



Our STN: BL 125746/249

SUPPLEMENT APPROVAL

October 10, 2025

Janssen Biotech, Inc.
Attention: Aline de Oliveira, PhD, RAC
920 US Highway 202, P.O. Box 300
Raritan, NJ 08869

Dear Dr. de Oliveira:

We have approved your request received December 13, 2024, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for ciltacabtagene autoleucel to update the US Prescribing Information (USPI) to include results from a protocol-specified second interim analysis from CARTITUDE-4. The supplement revises the Boxed Warning, Section 5 (Warnings and Precautions), Section 6 (Adverse Reactions), and the Medication Guide to include the risk of immune effector cell-associated enterocolitis, T cell lymphoma of the gastrointestinal tract, and gastrointestinal perforation. Additionally, the supplement revises Section 14 (Clinical Studies) of the USPI to include a protocol-specified analysis for overall survival from CARTITUDE-4.

The review of this supplement was associated with the following National Clinical Trial (NCT) number: NCT04181827.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft content of labeling Package Insert and Medication Guide submitted October 9, 2025.

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 and Medication Guide submitted on October 9, 2025. 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 125746 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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the changes approved today.

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,

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