VBI Vaccines Announces Initiation of Phase 3 Clinical Program for Sci-B-Vac® Hepatitis B Vaccine

- *Patient dosing commenced on December 18, 2017*
- *4,800 subjects across two Phase 3 studies: PROTECT and CONSTANT*
- *15-month program - headline data expected Q2 2019*

CAMBRIDGE, Mass., Dec. 19, 2017 (GLOBE NEWSWIRE) -- VBI Vaccines Inc. (Nasdaq:VBIV) (TSX:VBV) ("VBI") announced today the initiation of the global Phase 3 clinical program for Sci-B-Vac®, its third-generation hepatitis B vaccine, with the commencement of patient dosing on December 18, 2017.

The Phase 3 program will be a global 15-month program consisting of two concurrent Phase 3 studies – a safety and immunogenicity study (PROTECT) and a lot-to-lot consistency study (CONSTANT), enrolling a total of approximately 4,800 subjects. The Phase 3 program will be conducted at approximately 40 sites across the U.S., Europe, and Canada.

Dr. Francisco Diaz-Mitoma, VBI's Chief Medical Officer, commented, "The initiation of this Phase 3 program is a significant milestone for VBI. There is an extensive safety and efficacy data package that currently exists for Sci-B-Vac, with approximately 2,000 subjects in past clinical trials and over 500,000 subjects who have received the vaccine in the commercial setting. Pending data from this Phase 3 program, we expect to submit marketing authorization applications to U.S., European, and Canadian regulatory authorities in 2019. We believe there is a recognized need for an improved Hepatitis B vaccine and we are committed to advancing Sci-B-Vac through Phase 3 development as quickly as possible."

Dr. Nathan Segall, a certified internal medicine, allergy, and immunology specialist at Clinical Research Atlanta and a Principal Investigator in the program, added, "Sci-B-Vac is the only commercially-available vaccine that contains the pre-S1 and pre-S2 surface antigens. The field is looking forward to seeing the results of this pivotal program, adding to the growing body of research which suggests that the inclusion of these two antigens may prove more immunogenic, especially in subjects that currently do not respond optimally to current standard of care."

About PROTECT – Safety and Immunogenicity Study

PROTECT will be a double-blind, two-arm, randomized, controlled study. Approximately 1,600 adult subjects, 18 years of age and older, will be randomized in a 1:1 ratio to receive either a three-dose course of Sci-B-Vac 10µg or a three-dose course of the control vaccine, Engerix-B® 20µg. Enrollment will be stratified by age group.

The co-primary objectives of the study will be:

- To demonstrate non-inferiority of the seroprotection rate induced by Sci-B-Vac vs. Engerix-B® four weeks after the third vaccination in adults age 18 and older.
- To demonstrate superiority of the seroprotection rate induced by Sci-B-Vac vs. Engerix-B® four weeks after the third vaccination in adults older than 45 years of age.

The study will also include multiple secondary objectives to evaluate the speed to seroprotection, including assessment after two doses of Sci-B-Vac vs. three doses of Engerix-B®, and the overall safety and

tolerability of Sci-B-Vac vs. Engerix-B®.

About CONSTANT – Lot-to-Lot Consistency Study

CONSTANT will be a double-blind, four-arm, randomized, controlled study. Approximately 3,200 adult subjects, age 18-45 years, will be randomized in a 1:1:1:1 ratio to receive one of four three-dose courses: Lot A of Sci-B-Vac 10µg, Lot B of Sci-B-Vac 10µg, Lot C of Sci-B-Vac 10µg, or the control vaccine Engerix-B® 20µg.

The primary objective of this study will be:

- To demonstrate lot-to-lot consistency for immune response as measured by geometric mean concentration (GMC) of antibodies across three independent, consecutive lots of Sci-B-Vac four weeks after the third vaccination.

The secondary objective will be to evaluate safety and efficacy of Sci-B-Vac vs. Engerix-B®.

About Sci-B-Vac®

Sci-B-Vac® is a licensed third-generation hepatitis B vaccine that has demonstrated safety and efficacy in over 500,000 patients. Sci-B-Vac is currently approved for use in Israel and in 14 other countries. In contrast to second-generation hepatitis B vaccines, which contain only one surface antigen (the S antigen), Sci-B-Vac contains the S antigen and the pre-S1 and pre-S2 surface antigens. The composition of Sci-B-Vac may prove more immunogenic in subjects that currently do not respond optimally to second-generation vaccines.

To learn more about Sci-B-Vac®, visit: https://www.vbivaccines.com/sci-b-vac/

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 (HBV) 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 virus-like particle (eVLP) 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 (CMV) and glioblastoma multiforme (GBM). VBI is also advancing its LPV™ Thermostability Platform, a proprietary formulation and process that enables 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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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 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 prevailing market conditions 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 Securities and Exchange Commission and the Canadian securities authorities, including its Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 20, 2017, and filed with the Canadian security authorities at sedar.com on March 24, 2017, 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.