



Memorandum

DATE: July 30, 2024

TO: Elvira Argus, Chairperson
CBER/OTP/OGT/DGT2/GTB4
Tigist Assefa, Project Manager
CBER/OTP/ORMRR/DRMRR1/RRB1

FROM: Teresa Vu, Pharm.D., MBA.
Advertising and Promotional Labeling Branch (APLB)
Division of Case Management (DCM)
Office of Compliance and Biologics Quality (OCBQ)

THROUGH: Lisa L. Stockbridge, Ph.D.
Branch Chief
APLB/DCM/OCBQ

SUBJECT: Labeling Review
TECELRA (afamitresgene autoleucel)
BLA: 125789/0
Sponsor: Adaptimmune LLC

Background

The sponsor submitted:

☒ New Approval
☐ Changes Being Effectuated (CBE) supplement
☐ Prior Approval Supplement (PAS)
☐ Major Amendment

Submission contains:

☒ Prescribing Information (PI)
☒ Patient Package Insert (PPI)
☒ Package and/or container labels
☐ Other (Instructions for Use/User Manual)

Submission Date: December 5, 2023
PDUFA Action Date: **August 2, 2024**

APLB Comments/Recommendations

This labeling review is for an original Biologics License Application (BLA 125789) submitted by Adaptimmune LLC on December 5, 2023, for TECELRA (afamitresgene autoleucel). The current proposed indication is: melanoma-associated antigen A4 (MAGE-A4)-directed genetically modified autologous T cell immunotherapy for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared Companion Diagnostic devices.

Through July 29, 2024, APLB iteratively reviewed the draft PI, PPI, and package and container labels with the TECELRA Review Team. We provide the following additional comments on the revised labeling, dated July 26, 2024, from a comprehension, readability, and promotional perspective.

BOXED WARNING

The BOXED WARNING references subsection 2.2 to manage CRS; however, subsection 2.2 Preparation and Administration does not contain information on how to manage CRS.

CASSETT AND BAG LABELS

If there is more than one bag, the number of bags should be mentioned on the labels. While this has been added to the most recent labels, it has been added in an obscured place. Please move this statement closer to “Contains” rather than within the barcode and lot numbers.

If you have any questions regarding this review, please contact CAPT Teresa Vu, PharmD, at Teresa.Vu@fda.hhs.gov.
