



EVIVE BIOTECHNOLOGY SINGAPORE PTE LTD.
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April 28, 2026

Tanya Wroblewski, MD
Director, Division of Nonmalignant Hematology
Office of Cardiology, Hematology,
Endocrinology, and Nephrology
Office of New Drugs,
Center for Drug Evaluation and Research
5901-B Ammendale Road
Beltsville, MD 20705-1266

**RESPONSE TO PREA
NON-COMPLIANCE LETTER**

DEFERRAL EXTENSION REQUESTED

Re: **BLA # 761134, Sequence No. 0133**
Ryzneuta (efbemalenograstim alfa-vuxw) injection

Dear Dr. Wroblewski:

Reference is made to the Notification of Non-Compliance with the PREA letter (Reference ID: 5765803) dated March 18, 2026 for the following postmarketing study, and to IND 112198, to which the initial pediatric presentation development plan has been submitted.

PMR 4530-2 — Submit pediatric assessments for Ryzneuta (efbemalenograstim alfa) as described in section 505B(a)(2)(A) of the FD&C Act, including development of an “appropriate formulation” (presentation) that can be used to directly and accurately administer Ryzneuta (efbemalenograstim alpha) to pediatric patients (1 month to <17 years of age). Conduct any necessary human factors studies to evaluate the ability of healthcare providers and caregivers to measure the appropriate doses. The final Report should include a report for the pediatric presentation development and the completed human factors study.

Evive Biotechnology (Evive) is hereby providing a response to the Notification of Non-Compliance with the PREA, and requests a deferral extension for PMR 4530-2, until July 31, 2027.

Following the initial BLA approval, Evive initiated the required activities under PMR 4530-1 (evaluating the safety and PK/PD of Ryzneuta in pediatric patients) and PMR 4530-2, aiming to complete these studies within the agreed timelines. We submitted the initial pediatric presentation development plan for PMR 4530-2 on March 26, 2024 (IND 112198, Serial #0072), followed by a draft clinical study protocol for PMR 4530-1 submitted on December 19, 2024 (IND 112198, Serial #0074). Prior to




finalizing and implementing the study protocol for PMR 4530-1, Evive submitted a Type B meeting request on October 31, 2025, to seek FDA's alignment on key aspects of the PMR 4530-1 trial design and the human factors study for PMR 4530-2. As indicated in the written response dated December 31, 2025, the Agency did not agree with our initial pediatric presentation proposal. In response, Evive immediately initiated the development of a new pediatric presentation to ensure direct and accurate administration of Ryzneuta. However, given the inherent complexity and uncertainty associated with developing this new presentation, this process has taken longer than initially anticipated, requiring additional time to verify the suitability and applicability of the new presentation.

Based on the reasons provided above, Evive respectfully requests a deferral extension the PREA PMRs. The proposed new timeline is provided in [section 1.17.2](#) of this submission.

The information contained in this submission is confidential and as such should be handled in accordance with the provisions established in 21 CFR § 314.430.

Should you have any questions regarding the submission, please contact Yiping Li, the authorized representative of Evive in the U.S., by email at yiping.li@evivebiotech.com.

Sincerely,

Signed by:

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Jia Li
Director
Evive Biotechnology Singapore PTE. Ltd.