



Food & Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125868/0

From: Salil K Ghosh/LAC /DBSQC/OCBQ

Through: Maryna Eichelberger, Ph.D.
Division Director, DBSQC/OCBQ

Sponsor: Orca Biotherapeutics Inc. (Orca Bio)

Subject: Suitability of lot-release test methods for TREGZI ((b) (4)),
critical reagent(s)/drug substance/drug product

Recommendation: Approval

Executive Summary:

Analytical methods used for lot release of TREGZI ((b) (4)) were reviewed by Claire Wernly (LMIVTS) and Salil K Ghosh (LAC). Their review memoranda are attached to this cover letter.

Conclusion: The analytical methods and their qualifications reviewed for TREGZI ((b) (4)) were found to be adequate for their intended use.