CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761210Orig1s000

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:	April 20, 2021
Responsible OND Division:	Division of Oncology 2 (DO2)
Application Type and Number:	BLA 761210
Product Name and Strength:	Rybrevant (amivantamab-vmjw) injection, 350 mg/7 mL (50 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Janssen Biotech, Inc. (Janssen)
Nexus NPNS ID:	2020-8
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffix for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761210.

1.1 Regulatory History

Janssen was notified of the Agency's intention to designate a nonproprietary name that includes a four-letter distinguishing suffix that is devoid of meaning for their product in an Advice Letter[a].

2 ASSESSMENT OF THE NONPROPRIETARY NAME

amivantamab-vmjw

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

We determined that the FDA-generated suffix -vmjw, 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. On March 31, 2021, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA also communicated our findings to the Division of Oncology 2 (DO2) on April 19, 2021.

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[a] Harris, D. General Advice Letter for BLA 761210. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US) 2020 Dec 18.
[b] 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 the suffix -vmjw acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to amivantamab-vmjw. DMEPA will communicate our findings to the Applicant via letter.

4.1 Recommendation for Janssen Biotech, Inc.

We find the nonproprietary name, amivantamab-vmjw, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, amivantamab-vmjw 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.

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/s/

CARLOS M MENA-GRILLASCA
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DANIELLE M HARRIS
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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)

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

Date of This Review:	February 02, 2021
Application Type and Number:	BLA 761210
Product Name and Strength:	Rybrevant (ambivantamab) Injection, 50 mg/mL
Total Product Strength:	350 mg/7 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Janssen Research and Development LLC (Janssen)
Panorama #:	2020-43801402
DMEPA Safety Evaluator:	Sali Mahmoud, PharmD, BCPS
DMEPA Team Leader:	Ashleigh Lowery, PharmD, BCCCP

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Rybrevant, which was found conditionally acceptable under IND 135405 on July 17, 2020.[a] Thus, Janssen submitted the proposed proprietary name, Rybrevant, under BLA 761210 for review on November 6, 2020. We noted the proposed Rybrevant Prescribing Information submitted on December 2, 2020 to the BLA contains new information for dose reductions for adverse reactions. Besides the newly proposed dose reduction information, we note that all other product characteristics remain the same.

Table 1. Rybrevant Dose Reduction Schedule for Adverse Reactions[b]

Dose Level	Rybrevant Dose for Weight <80 kg	Rybrevant Dose for Weight ≥80 kg
Initial	1050 mg	1400 mg
1st dose modification	700 mg	1050 mg
2nd dose modification	350 mg	700 mg
3rd dose modification	Discontinue	Discontinue

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Rybrevant would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology 2 (DO2) concurred with the findings of OPDP's assessment for Rybrevant.

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, and taking into account the additional dose reductions (700 mg and 350 mg). Our reassessment did not change our conclusion regarding the acceptability of the proposed proprietary name, Rybrevant. 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

[a]Stewart, J. Proprietary Name Review for Rybrevant (IND 135405). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JUL 17. Panorama No.: 2020-39388333.

[b]BLA 761210 Prescribing Information, Horsham, PA. Janssen Biotech, Inc. 2020 DEC 02. Available from: \\CDSESUB1\evsprod\bla761210\0003\m1\us\draft-labeling-pi.doc

updates. The November 18, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Rybrevant.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Oncology 2 (DO2). At that time we also requested additional information or concerns that could inform our review. On February 1, 2021, the Division of Oncology 2 (DO2) stated no additional concerns with the proposed proprietary name, Rybrevant.

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, Rybrevant, 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 JANSSEN RESEARCH AND DEVELOPMENT LLC

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

If any of the proposed product characteristics as stated in your submission, received on November 06, 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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/s/

SALI MAHMOUD
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ASHLEIGH V LOWERY
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