Our STN: BL 125643/724 & 125703/432

SUPPLEMENT APPROVAL
June 26, 2025

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

Dear Dr. Lee:

We have approved your request received March 21, 2025 to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for axicabtagene ciloleucel (YESCARTA) and brexucabtagene autoleucel (TECARTUS), for proposed modifications to the approved YESCARTA and TECARTUS risk evaluation and mitigation strategy (REMS) to eliminate the REMS. This supplement is in response to our March 7, 2025, REMS Modification Notification letter.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENT

The REMS for YESCARTA and TECARTUS was originally approved on July 24, 2020, and the most recent REMS modification was approved on June 12, 2024. The REMS consists of elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS.

We also refer to your REMS assessment received on July 22, 2024.

In accordance with section 505-1(g)(4)(B) of the Federal Food, Drug, and Cosmetic Act (FDCA), because a REMS is no longer necessary to ensure that the benefits of YESCARTA and TECARTUS outweigh their risks and to minimize the burden on the healthcare delivery system of complying with the REMS, we determined that you were required to make the REMS modifications outlined in our REMS Modification Notification letter dated March 7, 2025.

We have determined that the goal of “Ensuring that hospitals and their associated clinics that dispense YESCARTA and/or TECARTUS are specially certified and have on-site, immediate access to tocilizumab” and the elements to assure safe use are no longer necessary to ensure the benefits of YESCARTA and TECARTUS outweigh its risks. This determination is based on:

- Given the established management guidelines and extensive experience of the medical hematology/oncology community in diagnosing and managing the risks of cytokine release syndrome (CRS) and neurologic toxicities across products in

the class of BCMA- and CD19-directed autologous CAR T cell immunotherapies, FDA has determined that the safe and effective use of YESCARTA and TECARTUS for the indicated population can be assured without a REMS. The risks for YESCARTA and TECARTUS can be conveyed adequately via the current product labeling including the Medication Guide which is a part of the approved labeling.

- Adverse event reporting for CRS and neurological toxicity have remained stable. Adverse event reporting requirements in accordance with 21 CFR 600.80 are adequate for continued routine safety monitoring for YESCARTA and TECARTUS.

Therefore, because the elements to assure safe use and implementation system are no longer necessary to ensure the benefits of YESCARTA and TECARTUS outweigh their risks, a REMS is no longer required for YESCARTA and TECARTUS.

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

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

If you have any questions, please contact the Regulatory Project Manager, Crystal Melendez, at (240) 772-6272 or by email at Crystal.Melendez@fda.hhs.gov.

Sincerely,

Asha Das, MD
Acting Director
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research