



DHT CONSULT REVIEW MEMO- Addendum

REVIEW DATE: June 26, 2026

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STN: 125868/0

SUBMISSION TYPE: Biological License Application (BLA)

PRODUCT: Allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq (non-proprietary name), TREGZI (proprietary name)

HCT/P SOURCE: Hematopoietic stem/progenitor cell apheresis (HPC, Apheresis)

APPLICANT: Orca Biosystems Inc (Orca Bio)

SUBJECT: Addendum to DHT Consult Review Memo, dated June 9, 2026

**INDICATIONS
FOR USE:**

An allogeneic stem cell and T-cell immunotherapy derived from an HLA-matched donor indicated for use in adult patients with hematologic malignancies to improve survival free of graft-versus-

host disease (GVHD) in conjunction with an appropriate preparative regimen.

SUMMARY:

This document is an addendum to the final DHT Consult Review Memo, dated June 9, 2026, which includes the detailed review of DE and tracking information.

This addendum is to document that the Proper/Nonproprietary Name is updated to “Allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq.” There are no other changes to the DHT Consult Review Memo, dated June 9, 2026.