

VBI Vaccines Announces Phase 3 Clinical Program for Sci-B-Vac™ Hepatitis B Vaccine

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July 11, 2017 | Conferences, Press Releases, Sci-B-Vac™

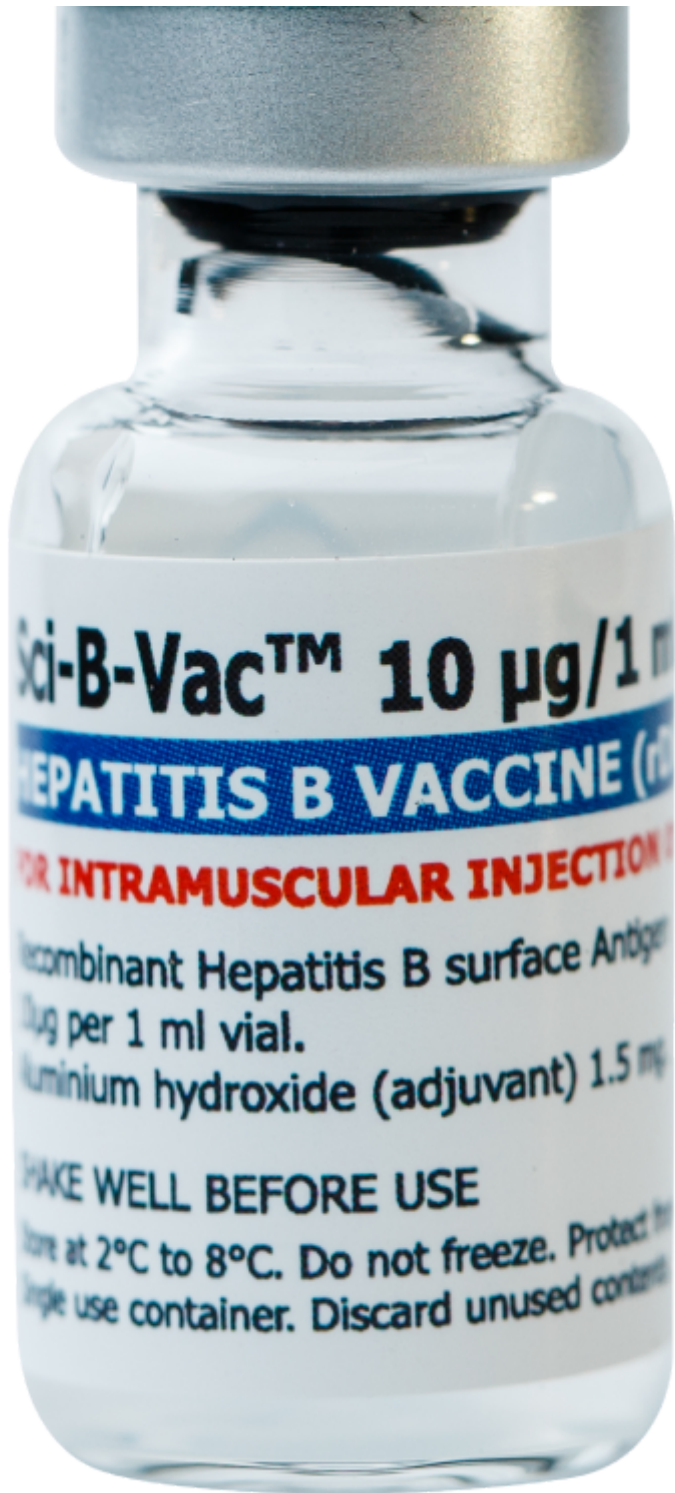
Watch Webcast (July 12, 2017)

VBI Vaccines Inc. (Nasdaq: VBIV) (TSX: VBV) (“VBI”) announced today its plans for a global Phase 3 clinical program for **Sci-B-Vac™**, its third-generation hepatitis B vaccine, following positive discussions with the U.S. Food & Drug Administration (FDA), the European Medicines Agency (EMA), and Health Canada.

The Phase 3 program will be a global 15-month program and will consist 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.

“We consider the outcome of discussions with the FDA, EMA, and Health Canada to be extremely positive,” said Jeff Baxter, president and CEO of VBI. “Sci-B-Vac’s extensive safety and efficacy data package demonstrates safe and effective vaccination of approximately 2,000 subjects in past clinical trials. Because of this track record, we are able to plan a Phase 3 program that will enroll only 4,800 subjects in total and will be only 15-months in duration. We anticipate initiating enrollment in both Phase 3 studies in the second half of 2017.”





About PROTECT – Safety and Immunogenicity Study

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 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®.

Conference Call and Webcast Details

VBI Vaccines will host a conference call and webcast with accompanying slides Wednesday, July 12, 2017, at 8:30 a.m. EDT, to provide a clinical and regulatory update on Sci-B-Vac. The webcast can be watched via the event link in the “[Events/Presentations](#)” section under the “[Investors](#)” page of the VBI corporate website at www.vbivaccines.com or by clicking this

link: <http://public.viavid.com/index.php?id=125400>

- International Dial-in: / 19-457-2603
- Conference ID: 9006835

A replay of the webcast will be available on VBI's website for 45 days after the event.

About Sci-B-Vac™

Sci-B-Vac™ is a licensed third-generation hepatitis B vaccine that has demonstrated safety and efficacy in over 300,000 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/>

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ABOUT VBI VACCINES

VBI Vaccines Inc. (Nasdaq: VBIV) is a commercial-stage biopharmaceutical company developing a next generation of vaccines to address unmet needs in infectious disease and immuno-oncology. Learn

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