

## SCI-B-VAC: THIRD GENERATION HBV VACCINE WORLD VACCINE CONGRESS 2017

NASDAQ: VBIV TSX: VBV

**APRIL 2017** 

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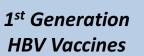
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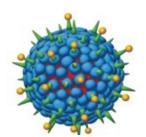
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# Introduction to Sci-B-Vac™

Sci-B-Vac<sup>™</sup> is a 3<sup>rd</sup> Generation HBV Vaccine Expressing All Major Surface Antigens of HBV – A Better Viral Mimic, Leads to Improved Potency

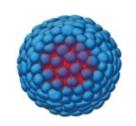




- Inactivated HBV particles derived from serum of infected individuals
- Native human glycosylation
- Include HBsAg, Pre-S1, Pre-S2
- Highly Potent

2<sup>nd</sup> Generation HBV Vaccines

Sci-B-Vac<sup>™</sup>



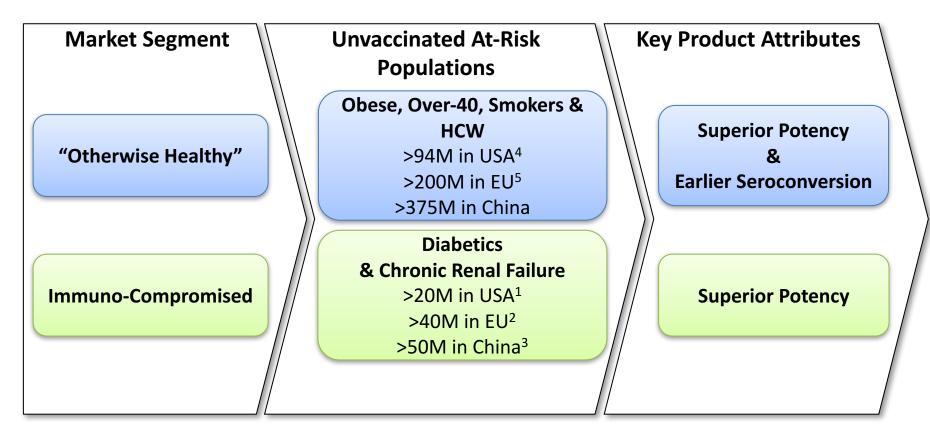
- Recombinant HBV VLPs produced in yeast
- Includes only HBsAg with yeast glycosylation
- Highly Potent in children
- Less potent in adults & immunocompromised

- Recombinant HBV VLPs produced in (CHO) cells
- Naturally mammalian glycosylated
- Include HBsAg, Pre-S1, Pre-S2
- Highly Potent in all studied populations

3

## Aging Cohorts of Unvaccinated Adults Define Key Market Segments for an Improved HBV Vaccine

Universal Pediatric Vaccination in 1990's Still Leave Majority of Adults Exposed (Adult Vaccination Rates in US & EU = 20 – 24%)



http://www.diabetes.org/diabetes-basics/statistics/
http://www.euro.who.int/en/health-topics/noncommunicable-diseases/diabetes
Yang, et al (2010), N Engl J Med, 362:1090-1101
http://www.cdc.gov/mmwr/volumes/65/ss/ss6501a1.htm
http://www.biomedcentral.com/1471-2458/8/132
Global Health Observatory Data <a href="http://apps.who.int/gho/data/view.main.80300?lang=en">http://www.biomedcentral.com/1471-2458/8/132</a>



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# The Unmet Need: High-Risk Populations of Non-Responders & Low Responders to Yeast-derived, Alum Adjuvanted, HBsAg Vaccination

### **EXEMPLAR SEROPROTECTION RATES:**

#### Immuno-compromised

o Pa	Patients with chronic liver disease ~50%		
。 C	hronic renal failure, dialysis & diabe	etes	34-81%
• P	re-transplantation candidates		28-36%
• P	ost-transplantation patients		. ~10%
"Oth	erwise Healthy"	~	50-85%
。 <b>O</b>	bese		
。 <b>O</b>	)ver age 40	Sources:	
o Si	mokers	Yang et al, Scientific Reports (2016) <u>http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4914839/</u> WHO - http://www.who.int/csr/disease/hepatitis/whocdscsrlyo20022/en/index4.htm http://jama.jamanetwork.com/article.aspx?articleid=409965 http://iama.jamanetwork.com/article.aspx?articleid=409967	
o Ti	ravellers & HCW		



# **Key Attributes of Sci-B-Vac**

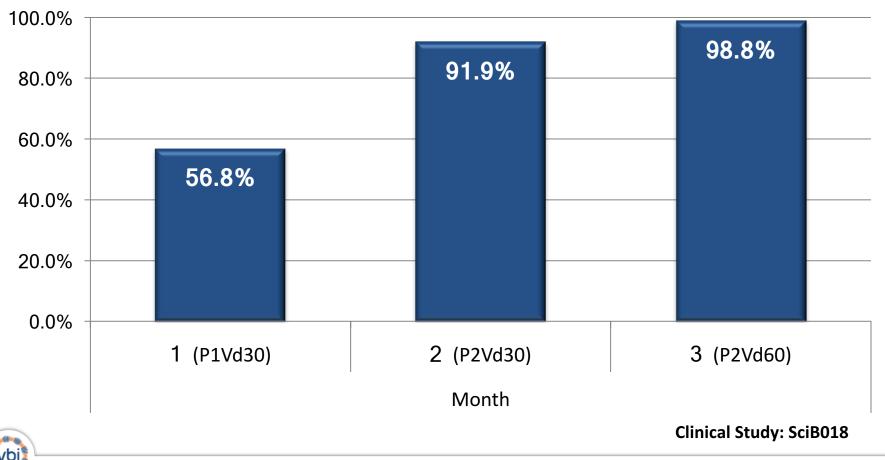
## **Opportunity for an Improved HBV Vaccine in Adult Populations**

- Improved Potency vs 2<sup>nd</sup> Generation Vaccines
- Rapid Onset of Immunity
- Potent in high-risk, non-responsive & immuno-compromised populations
- Safe, well-known adjuvant: Alum Hydroxide
- Exceptional Safety
  - Administered to over 300,000 (approx 50% neonates)



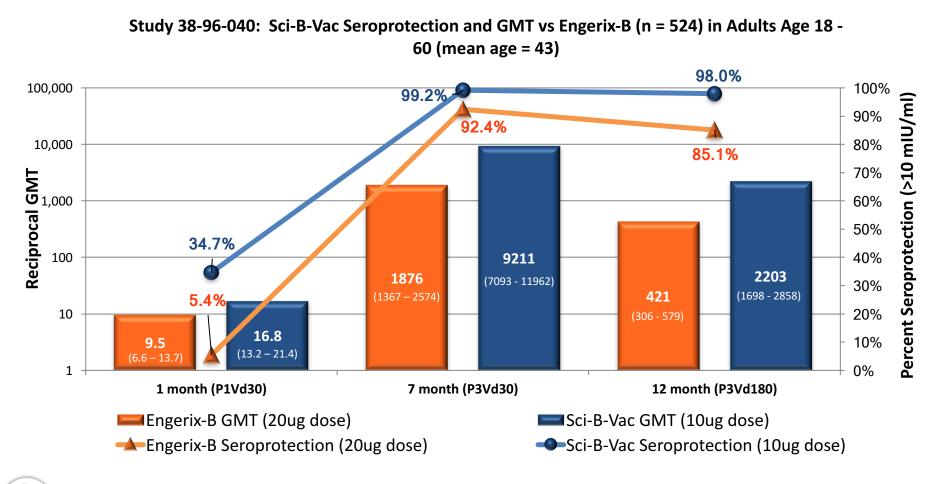
Sci-B-Vac Evokes Rapid Immunity – Recent Ph IV Study Showed Over 90% Sero-Protection After 2-Doses in Adults 18 - 40

> Sci-B-Vac Phase IV Study in Israeli Adults (age 18-40, N=88) Seroprotection (>10 mIU/mL)



# **Opportunity for Improved Potency vs 2<sup>nd</sup> Generation** Vaccines in Adult Populations

Additional Clinical Development to Define Benefits in Key Adult Populations



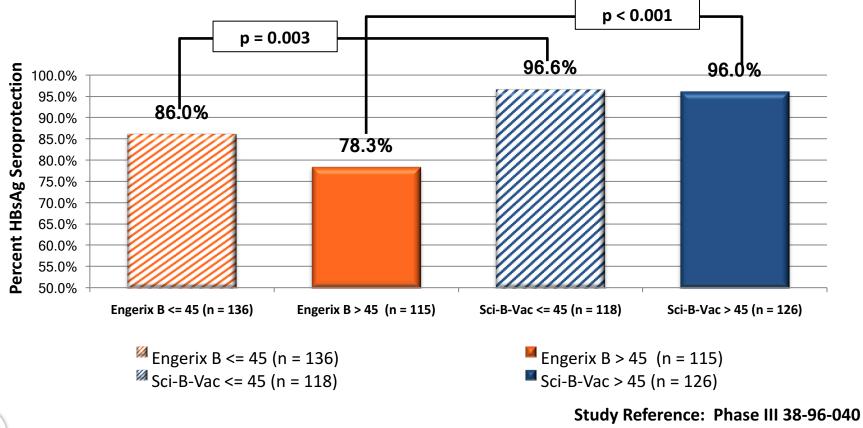
Clinical Study: 38-96-040

vbi

# Older Adults are one Population that may Benefit from Sci-B-Vac<sup>™</sup>: Superior Seroprotection Rates

Stratification by Age of Study 38-96-040 Demonstrates Significantly Improved Potency in Older Adults

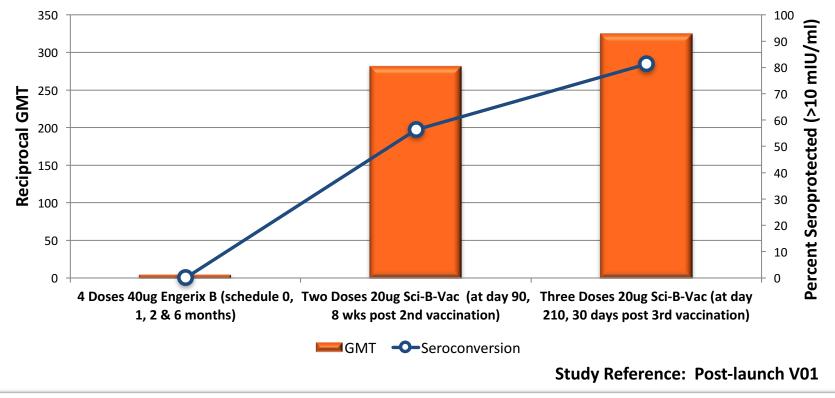




# Sci-B-Vac Offers Potential for Improved Potency in High-Risk Groups, Including Diabetics & CKD

Sci-B-Vac Stimulates Seroproective anti-HBsAg Immunity in CKD Populations That Had Not Responded to Double-Dose of Engerix-B

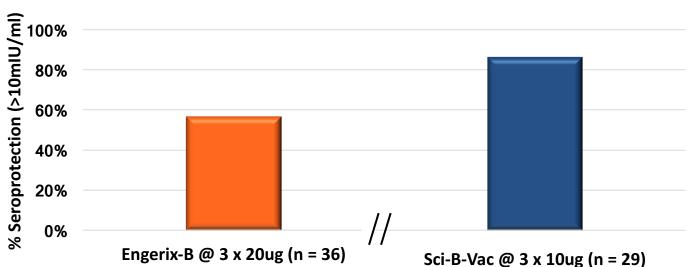
> Efficacy of Sci-B-Vac in Non-Responders: Study of 16 Chronic Kidney Disease Patients who had not responded (<10 intl. units) to 4x40ug doses of Engerix-B



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# Data in Immuno-compromised: End-Stage Renal Disease

Investigator Led (T. Weinstein, 2004) Study at Rabin Medical Center, Israel Evaluated Seroprotection Rate of Sci-B-Vac<sup>™</sup> in 29 ESRD Subjects – Notional Comparison Made to Historic Engerix-B<sup>®</sup> Responses in Same Department



Sci-B-Vac Seroprotection (>10mIU/ml) in Israeli ESRD Patients vs Historic Controls

#### Data supports further well-controlled study in Immunocompromised/ESRD populations



Study Publication: T. Weinstein, Nephron Clin Pract 2004;97:c67-c72

# Synopses of Existing Clinical Studies for Sci-B-Vac<sup>™</sup>

- 22 clinical trials conducted to date
- 14 open label clinical studies + extension studies
- 5 observer blind clinical studies
- 9 of the above studies conducted in adults, 7 of which will be used to support a phase 3 Clinical Trial Application
- More than 95% of patients are protected within 2 months after first vaccination
- Safe and well tolerated



# VBI is Discussing Its Clinical Development Priorities with Regulators in North America & Europe

## **EMA**

 Feb 2017: Received positive EMA Scientific Advice regarding Sci-B-Vac<sup>™</sup> Phase III clinical program

### **Health Canada**

 Feb 2017: Received positive response from Health Canada regarding Sci-B-Vac<sup>™</sup> Phase III clinical program

## FDA

• Expecting feedback on proposed clinical development plans in H1 2017



# **Prophylactic Sci-B-Vac™ Summary**

#### **OPPORTUNITY FOR IMPROVED POTENCY IN ADULT & AT-RISK POPULATIONS**

- Potent & Rapid HBV Immunity
  - Improved potency vs 2<sup>nd</sup> generation HBV vaccines
  - Rapid onset of immunity
  - Stimulation of immunity in non-responders
- VBI is currently developing Sci-B-Vac for prophylactic adult Indication in US/EU
  - History of safety with over 300,000 doses administered (all populations)
  - Established manufacturing protocols at GMP commercial scale
- Integrated regulatory feedback on VBI's proposed clinical development plan is expected from North American & European regulators in H1 2017





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