Our STN: BL 125703/18

SUPPLEMENT APPROVAL
February 24, 2021

Kite Pharma, Inc.
Attention: Polina Kinchev
2400 Broadway
Santa Monica, CA 90404

Dear Ms. Kinchev:

We have approved your request submitted August 25, 2020, received August 26, 2020, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for brexucabtagene autoleucel to update Section 5.5 (Serious Infections) of the Prescribing Information for consistency with the KTE-X19 Company Core Data Sheet based on a review of opportunistic infections as part of your ongoing pharmacovigilance procedures.

LABELING

We hereby approve the draft content of labeling Package Insert submitted under amendment 1, dated February 9, 2021.

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 [choose all that apply: Package Insert, Patient Package Insert, Instructions for Use, and Medication Guide] submitted on [DATE]. 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 at the time of use and include implementation information on Form FDA 356h.

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,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation
and Pharmacology/Toxicology
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research