



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

## **DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO**

**To:** Biologics License Application, STN 125846/0

**From:** Claire H. Wernly, Ph.D., LMIVTS/DBSQC/OCBQ

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

**Sponsor:** Fondazione Telethon ETS (Telethon)

**Subject:** Suitability of lot-release test methods for WASKYRA drug substance and drug product

**Recommendation:** Approval with Post Marketing Commitment (PMC)

### **Executive Summary:**

Analytical methods used for lot release of WASKYRA (etuvetidigene autotemcel) were reviewed by Claire H. Wernly, Ph.D., (LMIVTS), Wei Tu, Ph.D., (LBVI) and Tao Pan Ph.D., (LAC). Their review memoranda are attached to this cover letter. The validation of the mycoplasma analytical method for the WASKYRA drug product (DP) was found to be inadequate to demonstrate suitability of the method for release testing. Additional validation data provided in a PMC will be used to complete the review and make a final determination on the adequacy of the method.

**Conclusion:** The analytical methods and their validations and/or qualifications reviewed for the WASKYRA drug substance and drug product were found to be adequate for their intended use, except for the outstanding issue for the mycoplasma analytical method for the WASKYRA drug product. Fondazione Telethon ETS has provided written commitment to resolve the issue as a Post Marketing Commitment.