CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761171Orig1s000

PROPRIETARY NAME REVIEW(S)

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)

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Date of This Review:	October 7, 2020
Responsible OND Division:	Division of Oncology 2 (DO2)
Application Type and Number:	BLA 761171
Product Name and Strength:	Danyelza (naxitamab-gqgk) injection 40 mg/10 mL (4 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Y-mAbs Therapeutics, Inc. (Y-mAbs)
FDA Received Date:	March 31, 2020
OSE RCM #:	2020-667-1
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD

1 PURPOSE OF REVUEW

This review summarizes our evaluation of the four-letter suffix for inclusion in the nonproprietary name and communicates our findings for the nonproprietary name for BLA 761171.

1.1 Regulatory History

Y-mAbs was notified that all their proposed suffixes submitted on March 31, 2020 were found unacceptable in an Advice Letter[a]. Subsequently, Y-mAbs indicated that they will not propose any additional suffixes, allowing for an FDA generated suffix to be designated to BLA 761171 as explained in the advice letter[b].

2 ASSESSMENT OF THE NONPROPRIETARY NAME

naxitamab-gqgk

FDA generated a four-letter suffix, -gqgk. This suffix was evaluated using the principles described in the applicable guidance[c].

We determined that the FDA-generated suffix -gqgk, 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.

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[a] Harris, D. Nonproprietary Name Suffix Advice Letter for BLA 761171. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US) 2020 Aug 05.

[b] Response to Advice Letter for BLA 761171. New York (NY): Y-mAbs Therapeutic, Inc.; 2020 Aug 26. Available from: \\CDSESUB1\evsprod\bla761171\0054\m1\us\12-cover-letters\cover-letter-26-august-2020.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

3 COMMUNICATION OF DMEPA'S ANALYSIS

These findings were shared with OPDP. In email correspondence dated October 7, 2020, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA also communicated our findings to the Division of Oncology 2 (DO2) via e-mail on October 7, 2020.

4 CONCLUSION

We find the suffix -gqgk acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to naxitamab-gqgk. DMEPA will communicate our findings to the Applicant via letter.

4.1 Recommendations for Y-mAbs Therapeutics, Inc.

We find the nonproprietary name, naxitamab-gqgk, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, naxitamab-gqgk 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 this suffix will be re-evaluated when you respond to the deficiencies. If we find the suffix unacceptable upon our re-evaluation, we would inform you of our finding.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

CARLOS M MENA-GRILLASCA
10/07/2020 10:38:04 AM

DANIELLE M HARRIS
10/07/2020 02:36:37 PM

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:	May 21, 2020
Application Type and Number:	BLA 761171
Product Name and Strength:	Danyelza (naxitamab) Injection, 4 mg/mL
Total Product Strength:	40 mg/10mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Y-mAbs Therapeutics, Inc. (Y-mAbs)
Panorama #:	2020-38982288
DMEPA Safety Evaluator:	Janine Stewart, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD, BCPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Danyelza, which was found conditionally acceptable under IND 132793 on November 21, 2019.[a]

Thus, Y-mAbs submitted the name, Danyelza, under BLA 761171 for re-review on April 3, 2020. We note that there is a change in the infusion duration for the initial Danyelza dose since our previous review from (b) (4) to "over 60 minutes", as well as a change in the temperature required for storage from (b) (4) to "2°C to 8°C" for BLA 761171. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Danyelza would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology 3 (DO3) concurred with the findings of OPDP's assessment for Danyelza.

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. We also evaluated previously identified names taking into account the change in the infusion duration for the initial dose and the change in temperature required for storage. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Danyelza.

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The April 16, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Danyelza.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Oncology 3 (DO3) via e-mail on May 20, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Oncology 3 (DO3) on May 21, 2020, they stated no additional concerns with the proposed proprietary name, Danyelza.

[a] Stewart, J. Proprietary Name Review for Danyelza (IND 132793). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 NOV 21. Panorama No.: 2019-32308076.

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, Danyelza, is acceptable.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

3.1 COMMENTS TO Y-MABS THERAPEUTICS, INC.

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

If any of the proposed product characteristics as stated in your submission, received on April 3, 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.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JANINE A STEWART
05/21/2020 11:00:31 AM

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