



DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125786/0

From: Wei Tu/LBVI/DBSQC/OCBQ

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

Sponsor: Pfizer Inc

Subject: Suitability of lot-release test methods for fidanacogene elaparvovec (BEQVEZ) (b) (4) Drug Product

Recommendation: Approval

Executive Summary:

Analytical methods used for lot release of fidanacogene elaparvovec (BEQVEZ) were reviewed by Simleen Kaur (LMIVTS), Kouassi Ayikoe (LAC), and Wei Tu (LBVI). Their review memoranda are attached to this cover letter.

Conclusion: The analytical methods and their qualifications reviewed for fidanacogene elaparvovec (BEQVEZ) (b) (4) drug product were found to be adequate for their intended use.