

VBI Vaccines Completes Enrollment of Participants in the Phase I Clinical Trial of its Preventative Cytomegalovirus Vaccine Candidate

CAMBRIDGE, MA (September 20, 2016) – VBI Vaccines Inc. (Nasdaq: VBIV) (TSX: VBV) (“VBI”) today announced that it has completed enrollment and initial dosing of all participants in the Phase I clinical study to evaluate its [preventative cytomegalovirus \(“CMV”\) vaccine candidate](#).

The Phase I study is designed to assess the safety and tolerability of VBI’s CMV vaccine candidate in 128 healthy CMV-negative adults. The study will also measure levels of vaccine-induced CMV neutralizing antibodies that may prevent CMV infection. Preliminary results are anticipated in the first half of 2017.

“The completion of enrollment is an important milestone for VBI,” said Dr. Francisco Diaz-Mitoma, M.D., Ph.D., VBI’s Chief Medical Officer. “While safety and tolerability are our primary endpoints, we will also measure the immune response generated by our CMV vaccine candidate, and compare it to persons with naturally acquired CMV immunity. Naturally acquired CMV immunity may provide up to 90% protection from congenital CMV transmission,¹ providing a benchmark for our Phase I study that could allow for human immunological proof of concept at an early stage of clinical development.”

Study participants have been split into five groups that will receive three varying doses of VBI’s adjuvanted vaccine candidate, an unadjuvanted version of the vaccine candidate, or a placebo control, at zero, two, and six months. Additional information, including a detailed description of the study design, eligibility criteria, and investigator sites, is available at [ClinicalTrials.gov using identifier NCT02826798](#).

CMV can cause serious disease in newborns when a mother is infected during pregnancy. Each year, approximately 5,000 U.S. infants will develop permanent problems due to CMV, which can include deafness, blindness, and mental retardation.² CMV affects more live births than Down syndrome or fetal alcohol syndrome,³ making it a key public health priority and a strong candidate for recommended universal vaccination and reimbursement.⁴

“Congenital CMV infection is a leading cause of serious birth defects in the U.S. and globally,” said Jeff Baxter, VBI’s President and CEO. “Each year, thousands of newborns and their families are impacted by this devastating disease. We believe that developing a vaccine to prevent CMV offers the best chance of substantially eliminating congenital CMV infection and the resulting birth defects.”

To learn more about VBI’s CMV vaccine program, visit: <http://www.vbivaccines.com/cm/>

¹ Adler, et al. Immunity Induced by Primary Cytomegalovirus Infection Protects Against Secondary Infection Among Women of Childbearing Age. *Journal of Infectious Disease*, 1995; 171:26

² <http://www.cdc.gov/cmvtrends-stats.html>

³ Cannon, M. J., and K. F. Davis. 2005. Washing our hands of the congenital cytomegalovirus disease epidemic. *BMC Public Health* 5:70

⁴ Stratton KR et al, Committee to Study Priorities for Vaccine Development, Inst. of Med.; Washington, DC

About VBI Vaccines Inc.

VBI Vaccines Inc. (“VBI”) is a commercial-stage biopharmaceutical company developing a next generation of vaccines to address unmet needs in infectious disease and immuno-oncology. VBI’s first marketed product is Sci-B-Vac™, a hepatitis B vaccine that mimics all three viral surface antigens of the hepatitis B virus; Sci-B-Vac is approved for use in Israel and 14 other countries. VBI’s eVLP Platform technology allows for the development of enveloped (“e”) virus-like particle (“VLP”) vaccines that closely mimic the target virus to elicit a potent immune response. VBI is advancing a pipeline of eVLP vaccines, with lead programs in cytomegalovirus and glioblastoma multiforme. VBI is also advancing its LPV™ Thermostability Platform, a proprietary formulation and process that allows vaccines and biologics to preserve stability, potency, and safety. VBI is headquartered in Cambridge, MA with research operations in Ottawa, Canada and research and manufacturing facilities in Rehovot, Israel.

- Website Home: <http://www.vbivaccines.com/>
- News and Insights: <http://www.vbivaccines.com/wire/>
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Certain statements in this news release 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”, “continue”, “anticipate”, “expect” and similar expressions. All statements other than statements of historical fact included in this release are forward-looking statements. Such forward-looking statements include, but are not limited to: the design, purpose and implementation of the study, timing for receipt of results of the study and the potential effects of CMV.

Such forward-looking statements are based on a number of assumptions, including assumptions regarding the successful development and/or commercialization of the company’s products, including the receipt of necessary regulatory approvals; general economic conditions; competitive conditions; and changes in applicable laws, rules and regulations.

VBI cautions the reader that forward-looking statements and information involve known and unknown risks, uncertainties and other factors that may cause actual results and developments to differ materially from those expressed or implied by such forward-looking statements or information contained in this news release and VBI has made assumptions and estimates based on or related to many of these factors.

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. 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.