Memorandum

DATE: May 18, 2020

TO: Graeme Price, Chairperson
CBER/OTAT/DCGT/GTIB

Crystal Melendez, RPM
Adriane Fisher, RPM
CBER/OTAT/DRPM/RPMBI

FROM: Dana C. Jones, CSO
CBER/OCBQ/DCM/APLB

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

SUBJECT: Labeling Review
TECARTUS (brexucabtagene autoleucele)
BLA 125703/0
Sponsor: Kite Pharma, Inc.

Background: The sponsor 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 (Medication Guide)

Submission Date: December 11, 2019

PDUFA Action Date: August 10, 2020

APLB Comments/Recommendations

On December 11, 2019, Kite Pharma, submitted an original Biologics License Application (BLA) for TECARTUS (brexucabtagene autoleucele), a CD19-directed genetically modified autologous T cell immunotherapy indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL).

On January 16, 2020, APLB recommended that the proposed proprietary name, TECARTUS, be found acceptable.

APLB concurs with the revisions made by the review team (06MAY-2020 working version of prescribing information and Medication Guide). The following comments and recommendations are in addition to all changes already made from a promotional and comprehension perspective.

GENERAL

- Upon approval ensure that the 4-digit year is entered for the "Initial U.S. Approval."
- Use active voice when possible.
- Use command language for instructions when possible.
- For clarity write out the word "intravenous" instead of using the abbreviation "IV" throughout the PI.
- For consistency change the term "neurologic events" to "neurologic toxicities" throughout the PI.

HIGHLIGHTS

- In the first bullet point of the **BOXED WARNING**, should the statement "fatal or life-threatening reactions…" be included as found in the YESCARTA label?
- Include the section reference (5.3) in the third bullet point of the **BOXED WARNING**.
- Is there a "Limitation of Use" statement that should be included in the **INDICATIONS AND USAGE** section as found in the YESCARTA label?
- In the second bullet point of **WARNINGS AND PRECAUTIONS** should the term "Serious Infections" be included as found in the YESCARTA label?
- In the third bullet point of **WARNINGS AND PRECAUTIONS** should the term "Prolonged Cytopenias" be included as found in the YESCARTA label?
- Remove the **REVISION DATE.** This will be the initial approval and not a revision.

FULL PRESCRIBING INFORMATION (FPI)

BOXED WARNING

See comments above in the **HIGHLIGHTS** section.

2 DOSAGE AND ADMINISTRATION

- Correct the spelling of “Administration” in section heading **2.2 Administration.**
- The last bullet of sub-section ***Administration*** should read as follows:

  After the entire content~~s~~ of the TECARTUS bag ~~are~~ is infused, rinse the tubing with normal saline at the same infusion fate to ensure all product is delivered.

5 WARNINGS AND PRECAUTIONS

See comments above in the **HIGHLIGHTS** section.

5.2 Neurologic Toxicities

For consistency change the term “neurologic events” to “neurologic toxicities” throughout the PI.

5.4 Hypersensitivity Reactions

Should this section include the statement “Allergic reactions may occur with the infusion of TECARTUS” as found in the YESCARTA label?

6 ADVERSE REACTIONS

See comments above in the **HIGHLIGHTS** section.

11 DESCRIPTION

Please include the product’s proper name as well as the proprietary name in this section.

TECARTUS (brexucabtagene autoleucele)

14 CLINICAL STUDIES

Remove study number reference (i.e. ZUMA-2; NCT02601313).

17 PATIENT COUNSELING

See comments above in the **HIGHLIGHTS** section.

MEDICATION GUIDE

- Add the word "*pronounced"* within the parenthesis before the phonetic spelling of TECRATUS.

  (pronounced tee-KART-us)

- The verbatim statement *"This Medication Guide has been approved by the U.S. Food and Drug Administration"* should appear at the bottom of the medication guide.

CONTAINER LABEL

- Revise the presentation of the product names on the carton according to 21 CFR §610.62. Specifically,

  Position. The proper name of the product on the package label shall be placed above any trademark or trade name identifying the product and symmetrically arranged with respect to other printing on the label.

  Prominence. The point size and typeface of the proper name shall be at least as prominent as the point size and typeface used in designating the trademark and trade name.

If you have any questions regarding this review please contact Dana C. Jones, Consumer Safety Officer at 240-402-9012.