



**Department of Health and Human Services
Food and Drug Administration
Center for Biologics Evaluation and Research (CBER)
Office of Biostatistics and Pharmacovigilance (OBPV)
Division of Pharmacovigilance (DPV)**

PHARMACOVIGILANCE ORIGINAL BLA MEMORANDUM ADDENDUM

From: Sarada Panchanathan, MD, MS
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(PB3), DPV, OBPV, CBER, FDA

To: Bao Nguyen, PhD
Chair of the Review Committee
Office of Therapeutic Products (OTP)

Through: Kerry Welsh, MD, PhD
Branch Chief, PB3

Subject: Review of Pharmacovigilance Plan

Sponsor: Abeona Therapeutics

Product: Zevaskyn (Prademagene zamikeracel)*

Application Type / Number BLA / STN 125807

Proposed Indication Treatment of wounds associated with recessive dystrophic epidermolysis bullosa (RDEB)

Submission Date: September 25, 2023

Action Due Date: May 24, 2024

OVERVIEW AND ASSESSMENT

After DPV finalized its original BLA pharmacovigilance memorandum for Zevaskyn (STN 125807), mention of the required post-marketing safety study was removed from the CR letter.

The review team and SWG have concurred on the FDAAA Title IX PMR study as mentioned in the original BLA pharmacovigilance memorandum.

- A postmarketing, prospective, observational study to assess and characterize the risk of secondary malignancies, and long-term safety, following treatment with prademagene zamikeracel. This study will enroll a minimum of 100 patients and each enrolled patient will be followed for 15 years after product administration.

The Sponsor has not been notified of the review team decision regarding this study. Should the sponsor submit a response to this CR, OBPV/DPV will discuss further with the review team regarding sponsor PMR notification for the above study.