



Our STN: BL 125714/703

**SUPPLEMENT APPROVAL  
PMR/PMC FULFILLED**  
February 20, 2026

Juno Therapeutics, Inc., a Bristol-Myers Squibb Company  
Attention: Sree Deepthi Karampudi  
556 Morris Avenue  
Summit, NJ 07901

Dear Sree Deepthi Karampudi:

We have approved your request received August 21, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for lisocabtagene maraleucel, to fulfill the BL 125714/225 accelerated approval required study, final milestone, and to provide evidence of effectiveness necessary to support the conversion from an accelerated approval to a traditional approval of lisocabtagene maraleucel for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) who have received two or more prior lines of systemic therapy.

We approved BLA STN BL 125714/225 on May 15, 2024, 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 requirement for Accelerated approval made under 21 CFR 601.41:

### **FULFILLED ACCELERATED APPROVAL REQUIRED STUDIES**

PMR #1: Collect and submit the final report, including datasets from the TRANSCEND FL clinical trial (NCT04245839) to verify and describe the clinical benefit of lisocabtagene maraleucel (BREYANZI) in adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy (including an anti-CD20 antibody and an alkylating agent). All partial and complete responders should have completed at least 24 months of follow up starting from the initial objective response.

- Final Protocol Submission: August 15, 2022
- Study/Trial Completion: May 31, 2025
- Final Report Submission: August 31, 2025

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: NCT04245839 and NCT03435796.

## **LABELING**

We hereby approve the draft content of labeling Package Insert and Medication Guide submitted under amendment 7, dated February 6, 2026.

## **WAIVER OF HIGHLIGHTS**

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of prescribing information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

## **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 February 6, 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 125714 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)).

We remind you that there is a PMR 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:

2. A postmarketing, multicenter, prospective, observational study to assess the long-term safety and risk of secondary malignancies occurring after treatment with lisocabtagene maraleucel. The study will include at least 300 patients with relapsed or refractory follicular lymphoma; the enrolled patients will be followed for 15 years after the product administration.

We acknowledge the timetable you submitted on April 16, 2024, which states that you will conduct this study according to the following schedule:

- Final protocol submission: August 1, 2024
- Study completion date: August 31, 2044
- Final report submission: August 31, 2045

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