

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**213246Orig1s000**

**PROPRIETARY NAME REVIEW(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\*\*\***

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<b>Date of This Review:</b>	February 19, 2020
<b>Application Type and Number:</b>	NDA 213246
<b>Product Name and Strength:</b>	Retevmo (selpercatinib) Capsules, 40 mg and 80 mg
<b>Product Type:</b>	Single Ingredient Product
<b>Rx or OTC:</b>	Prescription (Rx)
<b>Applicant/Sponsor Name:</b>	Loxo Oncology Inc. (Loxo)
<b>Panorama #:</b>	2019-36188677
<b>DMEPA Safety Evaluator:</b>	Janine Stewart, PharmD
<b>DMEPA Team Leader:</b>	Chi-Ming (Alice) Tu, PharmD, BCPS

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## 1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Retevmo, which was found conditionally acceptable under IND 133193 on August 6, 2019.<sup>a</sup> Thus, Loxo submitted the name, Retevmo, under NDA 213246 for re-review on December 4, 2019. (b) (4)

(b) (4) dosages (40 mg orally twice daily, 80 mg orally twice daily, and 120 mg orally twice daily) for dosage modifications due to adverse reactions are proposed in the NDA. (b) (4) packaging configuration for the 80 mg strength ( (b) (4) 60 capsules per bottle and 120 capsules per bottle). (b) (4)

## 2 METHODS AND DISCUSSION

### 2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Retevmo 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 Retevmo.

### 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; considering the dosages added for dosage modifications due to adverse reactions proposed in the NDA. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Retevmo.

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 January 23, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Retevmo.

### 2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Oncology 2 (DO2) via e-mail on February 11, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Oncology 2 (DO2) on February 19, 2020, they stated no additional concerns with the proposed proprietary name, Retevmo.

## 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, Retevmo, is acceptable.

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<sup>a</sup> Stewart, J. Proprietary Name Review for Retevmo (IND 133193). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 AUG 06. Panorama No.: 2019-31411810.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

### **3.1 COMMENTS TO LOXO ONCOLOGY INC.**

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

If any of the proposed product characteristics as stated in your submission, received on December 4, 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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