



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

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125813/0

From: Alicia Howard, Ph.D., LBVI/DBSQC/OCBQ

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

Sponsor: Autolus Inc.

Subject: Suitability of lot-release test methods for Obecabtagene autoleucel critical component and drug product

Recommendation: Approval

Executive Summary:

Analytical methods used for lot release of Obecabtagene autoleucel were reviewed by Simleen Kaur (LMIVTS), Kouassi Ayikoe (LAC), and Alicia Howard (LBVI). Their review memoranda are attached to this cover letter.

Conclusion: The analytical methods and their qualifications reviewed for Obecabtagene autoleucel were found to be adequate for their intended use.