



U.S. FOOD & DRUG
ADMINISTRATION

Memorandum Addendum

DATE July 6, 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 (allogeneic regulatory T cell immunotherapy with HSPC and
T cells-vldq)
STN BLA 125868/0

This is an addendum to the Final Bioresearch Monitoring Memo originally signed on March 11, 2026, updating the finalized proper/nonproprietary name of the investigational product from [REDACTED] to allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq.

Jennifer Chan, PharmD.
Consumer Safety Officer