DATE: October 26, 2022

FROM: Peter Lenahan, DC, PhD, MPH
Bioresearch Monitoring Branch (BMB)
Division of Inspections and Surveillance (DIS)
Office of Compliance and Biologics Quality (OCBQ)

THROUGH: Dennis T. Cato, Chief BMB

THROUGH: Carrie M. Mampilly, MPH, Director DIS

TO: CBER Connect STN 125738/0
Elizabeth Lessey-Morillon, PhD, Chair
Najat Bouchkouj, MD, Clinical Reviewer
Cara Pardon, MS, RPM

SUBJECT: Bioresearch Monitoring Final Discipline Review Memo
SPONSOR: Gamida Cell, Ltd
PRODUCT: NiCord® (Omidubicel)
BLA/STN 125738/0

FINAL SUMMARY STATEMENT

Bioresearch Monitoring (BIMO) inspection assignments were issued for four domestic Clinical Investigators (CI) who participated in the conduct of Protocol GC P#05.01.020. The inspections did not reveal substantive issues that impact the data submitted in this original Biologics License Application (BLA).

BACKGROUND

BIMO inspection assignments were issued for four US clinical study sites that participated in the conduct of study protocol GC P#05.01.020. The BLA review committee concurred with the proposed sites. The sites were selected based upon sponsor-reported adverse events, subject deaths, protocol deviations, total numbers of enrolled subjects, previous BIMO inspection histories, BLA clinical review team recommendations, and clinical investigator financial disclosures.

The inspections were performed in accordance with FDA's Compliance Program (CP) 7348.811, Inspection Program for CI, and information submitted in the BLA was compared to source documents at each inspected site. The inspection assignment also included specific questions concerning the clinical study.

PROTOCOLS

Protocol Number: GC P#05.01.020; Protocol Title: A Multicenter, Randomized, Phase III Registration Trial of Transplantation of NiCord®, Ex Vivo Expanded, Umbilical Cord Blood-derived, Stem and Progenitor Cells, versus Unmanipulated Umbilical Cord Blood for Patients with Hematological Malignancies

BIMO INSPECTIONS SUMMARY

No significant BIMO inspectional findings were noted. The below table summarizes site information and outcomes from the BIMO inspections:

Site ID	Location	Final Inspection Classification
Site #: DUK01	Durham, North Carolina	Voluntary Action Indicated (VAI)
Site #: UMN01	Minneapolis, Minnesota	No Action Indicated (NAI)
Site #: SCI01	Stanford, California	VAI
Site #: LOY01	Maywood, Illinois	VAI

SPONSOR/MONITORING ISSUES

No significant sponsor or monitoring issues were identified during the above inspections.

CLINICAL INVESTIGATOR (CI) STUDY SITE ISSUES

A review was conducted of the clinical study records, regulatory binders, study specific standard operating procedures, and general study conduct. In addition, source documents, including records of adverse events, protocol deviations, and subject dispositions were reviewed, and the information contained was compared to the data tables submitted by the sponsor in the application.

Study Site UMN01 did not receive an FDA-483 and the inspection was classified No Action Indicated (NAI)

Study Site DUK01 received a Form FDA 483, and the inspection was classified VAI. The inspection revealed that the clinical investigator failed to accurately report all concomitant medications in the eCRF for four of five subjects reviewed.

Study Site LOY-009 received a Form FDA 483 and the inspection was classified VAI. The site enrolled one study subject who did not meet inclusion criteria.

Study Site SCI-003 received a Form FDA 483 and the inspection was classified VAI. The inspection revealed that 13 of 19 serious adverse events were not reported in a timely fashion to the sponsor as required by the Sponsor's written procedure.

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, and if and when the information was last updated. The information submitted to the BLA was verified for each of the inspected clinical study sites.

BIMO ADMINISTRATIVE FOLLOW-UP

The CI from the study sites that were issued a Form FDA-483 responded in a timely manner with corrective actions that were found to be acceptable, if properly implemented. Information letters were issued for all inspected study sites that received a Form FDA-483.

ADMINISTRATIVE FOLLOW-UP

Should you have any questions or comments about the contents of this memo or any aspect of Bioresearch Monitoring, please contact me at (973) 331-4947.

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CDR, USPHS
Regulatory Officer