



Memorandum

Date: May 8, 2017

To: Mark Davidson, RPM, OMPT/CBER/OTAT/DRPM/RPMBI
Maura O'Leary, Medical Officer, OMPT/CBER/OTAT/DCEPT/CHB

From: Oluchi Elekwachi, PharmD, MPH, Regulatory Review Officer
OCBQ/DCM/APLB

Through: Lisa Stockbridge, PhD, Branch Chief
OCBQ/DCM/APLB

Robert A. Sausville, Division Director
OCBQ/DCM

Subject: Review of Proposed Proprietary Name "**YESCARTA**" (axicabtagene
ciloleucel)
BLA 125643
Sponsor: KITE Pharma

Recommendation: **YESCARTA - Acceptable**

Executive Summary

The Advertising and Promotional Labeling Branch (APLB) has completed its review of the proposed proprietary name, **YESCARTA**, an autologous T cell immunotherapy. We recommend that the proposed proprietary name, **YESCARTA**, be found **Acceptable**.

According to SOPP 8001.4 Review of CBER Regulated Product Proprietary Names, the product office, Office of Tissues and Advanced Therapies (**OTAT**), makes the final decision on the acceptability of a proposed proprietary name. To meet the PDUFA performance goal, OTAT must communicate this decision to the sponsor within 90 days of the receipt of the proprietary name review (PNR) submission. The PDUFA goal date for this PNR is June 29, 2017.

If OTAT accepts our recommendation that the proposed proprietary name, **YESCARTA**, be found acceptable, we offer the following communication-ready language:

*In consultation with CBER's Advertising and Promotional Labeling Branch, we conclude that under the Federal Food, Drug, and Cosmetic Act and applicable regulations, your proposed proprietary name, **YESCARTA**, is acceptable.*

OTAT is responsible for communicating CBER's decision to the sponsor and should enter the

communication issuance date into RMS-BLA before June 29, 2017, in order to meet the deadline and stop the performance clock. Please notify APLB when this action has been completed.

Background

On March 31, 2017, Kite Pharma (Kite) submitted a PNR request for its autologous T cell immunotherapy. The proposed proprietary name is **YESCARTA**. There is no alternative proprietary name proposed.

According to the sponsor, the name **YESCARTA** (pronounced yes-KAR-tuh) was not derived from any one particular concept. The proposed indication is treatment of adult patients with aggressive B-cell non-Hodgkin lymphoma (NHL) who have not responded to their prior therapy or have had disease progression after autologous stem cell transplant (ASCT).

YESCARTA will be available as a cell suspension for intravenous infusion. A target dose of autologous T cells of 2.0×10^6 anti-CD19 CAR T cells/kg in (b) (4) will be supplied in a cryostorage infusion bag. To ensure that viable live autologous cells are administered to the patient, the bags must be stored in the vapor phase of liquid nitrogen and must remain frozen until the patient is ready for treatment. The product arrives frozen in a liquid nitrogen dry shipper labeled for the specific patient. The primary care environment for this product will be out-patient hospital infusion center.

The sponsor provided a proprietary name review conducted by the (b) (4) in June 2016, which found **YESCARTA** as an acceptable proprietary name candidate.

Method

APLB utilized the FDA Phonetic and Orthographic Computer Analysis (POCA) and the following databases:

1. CBER list of Licensed Products ending April 17, 2017, at <http://www.fda.gov/downloads/BiologicsBloodVaccines/UCM149970.pdf>
2. DailyMed at <http://dailymed.nlm.nih.gov/dailymed/about.cfm>
3. Drugs@FDA current through April 17, 2017, at <http://www.accessdata.fda.gov/scripts/cder/drugsatfda>
4. Electronic Orange Book current through April 17, 2017, at <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>
5. Google Internet search at <http://www.google.com>
6. Micromedex at <http://www.micromedexsolutions.com/micromedex2/librarian>
7. United States Patent and Trademark Office (USPTO) at <http://www.uspto.gov/trademarks/index.jsp>
8. USAN Stem at <http://www.ama-assn.org/ama1/pub/upload/mm/365/stem-list-cumulative.pdf>

APLB also consulted the review team and the input was incorporated into the results of this review.

Results

1. Prescreening for Objectionable Naming Practices

The proposed proprietary name, **YESCARTA**, was screened against the following:

- Obvious similarities in spelling and pronunciation
- Manufacturing characteristics
- Medical and/or coined abbreviations
- Inert or inactive ingredients
- Combination of active ingredients
- United States Adopted Name (USAN) stems
- Same proprietary name for products containing different active ingredients
- Reuse of proprietary names
- Dosage form or route of administration
- Dosing interval
- Established or proper name
- Modifiers as components of a proprietary name
 - Use of numerals as modifiers
 - Device-related modifiers
 - Descriptive modifiers
- Brand name extensions (Umbrella branding)
- Dual proprietary names
- Foreign drug proprietary name
- Prescription-to-OTC switch
- Use of symbols
- Incorporation of the sponsor's name

2. Evaluating for Promotional and Safety Concerns

a. Promotional Review [21 CFR 201.10 (c)(3), 202.1 (e)(5)(i), and (e)(6)(i)]

The proposed proprietary name, **YESCARTA**, is not regarded to be false, misleading or fanciful.

b. Look-alike Sound-alike Safety Review [21 CFR 201.10 (c)(5)]

Since drug products are prescribed through written, verbal, and/or electronic orders, such forms of communication may lead to medication errors, particularly if proprietary or established names sound or look alike. APLB conducted a search using POCA, with DPRF, Drugs@FDA, Cerner US Legend and OTC, CBER Biologic, Orange Book, and RxNorm as data sources, to identify names of concern with potential combined orthographic and phonetic similarity to **YESCARTA**.

The combined orthographic and phonetic matches are listed below:

Proposed name: YESCARTA Strength: 2.0×10^6 anti-CD19 CAR T cells/kg in (4) Dosage Form: Cell suspension for infusion Storage temperature: Frozen			
Name of Concern	Combined Match Percentage Score	Dosage Form and Strength	Notes
WESTCORT	69	Topical Cream or Ointment 0.2%	hydrocortisone valerate for steroid-responsive dermatoses
RESICORT	68	Lotion 1%	Hydrocortisone antipruritic, anti-inflammatory used on dogs, cats and horses
VASCARDIN	59	Oral tablet 5, 10, 20, 30 mg and 40 mg Extended Release	Isosorbide Dintrate indicated for angina prophylaxis and CHF (marketed under VASCARDIN in Indonesia)

Although these names are moderately similar, differences in dosage form, dose, and strength decrease the risk of confusion. Thus, APLB recommends that **YESCARTA** be found Acceptable.

If you have any questions regarding this review please contact Oluchi Elekwachi, PharmD, MPH Regulatory Review Officer, at 240-402-8930.