



Memorandum

DATE August 7, 2025

FROM Jennifer Chan, PharmD, Consumer Safety Officer
Bioresearch Monitoring Branch (BMB)
Division of Inspections and Surveillance (DIS)
Office of Compliance and Biologics Quality (OCBQ)

THROUGH Kanaeko R. Sharp, MS, Chief BMB

THROUGH Carrie M. Mampilly, MPH, Director DIS

TO Jennifer Reed, PhD, Chair
Avanti Golikeri, MD, Clinical Reviewer
Sairah Thommi, MD, Clinical Reviewer
Julia Wright, MHA, RN, RPM

SUBJECT Bioresearch Monitoring Final Discipline Review Memo
SPONSOR Kedrion SpA
PRODUCT QIVIGY (Kedrion Intravenous Human Immunoglobulin (IVIg) 10%;
Klg10)
STN BLA 125822/0

FINAL SUMMARY STATEMENT

Bioresearch Monitoring (BIMO) inspections were issued for the sponsor and three clinical investigator (CI) sites participating in the conduct of study Protocol KIG10-US3-PID01. The inspections did not reveal substantive issues that impact the data submitted in this Biologics License Application (BLA).

BACKGROUND

BIMO inspection assignments were issued for the sponsor and three domestic CI sites that participated in the conduct of study Protocol KIG10-US3-PID01. The sites were selected based on previous inspectional history, geographic location, and the data submitted in the BLA. The BLA review committee concurred with the sites selected for inspection. These inspections were conducted in accordance with FDA's Compliance Program (CP) 7348.810, Inspection Program for Sponsors and Contract Research Organizations and CP 7348.811, Inspection Program for Clinical Investigators.

PROTOCOL

Protocol KIG10-US3-PID01: A Phase III, Open-label, Prospective, Multicenter Study to Assess Efficacy, Safety and Pharmacokinetics of Kedrion Intravenous Immunoglobulin (IVIg) 10% in Primary Immunodeficiency Disease (PID) Patients.

The inspection assignment included specific questions related to the study protocol, and information submitted in the BLA was compared to source documents at each site. Study KIG10-US3-PID01 was conducted at 11 sites across the United States, enrolling a total of 59 subjects. The three CI sites inspected in support of this BLA covered approximately 34% of the total study population enrolled in the study.

INSPECTION SUMMARY AND OUTCOME

The inspections verified the data reported in the BLA, including but not limited to subject eligibility, study drug administration, protocol deviations, pharmacokinetic endpoint, and adverse events for all subjects enrolled at the inspected clinical sites. No significant objectionable inspectional findings were observed during the inspection. The table below summarizes the BIMO inspections:

Site ID	Study Site Name and Location	Form FDA 483 Issued?	Final Inspection Classification
04	Optimed Research, Ltd. Columbus, OH	No	No Action Indicated (NAI)
12	Toledo Institute of Clinical Research, Inc. Toledo, OH	No	Voluntary Action Indicated (VAI)*
15	Henry J. Kanarek-Allergy, Asthma & Immunology Overland Park, KS	No	NAI
Sponsor	Kedrion SpA Barga (Lucca), Italy	No	NAI

*Classification was changed by the Center. See details under Inspectional Findings.

Inspectional Findings:

The inspections did not reveal substantive issues that impact the data submitted in the BLA. However, the following issues were identified following the inspection and shared with the BLA review committee.

- Site 12: A Form FDA 483 was not issued, however a review of the EIR and corresponding exhibits noted that the CI had inadequate investigational product accountability records in which there were inaccurate subject records documenting the type of infusion visit, number of infusions and infusion times. The final classification was escalated from NAI to VAI by the Center.

Sponsor Issues:

No significant sponsor issues were noted.

FINANCIAL DISCLOSURE

The CI CP directs the FDA investigators 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, spouses, and dependent children, and if and when the information was last updated. The information submitted to the BLA was verified at the inspected sites.

ADMINISTRATIVE FOLLOW-UP

No administrative follow-up is warranted at this time. Should you have any questions about the contents of this memo or any aspect of BIMO, please contact Jennifer Chan at (301) 348-1897.

Jennifer Chan, PharmD.
Consumer Safety Officer

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