



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

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125758/0

From: Wei Tu/LBVI/DBSQC/OCBQ

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

Sponsor: Orchard Therapeutics (Europe) Limited

Subject: Suitability of lot-release test methods for LENMELDY (atidarsagene autotemcel) Drug Substance and Drug Product

Recommendation: Approval

Executive Summary:

Analytical methods used for lot release of LENMELDY (atidarsagene autotemcel) were reviewed by Seth Schulte (LMIVTS), Ritu Agarwal (LAC), and Wei Tu (LBVI). Their review memoranda are attached to this cover letter.

Conclusion: The analytical methods and their qualifications reviewed for LENMELDY (atidarsagene autotemcel) were found to be adequate for their intended use.