



Memorandum

DATE: November 4, 2024

TO: Andrew Timmons, Chairperson
CBER/OTP/OGT/DGT2/GTB5
Danielle Bauman, 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
AUCATZYL (obecabtagene autoleucel)
BLA: 125813/0
Sponsor: Autolus Inc.

Background

The sponsor submitted:

New Approval
 Changes Being Effected (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: November 17, 2023
PDUFA Action Date: **November 16, 2024**

APLB Comments/Recommendations

This labeling review is for AUCATZYL (obecabtagene autoleucel), an original Biologics License Application (BLA 125813) submitted by Autolus Inc. on November 17, 2023. The proposed indication is for the treatment of adults with relapsed or refractory B cell precursor acute lymphoblastic leukemia.

Through November 4, 2024, APLB iteratively reviewed the draft PI and package and container labels with the AUCATZYL Review Team. We provide the following additional comments, pertaining to revised labeling received on October 29, 2024, from a comprehension, readability, and promotional perspective.

OVERALL

Only bold regulatory headings and language throughout (except for tables, graphs, and figures).

BOXED WARNING

The BOXED WARNING references subsection 5.9 regarding T cell malignancies; however, there is no subsection 5.9. within the **FULL PRESCRIBING INFORMATION**.

FULL PRESCRIBING INFORMATION

Move the statement, “Strictly follow Administration instructions to minimize dosing errors [see *Overdosage (10)*].”, from immediately after the section heading **2 DOSAGE AND ADMINISTRATION** to the beginning of subsection **2.3 Administration**.

Under section **10 OVERDOSAGE**, remove the unreferenced language phrase, “In FELIX Study (all cohorts N=17)”. In the absence of a hyperlink to section **14 CLINICAL STUDIES** or a citation to a publication, this distracts from the information about the cause of the overdose, which is in section **2 DOSAGE AND ADMINISTRATION**. This should be the only hyperlink. Also, consider that many healthcare system stylesheets for use at patient point-of-care would display sections **2 DOSAGE AND ADMINISTRATION** and **10 OVERDOSAGE** but would not display section **14 CLINICAL STUDIES**.

PACKAGE AND CONTAINER

No further comments on the revised package and container labels.

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