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## Memorandum

DATE: February 12, 2025

TO: Konstantin Virnik, PhD, Chair BLA STN 125820/0  
Sixun Yang, MD, Clinical Reviewer, BLA STN 125820/0  
Judith Anesi, MD, Clinical Reviewers, BLA STN 125820/0  
Georgeta Crivat, PhD, RPM  
Vera Stupina, PhD, RPM  
Katherine Berkhausen, BSN, RPM

FROM: Malcolm Nasirah, PharmD, MS, Senior Regulatory Reviewer  
Bioresearch Monitoring Branch (BMB)  
Division of Inspections and Surveillance (DIS)  
Office of Compliance and Biologics Quality (OCBQ)

THROUGH: Kanaeko R. Ravenell, MS, Chief BMB  
THROUGH: Carrie M. Mampilly, MPH, Director DIS

SUBJECT: BIMO Discipline Review Memo

PRODUCT: Chikungunya Vaccine, Recombinant (VIMKUNYA)

SPONSOR: Bavarian Nordic A/S  
BLA STN: 125820/0

### REVIEW SUMMARY

Multiple information requests (IRs) were submitted to the sponsor requesting the Curriculum Vitae (CV) for all principal investigators listed for the pivotal studies, the study laboratory manual as referenced in study protocol(s), and the name and address of the central laboratory used by the sponsor responsible for handling immunogenicity analyses for study protocol(s) EBSI-CV-317-004 and EBSI-CV-317-005. The sponsors' responses to the IRs were submitted in amendment 5 and amendment 16 and were acceptable. BIMO Clinical Investigator (CI) inspection assignments were issued for three clinical study sites that participated in the conduct of studies EBSI-CV-317-004 and EBSI-CV-317-005. The completed inspections did not reveal substantive issues that impact the data submitted in this supplemental Biologics License Application (BLA).

## BACKGROUND

Three clinical study sites conducting the study protocol(s) EBSI-CV-317-004 and EBSI-CV-317-005 were identified for BIMO inspections. The study sites were selected for inspection based upon previous BIMO inspection history, number of subjects enrolled, sponsor-reported adverse events, and protocol deviations. The sites selected for inspection comprised approximately 10% and 18% of the total subjects enrolled in EBSI-CV-317-004 and EBSI-CV-317-005 respectively.

These inspections were conducted in accordance with FDA's Compliance Programs (CP) 7348.811, Inspection Program for CIs. Information and data submitted in the BLA was compared to source documents at the inspected site. The inspection assignment also included specific questions concerning the clinical study protocol(s) EBSI-CV-317-004 and EBSI-CV-317-005.

## PROTOCOL(S)

Protocol EBSI-CV-317-004 was a randomized, placebo-controlled, double-blind, parallel-group design with four treatment groups. Protocol EBSI-CV-317-005 was a Phase 3, randomized, double-blind, placebo-controlled, parallel-group study with two treatment groups.

## BIMO INSPECTIONS SUMMARY

The below table summarizes site information and outcomes from the BIMO inspections:

Study Site #	Firm Name	Location	FDA Form 483 Issued	Inspectional Final Classification
0019	Cayce Tangeman	North Charleston, SC	No	No Action Indicated (NAI)
0020	Harry Studdard	Mobile, Alabama	No	No Action Indicated (NAI)
0092	Jorge Caso	Miami, Florida	Yes	Voluntary Action Indicated (VAI)

## INSPECTIONAL FINDINGS:

### Site 0019:

The completed inspection of site 0019 revealed no significant data integrity observations. The safety and efficacy endpoint data were verified without incident. A Form FDA 483 was not issued at close of the inspection.

### Site 0020:

The completed inspection of site 0020 revealed no significant data integrity observations. The safety and efficacy endpoint data were verified without incident. A Form FDA 483 was not issued at close of the inspection.

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Site 0092:

There were seven subjects who were enrolled, randomized and administered investigational product (IP) that had study visit data from the paper source record entered incorrectly or not entered into the electronic case report forms (eCRF) for study EBSI-CV-317-004.

Nine subjects that were enrolled, randomized, and administered IP in study EBSI-CV-317-005, had study visit data from the paper source records that were entered incorrectly or not entered the electronic case report forms (eCRF).

Specifically, concomitant medications, several solicited and non-solicited adverse reactions, and medical histories were inaccurately recorded. A Form FDA 483 was issued at close of the inspection. The corrective action plan submitted by the clinical investigator is adequate.

SPONSOR/MONITORING ISSUES

No significant sponsor or monitoring issues were identified during the completed inspection.

FINANCIAL DISCLOSURE

The CI CP directs the FDA investigator to ask the CI if and when he/she disclosed information about his/her financial interests to the sponsor and/or interests of any sub-investigators, spouse(s) and dependent children, as well as if and when the information was last updated. The information submitted to the BLA was verified for each of the inspected clinical study sites.

ADMINISTRATIVE FOLLOW-UP

Should you have any questions or comments about the contents of this memo or any aspect of BIMO, please contact me at 301-796-6667 or [Malcolm.Nasirah@fda.hhs.gov](mailto:Malcolm.Nasirah@fda.hhs.gov).

Malcolm Nasirah, PharmD  
Consumer Safety Officer

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