# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 761181Orig1s000

# PROPRIETARY NAME REVIEW(S)

MEMORANDUM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis (DMEPA)

Office of Medication Error Prevention and Risk Management (OMEPRM)

Office of Surveillance and Epidemiology (OSE)

Center for Drug Evaluation and Research (CDER)

***** This document contains proprietary information that cannot be released to the public*****

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|---|---|
| **Date of This Review:** | May 18, 2020 |
| **Responsible OND Division:** | Division of Diabetes, Lipid Disorders, and Obesity (DDLO) |
| **Application Type and Number:** | BLA 761181 |
| **Product Name and Strength:** | Evkeeza (evinacumab-dgnb) injection<br>345 mg/2.3 mL and 1,200 mg/8 mL (150 mg/mL) |
| **Product Type:** | Single Ingredient Product |
| **Applicant/Sponsor Name:** | Regeneron Pharmaceuticals, Inc. (Regeneron) |
| **FDA Received Date:** | February 28, 2020 |
| **OSE RCM #:** | 2020-597 |
| **DMEPA Primary Reviewer:** | Carlos M Mena-Grillasca, BS Pharm |
| **DMEPA Deputy Director:** | Danielle Harris, PharmD |

## 1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the four-letter suffixes proposed by Regeneron for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761181.

## 2 ASSESSMENT OF THE NONPROPRIETARY NAME

On February 28, 2020, Regeneron submitted a list of 8 suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Regeneron also provided findings from an external study conducted by the (b) (4), evaluating the proposed four-letter suffixes in conjunction with the nonproprietary name, for our consideration. Table 1 presents a list of suffixes submitted by Regeneron:

**Table 1. Suffixes submitted by Regeneron*****

| | |
|---|---|
| 1. | (b) (4) |
| 2. | dgnb |
| 3. | (b) (4) |
| 4. | |
| 5. | |
| 6. | |
| 7. | |
| 8. | |

We reviewed Regeneron's proposed suffixes in order of preference listed by Regeneron, along with the supporting data they submitted, using the principles described in the applicable guidance.[c]

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[a] Request for Review of Suffixes for Proper Name BLA 761181. Tarrytown (NY): Regeneron Pharmaceuticals, Inc.; 2020 Feb 28. Available from: \\cdsesub1\evsprod\bla761181\0001\m1\us\112-other-corr\req-suffixes.pdf

[b] Data Summary for Proposed Suffixes BLA 761181. Miami (FL): (b) (6). Available from: \\cdsesub1\evsprod\bla761181\0001\m1\us\112-other-corr\data-summary-proposed-suffixes.pdf

[c] See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

## 2.1 (b) (4)

(b) (4)

## 2.2 evinacumab-dgnb

Regeneron's second proposed suffix, -dgnb, is comprised of 4 distinct letters.

We determined that the proposed suffix -dgnb, is not too similar to any other products' suffix designation, does not look similar to the names of other currently marketed products, that the suffix is devoid of meaning, does not include any abbreviations that could be misinterpreted, and does not make any misrepresentations with respect to safety or efficacy of this product.

# 3 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. Per an email correspondence dated May 15, 2020, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA also communicated our findings to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) via e-mail on May 18, 2020.

[a] See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

# 4 CONCLUSION

We find Regeneron's proposed suffix -dgnb acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to evinacumab-dgnb. DMEPA will communicate our findings to the Applicant via letter.

## 4.1 Recommendations for Regeneron Pharmaceuticals, Inc.

We find the nonproprietary name, evinacumab-dgnb, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, evinacumab-dgnb will be the proper name designated in the license. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review. However, please be advised that if your application receives a complete response, the acceptability of your proposed suffix will be re-evaluated when you respond to the deficiencies. If we find your suffix unacceptable upon our re-evaluation, we would inform you of our finding.

We also note that the first proposed suffix is unacceptable for the following reasons:

(b) (4)

[redacted]

[a] See Section VI which describes that any suffixes should be devoid of meaning in Guidance for Industry: Nonproprietary Naming of Biological Products. 2017. Available from: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM459987.pdf

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/s/

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**PROPRIETARY NAME MEMORANDUM**

Division of Medication Error Prevention and Analysis (DMEPA)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
Center for Drug Evaluation and Research (CDER)

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| | |
|---|---|
| **Date of This Review:** | March 25, 2020 |
| **Application Type and Number:** | BLA 761181 |
| **Product Name and Strength:** | Evkeeza (evinacumab-xxx)[a] injection, 150 mg/mL |
| **Total Product Strength:** | 345 mg/2.3 mL and 1200 mg/8 mL |
| **Product Type:** | Single Ingredient Product |
| **Rx or OTC:** | Prescription (Rx) |
| **Applicant/Sponsor Name:** | Regeneron Pharmaceuticals (Regeneron) |
| **Panorama #:** | 2020-38187341 |
| **DMEPA Safety Evaluator:** | Melina Fanari, R.Ph. |
| **DMEPA Team Leader:** | Sevan Kolejian, PharmD, MBA |

[a] Since the nonproprietary name for this IND has not yet been determined, the nonproprietary name placeholder, evinacumab-xxx, is used throughout this review.

# 1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Evkeeza, which was found conditionally acceptable under IND 116398 on February 6, 2020.[b] Thus, Regeneron submitted the name, Evkeeza, under BLA 761181 for review on February 28, 2020. We note that all product characteristics remain the same.

# 2 METHODS AND DISCUSSION

## 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Evkeeza would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Metabolism and Endocrinology Products (DMEP) concurred with the findings of OPDP's assessment for Evkeeza.

## 2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names of concern considering any lessons learned from recent post-marketing experience, which may have altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The March 19, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Evkeeza.

## 2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Metabolism and Endocrinology Products (DMEP) via e-mail on March 23, 2020. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Metabolism and Endocrinology Products (DMEP) on March 24, 2020, they stated no additional concerns with the proposed proprietary name, Evkeeza.

# 3 CONCLUSION

Our re-assessment did not identify any names that represent a potential source of drug name confusion. Therefore, we maintain that the proposed proprietary name, Evkeeza, is acceptable.

If you have any questions or need clarifications, please contact Deveonne Hamilton-Stokes, OSE project manager, at 301-796-2253.

## 3.1 COMMENTS TO REGENERON PHARMACEUTICALS

We have completed our review of the proposed proprietary name, Evkeeza, and have concluded that this name is acceptable.

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[b] Fanari, M. Proprietary Name Review for Evkeeza (IND 116398). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Feb 6. Panorama No.: 2019-35875680.

If any of the proposed product characteristics as stated in your submission, received on February 28, 2020, are altered prior to approval of the marketing application, the name must be resubmitted for review.

## 4 REFERENCE


1. **USAN Stems (**https://www.ama-assn.org/about/united-states-adopted-names-approved-stems**)**

   USAN Stems List contains all the recognized USAN stems.

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