CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761224Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Mitigation Assessment and Medication Error Surveillance (DMAMES)

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:	9/21/2021
Responsible OND Division:	Division of Pulmonology, Allergy, and Critical Care (DPACC)
Application Type and Number:	BLA 761224
Product Name and Strength:	Tezspire (tezepelumab-ekko) injection, 210 mg/1.91 mL (110 mg/mL)
Product Type:	Combination Product (Biologic-Device)
Applicant/Sponsor Name:	AstraZeneca AB (AstraZeneca)
FDA Received Date:	May 7, 2021
Nexus NPNS ID #:	2021-31
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
OMEPRM Deputy Director:	Lubna Merchant, MS, PharmD

1 PURPOSE OF REVIEW

This review summarizes our evaluation of the four-letter suffixes proposed by AstraZeneca for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761224.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

On May 7, 2021, AstraZeneca submitted a list of ten suffixes, in their order of preference, to be used in the nonproprietary name of their product[a]. Table 1 presents a list of suffixes submitted by AstraZeneca:

Table 1. Suffixes submitted by AstraZeneca***

1.	(b) (4)
2.	
3.	
4.	ekko
5.	(b) (4)
6.	
7.	
8.	
9.	
10.	

[a] Request for Review of Suffixes for Proper Name BLA 761224. Södertälje (Sweden): AstraZeneca AB; 2021 May 07. Available from: \\CDSESUB1\evsprod\bla761224\0001\m1\us\proprietary-names-suffix.pdf

We reviewed AstraZeneca's proposed suffixes in the order of preference listed by AstraZeneca using the principles described in the applicable guidance.[a]

2.1 (b) (4)

(b) (4)

2.2 (b) (4)

(b) (4)

[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

[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

2.3 (b) (4)

(b) (4)

2.4 tezepelumab-ekko

AstraZeneca's fourth proposed suffix, -ekko, is comprised of 3 distinct letters.

We determined that the proposed suffix -ekko, 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 DMAMES' ANALYSIS

These findings were shared with OPDP. On September 21, 2021, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMAMES also communicated our findings to the Division of Pulmonology, Allergy, and Critical Care (DPACC) on September 21, 2021.

4 CONCLUSION

We find AstraZeneca's proposed suffix -ekko acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to tezepelumab-ekko. DMAMES will communicate our findings to the Applicant via letter.

4.1 Recommendations for AstraZeneca AB

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[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

We find the nonproprietary name, tezepelumab-ekko, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, tezepelumab-ekko 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 three proposed suffixes are unacceptable for the following reasons:

[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


(b) (4)

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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)

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

Date of This Review:	June 24, 2021
Application Type and Number:	BLA 761224
Product Name and Strength:	Tezspire (tezepelumab-xxxx)[a] Injection, 210 mg/1.91 mL
Product Type:	Combination Product (Drug-Biologic-Device)
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	AstraZeneca
PNR ID #:	2021-1044723970
DMEPA Safety Evaluator:	Lissa C. Owens, PharmD
DMEPA Team Leader:	Idalia E. Rychlik, PharmD
DMEPA Director (Acting):	Lubna Merchant, MS, PharmD

[a] The proposed nonproprietary name has not yet been conditionally accepted. We therefore refer to the proposed product as "tezepelumab-xxxx" throughout this review in place of the nonproprietary name for this product.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Tezspire, which was found conditionally acceptable under IND 103031 on March 9, 2021.[b] Thus, AstraZeneca submitted the name, Tezspire, under BLA 761224 for review on May 7, 2021. 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 Tezspire would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Pulmonology, Allergy, and Critical Care (DPACC) concurred with the findings of OPDP's assessment for Tezspire.

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. Our reassessment did not change our conclusion regarding the previously identified names of concern. 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 June 22, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Tezspire.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Pulmonology, Allergy, and Critical Care (DPACC). At that time, we also requested additional information or concerns that could inform our review. On June 24, 2021, the Division of Pulmonology, Allergy, and Critical Care (DPACC) stated no additional concerns with the proposed proprietary name, Tezspire.

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, Tezspire, is acceptable.

If you have any questions or need clarifications, please contact Cristina Attinello, OSE project manager, at 301-796-3986.

3.1 COMMENTS TO ASTRAZENECA

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

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[b] Owens, L. Proprietary Name Review for Tezspire (IND 103031). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 MAR 9. Panorama No.: 2020-1044312126.

If any of the proposed product characteristics as stated in your submission, received on May 7, 2021, 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/

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