



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

DBSQC/OCBQ ANALYTICAL METHOD REVIEW MEMO

To: Biologics License Application, STN 125858/0

From: Salil K Ghosh/LAC /DBSQC/OCBQ

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

Sponsor: Ultragenyx Pharmaceuticals, Inc.

Subject: Suitability of lot-release test methods for pariglasgene breCAParvovec (GENGLYCOS), drug substance/drug product

Recommendation: Approval

Executive Summary:

Analytical methods used for lot release of pariglasgene breCAParvovec (GENGLYCOS) were reviewed by Simleen Kaur (LMIVTS), Anil Choudhary and Jing Lin (LBVI) and Salil K Ghosh (LAC). Their review memoranda are attached to this cover letter.

Conclusion: The analytical methods and their qualifications reviewed for pariglasgene breCAParvovec (GENGLYCOS) were found to be adequate for their intended use.