



**U.S. FOOD & DRUG
ADMINISTRATION**

Memorandum

DATE March 11, 2026

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 Elizabeth Lessey-Morillon, PhD, Chair
Ailian (Emily) Xiong, MD, PhD, Clinical Reviewer
Linda Le, RPM

SUBJECT Bioresearch Monitoring Final Discipline Review Memo
SPONSOR Orca Biosystems, Inc.
PRODUCT TREGZI ((b) (4))
STN BLA 125868/0

FINAL SUMMARY STATEMENT

Bioresearch Monitoring (BIMO) inspections were issued for the sponsor and two domestic clinical investigators (CI) participating in the conduct of study Protocol Precision-T. The inspections did not reveal significant issues impacting the data submitted in support of this Biologics License Application (BLA).

BACKGROUND

BIMO inspection assignments were issued for the sponsor and two domestic CIs that participated in the study conduct of study Protocol Precision-T. 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 Precision-T: A Randomized Phase III Trial of Patients with Advanced Hematologic Malignancies Undergoing Allogeneic Hematopoietic Cell Transplantation with Either Orca-T®, a T-cell-Depleted Graft with Additional Infusion of Conventional T cells and Regulatory T cells, or Standard-of-Care Allogeneic Graft

The inspection assignment included specific questions related to the study protocol and information submitted in the BLA was compared to source documents at the clinical sites.

Study Precision-T was conducted at 19 sites across the United States, enrolling a total of 187 subjects. The two CI sites inspected in support of this BLA covered approximately 39% 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, and adverse events for the reviewed subjects enrolled at the inspected clinical site. No significant objectionable inspectional findings were observed during the inspections. The table below summarizes the BIMO inspections:

Establishment Type	Site ID	Firm Name	Location	Form FDA 483 Issued?	Final Inspection Classification
Sponsor	N/A	Orca Biosystems, Inc.	Menlo Park, CA	No	No Action Indicated (NAI)
Clinical Investigator	001	Everett Meyer, MD, PhD	Palo Alto, CA	Yes	Voluntary Action Indicated (VAI)
Clinical Investigator	003	Amandeep Salhotra, MD	Duarte, CA	Yes	VAI

Inspectional Findings:

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

- Site 001: A Form FDA 483 was issued at the close of the inspection for failure to conduct an investigation in accordance with the protocol. Specifically, there were multiple instances in which adverse events (AEs) and serious adverse events (SAEs) were not reported on time to the sponsor. Furthermore, in at least two (2) subjects, required graft-versus-host disease (GVHD) prophylaxis was not administered in accordance to the study protocol and one of these protocol deviations was found not to have been properly documented.
- Site 003: A Form FDA 483 was issued at the close of the inspection for failure to conduct an investigation in accordance with the protocol. Specifically, there were multiple instances in which SAEs were not reported to the sponsor within 24 hours of awareness as required per protocol.

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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