



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

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125874/0

From: Esmeralda Alvarado Facundo/LBVI/DBSQC/OCBQ

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

Sponsor: Regeneron Pharmaceuticals, Inc.

Subject: Suitability of lot-release test methods for lunsotogene parvec-cwha (OTARMENI) drug substances and drug product.

Recommendation: Approval

Executive Summary:

Analytical methods used for lot release of lunsotogene parvec-cwha (OTARMENI) were reviewed by Hsiaoling Wang (LAC), Yen Phan and Simleen Kaur (LMIVTS) and Esmeralda Alvarado Facundo (LBVI). Their review memoranda are attached to this cover letter.

Conclusion: The analytical methods and their validations and/or qualifications reviewed for OTARMENI drug substances and drug product were found to be adequate for their intended use.