



**U.S. FOOD & DRUG
ADMINISTRATION**

Memorandum

Date: November 1, 2022

From: Lisa L. Stockbridge, Ph.D.
Branch Chief
OCBQ/DCM/APLB

To: Shalini Seetharaman, CBER/OTAT/DRPM/RPMB4
Edward Thompson, CBER/OTAT/DRPM/RPMB4
Megan Zimmerman, MD, CBER/OTAT/DCEPT/MHB

Subject: PROPER NAME SUFFIX RECOMMENDATION
STN 125772/0
Sponsor: CSL Behring, LLC

Background

HEMGENIX (etranacogene dezaparvovec), BLA125772, is a gene therapy product consisting of a recombinant adeno-associated viral vector, serotype 5, containing the Padua variant of human coagulation Factor IX (AAV5-hFIX). It will be provided as a solution for intravenous infusion, indicated to reduce the frequency of bleeding episodes (b) (4) in adults with hemophilia B (congenital Factor IX deficiency) (b) (4)

On March 21, 2022, CSL Behring, LLC (CSL) submitted proposed proper name suffixes for review. Listed in order of preference, they were: *-ixgt*, *-hbgt*, *-gthb*, *-fixb*, *-gtbr*, *-gtbe*, *-hemb*, *-hmbi*, *-frdm*, *-bfix*. All ten suffixes were unacceptable (see suffix memo dated September 26, 2022), and CSL was invited to propose additional suffixes for review or to request an FDA-generated suffix (see information request dated October 18, 2022).

On October 21, 2022, CSL proposed new proper name suffixes for review. Listed in order of preference, they are *-eaav*, *-cbbr*, *-drlb*, *-zbld*, *-lsts*, *-ahlf*, *-bhly*, *-derb*, *-brrc*, and *-lzts*.

Assessment of the proper name with suffix

The proposed suffixes were evaluated using the criteria set forth in *Guidance for Industry – Nonproprietary Naming of Biological Products*. A suffix should be unique, devoid of meaning, composed of four lowercase letters of which at least three are distinct, nonproprietary, and free

of legal barriers that would restrict its usage. A suffix should not include numbers or symbols, be false or misleading with respect to safety or efficacy of the product, include abbreviations commonly used in clinical practice in a manner that may lead it to be misinterpreted as another element on the prescription or order, contain or suggest a drug substance name or core name, look similar to or have the potential to be mistaken for the name of a currently marketed product, connote the name of the license holder, or be too similar to another FDA-designated suffix.

Using the above criteria, CSL's the first two proposed proper suffixes are not devoid of meaning and are unacceptable for the following reasons:

- Connoting the product proper name **etranacogene dezaparvovec** and the viral vector, **adeno-associated virus**: - **eaav**
- Connoting the indication of the product, **control hemophilia B bleeding rate**: - **cbbr**

Recommendation

CSL's proposed proper name suffixes were reviewed and the third proposed suffix, - *drlb*, was found acceptable. Thus, we offer the following letter-ready language to convey to the applicant:

*The Center for Biologics Evaluation and Research's Office of Tissues and Advanced Therapies and Office of Compliance and Biologics Quality have reviewed your proposed proper name suffixes, and we find your third proposed suffix, - *drlb*, conditionally acceptable for inclusion in your proper name. Should your 351(a) BLA be approved during this review cycle, etranacogene dezaparvovec- *drlb* will be the proper name designated in the license, and you should revise your proposed labels and labeling accordingly. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your proposed proper name unacceptable upon our re-evaluation at that time, we will inform you of our finding.*

The proposed suffixes were evaluated using the criteria set forth in Guidance for Industry Nonproprietary Naming of Biological Products (<https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf>). A suffix should be unique, devoid of meaning, composed of four lowercase letters of which at least three are distinct, nonproprietary, and free of legal barriers that would restrict its usage. A suffix should not include numbers or symbols, be false or misleading with respect to safety or efficacy of the product, include abbreviations commonly used in clinical practice in a manner that may lead it to be misinterpreted as another element on the prescription or order, contain or suggest a drug substance name or core name, look similar to or have the potential to be mistaken for the name of a currently marketed product, connote the name of the license holder, or be too similar to another FDA-designated suffix. Using the above criteria, your proposed suffixes are not devoid of meaning and thus were found unacceptable for the following reasons:

- *Connotes the product proper name **etranacogene dezaparvovec** and the viral vector, **adeno-associated virus**: - **eaav***
 - *Connotes the indication of the product, **control hemophilia B bleeding rate**: - **cbbr***
-