

**VBI**  
VACCINES

ACTIVATING THE POWER WITHIN

# Corporate Overview

# Forward-Looking & Safe Harbor Statements

Certain statements in this presentation that are forward-looking and not statements of historical fact are forward-looking statements within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and are forward-looking information within the meaning of Canadian securities laws (collectively “forward-looking statements”).

The Company cautions that such statements involve risks and uncertainties that may materially affect the Company’s results of operations. Such forward-looking statements are based on the beliefs of management as well as assumptions made by and information currently available to management.

Actual results could differ materially from those contemplated by the forward-looking statements as a result of certain factors, including but not limited to, the impact of general economic, industry or political conditions in the United States or internationally; the impact of the COVID-19 pandemic and the continuing effects of the COVID-19 pandemic on our clinical studies, manufacturing, business plan, and the global economy; the ability to successfully manufacture and commercialize PreHevbrio/PreHevbri; the ability to establish that potential products are efficacious or safe in preclinical or clinical trials; the ability to establish or maintain collaborations on the development of pipeline candidates and the commercialization of PreHevbrio/PreHevbri; the ability to obtain appropriate or necessary regulatory approvals to market potential products; the ability to obtain future funding for developmental products and working capital and to obtain such funding on commercially reasonable terms; the Company’s ability to manufacture product candidates on a commercial scale or in collaborations with third parties; changes in the size and nature of competitors; the ability to retain key executives and scientists; and the ability to secure and enforce legal rights related to the Company’s products.

A discussion of these and other factors, including risks and uncertainties with respect to the Company, is set forth in the Company’s filings with the SEC and the Canadian securities authorities, including its Annual Report on Form 10-K filed with the SEC on March 7, 2022, and filed with the Canadian security authorities at [sedar.com](https://www.sedar.com) on March 7, 2022, as may be supplemented or amended by the Company’s Quarterly Reports on Form 10-Q.

Given these risks, uncertainties and factors, you are cautioned not to place undue reliance on such forward-looking statements, which are qualified in their entirety by this cautionary statement.

All such forward-looking statements made herein are based on our current expectations and we undertake no duty or obligation to update or revise any forward-looking statements for any reason, except as required by law.



# About VBI : Immune to Limitations



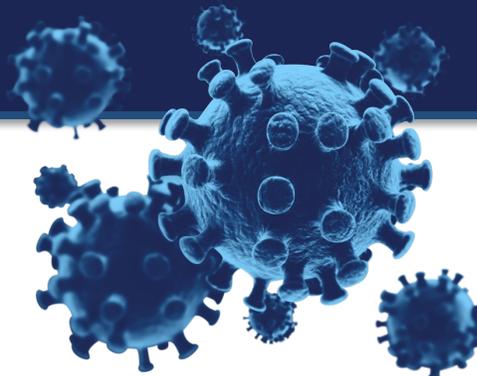
We are a biotechnology company **driven by immunology** in the pursuit of powerful prevention and treatment of disease



Through our innovative approach to **virus-like particles**, our vision is to stimulate and amplify the human immune system to **target and overcome significant, aggressive, and urgent infectious diseases and cancers**



Our belief in the importance of **protecting and enhancing human life** is at the core of everything we do



# The Science of Virus-Like Particles (VLPs)

Transforming natural immunity into potent protection and treatment

## VLPs

*Virus-Like Particles*

Sub-unit vaccines with no infectious material

VLPs mimic the natural presentation of viruses

Limited targets, however, as only a few antigens self-assemble into orderly VLP structures (incl. the hepatitis B surface antigens)



## eVLPs

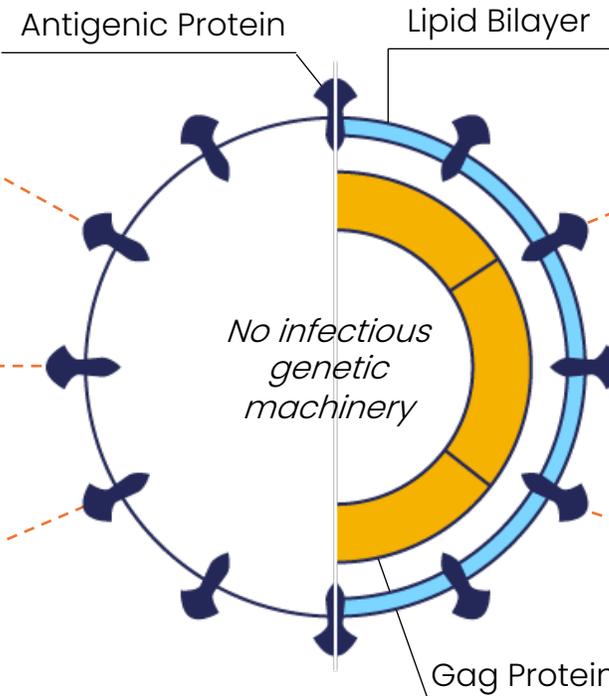
*Enveloped Virus-Like Particles*

- VBI's Proprietary Platform Technology -

eVLPs expand the list of potentially-viable target indications by providing a stable core (Gag Protein) and lipid bilayer

Flexible and customizable

Highly immunogenic with demonstrated safety profile



VBI's pipeline programs consist of both self-assembling VLP candidates and eVLP candidates

# VBI's Portfolio : Both Sides of the Fight

VBI's broad portfolio is designed to power the immune system to prevent and treat disease

Disease	Name/Program	Technology	Preclinical	Phase 1	Phase 2	Phase 3	Registration/ Commercial
<b>Approved Prophylactic Vaccine</b>							
Hepatitis B (HBV)	 <b>PreHevbrio</b> <sup>1,2,3,4</sup> Hepatitis B Vaccine (Recombinant)	VLP					
<b>Prophylactic Candidates</b>							
Cytomegalovirus (CMV)	VBI-1501	eVLP					
COVID-19 (Ancestral)	VBI-2902 (monovalent)	eVLP					
COVID-19 (Beta Variant)	VBI-2905 (monovalent)	eVLP					
Coronaviruses	VBI-2901 (multivalent)	eVLP					
Coronaviruses	Undisclosed (multivalent)	eVLP					
Zika	VBI-2501	eVLP					
<b>Therapeutic Candidates</b>							
Hepatitis B (HBV)	VBI-2601 (BR11-179)	VLP					
Glioblastoma (GBM)	VBI-1901	eVLP					
Other CMV+ Tumors	Undisclosed	eVLP					



<sup>1</sup>Approved for use in the U.S. for the prevention of infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older

<sup>2</sup>Approved for use in Israel, under the brand name Sci-B-Vac®, for active immunization against hepatitis B virus (HBV) infection

<sup>3</sup>Approved for use in the E.U., EEA, and U.K. under the brand name PreHevbri™ [Hepatitis B vaccine (recombinant, adsorbed)] for active immunisation against infection caused by all known subtypes of the hepatitis B virus in adults

<sup>4</sup>Approved for use in Canada for active immunization against infection caused by all known subtypes of hepatitis B virus in adults 18 years of age and older

# Notable Recent Accomplishments Prepare VBI for a Transformative 2023



First U.S., E.U., & Canadian Approval

- PreHevbrio™ (Hepatitis B Vaccine [Recombinant]) **approved by the FDA in Nov. 2021**, added to the ACIP list of recommended HBV vaccines in Feb. 2022, and launched in the U.S. at the end of March 2022
- PreHevbri™ (Hepatitis B vaccine [recombinant, adsorbed]) **approved by the European Commission in April 2022 and by the UK MHRA in May 2022**
- U.S. CDC published updated ACIP recommendation that all adults aged 19–59 be immunized against HBV in April 2022
- PreHevbrio **approved by Health Canada in December 2022**



Advancement & Expansion of Pipeline

#### Chronic HBV:

- Positive interim Phase 2 data from combination with siRNA demonstrated robust induction of HBV-specific T-cells and antibody responses in chronically infected patients

#### GBM:

- FDA Fast Track Designation granted in Jun. 2021; Orphan Drug Designation granted in Jun. 2022 for VBI-1901
- Improvements in median overall survival (mOS), 12-mo. OS, and 18-mo. OS demonstrated in both arms of ongoing Phase 1/2a study relative to historical controls

#### COVID-19 & Coronaviruses:

- Initiated first human study of multivalent coronavirus vaccine, VBI-2901, designed to increase breadth of protection against COVID-19 and related coronaviruses



Strong Financial Position

- **Ended Q3 2022 with \$83.6M on balance sheet**
- **Coronavirus Vaccine Collaborations** : Ongoing collaborations with CEPI (up to USD\$33M) and the Gov. of Canada (up to CAD\$56M) to support development of coronavirus program



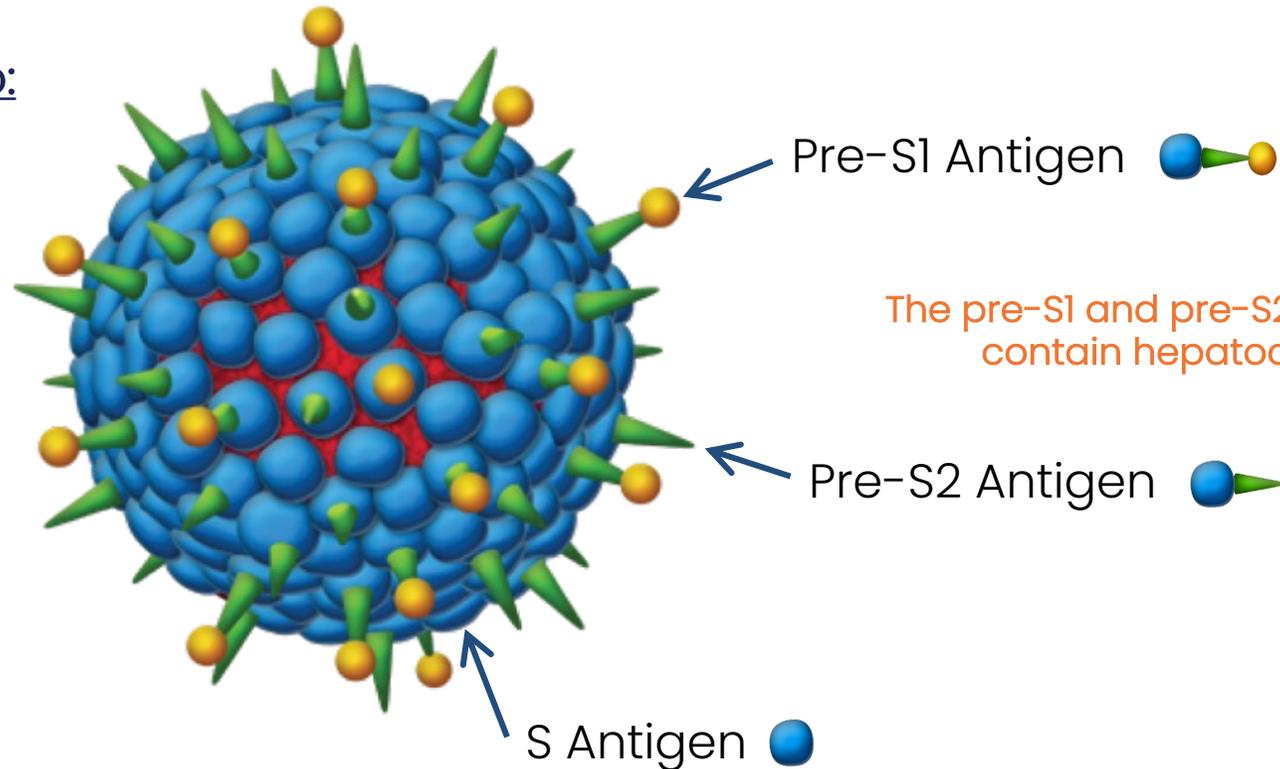
# PreHevbrio

Hepatitis B Vaccine (Recombinant)

# PreHevbrio is the Only 3-Antigen HBV Vaccine

PreHevbrio is scientifically differentiated from other HBV vaccines – expressing the three hepatitis B surface antigens (S, pre-S1, and pre-S2), and manufactured in mammalian cells (vs. yeast)

PreHevbrio:



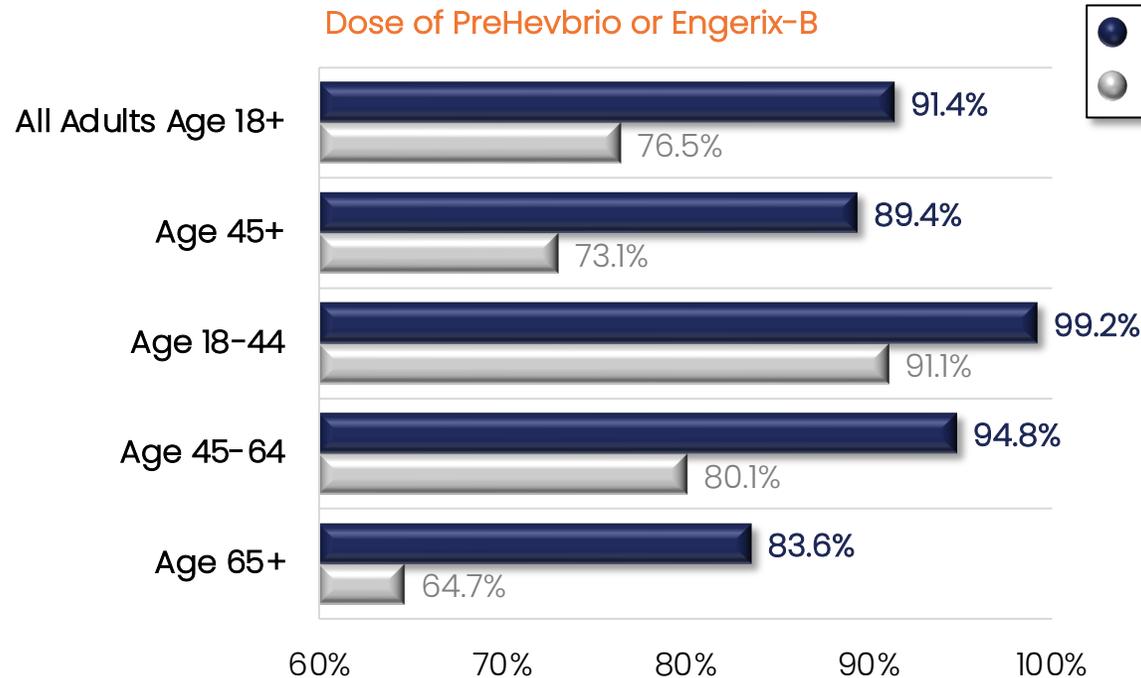
The pre-S1 and pre-S2 regions of the hepatitis B virus contain hepatocyte receptor binding sites

# More Adults Achieved Seroprotection with PreHevbrio in Phase 3 Studies

## PROTECT Phase 3 Study

2-arm safety and immunogenicity study  
N=1,607 adults aged 18-90 years

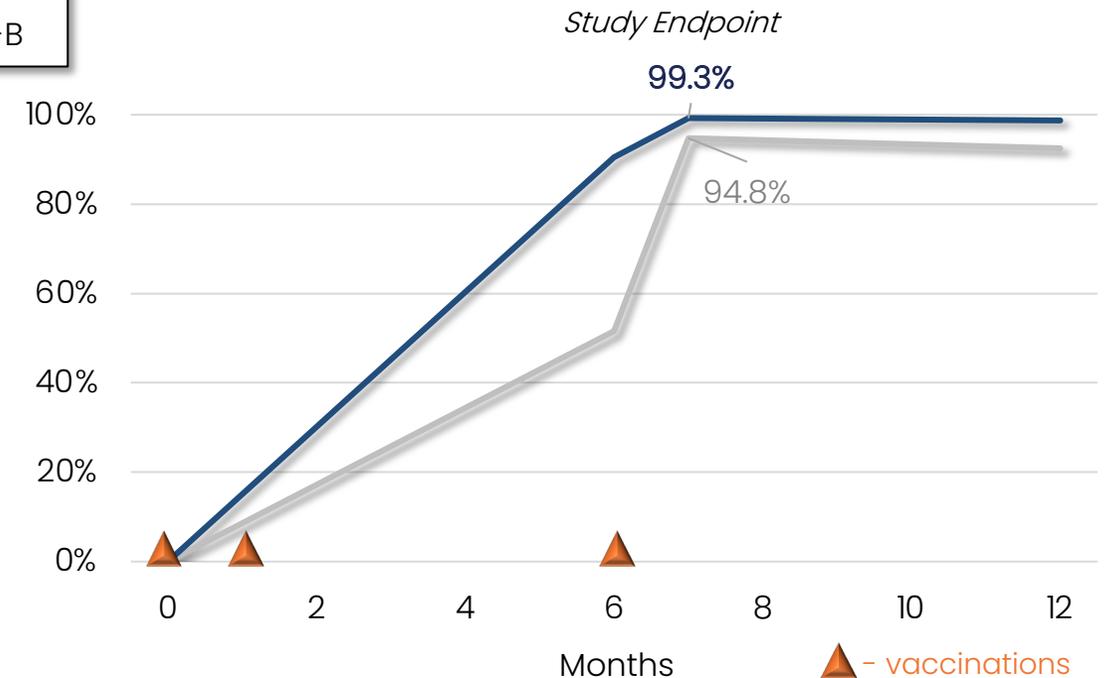
Seroprotection Rate<sup>1</sup> (SPR) 4 Weeks After Receiving the 3<sup>rd</sup>  
Dose of PreHevbrio or Engerix-B



## CONSTANT Phase 3 Study

4-arm lot-to-lot consistency study  
N=2,838 adults aged 18-45 years

Seroprotection Rate<sup>1</sup> (SPR) in Adults Age 18-45 After  
Receiving PreHevbrio or Engerix-B



The integrated safety analysis demonstrated good tolerability with no unexpected reactogenicity. The most common adverse events in all age groups were injection site pain and tenderness, myalgia, and fatigue, all which generally resolved without intervention in 1-2 days

<sup>1</sup>Seroprotection rate defined as % of subjects who achieve anti-HBs titers  $\geq 10$  mIU/mL

Sources: PreHevbrio U.S. Full Prescribing Information; Vesikari T, et al. "Immunogenicity and safety of a 3-antigen hepatitis B vaccine vs a single-antigen hepatitis B vaccine: a phase 3 randomized clinical trial". *JAMA Network Open* 2021; 4(10).

# Hepatitis B Remains a Persistent Public Health Problem

HBV infection is the most common blood-borne infection, with an estimated 240M–350M chronically-infected individuals worldwide

## U.S. & Europe : HBV Disease Burden and Challenges



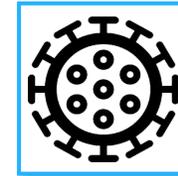
Suboptimal surveillance results in under-representation of true disease burden

- No. of chronically-infected adults:
- 2018 U.S. surveillance data estimates **862,000 adults**, but may be as high as **2.2 million**<sup>1</sup>
  - European estimates report **~5 million** are chronically infected<sup>2</sup>



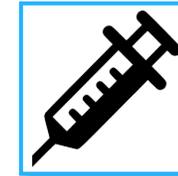
Acute HBV disease rates have increased in recent years

- U.S. acute HBV Adult Infections **increased 11%** from 2014–2018<sup>3</sup>
- In Europe, the highest rate of acute infections is among **35–44-year-olds**<sup>4</sup>



Low awareness of infection status leads to increased risk of transmission

- **68%** of chronically-infected adults in the U.S. are **unaware of their infection status**<sup>5</sup>
- A recent ECDC survey showed proportion of **undiagnosed infections range between 45%–85%**<sup>2</sup>



Adult vaccination rates remain persistently low

- The 2018 reported U.S. HBV vaccination rate for adults age 19+ was **only 30.0%**, leaving almost **200 million unprotected adults**<sup>6</sup>



# Public Health Bodies are Changing Tactics, Bringing Renewed Prioritization in the Fight to Eliminate HBV

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## Changing U.S. Adult HBV Vaccination Guidelines

- In November 2021, the CDC's Advisory Committee on Immunization Practices (ACIP) unanimously voted to move from a risk-based HBV adult vaccination recommendation to a universal recommendation for adults aged 19–59 years
  - A risk-based recommendation remains for adults age 60+
- April 2022 MMWR publication detailed new guidelines and PreHevbrio's inclusion into the list of recommended products for adult prophylactic HBV vaccination

## Public Health Action Plans for Elimination of Hepatitis B

- Both Healthy People 2020 & the Viral Hepatitis Strategic Plan 2021–2025 include notable targets to:
  - Reduce the rate of acute HBV infection
  - Increase infection awareness
  - Reduce the rate of HBV-related deaths
- The WHO has adopted the goal of eliminating HBV globally by 2030



# Commercialization & Upcoming Milestones

## Commercialization Partnerships :



- VBI entered into a full end-to-end commercialization partnership with Syneos Health in 2019 to support the U.S. launch of PreHevbrio™, including VBI-dedicated leadership, medical, market access, and sales teams
- Syneos Health selected as partner for their robust and innovative commercialization experience and deep vaccine expertise, including successful partnerships with leading vaccine manufacturers

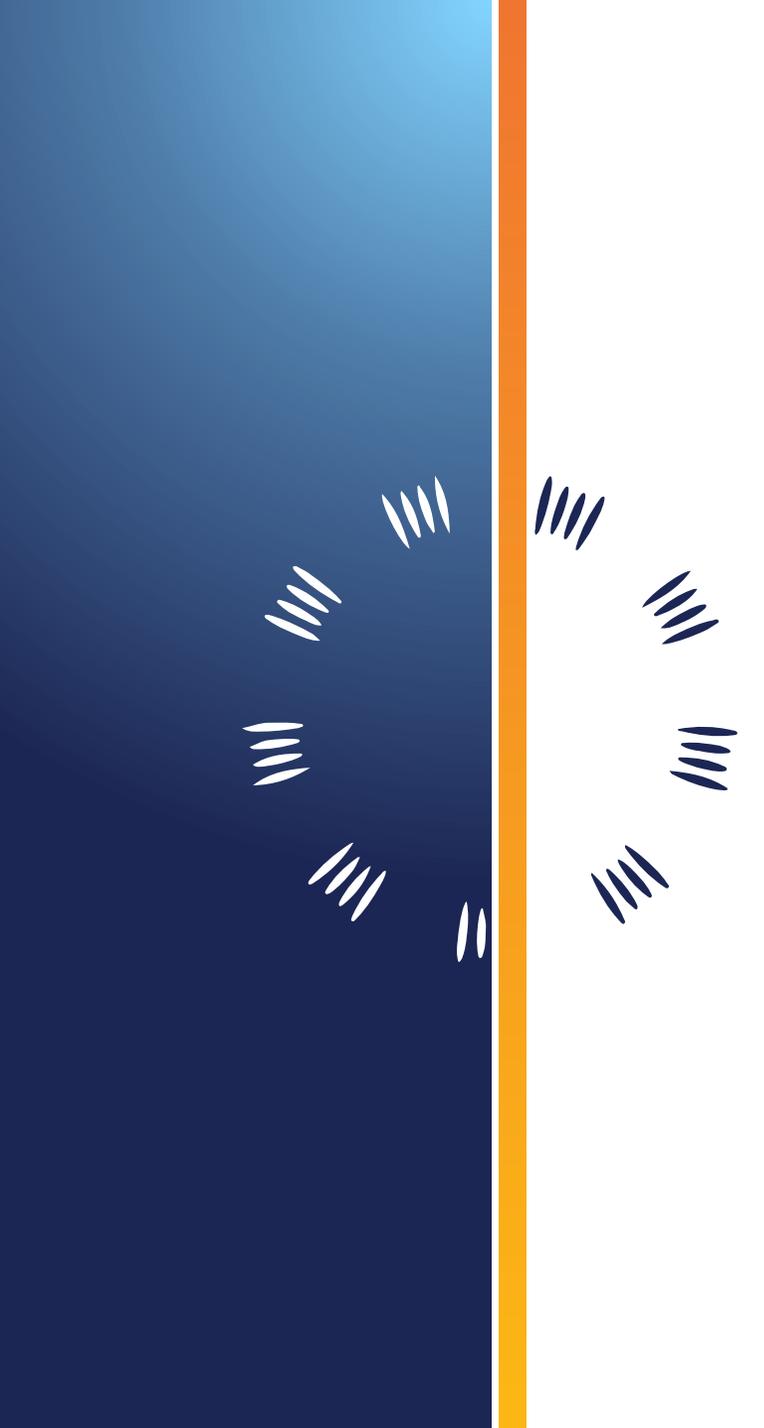


- VBI and specialty vaccine company Valneva entered into a partnership in 2022 for the commercialization of PreHevbri® in the following initial markets : the U.K., Sweden, Norway, Denmark, Finland, Belgium, and the Netherlands
- Valneva will be responsible for all marketing, sales, and in-country distribution in these European markets, and was chosen as a partner for their extensive vaccine commercialization experience, local knowledge, and relationships

## Upcoming Milestones :

- **H1 2023** : Following European Commission and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA) approvals, VBI expects to make PreHevbri available in certain European countries beginning in H1 2023
- **2023** : Following Health Canada approval in December 2022, VBI expects to make PreHevbrio available in Canada in 2023





# Hepatitis B (HBV)

Therapeutic Candidate : VBI-2601

# Current Chronic Hepatitis B Landscape

Chronic HBV infection represents a critical unmet public health need and an opportunity for meaningful innovation to achieve a functional cure

<b>Global chronic HBV (cHBV) unmet need:</b>	<b>Current standard-of-care treatments are suboptimal:</b>	<b>A functional cure for HBV is defined as:</b>
<ul style="list-style-type: none"><li>• Over <b>290 million</b> adults estimated to be infected with cHBV worldwide</li><li>• Nearly <b>1 million</b> annual deaths from HBV-related causes<sup>1</sup></li></ul>	<ul style="list-style-type: none"><li>• Nucleotide/nucleoside reverse transcriptase inhibitors (NRTIs) and interferon regimen <b>require lifelong treatment</b></li><li>• Studies and real-world use have shown this treatment lowers but does not fully clear the virus</li></ul>	<ul style="list-style-type: none"><li>• Achievement of undetectable HBV surface antigen (HBsAg) levels</li><li>• Sustained suppression of HBV DNA</li></ul>



# VBI-2601 : Potential to be a Critical Component of a Functional Cure for Chronic HBV Infection

Scientific consensus is that a functional cure for HBV is within reach, but will likely require the use of an immunotherapeutic as part of a combination approach

A functional cure will likely require the achievement of :

1. Drive down hepatitis B virus (HBV) DNA
2. Drive down immuno-suppressive HBV S-antigen
3. Achieve long-term immunologic control

VBI-2601 has a similar conformation to PreHevbrio, but has been reformulated to enhance B and T cell responses, with the aim of restoring defective HBV-specific humoral and cellular immunity in chronic HBV patients



# VBI-2601 Development Plan & Status

Studies designed & executed in partnership with Bii Biosciences

## Phase 1b/2a Study *Completed in 2021*

- Two-part, multi-center, controlled, dose-escalation study (n=44)
- Assessed VBI-2601 safety, tolerability, and immunologic antiviral activity in non-cirrhotic patients with chronic HBV infection
- Conducted in Australia, New Zealand, Thailand, South Korea, Hong Kong, and China

Data demonstrated that VBI-2601 induced both B cell and T cell responses and was well tolerated with no safety signals observed

ANZCTR.org.au Identifier : ACTRN12619001210167

## Phase 2 Combination Study

*Initiated April 2021*

- First-in-class study to evaluate safety and efficacy of VBI-2601 in combination with an HBV-targeting siRNA (VIR-2218)
- Multi-center study to be conducted in Australia, New Zealand, Thailand, South Korea, Hong Kong, China, Singapore, and Taiwan
- Expected enrollment of ~135 adults aged 18-60 years with chronic HBV infection
- **Interim topline Phase 2 data presented February 2023 at APASL**

ClinicalTrials.gov Identifier : NCT04749368

## Phase 2a/2b "Add-On" Study to Standard-of-Care

*Initiated December 2021*

- Two-part Phase 2 study designed to evaluate the clinical effect of adding VBI-2601 to existing standard of care therapy (PEG-IFN- $\alpha$  and NrtI) in non-cirrhotic HBV patients
- Expected enrollment of ~600 subjects in China
- **Interim topline results expected Q3 2023**

ChinaDrugTrials.org.cn Identifier : CTR20213100



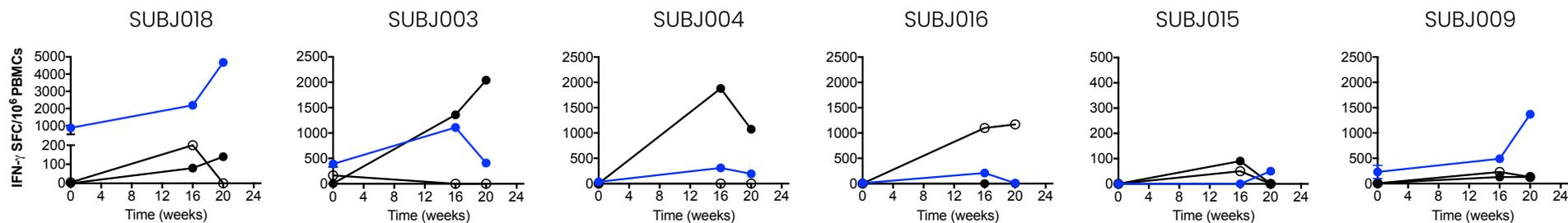
# Proof of Mechanism : Significant Restoration of Antibody and T Cell Responses Demonstrated in Phase 1b/2a Study

Complete dataset announced at the International Liver Congress 2021

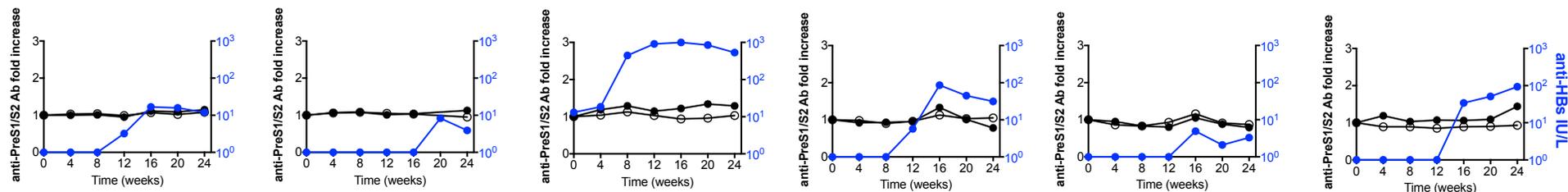
- Potent re-stimulation of T cell responses to HBV surface antigens (S, Pre-S1, Pre-S2) seen in 67% (Cohort B n=6/9) and 78% (Cohort C n=7/9) of evaluable patients in the low-dose VBI-2601 unadjuvanted and adjuvanted, respectively
- Boosting of antibodies to HBV surface antigens observed in 19/43 (44.2%) of evaluable patients

## VBI-2601 Unadjuvanted Data – Responders

T cell Responses

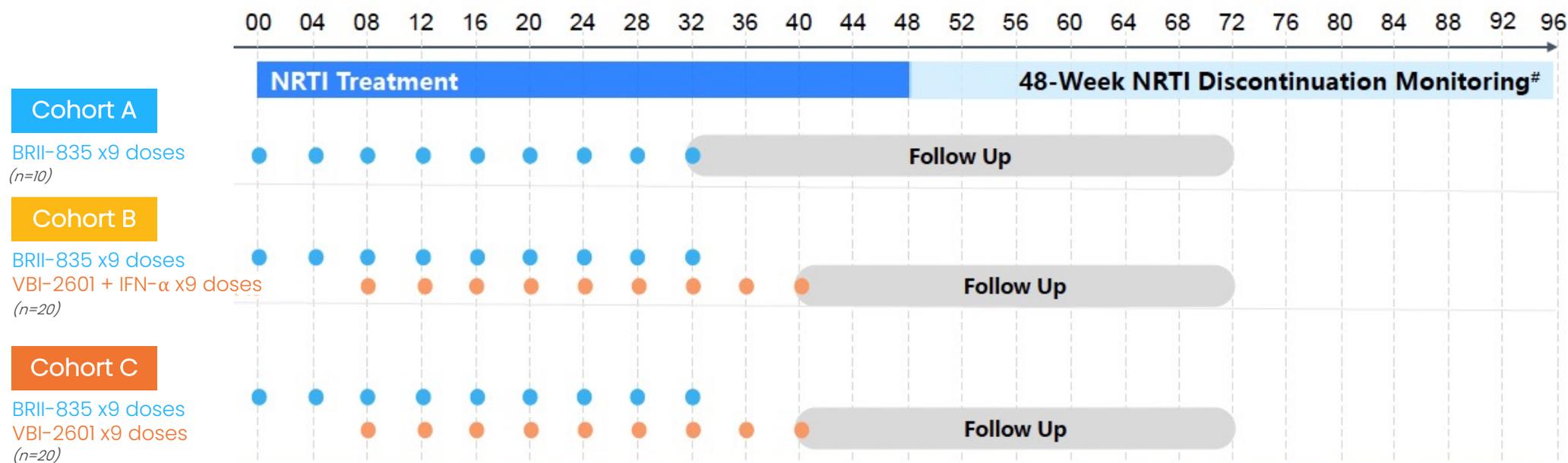


Antibody Responses



# Phase 2 Combination Study : Design

n=50 adult, non-cirrhotic patients who received ≥ 12 months NRTI treatment were randomized across 3 cohorts



BRII-835 100mg via subcutaneous injection (SC) | VBI-2601 (BRII-179) 40µg ± coadjuvant IFN-α 3 MIU via intramuscular injection (IM)

# Participants meeting NRTI discontinuation criteria, defined as undetectable HBsAg and HBeAg, alanine aminotransferase < 2x upper limit of normal, and HBV DNA < LLOQ, will be eligible to withdraw NRTI therapy

IFN-α, interferon-alpha; LLOQ, lower limit of quantification; NRTI, nucleos(t)ide reverse transcriptase inhibitor

- Adult participants on NRTI ≥ 12 months with HBV DNA < LLOQ were enrolled
- Preliminary safety and efficacy data through Week 40 are presented



# Phase 2 Combination Study : Patient Demographics

	Cohort A n=11*	Cohort B n=20	Cohort C n=20
Mean Age ± SD (years)	45.9 ± 10.5	47.6 ± 9.1	45.3 ± 9.5
Male, n (%)	8 (72.7%)	14 (70.0%)	15 (75.0%)
Race, n (%)			
Asian	11 (100%)	18 (90%)	18 (90.0%)
Black or African American	0	2 (10.0%)	1 (5.0%)
White	0	0	1 (5.0%)
HBeAg Status at Baseline, n (%)			
Negative	9 (81.8%)	15 (75.0%)	14 (70.0%)
Positive	2 (18.2%)	5 (25.0%)	6 (30.0%)
Median (Range) Baseline HBsAg (IU/mL)	387.3 (145.4, 1222.0)	694.7 (175.8, 6479.0)	832.7 (160.2, 3169.0)
Mean Baseline log <sub>10</sub> HBsAg ± SD (IU/mL)	2.63 ± 0.30	2.97 ± 0.42	2.90 ± 0.35
Mean Baseline ALT ± SD (U/L)	20.3 ± 11.4	21.4 ± 9.5	21.6 ± 9.9

\* One participant withdrew consent prior to study drug administration  
 ALT, alanine aminotransferase; HBeAg, hepatitis B virus E antigen; HBsAg, hepatitis B virus surface antigen; SD, standard deviation

- Baseline HBV S antigen (HBsAg) notably lower in Cohort A compared with baseline levels in Cohorts B and C



# VBI-2601 Well Tolerated in Both Combination Cohorts

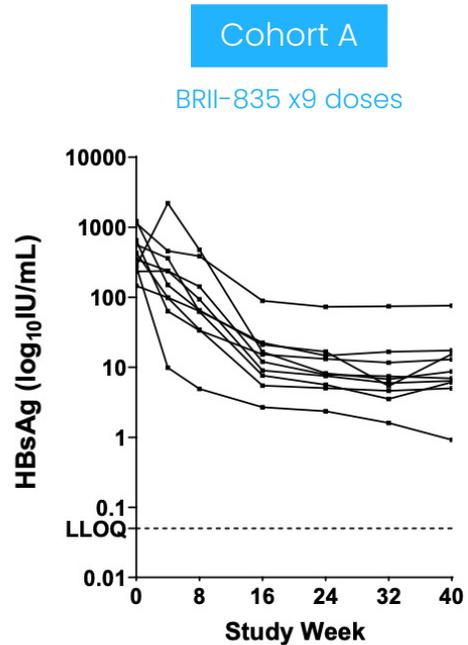
	Cohort A n=10	Cohort B n=20	Cohort C n=20
Any TEAEs	10 (100%)	19 (95.0%)	20 (100%)
Grade 1 TEAEs	10 (100%)	19 (95.0%)	17 (85.0%)
Grade 2 TEAEs	1 (10.0%)	7 (35.0%)	6 (30.0%)
≥ Grade 3 TEAEs	0	0	2 (10.0%)
BR11-835 Related TEAEs	7 (70.0%)	13 (65.0%)	10 (50.0%)
VBI-2601 (BR11-179) + IFN-α Related TEAEs	NA	17 (85.0%)	NA
VBI-2601 (BR11-179) Related TEAEs	NA	NA	10 (50.0%)
Serious TEAEs*	0	1 (5.0%)	3 (15.0%)
AEs Leading to Treatment Discontinuation <sup>#</sup>	0	0	1 (5.0%)
AEs Leading to Study Discontinuation <sup>#</sup>	0	0	1 (5.0%)
ALT Increased			
Grade 1	5 (50.0%)	6 (30.0%)	10 (50.0%)
Grade 2	0	0	0
≥ Grade 3	0	0	0
AST Increased			
Grade 1	3 (30.0%)	7 (35.0%)	6 (30.0%)
Grade 2	0	1 (5.0%)	0
≥ Grade 3			
Total Bilirubin Increased			
Grade 1	0	2 (10.0%)	0
Grade 2	0	0	0
≥ Grade 3	0	0	0

- Majority of TEAEs were Grade 1 or 2 in severity; none of ≥ Grade 3 or serious TEAEs were treatment related
- Most common TEAEs across cohorts were injection site reactions (56.0%)
- TEAEs with higher incidence in Cohort B (i.e., headache, fatigue, myalgia, and pyrexia) were consistent with the known side effects of IFN-α
- Mild asymptomatic ALT and/or AST elevations were observed; mostly grade 1 in severity
- Two participants experienced borderline total bilirubin elevations (22 and 23 μmol/L, respectively); none were reported as an AE

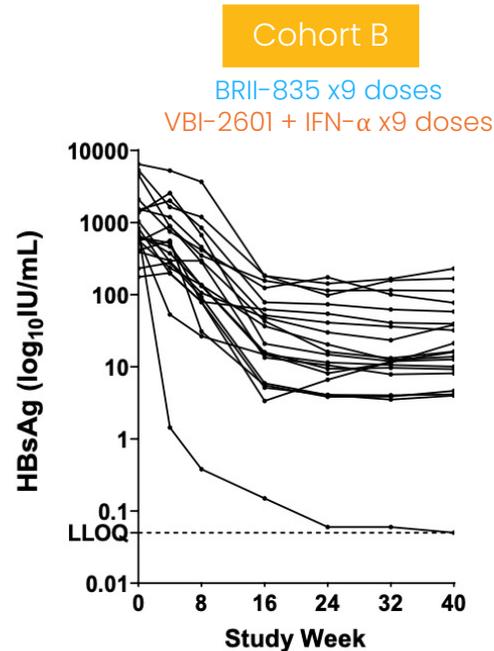


NA, not applicable; TEAE, treatment-emergent adverse event  
 \* One chest pain (non-cardiac) in Cohort B; one each of duodenal ulcer, Ludwig's angina, and chest pain (non-cardiac) in Cohort C  
 # One participant experiencing duodenal ulcer withdrew study prematurely  
 ALT, alanine aminotransferase; AST, aspartate aminotransferase

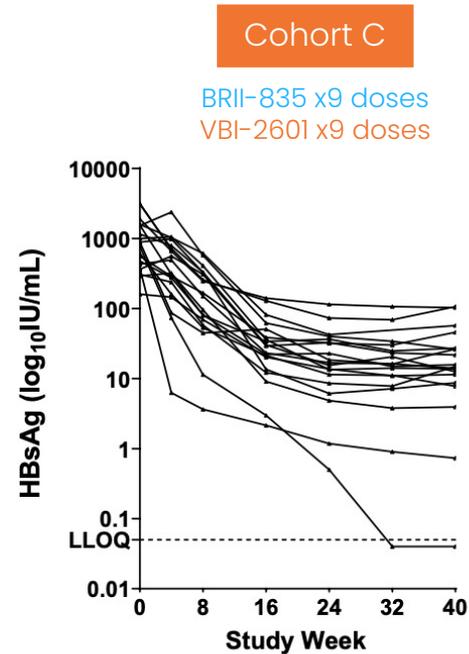
# Notable Reductions in S Antigen Seen Across Cohorts



Baseline HBsAg : 387.3 IU/mL  
(145.4, 1222.0)



Baseline HBsAg : 694.7 IU/mL  
(175.8, 6479.0)



Baseline HBsAg : 832.7 IU/mL  
(160.2, 3169.0)

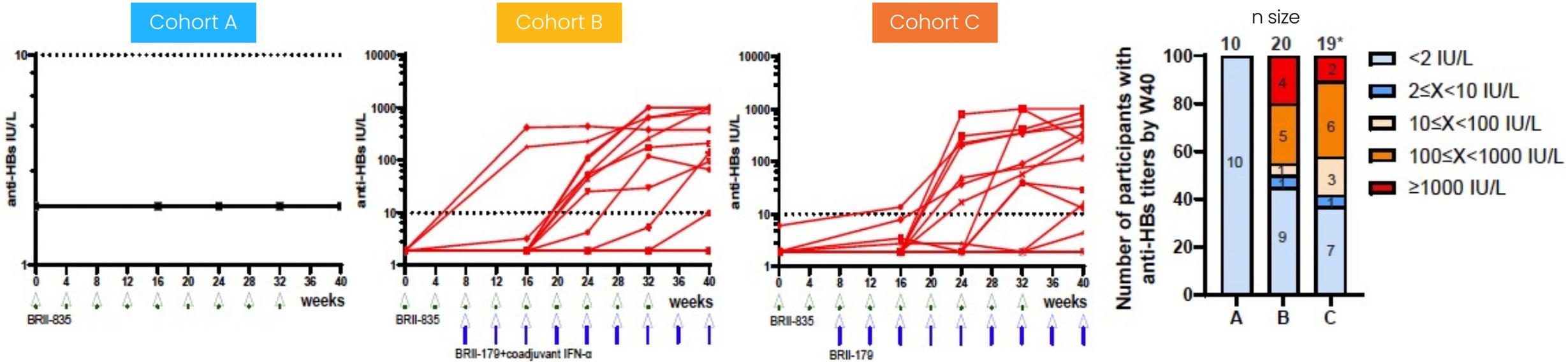
## Mean (SD) Change From Baseline ( $\log_{10}$ IU/mL)

	Week 32 (siRNA EOT)	Week 40 (Combo EOT)
Cohort A (n=10)	-1.75 (0.39)	
Cohort B (n=20)	-1.78 (0.58)	-1.75 (0.60)
Cohort C (n=20)	-1.81 (0.71)	-1.77 (0.72)

- Mean HBV S antigen (HBsAg) reductions from baseline were comparable across all cohorts



# VBI-2601 + siRNA (BRII-835) Combination Elicited Robust Restoration of HBV Surface Antibodies

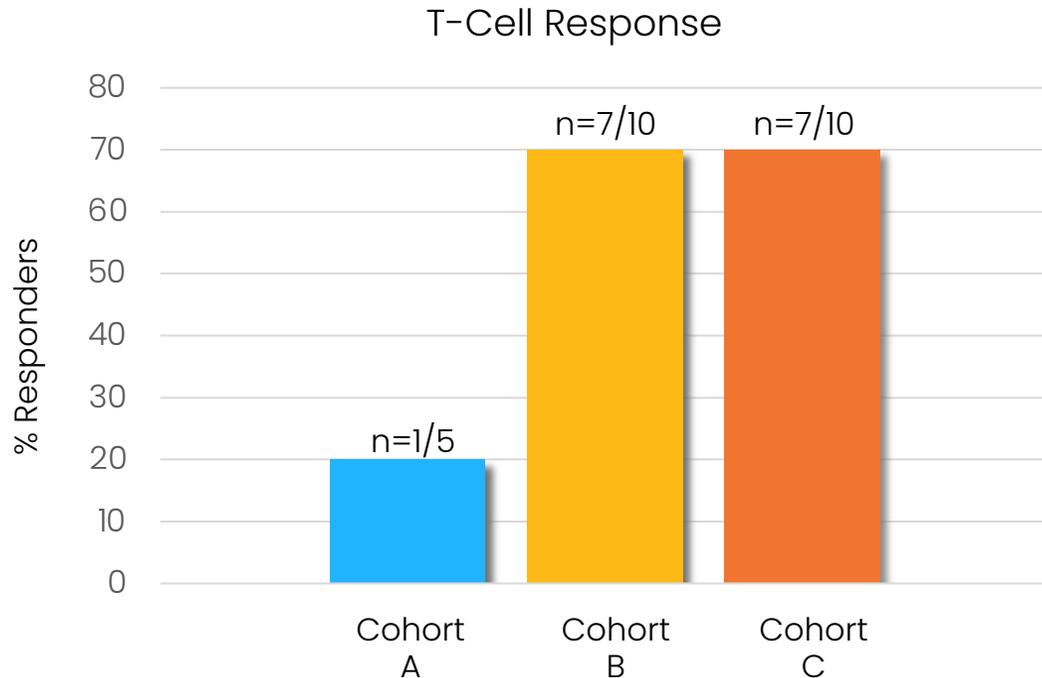


- High antibody titers  $\geq 10$  IU/L induced in 50% (Cohort B n=10/20) and 58% (Cohort C n=11/19) of patients who received combination regimen – no antibody responses were detected in Cohort A (siRNA control arm)
- VBI-2601 induced potent anti-HBs responses with titers reaching the upper limit of the assay (1000 IU/L)
- Two early responders in Cohort B achieved robust boosting of antibody titers ( $> 100$  IU/L) after two doses of VBI-2601



# VBI-2601 + siRNA Combination Induced Strong S Antigen-Specific T-Cell Responses

VBI-2601 with or without co-adjuvant IFN- $\alpha$  generated notable improvements in HBV S Antigen (HBsAg)-specific T-Cell responses compared to siRNA alone

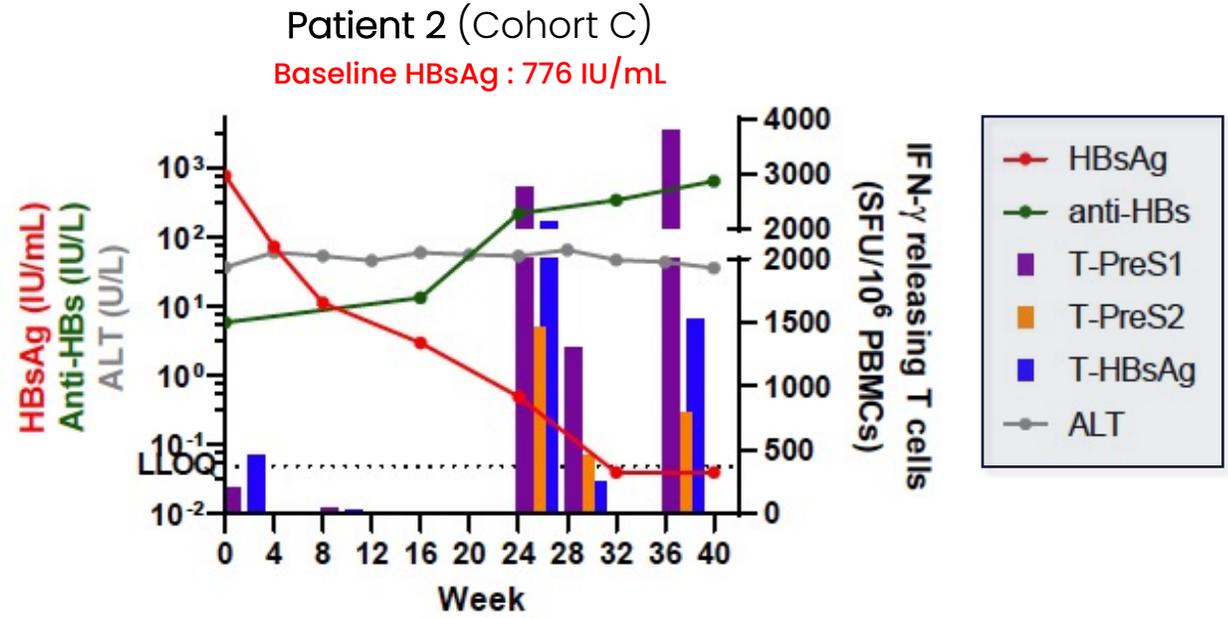
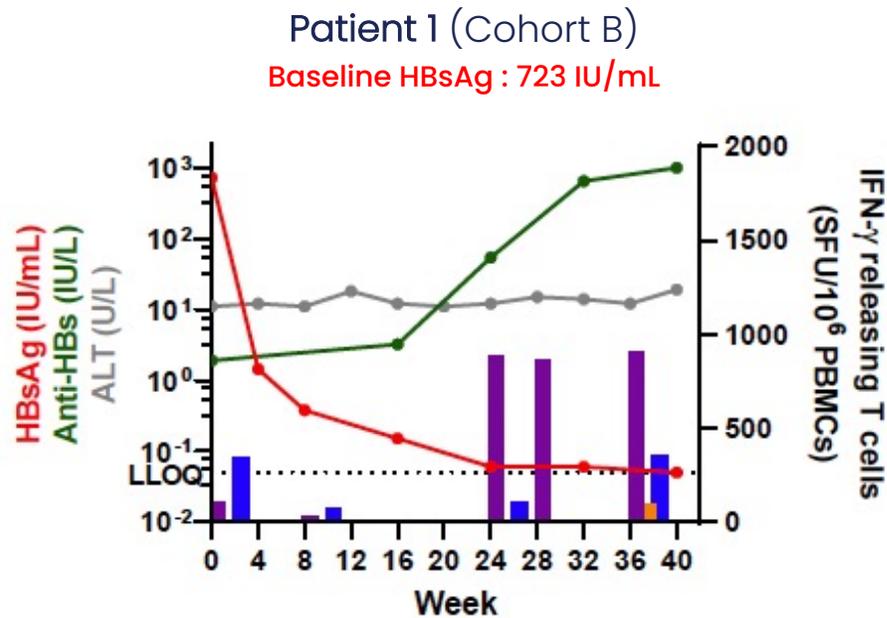


- Addition of VBI-2601 in treatment regimen resulted in higher proportion of patients with potent T-cell responses (> 3x baseline)
- Comparable T-cell responses observed in combination cohorts – with or without IFN- $\alpha$
- Available data through Week 44 from first 25 evaluable patients; analyses of remaining samples ongoing



# S Antigen Reductions to LLOQ or Below, to an Undetectable Level, Achieved in Two Patients

Robust HBV-specific antibody and T-cell responses associated with S Antigen (HBsAg) reduction observed in both patients



- Patient 1 achieved HBsAg at LLOQ (0.05 IU/mL) at Week 40
- > 4 log<sub>10</sub> maximum HBsAg reduction from baseline

- Patient 2 achieved undetectable HBsAg levels (below LLOQ) at Week 32
- > 4 log<sub>10</sub> maximum HBsAg reduction from baseline



Follow up for longer-term responses and immune correlation ongoing

# VBI-2601 Ongoing Partnership & Upcoming Milestones

## Brii Partnership:

- In December 2018, VBI announced a license and collaboration agreement with Brii Biosciences (Brii Bio) to develop a functional cure for Hepatitis B
- **Upfront** : \$11M - \$4M upfront payment + \$7M equity investment
- **Milestones & Royalties** : Up to \$117.5M in potential milestone payments and potential low double-digit royalties on commercial sales in the licensed territory
- **Licensed Territories** : China, Hong Kong, Macau, and Taiwan
- VBI will retain all rights outside of the licensed territory with respect to the treatment of hepatitis B



## Upcoming Milestones:

- **Q3 2023** : Interim topline results from Phase 2a/2b "add-on" study of VBI-2601 (BR11-179) + current standard-of-care therapy expected
- **2023** : Additional clinical data from Phase 2 combination study of VBI-2601 (BR11-179) and BR11-835 (VIR-2218) expected later in 2023

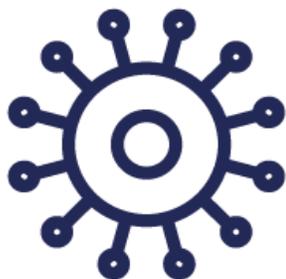




# Coronaviruses

# The Virus that Causes COVID-19 Continues to Evolve, Leading to Increasing Number of Mutations and Variants of Concerns

## COVID-19



- A strain of coronavirus first identified in December 2019 in Wuhan, China
- Since then, as of February 2023, there have been **~675M confirmed cases** worldwide, responsible for **6.9M deaths**<sup>1</sup>

## Variants of Concern

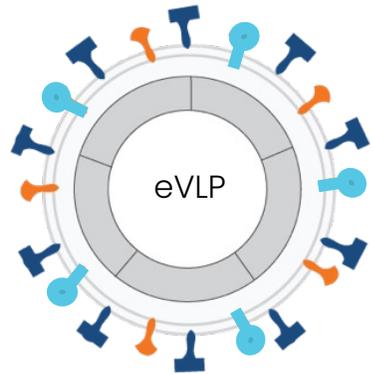
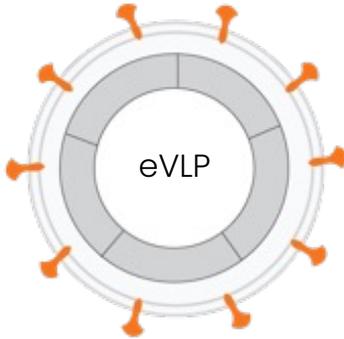
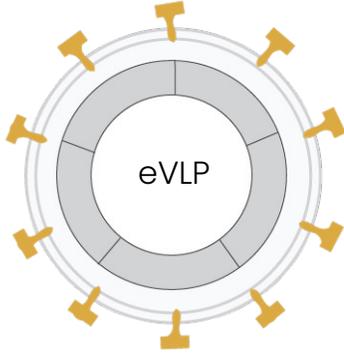
Several variants of concern have been identified<sup>2</sup>, including:

- ● **B.1.1.7 – “Alpha”**  
First detected in UK
- ● **B.1.351 – “Beta”**  
First detected in South Africa
- ● **B.1.617.2 – “Delta”**  
First detected in India
- ● **P.1 – “Gamma”**  
First detected in Japan/Brazil
- ● **B.1.1.529, BA.1-BA.5 – “Omicron”**  
First detected in South Africa



# VBI is Committed to the Long-Term Protection Against Coronaviruses

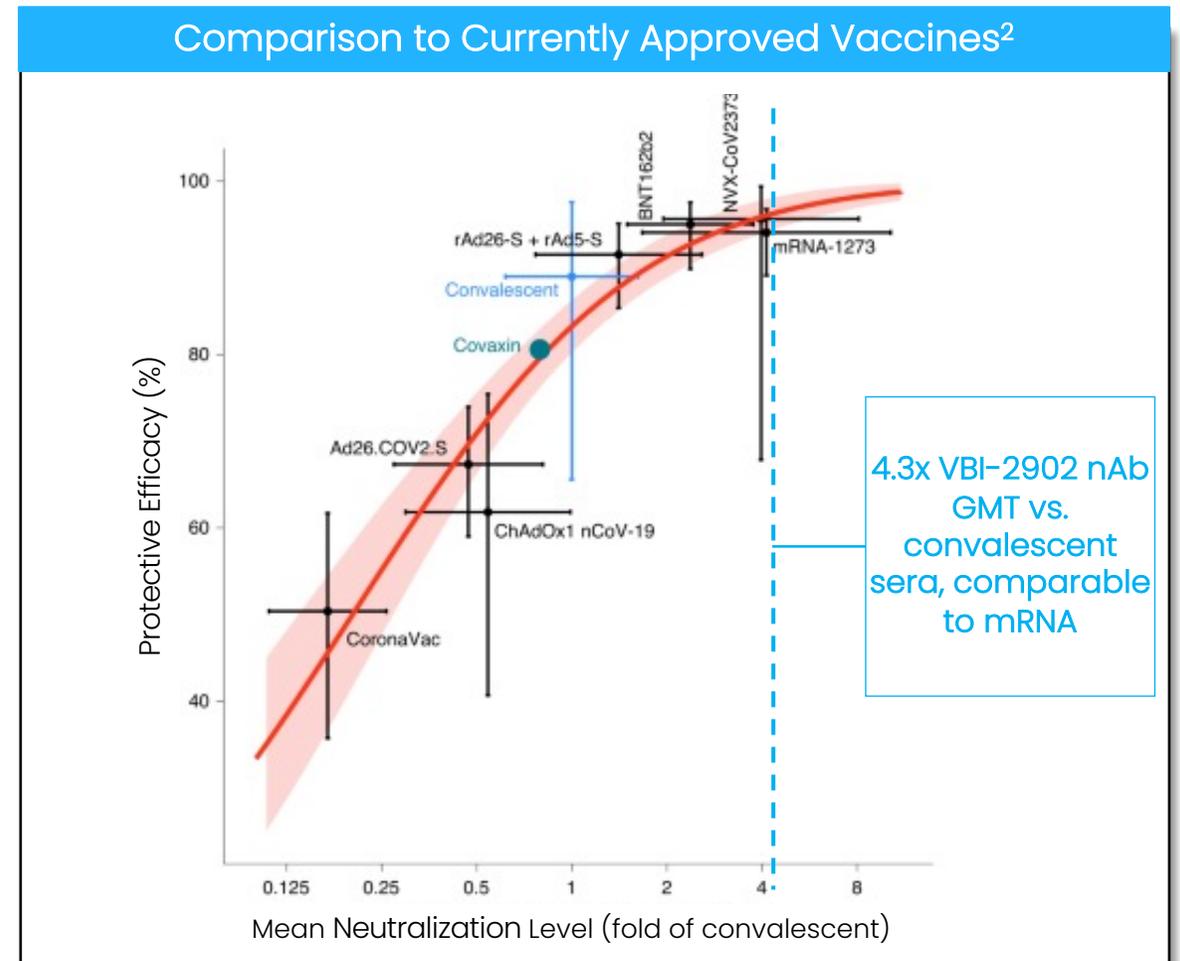
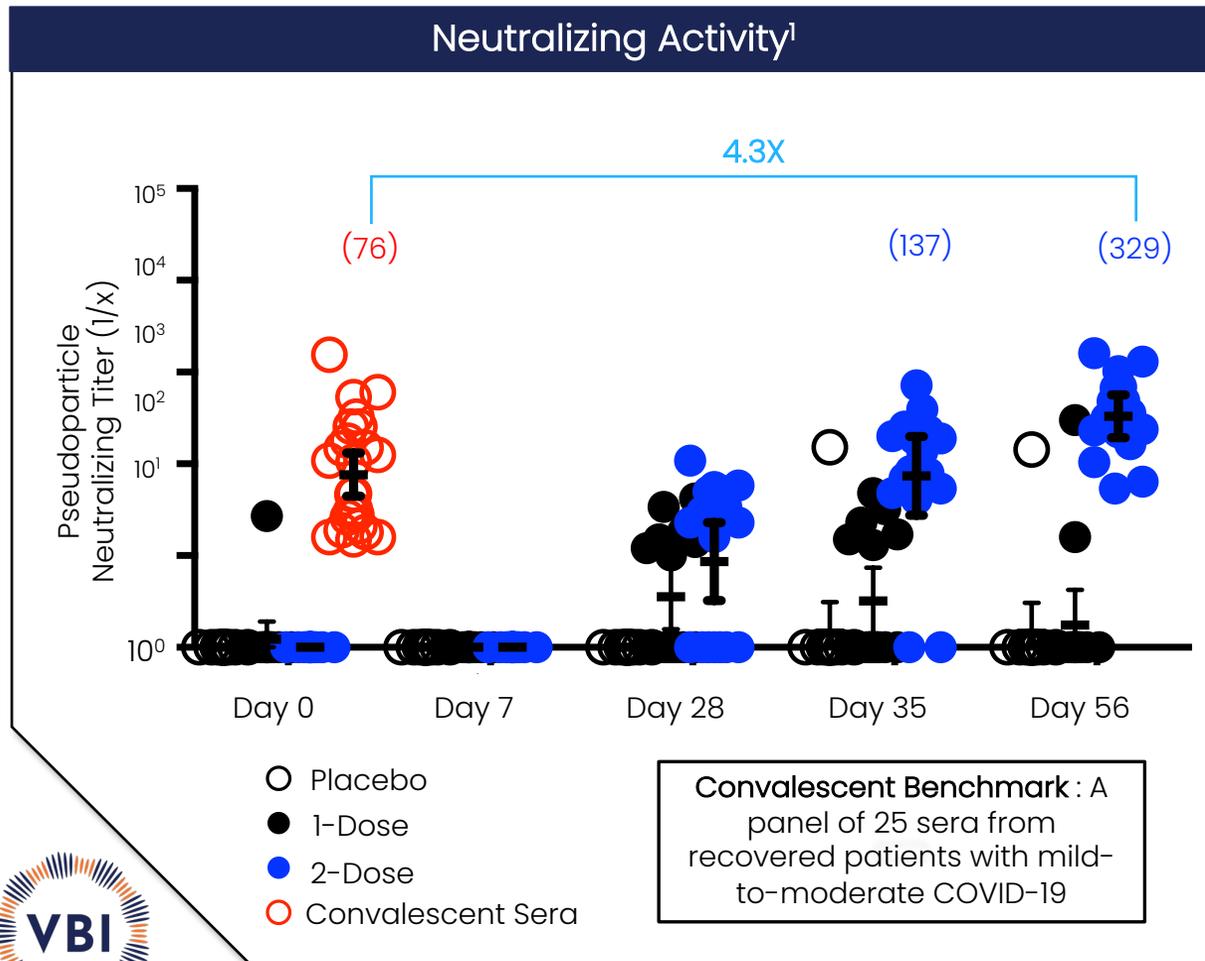
VBI's coronavirus pipeline program (VBI-2900) is designed with the goal of eliciting broad and durable immune responses against COVID-19 and coronaviruses

	VBI-2901 <i>Trivalent Pan-Coronavirus</i>	VBI-2902 <i>Monovalent COVID-19</i>	VBI-2905 <i>Monovalent COVID-19 B.1.351 Variant</i>	Undisclosed <i>Multivalent Candidates</i>
Schematic				<i>A suite of additional multivalent coronavirus vaccine candidates designed to evaluate the potential breadth of VBI's eVLP technology</i>
Construct Design	Ancestral COVID-19, MERS, SARS spike antigens	Ancestral COVID-19 spike antigen	COVID-19 B.1.351 (501Y.V2) spike antigen	Undisclosed



# In Phase 1a Clinical Study, VBI-2902 Induced Neutralizing Titers Comparable to Approved mRNA Vaccines

After two doses of 5ug, VBI-2902a elicited neutralizing antibody (nAb) responses 4.3X higher than a panel of convalescent sera, without the use of a next-generation adjuvant

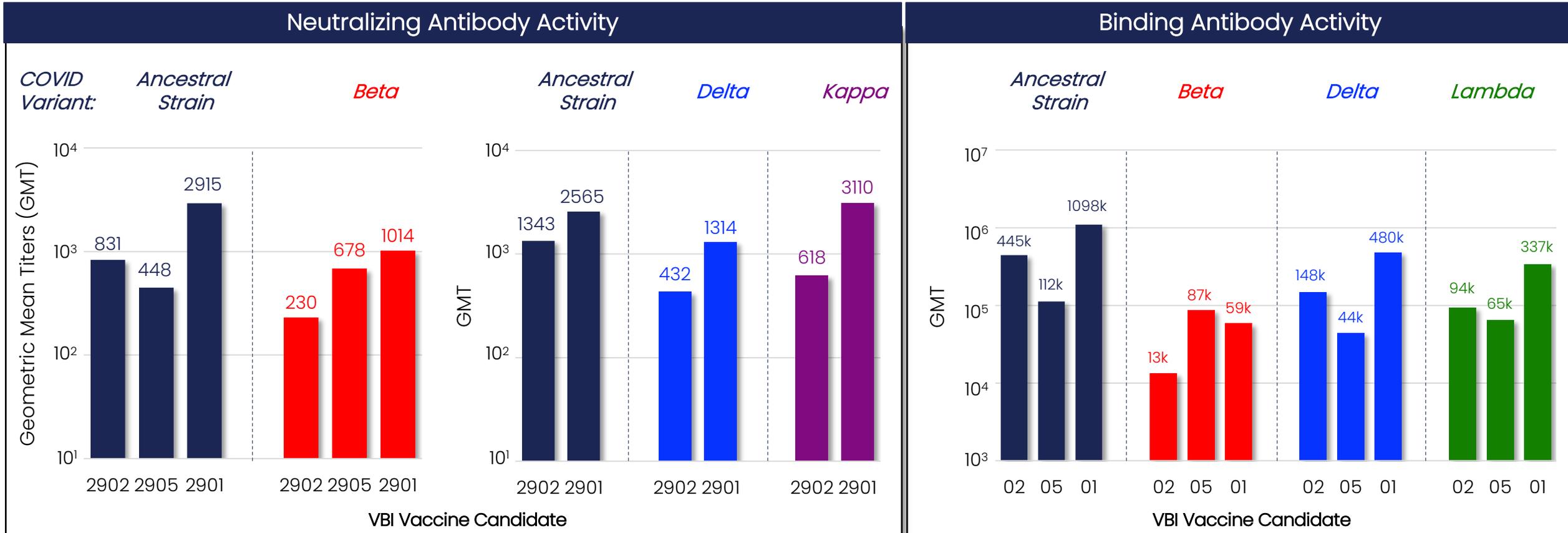


Note: Data does not include n=11 participants who got vaccinated with a separate COVID-19 vaccine (not VBI-2902) during the study

Sources: <sup>1</sup>Bozic et al., bioRxiv, September 2021; additional data presented by VBI in conference call held September 29, 2021; <sup>2</sup>Khoury, Nature Medicine, 2021.

# Trivalent VBI-2901 Induced Robust Antibody and Neutralizing Titers Against an Extended Panel of Variants

VBI-2901 induced higher and more consistent immunogenicity against Beta, Delta, Kappa, and Lambda variants, with evidence for broadening immunity rather than just boosting cross-reactive antibodies



Immunogenicity of trivalent VBI-2901a: Three groups of 10 mice were immunized with 2 doses of VBI-2901a, VBI-2902a, or VBI-2905a 3 weeks apart. Blood was collected at day 14 after the last injection for monitoring of humoral responses. Neutralization EPT measured by PRNT90 against Wu-1 virus and Beta variant. Neutralization of pseudoparticles expressing S from Wu-1, Delta, and Kappa variants are represented as half-maximum inhibitory dilutions (neutralization ID50). Due to technical limitations, only 8 sera per group were tested against Wu-1 and Kappa pseudoparticles and 4 sera against Delta pseudoparticles. Ab binding titers measured in ELISA against recombinant RBD from Wu-1 ancestral virus, or Beta, Delta, and Kappa variants.

# VBI-2900 Program Summary & Next Steps



## eVLP Benefits

- ✓ Strong immune responses when compared to standard recombinants
- ✓ Multivalency allows for broadly reactive vaccines



## Proof-of-Concept Data Obtained

- ✓ Highly potent immunogenicity, comparable to licensed vaccines
- ✓ Low clinical doses (5ug) & no requirement for novel adjuvants
- ✓ Exceptional safety/tolerability profile typical of alum-adjuvanted subunit vaccines
- ✓ Preclinical data demonstrated improvement of VBI-2901 over monovalent eVLPs

VBI's coronavirus program is supported by partnerships with:

**CEPI**

**NRC · CMRC**

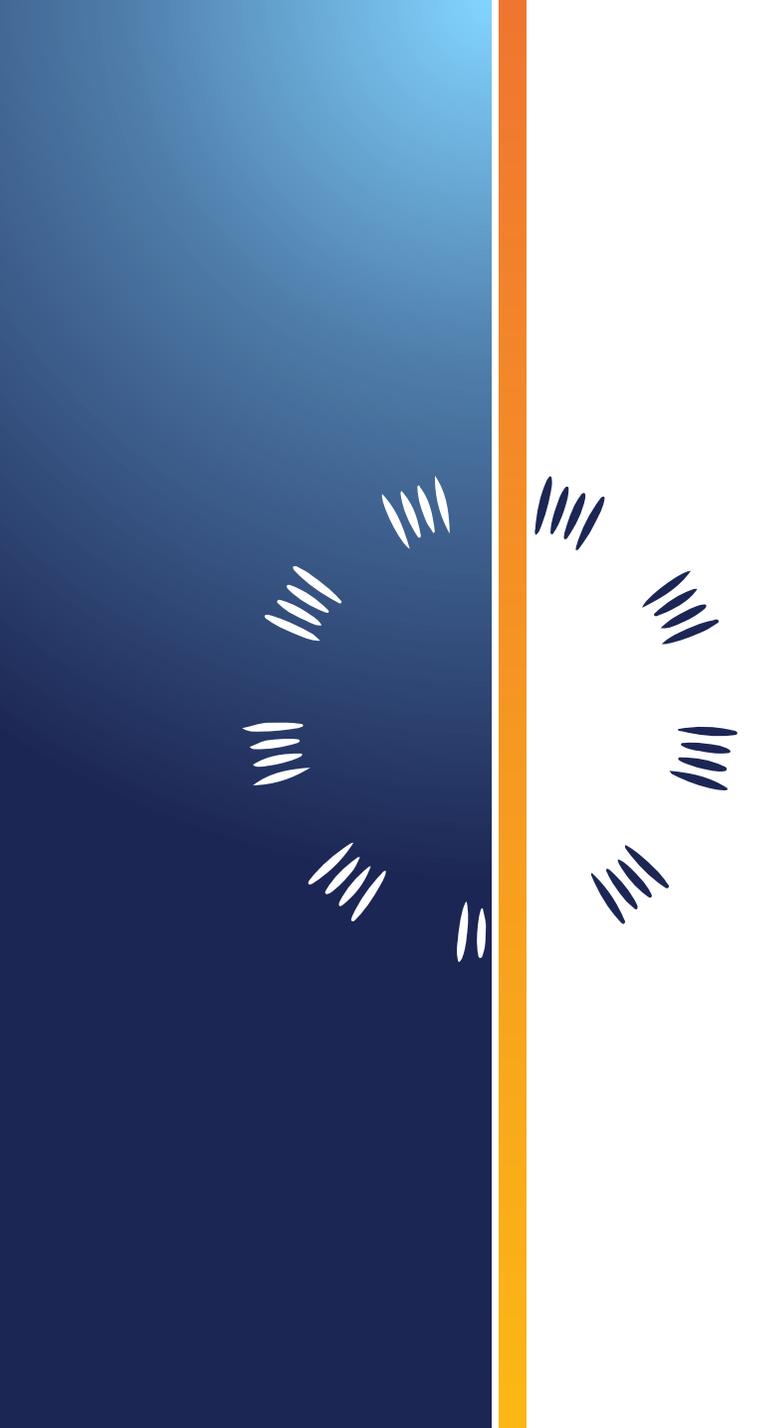
**Canada**

**RESILIENCE**

### Upcoming Milestones:

- Mid-Year 2023: Interim data from Phase 1 study of VBI-2901 expected, subject to speed of enrollment





# **Glioblastoma (GBM)**

# Unique Approach to Immuno-Oncology

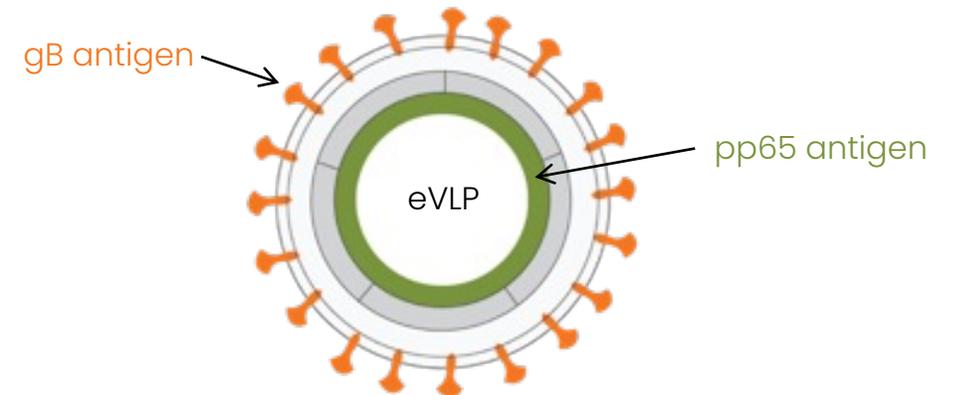
## CMV as a Foreign Viral Antigen

- 90% of some solid tumors, including glioblastoma (GBM)<sup>1</sup>, breast cancers<sup>2</sup>, and medulloblastomas<sup>3</sup> are CMV+ tumors
- CMV is not causative, but can influence disease progression of CMV+ tumors
- Because CMV is so broadly (and differentially) expressed on tumor cells, but not on healthy cells, a potent CMV vaccine has the potential to make “cold tumors, hot”
- GBM is one of the most aggressive cancers with few treatment options and no standard of care in the recurrent setting



## VBI's eVLP Immunotherapeutic Candidate

*VBI-1901: Bivalent eVLP expressing two of the most immunogenic CMV antigens*



### Key Features:

- Internal antigen expression elicits T cell immunity
- Stimulated innate immunity

# Phase 1/2a Study Design & Objectives

Two-part, open-label, dose escalation study designed to assess the safety, tolerability, and optimal therapeutic dose level of VBI-1901 in recurrent GBM patients

## Phase 1 (Part A) : Dose-Escalation Phase – Recurrent GBM (any # of recurrences)

Study Arm 1 : **Low Dose** (n=6)  
0.4µg + GM-CSF

vs.

Study Arm 2 : **Int. Dose** (n=6)  
2.0µg + GM-CSF

vs.

Study Arm 3 : **High Dose** (n=6)  
10.0µg + GM-CSF

- Enrollment completed December 2018 (n=18)
- 12-month overall survival (OS) rate of 83% in Vaccine Responders (n=6) vs. 33% in Non-Responders (n=9)
- Vaccine Responders saw a 6.25-month improvement in median OS (14.0 mos) vs. Non-Responders (7.75 mos)
- Tumor responses observed in 3 patients in the high-dose cohort, with evidence of stable disease based on two or more consecutive MRI scans

## Phase 2a (Part B) : Extension Phase – Recurrent GBM (1<sup>st</sup> recurrence only)

Study Arm 1 : **High Dose** (n=10)  
10.0µg + GM-CSF

vs.

Study Arm 2 : **High Dose** (n=10)  
10.0µg + GSK's AS01<sub>B</sub> Adjuvant

*VBI-1901 + GM-CSF:*

- Enrollment completed April 2020 (n=10)
- Tumor Responses : 2 partial responses + 2 stable disease observed

*VBI-1901 + GSK's AS01 adjuvant:*

- Enrollment completed October 2020 (n=10)
- Tumor Responses : 5 stable disease observed



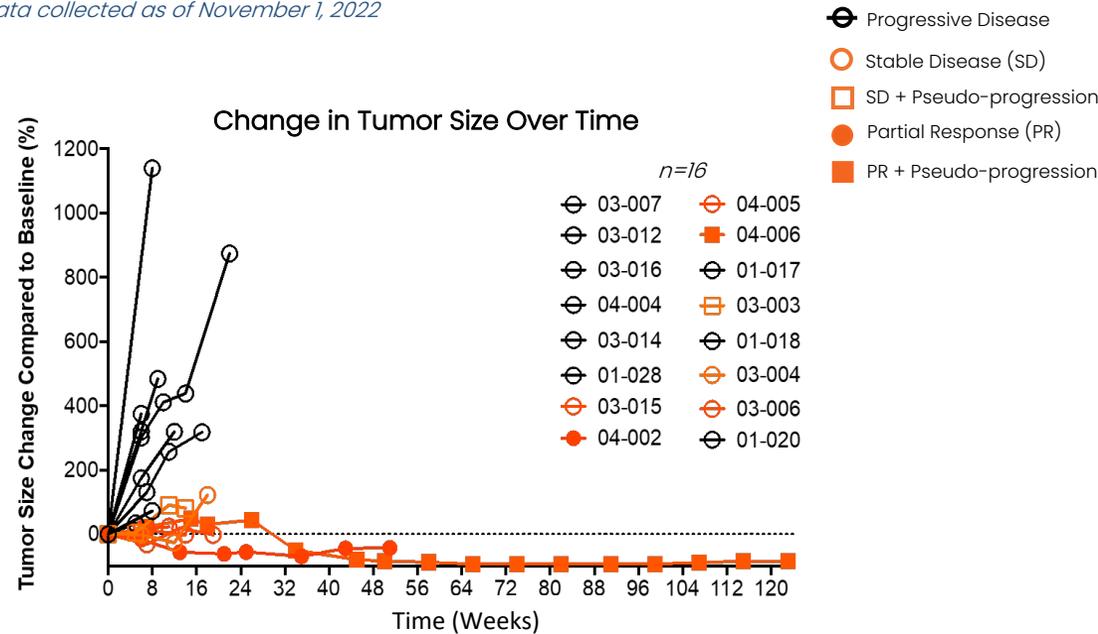
# Tumor Responses Translated to Clinical Benefit in Phase 1/2a High-Dose Cohorts

Based upon these rGBM data, U.S. FDA granted Fast Track Designation in June 2021 for VBI-1901 + GM-CSF<sup>1</sup> for the treatment of recurrent GBM patients with first tumor recurrence

## Tumor Responses

VBI-1901 10µg + GM-CSF<sup>1</sup> (High Dose Part A + Part B)

Data collected as of November 1, 2022



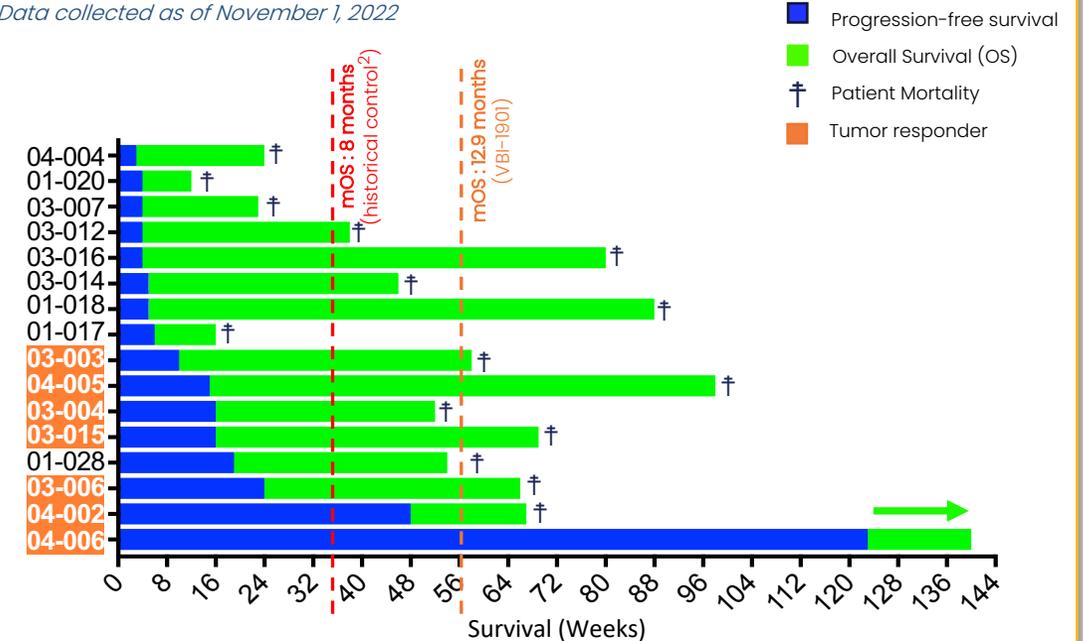
Tumor Responses :

- ✓ 2 Partial Responses (PRs)\*
- ✓ 5 Stable Disease (SD)

## Clinical Responses

VBI-1901 10µg + GM-CSF<sup>1</sup> (High Dose Part A + Part B)

Data collected as of November 1, 2022



Median & Overall Survival (mOS & OS) :

- ✓ mOS reached at : 12.9 months
- ✓ 12-month : 62.5% (n=10/16)
- ✓ 18-month : 25% (n=4/16)



Source: <sup>1</sup>2022 Society for Neuro-Oncology (SNO) Annual Meeting 2022 (VBI presentation); <sup>2</sup>Taal W, Oosterkamp HM, Walenkamp AME, et al. Single-agent bevacizumab or lomustine versus a combination of bevacizumab plus lomustine in patients with recurrent glioblastoma (BELOB trial): a randomized controlled phase 2 trial. *Lancet Oncol.* 2014; 15: 943-953; \*Tumor responses in glioblastoma patients are classified according to the Response Assessment in Neuro-Oncology (RANO) criteria, which defines a partial response (PR) as a greater than 50% reduction in the sum of products of perpendicular diameters of all measurable enhancing lesions compared with the baseline, sustained for at least four weeks, with no new lesions or clinical progression of disease

# VBI-1901 Unmet Need & Upcoming Milestones

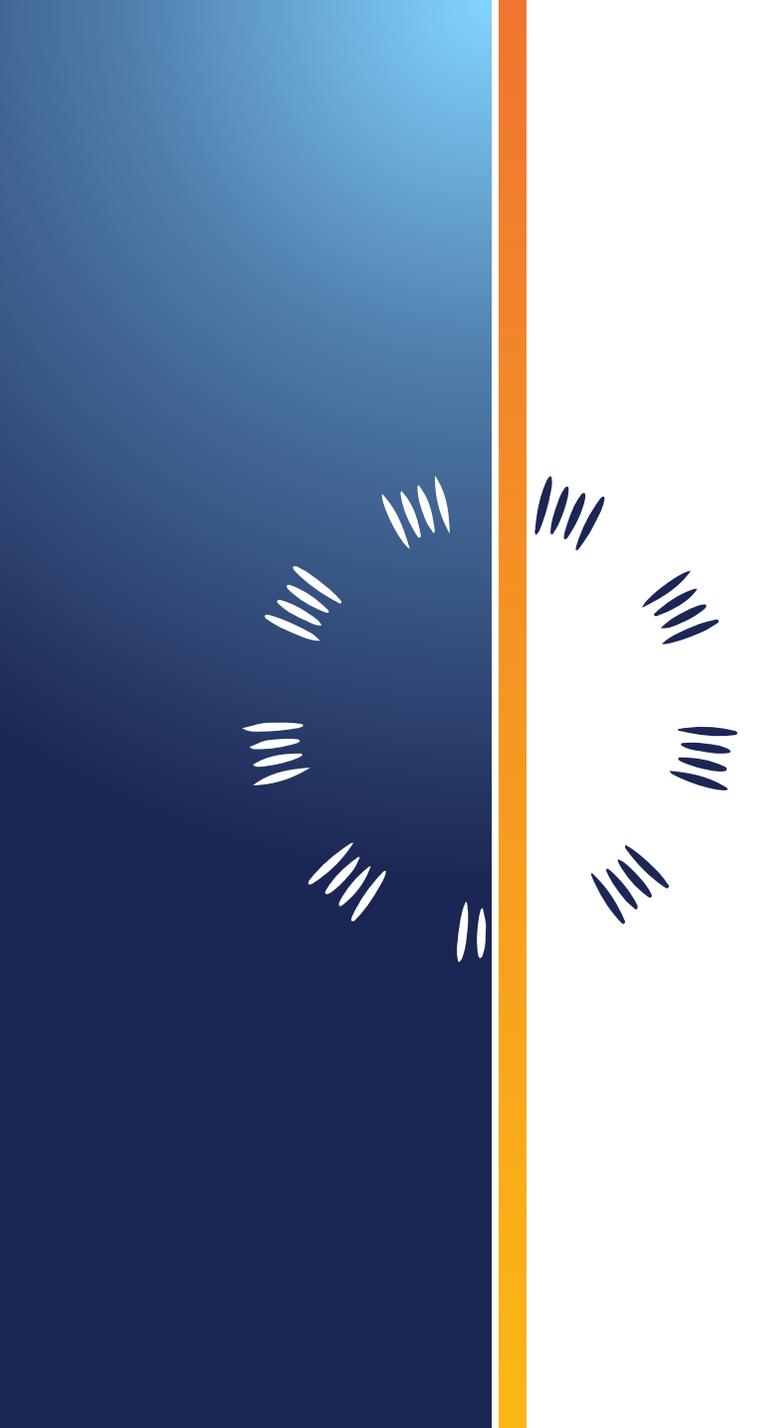
## GBM Represents a Significant Unmet Medical Need:

- GBM is the most common primary brain cancer with approximately 14,000 annual diagnoses in the U.S., and a low median overall survival of 15-18 months after initial diagnosis<sup>1</sup>
- There is no standard of care in the recurrent setting – median overall survival is approximately eight months<sup>2</sup>
- Any therapeutic option that could demonstrate clinical benefit would be meaningful in this difficult-to-treat patient population, with tumor response regarded as one of the most objective measures of efficacy
- **FDA Fast Track Designation for VBI-1901 + GM-CSF granted June 2021** : Fast Track Designation facilitates the development and expedites the review of new therapies to treat serious conditions and fill an unmet medical need
- **FDA Orphan Drug Designation for VBI-1901 granted June 2022** for treatment of GBM : Orphan Drug Designation is granted to investigational drugs and biologics that target conditions that affect fewer than 200,000 people in the U.S.

### Upcoming Milestones:

- **Q2 2023** : Expected initiation of expanded n-size of patients in ongoing VBI-1901 study in recurrent GBM – expansion study to include addition of control arm to support potential accelerated approval based upon tumor response, improvement in overall survival, and discussions with regulatory bodies
- **Mid-Year 2023** : Expected initiation of VBI-1901 in the frontline setting in combination with Agenus' anti-PD-1 monoclonal antibody, balstilimab – expected to initiate as part of the Phase 2 INSIGHt trial, an adaptive platform clinical study





# Summary

# VBI Team

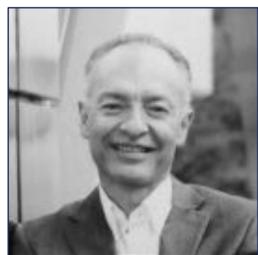
## Management



**Jeff Baxter**  
President & CEO



**David E. Anderson, Ph.D.**  
Chief Scientific Officer



**Francisco Diaz-Mitoma, M.D., Ph.D.**  
Chief Medical Officer



**Christopher McNulty**  
Chief Financial Officer & Head of Business Development



**Nell Beattie**  
Chief Business Officer



**John Dillman**  
Chief Commercial Officer



**Avi Mazaltov**  
Global Head of Manufacturing & SciVac General Manager

## Board of Directors



**Steve Gillis, Ph.D.**  
Chair



**Damian Braga**  
Director



**Joanne Cordeiro**  
Director



**Michel De Wilde, Ph.D.**  
Director



**Blaine H. McKee, Ph.D.**  
Director



**Jeff Baxter**  
Director



**Christopher McNulty**  
Director



# VBI Vaccines Global Footprint

**Ottawa, Canada** •  
Research Operations  
*R&D headquarters and facility*

**Cambridge, MA, USA** •  
Corporate Headquarters  
*Central location in biotechnology hub*

**Rehovot, Israel** •  
Manufacturing Facility  
*GMP manufacturing facility for the production of the HBV program candidates*



# Summary of Anticipated Upcoming Milestones

## Px HBV

*PreHevbrio (U.S.)*

- **HI 2023** : Following European Commission and UK Medicines and Healthcare products Regulatory Agency (MHRA) approvals, VBI expects to make PreHevbri available in certain European countries beginning in HI 2023
- **2023** : Following Health Canada approval in December 2022, VBI expects to make PreHevbrio available in Canada in 2023

## Tx HBV

*VBI-2601*

- **Q3 2023** : Interim topline results expected from Phase 2 study evaluating VBI-2601 as an add-on therapy to potentially improve current standard of care treatment outcomes
- **2023** : Additional clinical data from Phase 2 combination study of VBI-2601 (BR11-179) and BR11-835 (VIR-2218) expected later in 2023

## Coronaviruses

*VBI-2901*

- **Mid-Year 2023**: Interim data from Phase 1 study of VBI-2901 (multivalent coronavirus) expected, subject to speed of enrollment

## GBM

*VBI-1901*

- **Q2 2023** : Expected initiation of expanded n-size of patients in ongoing VBI-1901 study in recurrent GBM - expansion study to include addition of control arm to support potential accelerated approval, subject to tumor response, improvement in overall survival, and discussions with regulatory bodies
- **Mid-Year 2023** : Expected initiation of VBI-1901 in the frontline setting in combination with Agenus' anti-PD-1 monoclonal antibody, balstilimab - expected to initiate as part of the Phase 2 INSIGHt trial, an adaptive platform clinical study





VBI Vaccines Inc. | [www.vbivaccines.com](http://www.vbivaccines.com)