



Our STN: BL 125703/464

SUPPLEMENT APPROVAL
PMR/PMC FULFILLED
April 1, 2026

Kite Pharma, Inc.
Attention: Alissa Lee, PharmD
2400 Broadway
Santa Monica, CA 90404

Dear Dr. Lee:

We have approved your request received September 30, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for brexucabtagene autoleucel to include the completed accelerated approval required study (ZUMA-2) final report for PMR #2 in the approval letter issued on July 24, 2020 for BLA STN 125703/0 to convert from an accelerated to a traditional approval for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) with revisions to sections 1 INDICATIONS AND USAGE, 2 DOSAGE AND ADMINISTRATION, 5 WARNINGS AND PRECAUTIONS, 6 ADVERSE REACTIONS, 12 CLINICAL PHARMACOLOGY, 14 CLINICAL STUDIES and MEDICATION GUIDE in the prescribing information label.

We approved BLA STN BL 125703/0 on July 24, 2020, under 21 CFR 601 Subpart E for Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses. Approval of this supplement fulfills the following postmarketing requirements for transition from accelerated to traditional approval of the r/r MCL indication made under 21 CFR 601.41:

FULFILLED ACCELERATED APPROVAL REQUIRED STUDIES

PMR #2: Conduct a study of brexucabtagene autoleucel treatment of subjects with relapsed or refractory mantle cell lymphoma who have not been exposed to a Bruton tyrosine kinase (BTK) inhibitor. A cohort of subjects naïve to BTK inhibitor therapy will be added to the ongoing ZUMA-2 study to fulfill this requirement. Eighty-six subjects will be enrolled. The primary efficacy endpoint will be objective response rate with a supportive efficacy endpoint of duration of response based on a minimum follow-up of 18 months after first objective disease response.

Final Protocol Submission: January 15, 2021

Study/Trial Completion: April 30, 2025

Final Report Submission: October 31, 2025

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: 04880434, 02601313

LABELING

We hereby approve the draft content of labeling for the Package Insert submitted under amendment 13, dated March 31, 2026.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>. Content of labeling must be identical to the Package Insert submitted on March 31, 2026. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at <http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125703/0 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

We remind you that there are PMRs still open. For each postmarketing study subject to the reporting requirements of 21 CFR 601.70, you must describe the status in an annual report on postmarketing studies for this product. Label your annual report as an **Annual Status Report of Postmarketing Requirements/Commitments** and submit it to the FDA each year within 60 calendar days of the anniversary date of the approval of this BLA until all Requirements and Commitments subject to the reporting requirements of section 506B of the Federal Food, Drug, and Cosmetic Act are fulfilled or released. The status report for each study should include:

- the sequential number for each study;
- information to identify and describe the postmarketing commitment;
- the original schedule for the commitment;
- the status of the commitment (i.e., pending, ongoing, delayed, terminated, or submitted); and,
- an explanation of the status including, for clinical studies, the patient accrual rate (i.e., number enrolled to date and the total planned enrollment).

As described in 21 CFR 601.70(e), we may publicly disclose information regarding these postmarketing studies on our website <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/postmarket-requirements-and-commitments>.

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because the biological product for this indication has an orphan drug designation, you are exempt from this requirement.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Bindu George, MD
Acting Director
Division of Clinical Evaluation Hematology
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research