



## MEMORANDUM

**Date:** November 18, 2022

**From:** Varsha Garnepudi, MS  
Branch Chief, QAB  
Division of Biological Standards and Quality Control (DBSQC)  
Office of Compliance and Biologics Quality (OCBQ)  
Center for Biologics Evaluation and Research (CBER)  
Food and Drug Administration (FDA)

**To:** Biologics License Application STN125772

**Subject:** Lot Release Protocol (LRP) Template for HEMGENIX (etranacogene dezaparvovec-drlb).

**Through:** Maryna Eichelberger, PhD, Director DBSQC/OCBQ/CBER/FDA

**Cc:** Anurag Sharma, PhD, Chair, DCGT/OTAT/CBER/FDA  
Shalini Seetharaman, PhD, DRPM/OTAT/CBER/FDA  
Marie Anderson, MS, PhD, DBSQC/OCBQ/CBER/FDA

**Applicant:** CSL Behring  
**Product:** etranacogene dezaparvovec-drlb  
**Trade Name:** HEMGENIX

**Summary:** The LRP template for HEMGENIX submitted in amendment 125772/0.75 on November 18, 2022, is suitable for use.

## **1 General Information**

### **1.1 CMC Review Identifiers and Dates**

**1.1.1 Biologics License Application (BLA) Submission Tracking Number (STN):**  
125772

**1.1.2 Submission received by CBER:** March 24, 2022

**1.1.3 Review completed:** November 18, 2022

## **2 Review**

### **2.1 Documents Reviewed**

LRP template submitted in amendment 125772/0.12 on June 14, 2022.

Revised LRP template and response submitted in amendment 125772/0.39 on September 14, 2022

Revised LRP template and response submitted in amendment 125772/0.51 on October 24, 2022

Revised LRP template and response submitted in amendment 125772/0.53 on October 26, 2022

Response submitted in amendment 125772/0.60 on November 4, 2022

Response 125772/0.61 received on November 7, 2022

Response 125772/0.75 received on November 18, 2022

Note: Submissions were reviewed, and information requests (IRs) were generated by Marie Anderson (DBSQC/OCBQ) until October 7, 2022.

### **2.2 Review**

CSL Behring submitted an LRP template to amendment 125772/0.12 on June 14, 2022. This template was reviewed by OTAT/DCGT and OCBQ/DBSQC with comments. An IR was submitted to CSL Behring on September 02, 2022, requesting the following revisions: To include the results of release tests for DS and DP, add the results obtained from testing the (b) (4)

(b) (4) and to include test results for (b) (4) assay, for details refer to: Information Request # 28.

The LRP template submitted in 125772/0.39 was reviewed by OTAT/DCGT and OCBQ/DBSQC with comments. An IR was submitted to CSL Behring on October 18, 2022, requesting the following revisions: To include the proposed action limits for (b) (4) DP attributes, revise the acceptance criteria for the (b) (4) in the LRP template and add line items for (b) (4) samples in the table for endotoxin testing; for details refer to: Information Request # 38. The LRP template submitted in 125772/0.51 as a response to this request was reviewed by OCBQ/DBSQC with comments. An IR was submitted to CSL Behring on October 25, 2022, to include the information for endotoxin testing previously requested. The LRP template submitted in 125772/0.53 was reviewed by OCBQ/DBSQC and the sponsor was subsequently asked to add the suffix to the proper name of their product and to comment on whether they would have launch lots (information request November 1, 2022). They responded affirmatively in 125772/0.60 on November 4, 2022. The LRP was also reviewed by OCBQ/DMPQ/PRB and consequently, another IR was sent to the sponsor on November 2, 2022, asking the firm to include an electronic signature page at the front of each LRP and to contact Cheryl Hulme if they do not have access to the gateway. In their response (125772/0.61 received on November 7, 2022), the firm committed to contacting Ms Hulme and including the signature page once the electronic pathway has been established at CSL Behring. DBSQC and PRB agreed that the firm should use the LRP template submitted in 125772/0.53 on October 26, 2022 for their launch lots but that an updated LRP template with the electronic cover page should be used for all future electronic lot release submissions. This was communicated to the firm on November 15, 2022 and a template with an electronic signature page that includes the product name suffix was received on November 18, 2022 (125772/0.75).

### **3 Conclusions**

The LRP template for HEMGENIX (etranacogene dezaparvovec-drlb) submitted in amendment 125772/0.75 on November 18, 2022, is acceptable for use.