CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761258Orig1s000

PROPRIETARY NAME REVIEW(S)

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)

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:	1/10/2025
Responsible OND Division:	Division of Oncology 2 (DO2)
Application Type and Number:	BLA 761258
Product Name and Strength:	(penpulimab-kcqx) injection 100 mg/10 mL (10 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Akeso Biopharma Co., Ltd. (Akeso)
Nexus NPNS ID #:	2024-294
DMEPA 2 Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD

1 PURPOSE OF REVIEW

This review is to reassess the FDA-generated suffix, -kcqx, for BLA 761258, which was found conditionally acceptable on February 23, 2022[a], for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761258.

1.1 Regulatory History

FDA generated a four-letter suffix, -kcqx, for BLA 761258 on February 23, 2022[a]. However, BLA 761258 received a Complete Response (CR) letter on January 19, 2024[b]. Thus, Akeso submitted a Class 2 Resubmission on October 2, 2024.

2 ASSESSMENT OF THE NONPROPRIETARY NAME

We reassessed the previously generated four-letter suffix, -kcqx, using the principles described in the applicable guidance[c].

We determined that the FDA-generated suffix -kcqx, 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 2 ANALYSIS

These findings were shared with OPDP. On January 8, 2025, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Oncology 2 (DO2) on January 10, 2025.

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[a] Mena-Grillasca, C. Nonproprietary Name Suffix Review for penpulimab-kcqx (BLA 761258). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2022 Feb 23. Nexus No.: 2021-42.

[b] Kluetz, P. Complete Response (BLA 761258). Silver Spring (MD): FDA, CDER, OND, OOD (US); 2024 Jan 19.

[c] 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 -kcqx acceptable and recommend the nonproprietary name penpulimab-kcqx be used throughout the draft labels and labeling.

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/s/

CARLOS M MENA-GRILLASCA
01/10/2025 08:48:22 PM

CHI-MING TU
01/23/2025 03:52:44 PM

SUFFIX REVIEW FOR NONPROPRIETARY NAME

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)

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:	2/23/2022
Responsible OND Division:	Division of Oncology 2 (DO2)
Application Type and Number:	BLA 761258
Product Name and Strength:	(b) (4) (penpulimab-kcqx) injection 100 mg/10 mL (10 mg/mL)
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Akeso Biopharma Co., Ltd. (Akeso)
Nexus NPNS ID #:	2021-42
DMAMES Biologics Suffix Specialist:	Carlos M Mena-Grillasca, BS Pharm
DMEPA 2 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 761258.

1.1 Regulatory History

Akeso 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

penpulimab-kcqx

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

We determined that the FDA-generated suffix -kcqx, 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 2 ANALYSIS

These findings were shared with OPDP. On February 23, 2022, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA 2 also communicated our findings to the Division of Oncology 2 (DO2) on February 23, 2022.

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[a] Merchant, L. General Advice Letter for BLA 761258. Silver Spring (MD): FDA, CDER, OSE, DMAMES (US) 2021 Sep 14.
[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 -kcqx acceptable and recommend the nonproprietary name be revised throughout the draft labels and labeling to penpulimab-kcqx. DMEPA 2 will communicate our findings to the Applicant via letter.

4.1 Recommendation for Akeso Biopharma Co., Ltd.

We find the nonproprietary name, penpulimab-kcqx, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, penpulimab-kcqx 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
02/23/2022 03:58:38 PM

DANIELLE M HARRIS
02/24/2022 07:28:26 AM

PROPRIETARY NAME REVIEW

Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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 6, 2020
Application Type and Number:	BLA 761258
Product Name and Strength:	(b) (4) (penpulimab) injection, 100 mg/10 mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Akeso Biopharma, Co., Ltd. (Akeso)
PNR ID #:	2021-1044724063
DMEPA 2 Safety Evaluator:	Sali Mahmoud, PharmD, BCPS
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD, BCCCP
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, BCPS

19 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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/s/

SALI MAHMOUD
10/06/2021 02:00:48 PM

ASHLEIGH V LOWERY
10/06/2021 03:35:38 PM

CHI-MING TU
10/07/2021 03:51:48 PM