



DATE December 4, 2023

FROM Triet M. Tran, PharmD, BCSCP, Regulatory Officer
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THROUGH Dennis T. Cato, Chief, BMB

THROUGH Carrie M. Mampilly, MPH, Director DIS

TO Michael Kennedy, PhD, Chair STN 125743/0
Vijay Kumar, MD, Clinical Reviewer
Nancy Skeeter, RPM

SUBJECT Addendum Bioresearch Monitoring Final Review Memo
SPONSOR Greencross Corporation
PRODUCT Immune Globulin Intravenous (Human) 10% Liquid
BLA STN 125743/0

FINAL SUMMARY STATEMENT

Bioresearch Monitoring (BIMO) inspections were conducted at three domestic clinical investigator (CI) sites participating in the conduct of study protocol GC5107B_P3. The inspections did not reveal substantive problems impacting the data submitted in support of this Biologics License Application (BLA).

Background

Three CIs were inspected in support of this BLA. The inspection was conducted in accordance with FDA's Compliance Program (CP) 7348.811, Inspection Program for CI. The inspection assignments were issued for the following study protocol:

GC5107B_P3: An Open-Label, Single-Arm, Historically Controlled, Prospective, Multicenter Phase III Study to Evaluate the Safety, Efficacy and Pharmacokinetics of Immune Globulin Intravenous (Human) GC5107 in Subjects with Primary Humoral Immunodeficiency.

The sites were selected based on previous inspectional history, geographic location, and the data submitted in the BLA. The inspection assignment included specific questions concerning the study protocol, and information submitted in the BLA was compared to source documents at the site. Study GC5107B_P3 was conducted at 17 study centers enrolling a total of 49 subjects aged ≥ 2 to ≤ 70 years with Primary Humoral

Immunodeficiency requiring Immune Globulin Intravenous (IGIV) treatment. The domestic CI sites inspected in support of this BLA covered all subjects enrolled in the study.

Inspection Outcome

Site ID	Number of subjects enrolled	Location	Form FDA 483 issued	Final Inspection Classification
21	3	Oklahoma Institute of Allergy and Asthma Clinical Research, LLC Oklahoma City, OK 73131	No	No Action Indicated (NAI)
27	5	Allergy Associates of The Palm Beaches, P.A. North Palm Beach, FL 33408	No	NAI
30	5	Pediatric Pulmonary Associates of North Texas, P.A. Frisco, TX 75043	No	NAI

The inspections verified the data reported in the BLA, including but not limited to subject eligibility, protocol deviations, IGIV infusion including any interruptions, serious bacterial infections, and adverse events for the 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 483s were issued for the four inspected study sites.

Noteworthy inspectional findings

None.

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 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 CIs. Should you have any questions about the contents of this memo or any aspect of BIMO, please contact Dennis Cato at 301-741-7326.

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History:

Kannan draft: 11/09/2021

Tran addendum: 12/01/2023