CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761139Orig1s000

PROPRIETARY NAME REVIEW(S)

MEMORANDUM

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)

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

Date of This Review:	October 31, 2019
Responsible OND Division:	Division of Oncology Products 1 (DOP1)
Application Type and Number:	BLA 761139
Product Name and Strength:	Enhertu (fam-trastuzumab deruxtecan-nxki) for injection, 100 mg per vial
Product Type:	Single Ingredient Product
Applicant/Sponsor Name:	Daiichi Sankyo, Inc. (Daiichi)
OSE RCM #:	2019-2056
DMEPA Primary Reviewer:	Carlos M Mena-Grillasca, BS Pharmacy
DMEPA Deputy Director:	Danielle Harris, PharmD, BCPS

1 PURPOSE OF MEMO

This memorandum summarizes our evaluation of the four-letter suffix for inclusion in the nonproprietary name and communicates our recommendation for the nonproprietary name for BLA 761139.

1.1 Regulatory History

Daiichi 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 a General Advice Letter[a].

2 ASSESSMENT OF THE NONPROPRIETARY NAME

fam-trastuzumab deruxtecan-nxki

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

We determined that the FDA-generated suffix -nxki, 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. In email correspondence dated October 30, 2019, OPDP did not identify any concerns that would render this suffix unacceptable. DMEPA also communicated our findings to the Division of Oncology Products 1 (DOP1) via e-mail on October 31, 2019.

4 CONCLUSION

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

4.1 Recommendation for Daiichi Sankyo, Inc.

We find the nonproprietary name, fam-trastuzumab deruxtecan-nxki, conditionally acceptable for your proposed product. Should your 351(a) BLA be approved during this review cycle, fam-trastuzumab deruxtecan-nxki 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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[a] Harris, D. General Advice Letter for BLA 761139. Silver Spring (MD): FDA, CDER, OSE, DMEPA (US) 2019 OCT 11.

[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

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/s/

CARLOS M MENA-GRILLASCA
10/31/2019 05:30:36 PM

DANIELLE M HARRIS
11/01/2019 01:30:58 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:	October 31, 2019
Application Type and Number:	BLA 761139
Product Name and Strength:	Enhertu (fam-trastuzumab deruxtecan-xxxx)[a] for Injection, 100 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Daiichi Sankyo, Inc.
Panorama #:	2019-34134970
DMEPA Safety Evaluator:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

[a] Since the proper name for Enhertu has not yet been determined, "fam-trastuzumab deruxtecan-xxxx" is used in this review as the nonproprietary name for this product.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Enhertu, which was found conditionally acceptable under IND 127553 on June 21, 2019.[b]

We note that there is additional information regarding dose modifications for adverse reactions (4.4 mg/kg for first dose reduction and 3.2 mg/kg for second dose reduction) proposed for BLA 761139, which is new information since our last review. All other product characteristics remain the same.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Enhertu would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology Products 1 (DOP1) concurred with the findings of OPDP's assessment for Enhertu.

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 additional information regarding to dose modifications for adverse reactions (4.4 mg/kg for first dose reduction and 3.2 mg/kg for second dose reduction). Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Enhertu.

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 September 27, 2019 search of USAN stems did not find any USAN stems in the proposed proprietary name, Enhertu.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Oncology Products 1 (DOP1) via e-mail on October 24, 2019. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Oncology Products 1 (DOP1) on October 30, 2019, they stated no additional concerns with the proposed proprietary name, Enhertu.

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, Enhertu, is acceptable.

[b] Gao, T. Proprietary Name Review for Enhertu (IND 127553). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 June 21. Panorama No.: 2019-30375043.

If you have any questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO DAIICHI SANKYO, INC.

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

If any of the proposed product characteristics as stated in your submission, received on August 29, 2019, 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/

TINGTING N GAO
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CHI-MING TU
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