

# VBI Vaccines' Pan-Coronavirus Vaccine Candidate, VBI-2901, Induced Broad and Durable Protective Titers Against Variants of Concern

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- First clinical data from a pan-coronavirus vaccine candidate
- Elicited high and sustained neutralizing responses against a panel of COVID-19 variants, including Wuhan, Delta, Beta, Omicron BA.5, as well as multiple animal coronaviruses including bat and pangolin variants
- Durability of protective titers maintained through interim data point at six months – substantially more persistent compared to published durability of responses to a licensed mRNA vaccine<sup>1</sup>
- Safety consistent with known safety profile of VBI's proprietary eVLP platform technology, with no safety signals or grade 3 or 4 adverse events observed
- Funds from existing partners, including the Canadian Government and the Coalition for Epidemic Preparedness Innovations (CEPI), available to fund next phase of clinical development

CAMBRIDGE, Mass.--(BUSINESS WIRE)-- VBI Vaccines Inc. (Nasdaq: VBIV) (VBI), a biopharmaceutical company driven by immunology in the pursuit of powerful prevention and treatment of disease, today announced interim data from the Phase 1 clinical study of its multivalent pan-coronavirus vaccine candidate, VBI-2901, which expresses the ancestral COVID-19, SARS, and MERS spike antigens. The Phase 1 clinical study enrolled 101 adults, aged 18-64 years who had received either two or three doses of a messenger RNA (mRNA) COVID-19 vaccine licensed by Health Canada, and assessed both one and two dose booster regimens of VBI-2901. Based on interim data, however, peak responses were achieved with only a single 10µg dose of VBI-2901.

"As we've previously said, we endeavor to develop a vaccine with meaningful differentiation to those COVID-19 vaccines already approved – we believe these initial data are evidence of just that, demonstrating an ability to safely broaden durable, protective levels of immune responses and significantly boost neutralizing responses in

participants with low baseline antibody titers,” said Jeff Baxter, VBI’s President and CEO. “With sufficient funding available under our current partnerships, subject to discussions with our partners and with regulatory bodies, we look forward to advancing this program and being a part of the innovative next-generation of protection against coronaviruses.”

#### Breadth of Immune Response

- All participants saw boosting and/or high neutralizing responses against a panel of COVID-19 variants, including Wuhan, Delta, Beta, Omicron BA.5, as well as multiple animal coronaviruses including bat and pangolin variants
- Participants with low baseline neutralization titers (geometric mean titer (GMT): 148 IU50/mL), who are at the highest risk of infection, saw the greatest vaccine-induced boosting effects across all variants tested at Day 28, after one dose, with increases of: 8.5x against Wuhan, 9.1x against Delta, 14.2x against Beta, and 5.8x against Omicron BA.5

#### Durability of Immune Response

- All participants who received one dose had enhanced persistence of neutralizing responses, with only about 25% reduction in GMT against Wuhan after 5 months vs. peak responses
- Similar enhanced durability trends were observed against all tested variants
- By comparison, a recently published study [Gilboa et al., 2022] evaluating immune responses after a third dose of a licensed mRNA vaccine in nearly 4,000 healthcare workers in Israel demonstrated an approximate 77% decline in GMT against Wuhan after 5 months vs. peak responses<sup>1</sup>
  - In the same study [Gilboa et al., 2022], durability trends against other variants, including Omicron, were seen to wane even more aggressively, with 4-fold to 10-fold lower neutralization titers within 4 months of the third dose

### About the Phase 1 Study

The Phase 1 randomized, open-label study enrolled 101 subjects across three cohorts, randomized 1:1:1, to compare either two intramuscular doses of VBI-2901 at a low- (5µg) or high- (10µg) dose level, or one dose of VBI-2901 at the high-dose level (10µg) healthy adults age 18-64 who have previously received two or three immunizations with COVID-19 vaccines licensed by Health Canada. Each participant had received their previous dose of a licensed COVID-19 vaccine at least six months prior to study enrollment.

### About VBI-2900 Coronavirus Vaccine Program

The VBI-2900 program consists of multiple undisclosed, multivalent vaccine constructs developed using VBI’s

proprietary eVLP platform technology, in addition to the three candidates that have generated clinical data: (1) VBI-2901, a multivalent coronavirus vaccine expressing the ancestral SARS-CoV-2, SARS-CoV, and MERS-CoV spike proteins, (2) VBI-2902, a monovalent COVID-19 vaccine expressing a modified prefusion form of the SARS-CoV-2 ancestral spike protein, and (3) VBI-2905, a monovalent COVID-19 vaccine expressing a modified prefusion form of the spike protein from the Beta variant (B.1.351).

VBI's coronavirus vaccine program has been developed through collaborations with the National Research Council of Canada (NRC), the Coalition for Epidemic Preparedness Innovations (CEPI), and the Government of Canada, through their Strategic Innovation Fund.

## About VBI Vaccines Inc.

VBI Vaccines Inc. ("VBI") is a biopharmaceutical company driven by immunology in the pursuit of powerful prevention and treatment of disease. Through its innovative approach to virus-like particles ("VLPs"), including a proprietary enveloped VLP ("eVLP") platform technology, VBI develops vaccine candidates that mimic the natural presentation of viruses, designed to elicit the innate power of the human immune system. VBI is committed to targeting and overcoming significant infectious diseases, including hepatitis B, coronaviruses, and cytomegalovirus (CMV), as well as aggressive cancers including glioblastoma (GBM). VBI is headquartered in Cambridge, Massachusetts, with research operations in Ottawa, Canada, and a research and manufacturing site in Rehovot, Israel.

Website Home: <http://www.vbivaccines.com/>

News and Resources: <http://www.vbivaccines.com/news-and-resources/>

Investors: <http://www.vbivaccines.com/investors/>

## References

1. Gilboa, Mayan, Regev-Yochay, Gili, Mandelboim, Michael et al. Durability of Immune Response After COVID-19 Booster Vaccination and Association With COVID-19 Omicron Infection. JAMA Network Open. September, 2022

## Cautionary Statement on Forward-looking Information

Certain statements in this press release 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 forward-looking 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 endemic and its continuing effects 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 13, 2023, and filed with the Canadian security authorities at [sedar.com](https://www.sedar.com) on March 13, 2023, 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.

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