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THROUGH Dennis Cato, Chief, BMB

THROUGH Carrie Mampilly, M.P.H., Director, DIS

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SUBJECT Bioresearch Monitoring Final Review Memo
SPONSOR VBI Vaccines, Inc.
PRODUCT Sci-B-Vac® (Hepatitis B Vaccine recombinant)
BLA STN 125737/0

FINAL SUMMARY STATEMENT

Bioresearch Monitoring (BIMO) inspections were conducted at three domestic clinical investigator (CI) sites participating in the conduct of study protocols Sci-B-Vac-001 and Sci-B-Vac-002 and one domestic CI site participating in the conduct of study protocol Sci-B-Vac-002. The inspections did not reveal substantive problems impacting the data submitted in support of this Biologics License Application (BLA).

Background

Four CIs were inspected in support of this BLA. The inspections were conducted in accordance with FDA's Compliance Program (CP) 7348.811, Inspection Program for Clinical Investigators. The inspection assignments were issued for the following study protocols:

Study Sci-B-Vac 001: A Phase 3 Double-Blind Randomized Controlled Trial to Compare the Immunogenicity and Safety of a Three-dose Regimen of Sci-B-Vac® to a Three-dose Regimen of Engerix-B® in Adults (PROTECT).

Study Sci-B-Vac 002: A Double-Blind Randomized Controlled Trial to Assess the Lot-to-lot Consistency of Sci-B-Vac® in Adults (CONSTANT)

The sites were selected based on previous inspectional history, geographic location, and the data submitted in the BLA. The inspection assignments included specific questions concerning the study protocol, and information submitted in the BLA was compared to source documents at the sites. Study Sci-B-Vac-001 was conducted globally in 28 study centers and a total of 1607 subjects were randomized to two study arms. Study Sci-B-Vac-002 was conducted globally in 37 study centers and a total of 2838 subjects were randomized to four study arms. The domestic CI sites inspected in support of this BLA covered approximately 14% and 10% of the subjects randomized in studies Sci-B-Vac-001 and Sci-B-Vac-002, respectively.

Inspection Outcome

Site ID	Study ID /Number of subjects randomized	Location	483 Issued	Final Inspection Classification
200	Sci-B-Vac-001/ 77 Sci-B-Vac-002/ 55	Clinical Research Atlanta Stockbridge, Georgia	No	No Action Indicated
204	Sci-B-Vac-001/ 72 Sci-B-Vac-002/ 57	Lynn Health Science Institute Oklahoma City, Oklahoma	No	No Action Indicated
205	Sci-B-Vac-001/ 77 Sci-B-Vac-002/ 84	Anaheim Clinical Trials Anaheim, California	No	No Action Indicated
211	Sci-B-Vac-002/ 95	Care One Research North Hollywood, California	No	No Action Indicated

The inspections verified the data reported in the BLA, including but not limited to subject eligibility, protocol deviations, study drug administration, immunogenicity data, safety and reactogenicity events, concomitant medication administration, and adverse events for randomly and equitable selected subjects enrolled at the inspected clinical sites. The inspections further evaluated the adequacy of the study and site monitoring by the sponsor. No Form FDA 483 was issued for any of the four inspected sites that participated in the conduct of the study.

Noteworthy inspectional findings

None.

Sponsor Issues

No significant sponsor issues were noted.

Financial Disclosure

The Clinical Investigator Compliance Program directs the FDA investigators to ask the clinical investigator if and when he/she disclosed information about his/her financial interests to the sponsor and/or interests of any sub-investigators, spouses and dependent children, and if and when the information was updated. The information submitted to the BLA was verified at the inspected clinical sites and found no deviations in the submitted data.

Administrative follow-up

No administrative follow-up is warranted at this time from BIMO for the inspected clinical investigators. Should you have any questions about the contents of this memo or any aspect of BIMO, please contact me at 240-402-8979.

Bhanu Kannan, M.S.
Consumer Safety Officer