



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.