



Our STN: BL 125643/362

**SUPPLEMENT APPROVAL**

January 25, 2022

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

Dear Dr. Shu:

We have approved your request submitted July 23, 2021, received July 26, 2021, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for axicabtagene ciloleucel, to update the U.S. Prescribing Information with clinical safety data from Cohort 6 of the Phase 2 Safety Management ZUMA-1 study.

## **LABELING**

We hereby approve the draft content of labeling and Package Insert submitted under amendment 11, dated January 12, 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 January 12, 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 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.

## **RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS**

The “YESCARTA and TECARTUS REMS” was originally approved on July 24, 2020. The REMS 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 125703/135 and BL 125643/387 is approved on January 25, 2022 and includes changes to the REMS training material to align with labeling changes based on the submitted clinical safety data from Phase 2 safety management study of ZUMA 1 cohort 6.

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 files.

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

REMS