



Our STN: BL 125643/394

SUPPLEMENT APPROVAL

April 1, 2022

Kite Pharma, Inc.
Attention: Daniel Shu, PharmD
2400 Broadway
Santa Monica, CA 90404

Dear Dr. Shu:

We have approved your request received September 30, 2021, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for axicabtagene ciloleucel to add a new indication for the treatment of adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy. Axicabtagene ciloleucel is not indicated for the treatment of patients with primary central nervous system lymphoma.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: 03391466.

LABELING

We hereby approve the draft content of labeling: Package Insert submitted under amendment 36, dated March 31, 2022.

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, 2022. 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.

We request that the labeling approved today be available on your website within 10 days of receipt of this letter.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125643/0 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)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

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 and since this is a supplemental BLA, you are exempt from this requirement.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The “YESCARTA and TECARTUS REMS” was originally approved on July 24, 2020, and consists of elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS.

The most recent REMS modification under STNs BL 125703/164 and BL 125643/403 approved on April 1, 2022, includes changes to the REMS Program Training, REMS Knowledge Assessment, REMS Hospital Enrollment Form and REMS Website to align with labeling changes related to your new indication for the treatment of adult patients with large B-cell lymphoma that is refractory to first-line chemoimmunotherapy or that relapses within 12 months of first-line chemoimmunotherapy. Limitations of Use: axicabtagene ciloleucel is not indicated for the treatment of patients with primary central nervous system lymphoma.

The timetable for submission of assessments of the REMS remains the same as that approved on July 24, 2020. There are no changes to the REMS assessment plan described in our July 24, 2020, letter.

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

Enclosures:
REMS