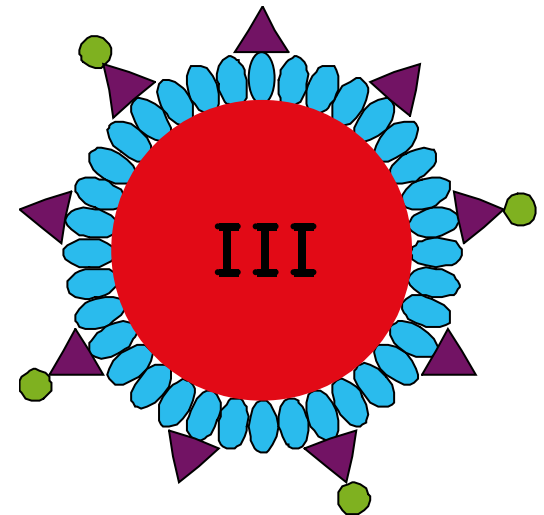
## PLASMA DERIVED VACCINES



## rDNA YEAST DERIVED



## rDNA MAMMALIAN CELL DERIVED VACCINES



# Means for Improving the Immunogenicity of HBV Vaccines

- **Dual or triple antigen vaccines (Pre-S<sub>1</sub>/Pre-S<sub>2</sub>/S)**
- **New adjuvants:**
  - Fendrix GSK™ (*MPL /A&QS21*)
  - Toll -like Receptors, e.g. Heplisav, Dynavax™ (*TLR9, CpG ODNs*)
  - MF 59 (*oil in water*)
  - AgB/RC 529 (*MPL, Corixa, Berna Biotech*)
  - Cytokines (*GM-CSF, IL-2, IL-4, IL-12, IFN α, TLR*)
  - Miscellaneous (*Cationic lipid, Virosomes ,HBcAg*)

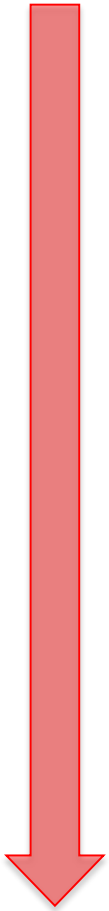
# What is the Rationale for Developing HBV Vaccines with Enhanced Immunogenicity?

- Non-response to conventional HBV vaccines in special populations
  - Fast induction of immunity to HBV in defined populations
  - Low compliance with the 3-dose regimen of conventional HBV vaccines
  - Emerging evidence of waning of post-vaccination immune memory 20 years post-primary immunization
  - Possible protection against HBV envelope mutant(s)
- 
- **Intervention in persistent HBV infection?**



# Factors Related to Non-Response to Hepatitis B Vaccines

**ENHANCING**



- Genetically determined resistance
- Advanced age
- Overweight
- Age
- Gender
- Smoking
- Immune suppression
- Chronic liver disease
- Miscellaneous (RF, systemic disease)

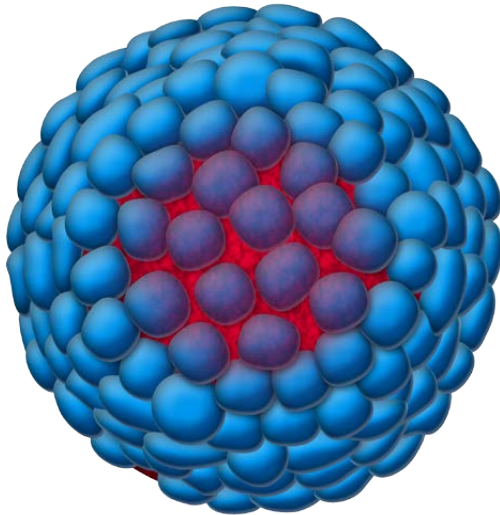


Pre-S

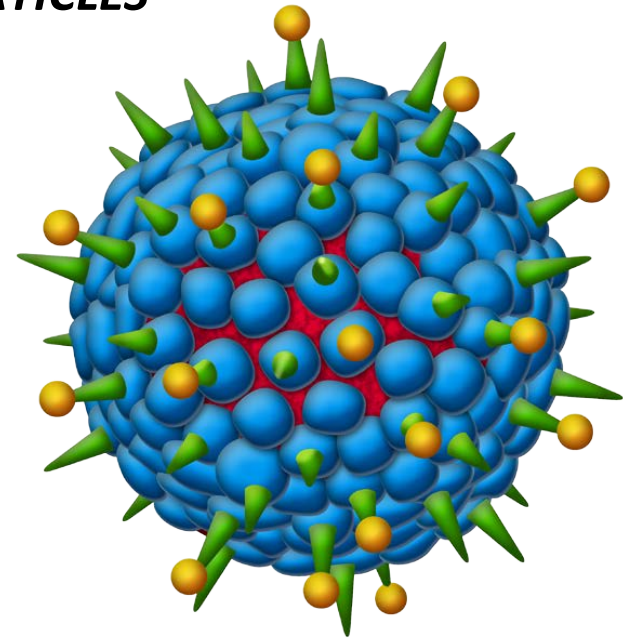
**ATTENUATING**

# Sci-B-Vac™ : 3<sup>rd</sup> Generation HBV Vaccine

***THE UNIQUE COMPOSITION OF HBV ENVELOPE PROTEINS IN SCI-B-VAC™ VS. YEAST-DERIVED PARTICLES***



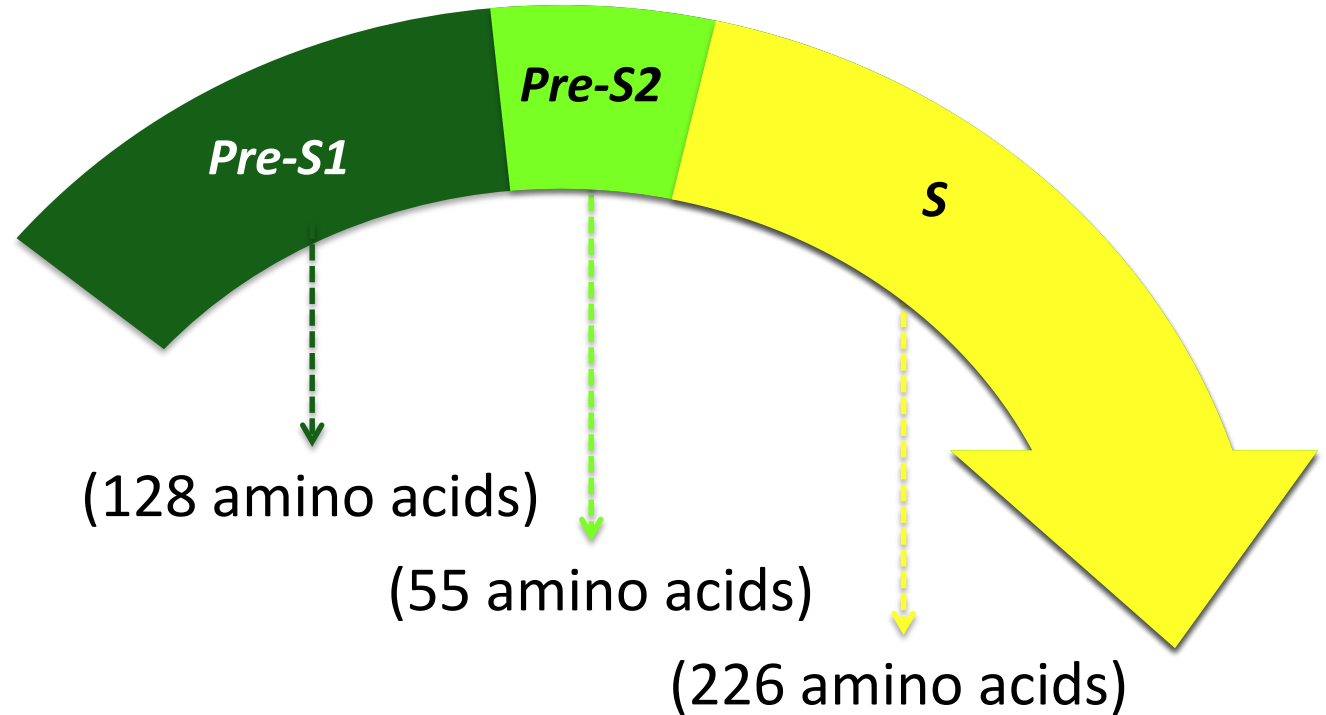
Yeast derived particles formulated  
With alum hydroxide in Engerix B<sup>R</sup>  
and Recombivax<sup>R</sup>



Mammalian cell derived particles  
Formulated with alum hydroxide  
in Sci B vac™

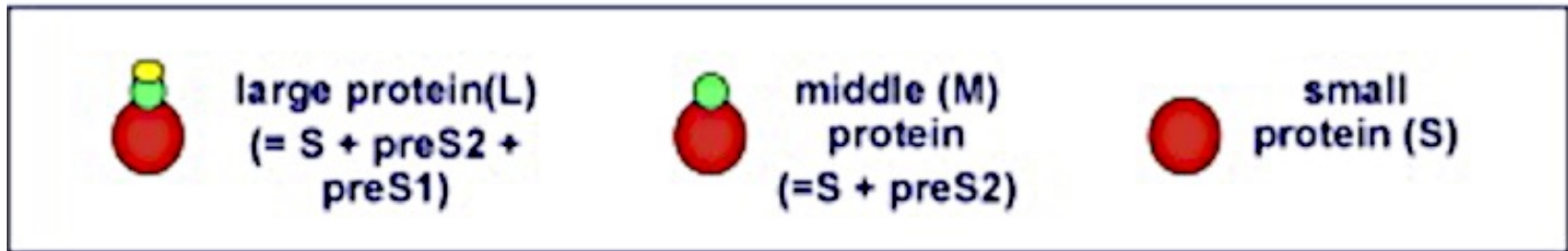
● S antigen    ▲ Pre-S1 antigen    ● Pre-S2 antigen

# HBV Envelope Proteins

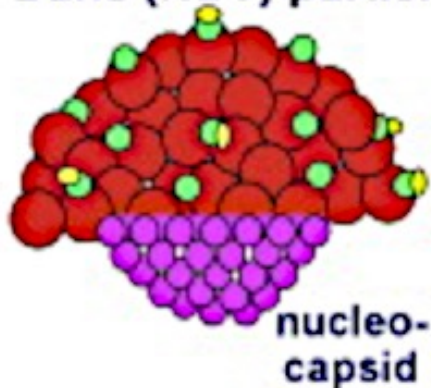


- + ■ + ■ = "Large Protein"
- + ■ = "Middle Protein"
- = "Major Protein"

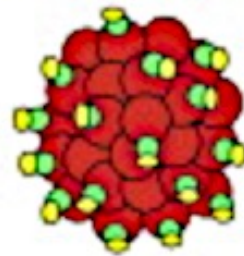
# The Unique Composition of HBV Envelope Proteins in Sci-B-Vac™



**Dane (HBV) particle**



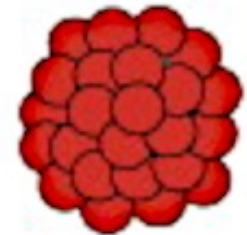
**preS1/S2/HBsAg**



**preS2/HBsAg**



**HBsAg**

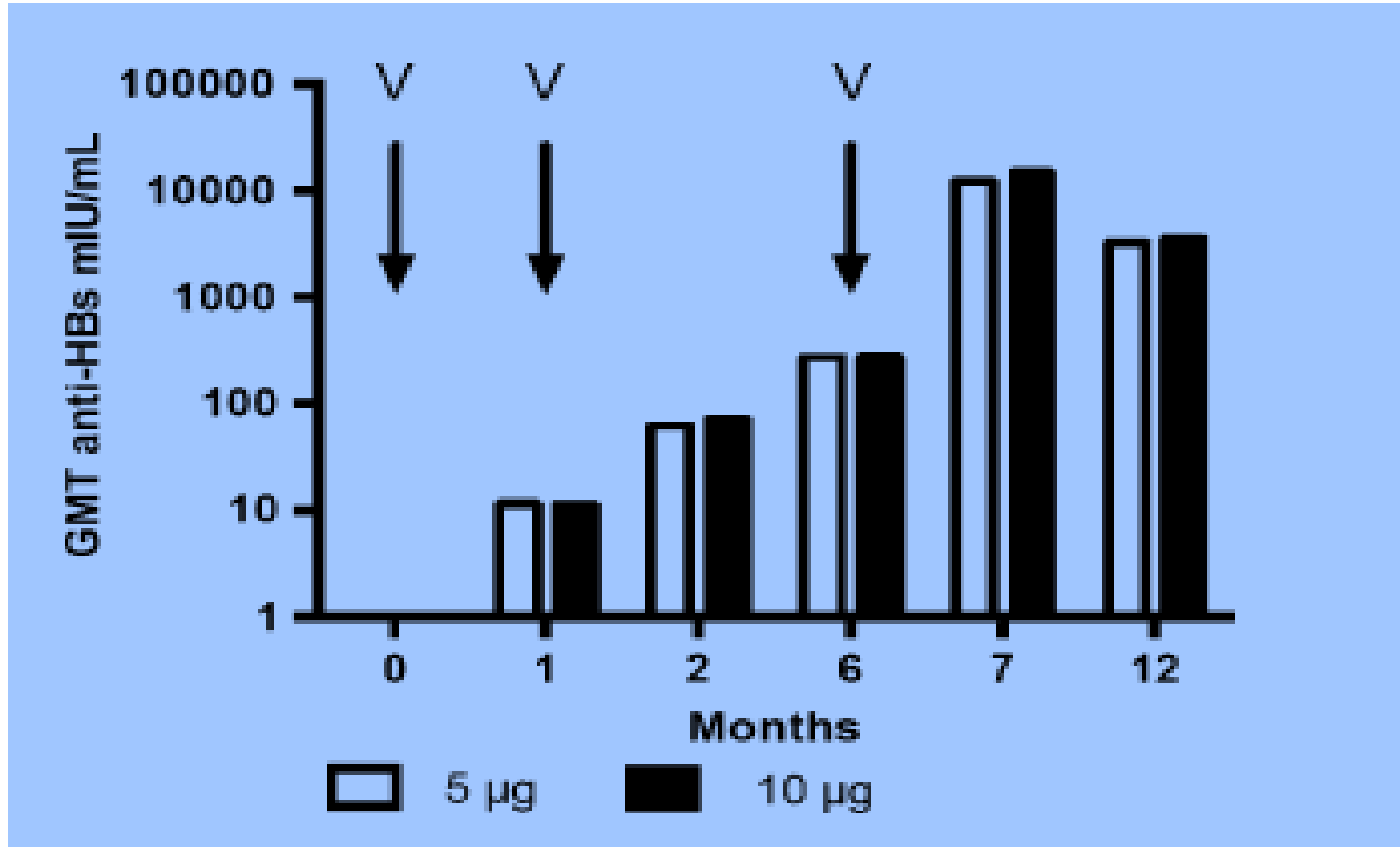


# Evidence of the Enhanced Immunogenicity of Sci-B-Vac™

**To date, over 20 clinical studies have been completed in >3,000 patients immunized with Sci-B-Vac™ with an excellent safety record, including healthy adults, children and neonates**

*Reference: Shouval D. et al. Enhanced immune response to hepatitis B vaccination through immunization with a Pre-S1/Pre-S2/S vaccine. Med Microbiol Immunol 2015;204:57-68*

# Anti-HBs Response Following Immunization with Sci-B-Vac™ in 18-29 Year Old Adults (N=105)

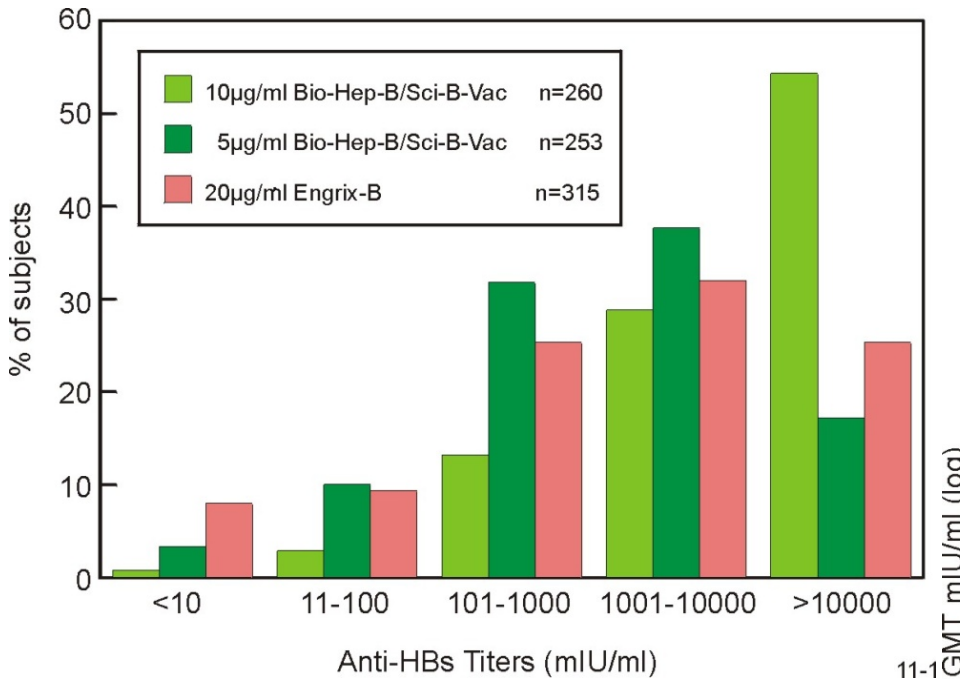


## Seroprotection Rates

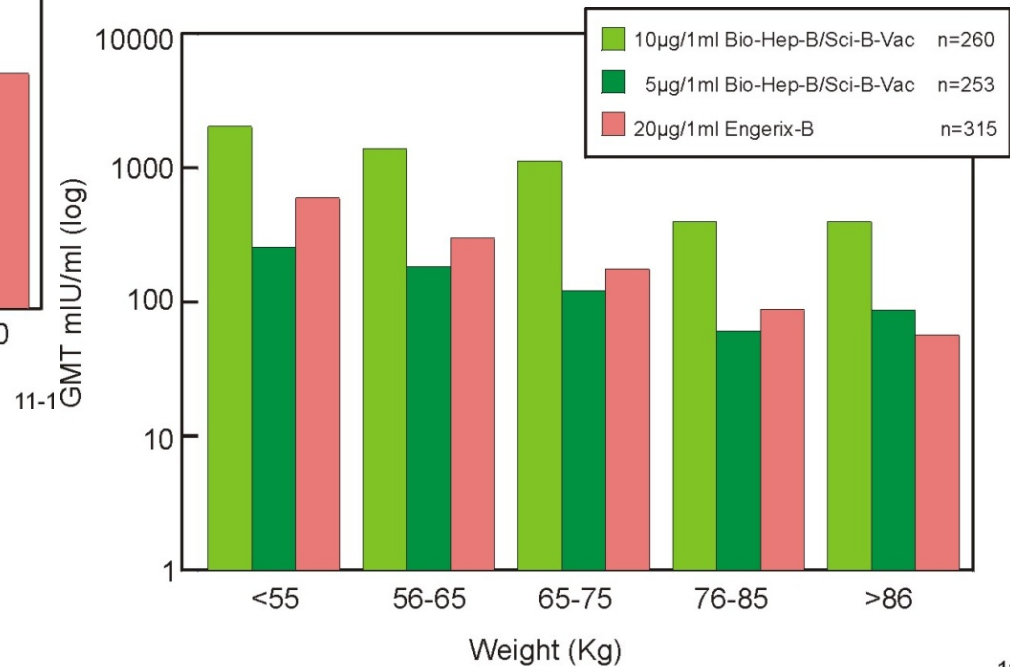
**2 mo: 79-83%, 6 mo: 97-98%, 12 mo: 100%**

# Comparative Immunogenicity of Sci-B-Vac™ Vaccine to Engerix-B After 3 Doses

## Quantification of anti-HBs



## Impact of body weight on anti-HBs levels



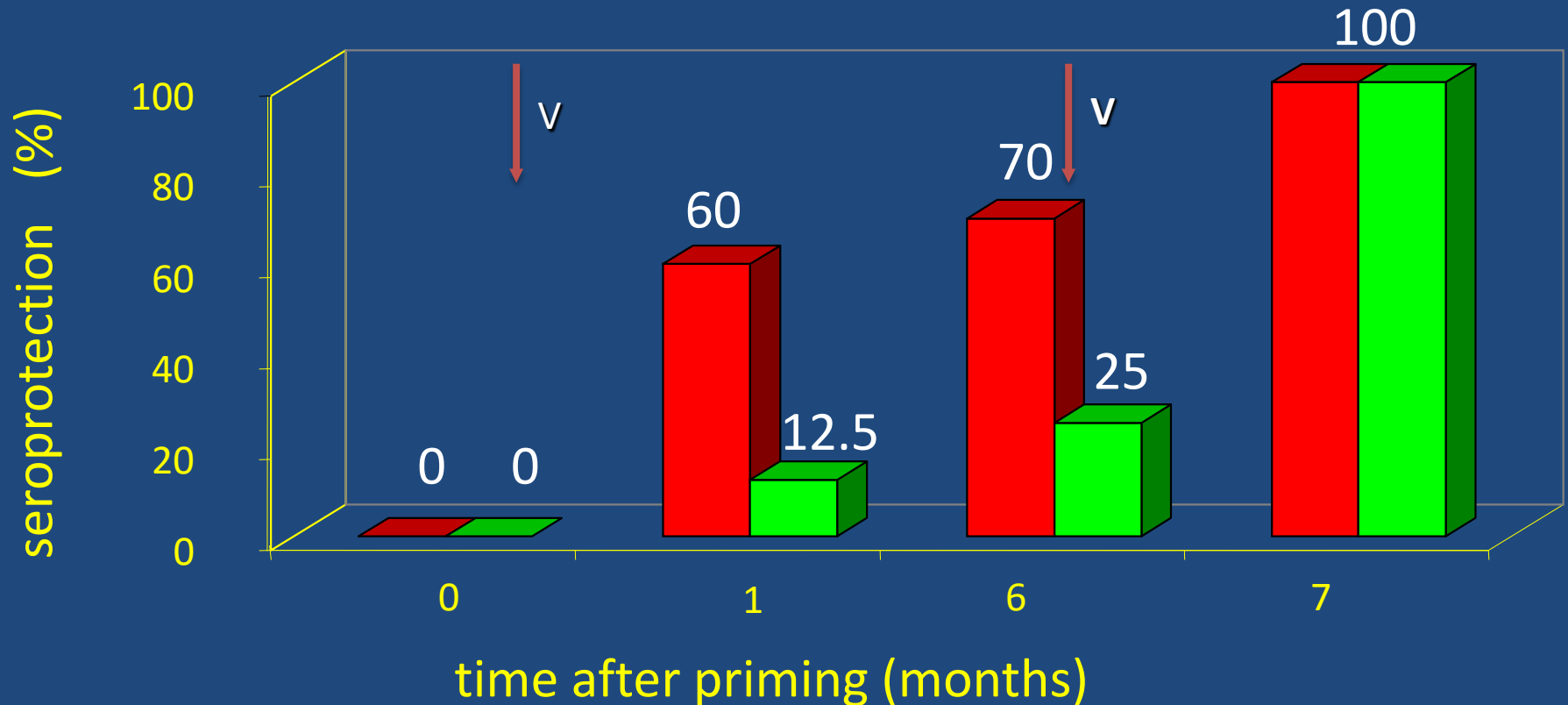
- **10µg/ml Bio-Hep-B/Sci-B-Vac™**
- **5µg/ml Bio-Hep-B/Sci-B-Vac™**
- **20µg/ml Engerix-B**

# Comparative Immunogenicity of Hepatitis B Vaccines

- N = 36 (20M/16F)
- Mean Age – 23 years (19-28)
- Protocol:
  - 2 doses of Sci-B-Vac™ 10µg/dose
  - 2 doses of Engerix B 20µg/dose
- Time of intra-muscular injections: Day 0 & 6 months



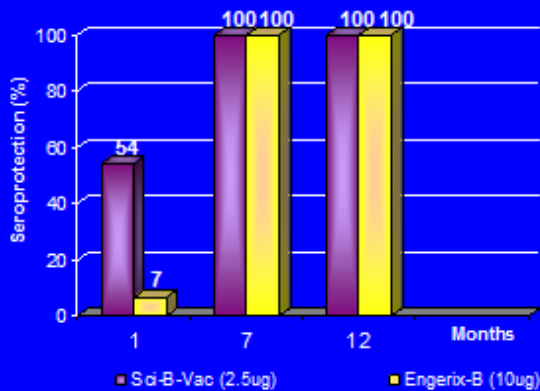
# Comparative Seroprotection of Two HBV Vaccines *Response After 1 and 2 Doses*



- Sci-B-Vac™
- Engerix B®

# Immunogenicity of Sci-B-Vac™ in Neonates

## EFFICACY OF SCI-B-VAC IN NEONATES\* (COMPARATIVE STUDY)

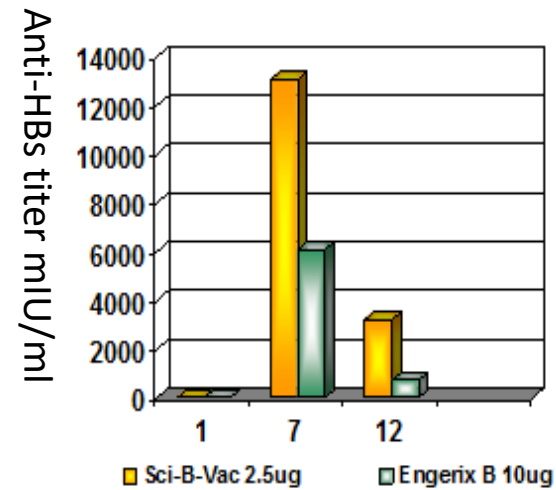


NB: Study was conducted in non-endemic populations

\*Three doses 0,1,6m

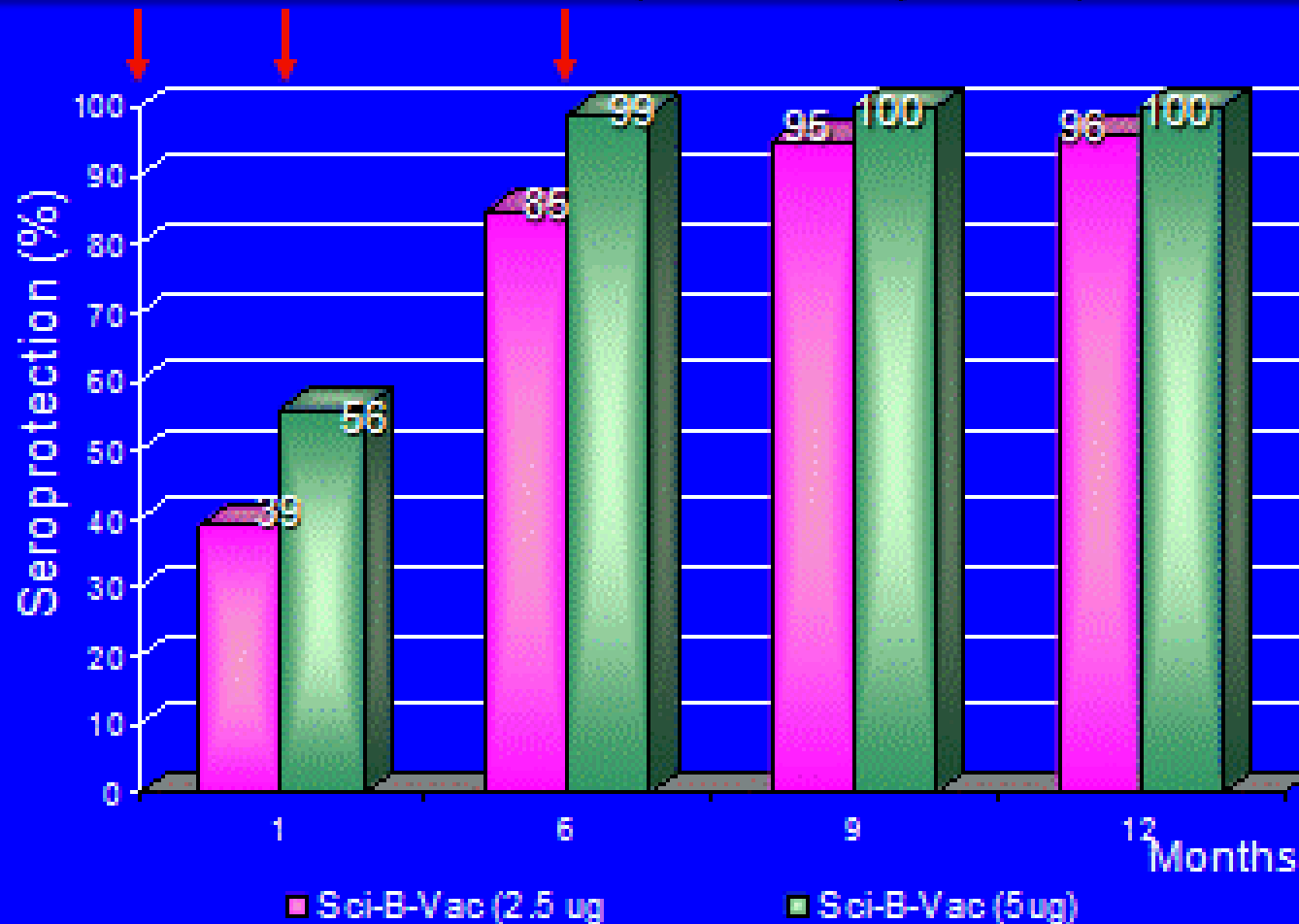
A

## Immunogenicity of Sci-B-Vac in Neonates by anti-HBs levels (n=205, Comparative study)



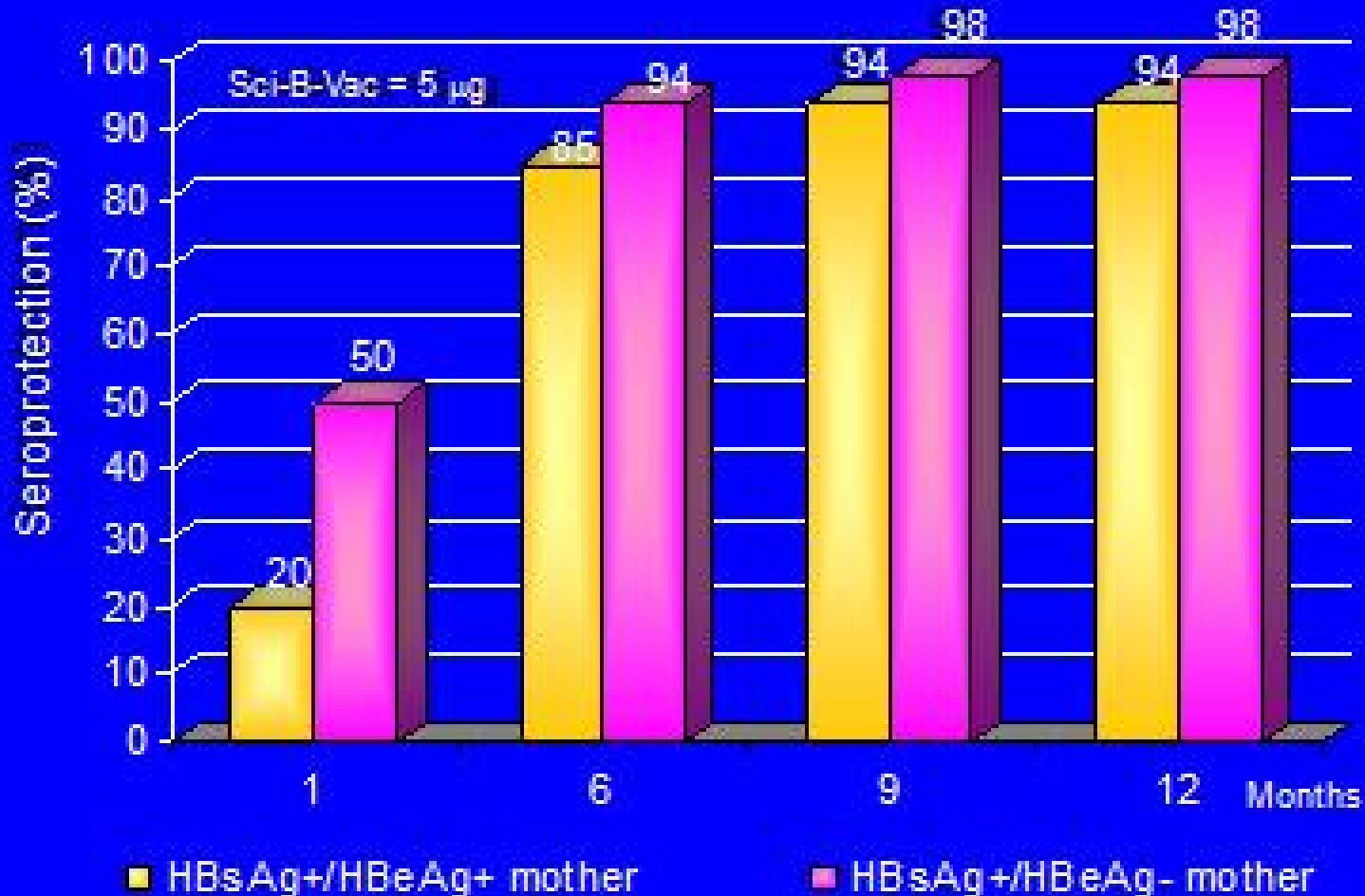
B

# Immunogenicity of Sci-B-Vac™ in Neonates Born to HBsAg+ Mothers (Dose Response)



*\*Three doses 0,1,6m*

# Immunogenicity of Sci-B-Vac™ in Neonates Born to HBsAg+ Mothers (by HBeAg Status)



**Induction of a robust T- and B-cell immune response in non- and low-responders to conventional vaccination against hepatitis B by using a third generation PreS/S vaccine.**

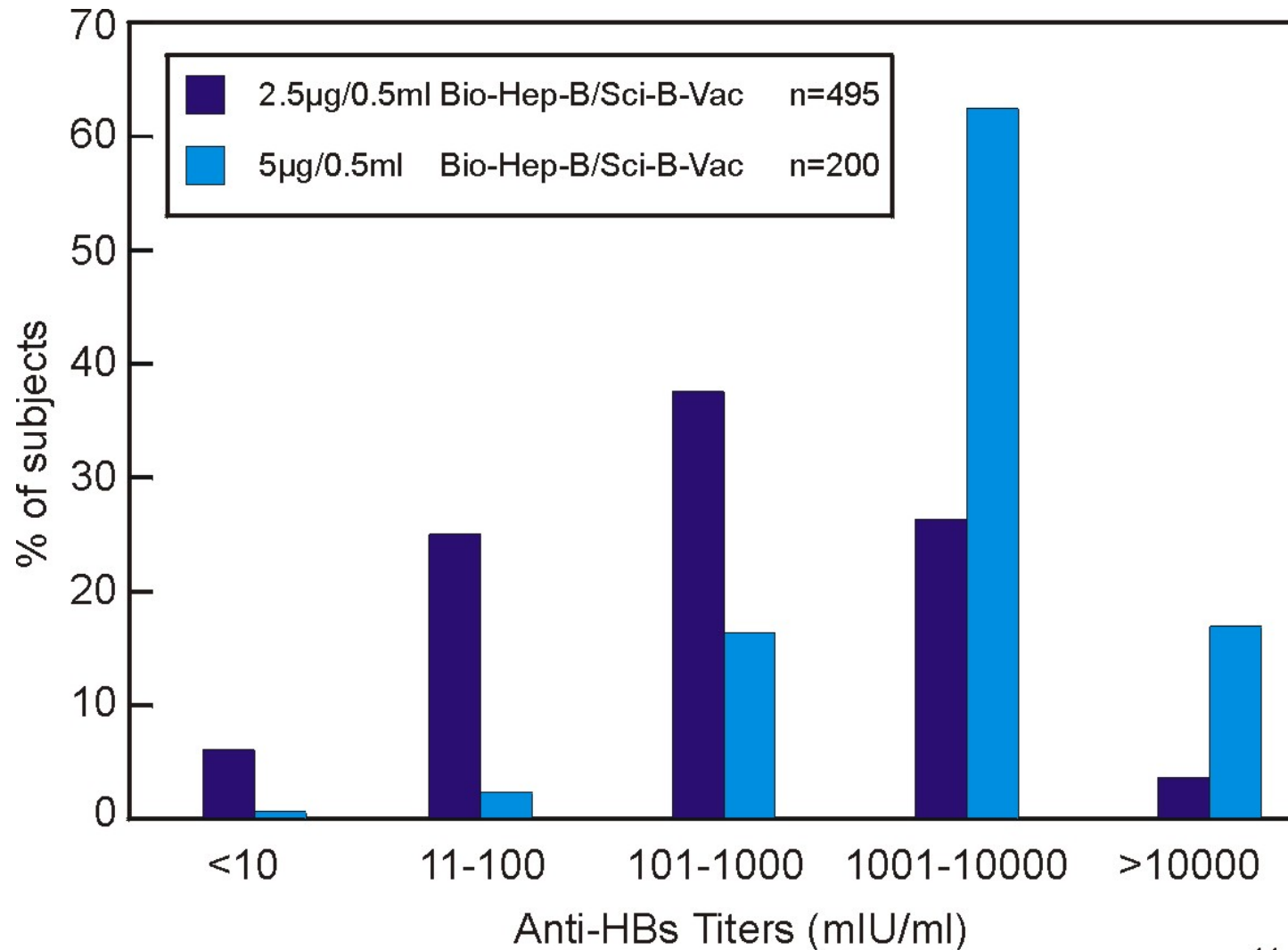
*Krawczyk A, Ludwig C, Jochum C, Fiedler M, Heinemann FM, Shouval D, Roggendorf M, Roggendorf H, Lindemann M*  
*.Vaccine 2014,32 5077-82 :*

# Pre S/S Vaccine in Non-Responders

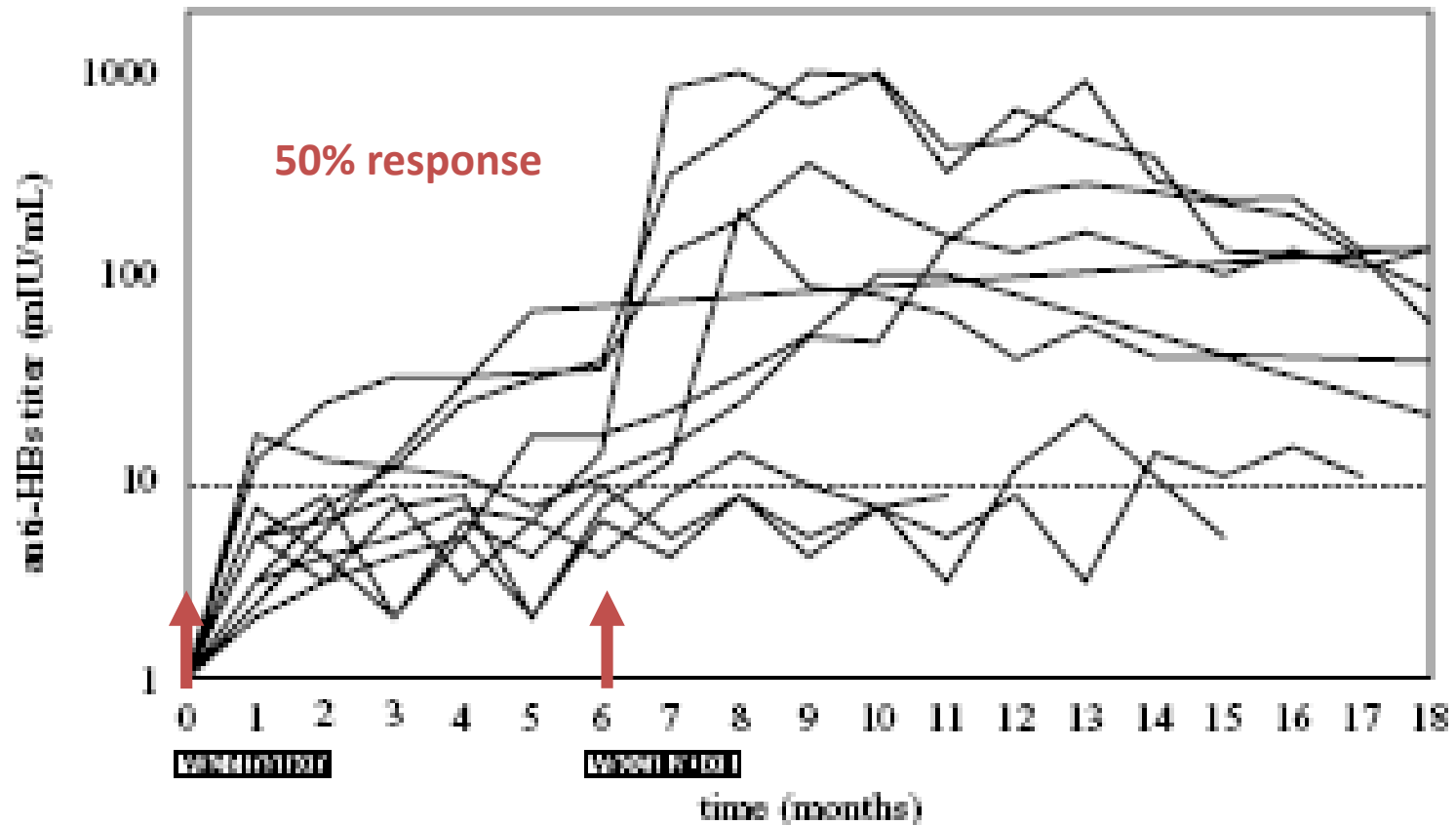
## SUMMARY:

- Significantly higher immunogenicity after 2 additional injections of 3<sup>rd</sup> generation PreS/S vaccine compared to conventional S vaccine at anti-HBs 10 and 100 IU/l level
- Influence of age, BMI and gender less pronounced in 3<sup>rd</sup> generation PreS/S vaccinees
- Higher reactogenicity after 3<sup>rd</sup> generation compared to conventional vaccine
- Confirms link between non response and DRB1\*03 and \*07, DQB1\*02 HLA loci

# Sci-B-Vac™ Dose Ranging Study : Neonates Vietnam

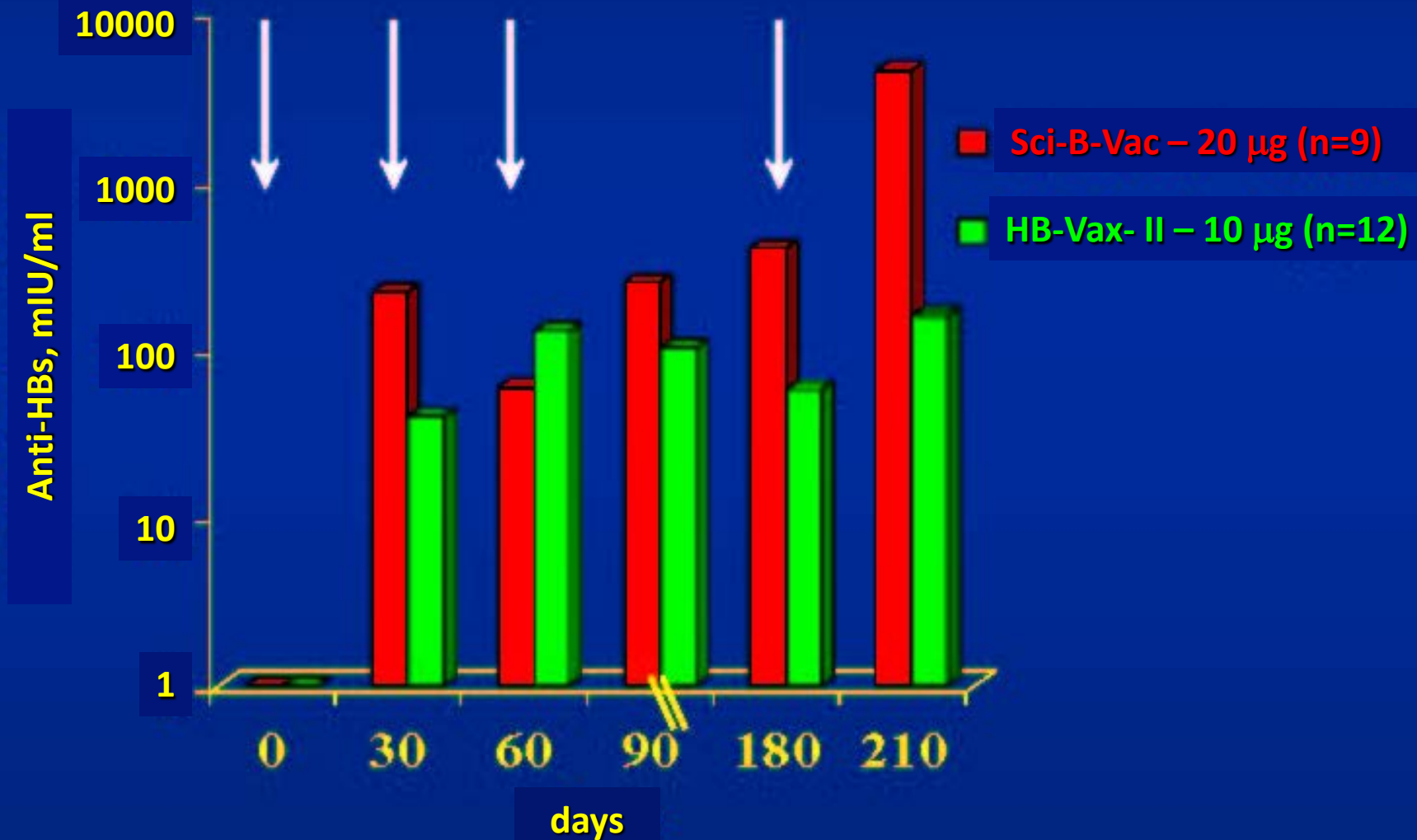


# Efficacy of a Pre-S/S Sci-B-Vac™ Vaccine in Patients Receiving Lamivudine Prophylaxis After Liver Transplantation for Chronic Hepatitis B





# Enhanced Immunogenicity of Sci-B-Vac™ in Dialysis Patients with Kidney Failure



# Special Subpopulations which may Benefit from Immunization with Sci-B-Vac™

- Non-responders to conventional HBV vaccines
- Healthcare workers involved in exposure prone procedures
- Immune suppressed patients at risk (i.e. transplant patients, candidates for chemotherapy, patients with auto-immune diseases, patients with chronic liver disease)
- Patients with renal failure before or after dialysis
- Travelers from HBV non-endemic to endemic countries who need protection on short notice
- Babies born to highly viremic HBsAg carrier mothers

# Summary : Sci-B-Vac™

- ✓ **Mimics all three HBV surface antigens of the hepatitis B virus**
- ✓ **Offers rapid onset of protection**
- ✓ **Induces high levels of anti-HBs antibodies**
- ✓ **Can be administered at lower doses than other currently available HBV vaccines**
- ✓ **Free of next-generation adjuvants**
- ✓ **Produced in mammalian cells (CHO cells)**

# The Hadassah Medical Center in Jerusalem

Thank You





# VBI VACCINES

## EXECUTIVE SUMMARY

*KEY OPINION LEADER LUNCH  
ADVANCES IN VACCINATION AGAINST HEPATITIS B*

NASDAQ: VBIV  
TSX: VBV

JUNE 13 2016

# Cautionary Statement Regarding Forward-Looking Information

*Certain statements in this presentation contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 or forward-looking information under applicable Canadian securities legislation (collectively, “forward-looking statements”) that may not be based on historical fact, but instead relate to future events, including, without limitation, statements containing the words “believe”, “may”, “plan”, “will”, “estimate”, “continue”, “anticipate”, “intend”, “expect”, “goals” and similar expressions. All statements other than statements of historical fact included in this presentation are forward-looking statements.*

*Such forward-looking statements are based on a number of assumptions, including, without limitation, assumptions regarding the successful development and/or commercialization of the company’s products, such as the receipt of necessary regulatory approvals; general economic conditions; that the company’s business is able to operate as anticipated without interruptions; competitive conditions; and changes in applicable laws, rules and regulations.*

*Although management believes that the assumptions made and expectations represented by such statements are reasonable, there can be no assurance that a forward-looking statement contained herein will prove to be accurate. Actual results and developments may differ materially from those expressed or implied by the forward-looking statements contained herein, and, even if such actual results and developments are realized or substantially realized, there can be no assurance that they will have the expected consequences or effects. Factors which could cause actual results to differ materially from current expectations include, without limitation: the failure to successfully develop or commercialize the company’s products; adverse changes in general economic conditions or applicable laws, rules and regulations; and other factors detailed from time to time in the company’s reports filed with the U.S Securities and Exchange Commission and the Canadian Securities Commissions.*

*Given these risks, uncertainties and factors, you are cautioned not to place undue reliance on such forward-looking statements and information, which are qualified in their entirety by this cautionary statement and are made only as of the date of this presentation. All forward-looking statements and information made herein are based on the company’s current expectations, and the company undertakes no obligation to revise or update such forward-looking statements and information to reflect subsequent events or circumstances, except as required by law.*



# Agenda

1. INTRODUCTION TO VBI VACCINES
2. SCI-B-VAC™ OPPORTUNITY
3. SUMMARY





# 1. Introduction to VBI Vaccines





# About VBI Vaccines

**VBI Vaccines Inc. (NASDAQ: VBIV) is developing novel technologies that seek to expand vaccine protection in significant markets of unmet medical need.**

## **VBI OVERVIEW**

- **NASDAQ: VBIV** (as at close on 6/10/2016)
  - Common Stock Currently Outstanding: 33MM Shares
  - Share Price: \$4.36
  - Market Cap: \$143MM
  - 3-Month Average Volume: 70,000
- Domiciled in Vancouver, British Columbia
- Headquartered in Cambridge, MA with its main research site in Ottawa, Canada, and a manufacturing and research facility in Rehovot, Israel



# Leading 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
- **Lipid Particle Vaccine (“LPV™”)**  
platform enables thermostable delivery, and increased access, safety, and efficacy

## PIPELINE

- **Hepatitis B Vaccine:** 3<sup>rd</sup> generation vaccine targeting non-responders to standard of care
- **Congenital CMV Vaccine:** Target young women to prevent birth defects
- **GBM Therapeutic:** Therapeutic vaccine for most common brain tumor type
- **RSV Vaccine:** Target infants to prevent respiratory disease



## 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



# VBI Vaccines Board of Directors



**DR. STEVEN GILLIS**  
CHAIRMAN OF THE BOARD



**JEFF BAXTER**  
PRESIDENT & CEO



**DR. MICHEL DE WILDE, PH.D.**



**STEVEN RUBIN**



**SCOTT REQUADT, JD**



**ADAM LOGAL**



**SAM CHAWLA**



# VBI Vaccines Global Footprint



## 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

	Research	Lead	Preclinical	Phase I	Phase II	Phase III
<b>eVLP Platform</b>						
<b>Infectious Disease</b>						
HBV (Sci-B-Vac) <i>(Licensed in 15 countries)</i>						EMA/FDA Reg. Discussions H2 2016
CMV (VBI-1501A)				Expected Ph I Start H1 2016		
RSV						
<b>Immuno-Oncology</b>						
GBM						
Undisclosed						
<b>Thermostable LPV™ Platform</b>						
Undisclosed						
Undisclosed						



## 2. Sci-B-Vac™ Opportunity

# Sci-B-Vac™ (15) Approved Markets

ONLY COMMERCIAL HBV VACCINE TO MIMIC ALL 3 VIRAL SURFACE ANTIGENS  
– ALREADY SAFELY USED IN 300,000+ PATIENTS



# Excerpt of Publicly Available Sci-B-Vac™ Data

SEVERAL PHASE II & III STUDIES HAVE BEEN CONDUCTED IN > 4,500 PATIENTS– RESULTS OF WHICH INCLUDE:

Size	Population	Sci-B-Vac™	1 <sup>st</sup> Generation HBV Vaccine
N=105	Young adults	98% SPR - month 6, post 2 <sup>nd</sup> injection; 100% SPR - post 3 <sup>rd</sup> injection	NA
N=29	ESRD	86% SPR - post 3 <sup>rd</sup> vaccination <i>(previous non-responders to double-dose of 1<sup>st</sup> generation vaccine)</i>	56% SPR - post repeated 2x-dose immunizations <i>(comparison, retrospective evaluation in same study center over 3 years)</i>
N=716	Previous low/non-responders (mean age 50 yrs)	82% SPR - post 2 <sup>nd</sup> vaccination	49% SPR - post 2 <sup>nd</sup> vaccination

Sources: Shouval D, “Enhanced Immune Response to Hepatitis B Vaccination Through Immunization with a Pre-S1/Pre-S2/S Vaccine” 2015





# Overview of Commercial Opportunity

## IMPLICATIONS FOR KEY PATIENT SEGMENTS INCLUDE:

- |  |   |
|--|---|
| <b>Diabetics</b>                               | <ul style="list-style-type: none"><li>• High unmet need</li><li>• Easy patient identification</li><li>• Superiority vs. current SoC may warrant small price premium</li></ul>                                 |
| <b>Otherwise Healthy Elderly (Age 40 - 75)</b> | <ul style="list-style-type: none"><li>• Large population – small market penetration will still produce large commercial opportunity</li><li>• Unmet need</li></ul>  |
| <b>HCWs</b>                                    | <ul style="list-style-type: none"><li>• Unmet need especially with speed to peak SPR</li><li>• Easy way to identify “otherwise healthy” population</li></ul>  |
| <b>Smokers</b>                                 | <ul style="list-style-type: none"><li>• Only slightly less immunogenic than otherwise healthy</li><li>• Recognized unmet need</li><li>• Large population but behavioral tendencies may limit access</li></ul> |
| <b>ESRD</b>                                    | <ul style="list-style-type: none"><li>• Clear unmet need</li><li>• Very small patient population</li><li>• Different dosing schedule than other segments</li></ul>  |
| <b>Other High-Risk</b>                         | <ul style="list-style-type: none"><li>• Hard to reach entire population - target specialist clinics</li><li>• High unmet need</li></ul>   |
| <b>Otherwise Healthy (Age 18-40)</b>           | <ul style="list-style-type: none"><li>• Very large (shrinking) population but small unmet need and difficult to access</li><li>• Very low commercial opportunity, hard to compete vs. Engerix-B</li></ul>     |

# Existing Requests for Named Patient Sales

**STRONG DEMAND FOR SCI-B-VAC™ OUTSIDE OF ISRAEL – SCIVAC HAS RECEIVED THE FOLLOWING REQUESTS FOR ACCESS TO SCI-B-VAC™ IN THE BELOW MARKETS:**

## *Named Patient Use:*

- April 10, 2016 – India (patient)
- March 31, 2016 – Germany (patient)
- March 1, 2016 – Germany (hospital)
- February 26, 2016 – Germany (regional German police force)
- January 28, 2016 – Hong Kong (private clinic – already registered here)
- January 25, 2016 – UK (patient)
- December 20, 2016 – UK (patient)
- October 20, 2015 – Germany (private pharmacy)
- October 14, 2015 – Germany (hospital)
- September 10, 2015 – Hong Kong (patient – already registered here)

## *Research Requests:*

- March 31, 2016 – Argentina (university)
- November 25, 2015 – Sweden (premier academic institute)



## 3. Summary

# VBI Vaccines Strategic Vision

BECOME A LEADER IN IMMUNOLOGY INNOVATION BY  
LEVERAGING VBI ASSETS & CAPABILITIES IN SIGNIFICANT  
MARKETS WITH HIGH UNMET MEDICAL NEEDS

## Infectious Disease

*Target public health priorities with high unmet need*

- Hepatitis B vaccine (VLP)
- Congenital CMV vaccine (eVLP)
- Additional targets to be announced in 2016 (eVLP)

## Immuno-Oncology

*Explore combinations with Cancer Immunotherapeutic platforms*

- GBM (eVLP)
- Additional tumors to be announced in 2016 (eVLP)
- Potential acquisition targets include Oncolytic virus platforms and other NeoAntigens

## Partnership Programs

*Leverage assets through strategic collaborations*

- Sanofi – Thermostability (LPV)
- GSK – Thermostability (LPV)



# Value Proposition for VBI Vaccines

## FOUR KEY VALUE DRIVERS IN NEXT 18 MONTHS:

- 1 **Sci-B-Vac™**: Meeting with EMA/FDA H2 2016 to determine clinical development path
- 2 **CMV**: CTA approval and Ph I trial start H1 2016
- 3 **GBM**: Pre-IND meeting with FDA H1 2016 to determine clinical development path
- 4 **Business Development**: Additional non-dilutive collaborations/partnerships H2 2016+



**VBI Vaccines Inc.**

222 Third Street, Suite 2241

Cambridge, MA 02142

(617) 830-3031

[info@vbivaccines.com](mailto:info@vbivaccines.com)

