



U.S. FOOD & DRUG
ADMINISTRATION

Memorandum

DATE: May 2, 2023

TO: Rommel Maglalang, RPM, CBER/OTAT/DRPM
Anna Kwilas, Ph.D., Committee Chair, CBER/OTAT/DCGT
Ning Hu, M.D., Clinical Reviewer, CBER/OTAT/DCEPT

FROM: Benjamin S. Cyge, Ph.D.
Consumer Safety Officer
APLB/DCM/OCBQ

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

SUBJECT: VYJUVEK (beremagene geperpavec-svdt)
BLA: 125774/0
Sponsor: Krystal Biotech, Inc.

Background

The sponsor submitted:

☒ New Approval
☐ Changes Being Effectuated (CBE) supplement
☐ Prior Approval Supplement (PAS)
☐ Major Amendment

Submission contains:

☒ Prescribing Information (PI)
☐ Patient Package Insert (PPI)
☒ Package and/or container labels
☐ Other

Submission Date: June 20, 2022

PDUFA Action Date: May 19, 2023

APLB Comments/Recommendations

This is a labeling review for BLA 125774, submitted by Krystal Biotech, Inc. for VYJUVEK (beremagene geperpavec-svdt) on June 20, 2022. VYJUVEK is a herpes-simplex virus type 1 (HSV-1) vector-based gene therapy indicated for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa with mutation(s) in the *collagen type VII alpha 1 chain (COL7A1)* gene.

APLB reviewed the draft package and container labels, dated April 5, 2023, and prescribing information (PI), dated April 18, 2022. The following comments are from a promotional and comprehension perspective.

FULL PRESCRIBING INFORMATION

2 DOSAGE AND ADMINISTRATION

For improved readability and for ensuring that all important relevant information is accessible in most stylesheets, consider having only the common three subsections in **2 DOSAGE AND ADMINISTRATION** and placing the important risk considerations in the relevant section(s):

2.1 Dose

2.2 Preparation

2.3 Administration

For example, statements about potential risks when handling the product should be placed in **Preparation** or **Administration** with cross referencing to a precaution in **WARNINGS AND PRECAUTIONS**.

PACKAGE AND CONTAINER LABELS

- The name of the manufacturer should be added to the vial labels for VYJUVEK and the excipient gel. If the container is capable of bearing a partial label, the container shall show a minimum of the name, the lot number, and the name of the manufacturer. (See 21 CFR §610.60(c))
- The proper name is currently placed below the trade name in vial and carton labels. The proper name must go above the proprietary name. In addition, the graphic currently above the proprietary name in the carton label must be removed, as this will be considered intervening matter once the positions of the proper and proprietary names are switched.

If you have any questions regarding this review, please contact Benjamin S. Cyge, Consumer Safety Officer at (301) 796-4212.
