U.S. FOOD & DRUG ADMINISTRATION

Memorandum

DATE: January 7, 2021

TO: Anna Kwilas, Ph.D., Chairperson
CBER/OTAT/DCGT/GTB

Juliane Carvalho, MS, RPM
CBER/OTAT/DRPM

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FROM: Jun H. Lee, Pharm.D., Ph.D.
CBER/OCBQ/DCM/APLB

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

SUBJECT: Labeling Review
ABECMA (idecabtagene vicleucel)
BLA 125736/0
Applicant: Celgene Corporation

Background: The applicant submitted:

X New Approval
____ Changes Being Effected (CBE) supplement
____ Prior Approval Supplement (PAS) Amendment
____ Major Amendment

Submission contains:
X Prescribing Information (PI)
____ Patient Package Insert (PPI)
X Package and/or container labels
X Other (IFU, Medication Guide)

Submission Date: July 27, 2020

PDUFA Action Date: March 26, 2021

Background

On July 27, 2020, Celgene Corporation submitted an original Biologics License Application (BLA) 125736 for ABECMA® (idecabtagene vicleucel), a B-cell maturation antigen (BCMA)-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with multiple myeloma who have received at least three prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 antibody. On October 15, 2020, APLB found the proposed proprietary name, ABECMA, acceptable.

The following APLB review addresses the proposed prescribing information and the proposed package and container labels, submitted on July 27, 2020. Please note that the comments below, provided from a promotional and comprehension perspective, are not exhaustive. We recommend that the applicant consult the regulations (21 CFR §201.57, §610.61, §610.62, and §610.63) and associated labeling guidances (https://www.fda.gov/drugs/laws-acts-and-rules/prescription-drug-labeling-resources) to ensure that their edited draft labeling comports with the regulations.

GENERAL

Proofread the PI to ensure that there are no editorial errors and there is consistency in fonts.

CONTENTS (TOC)

Include the required subsection of 12.2 Pharmacodynamics under **12 CLINICAL PHARMACOLOGY**.

FULL PRESCRIBING INFORMATION

2 DOSAGE AND ADMINISTRATION

Consider numbering steps and adding figures for preparation and administration.

3 DOSAGE FORMS AND STRENGTHS

Include volume to product.

7 DRUG INTERACTIONS

Remove the subsection **7.1 Drug/Laboratory Test Interactions**, since there is only one subsection and it is not pre-specified subsection.

11 DESCRIPTION

- Ensure that information in this section does not belong in other section (i.e. mechanism of action)
- Use alpha and zeta for Greek letters in consistency to other sections.

12 CLINICAL PHARMACOLOGY

Include the required subsection of **12.2 Pharmacodynamics**.

13 NONCLINCAL TOXICOLOGY

For clarity, include the proprietary name (ABECMA) with the nonproprietary name (idecabtagene vicleucel).

14 CLINICAL STUDIES

Avoid National Clinical Trial numbers (NCT03361748).

MEDICATION GUIDE

Medication guide must be consistent with the REMS document.

- In the REMS it specifies how close the patient should remain to their treatment location: “Instruct patients to remain within 2 hours of the REMS-certified healthcare facility for at least 4 weeks following infusion”
- In the Medication guide: “You should plan to stay close to this location at least 4 weeks after getting ABECMA.”

CONTAINER LABEL

APLB has no comments on the container label at this time.

PACKAGE LABEL

APLB has no comments on the container label at this time.