CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761196Orig1s000

PROPRIETARY NAME REVIEW(S)

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:	April 5, 2021
Application Type and Number:	BLA 761196
Product Name and Strength:	Zynlonta (Lyntola) for injection, 10 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	ADC Therapeutics SA (ADC)
PNR ID #:	2021-1044723820
DMEPA Primary Reviewer:	Maximilian Straka, PharmD, FISMP
DMEPA Team Leader:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Zynlonta, which was found unacceptable via a decision memo under IND 126138 on September 10, 2020.[a]

1.1 REGULATORY HISTORY

ADC previously submitted the proposed proprietary name, Zynlonta on September 12, 2019. We initially found the name acceptable[b], however via a decision memo the proposed proprietary name, Zynlonta, was found to be vulnerable to medication errors due to confusion with another product, (b) (4) ***, under review at the time. Therefore, the ultimate acceptability of the proposed proprietary name, Zynlonta, was dependent upon which underlying application was approved first.

ADC then submitted the proposed proprietary name (b) (4) ***, for review on December 3, 2020. Separately, the underlying application for (b) (4) *** was approved under NDA 214200 with the proprietary name Cosela on February 12, 2021.[c]

ADC withdrew (b) (4) *** and resubmitted the proposed proprietary name, Zynlonta, under BLA 761196 for review on February 19, 2021. We note that all product characteristics remain the same since our original review on March 4, 2020.

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA 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, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The March 16, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name.

Based upon our safety assessment of the proposed proprietary name, Zynlonta, and that NDA 214200 has been approved under the proprietary name, Cosela, we find Zynlonta conditionally acceptable.

2.2 COMMUNICATION OF DMEPA'S ANALYSIS

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on March 30, 2021.

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[a] DeGraw, S. Proprietary Name Review for Zynlonta (IND 126138). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 SEP 10. Panorama No. 2019-34392103-1.

[b] Iverson, N. Proprietary Name Review for Zynlonta (IND 126138). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 MAR 4. Panorama No: 2019-34392103

[c] DeGraw, S. Proprietary Name Review for Cosela (NDA 214200). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 DEC 9. Panorama No. 2020-43071366

3 CONCLUSIONS

We conclude that the proposed proprietary name, Zynlonta, is acceptable.

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 204-402-4845.

3.1 COMMENTS TO ADC THERAPEUTICS SA

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

If any of the proposed product characteristics as stated in your submission, received on February 19, 2021, are altered prior to approval of the marketing application, the name must be resubmitted for review.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

4 REFERENCE

1. **USAN Stems (http://www.ama-assn.org/ama/pub/physician-resources/medical-science/united-states-adopted-names-council/naming-guidelines/approved-stems.page)**

   USAN Stems List contains all the recognized USAN stems.

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/s/

MAXIMILIAN STRAKA
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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:	February 25, 2021
Responsible OND Division:	Division of Hematologic Malignancies 2 (DHM 2)
Application Type and Number:	BLA 761196
Product Name and Strength:	(loncastuximab tesirine-lpyl)[a] for injection, 10 mg/vial
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	ADC Therapeutics SA (ADC)
FDA Received Date:	January 19, 2021
Nexus NPNS ID #:	2021-5
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharm
DMEPA Deputy Director:	Danielle Harris, PharmD

[a] Proprietary Name has not been designated.

1 PURPOSE OF MEMO

This review summarizes our evaluation of the four-letter suffixes proposed by ADC for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761196.

1.1 Regulatory History

ADC 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

On January 19, 2021, ADC submitted a list of 10 suffixes, in their order of preference, to be used in the nonproprietary name of their product[b]. Table 1 presents a list of suffixes submitted by ADC:

Table 1. Suffixes submitted by ADC***

1.	Ipyl
	(b) (4)

[a] Harris, D. General Advice Letter for BLA 761196. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 Nov 03.

[b] Request for Review of Suffixes for Proper Name BLA 761196. Vaud (Switzerland): ADC Therapeutics SA; 2021 Jan 19. Available from: \\CDSESUB1\evsprod\bla761196\0019\m1\us\comments-advice-req-0019.pdf

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

2.1 loncastuximab tesirine-lpyl

ADC's first proposed suffix, -lpyl, is comprised of 3 distinct letters (l, p, y).

We determined that the proposed suffix -lpyl, 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 February 23, 2021, OPDP did not identify any concerns that would render this proposed suffix unacceptable. DMEPA also communicated our findings to the Division of Hematologic Malignancies 2 (DHM 2) on February 25, 2021.

4 CONCLUSION

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

4.1 Recommendations for ADC Therapeutics SA

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

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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

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/s/

CARLOS M MENA-GRILLASCA
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