

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**211155Orig1s000**

**211155Orig2s000**

**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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**Date of This Review:** June 12, 2018  
**Application Type and Number:** NDA 211155  
**Product Name and Strength:** Copiktra (duvelisib) Oral Capsules  
(b) (4) 15 mg, and 25 mg  
**Product Type:** Single-Ingredient  
**Rx or OTC:** Rx  
**Applicant/Sponsor Name:** Verastem  
**Panorama #:** 2018-21770585  
**DMEPA Safety Evaluator:** Leeza Rahimi, Pharm.D.  
**DMEPA Team Leader:** Hina Mehta, Pharm.D.

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## 1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Copiktra, which was found conditionally acceptable under IND 112486 on January 25, 2018.<sup>a</sup> 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 the proposed name would not misbrand the proposed product. DMEPA and the Division of Hematology Products (DHP) concurred with the findings of OPDP's misbranding assessment of the proposed name.

### 2.2 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 April 29, 2018 search of USAN stems did not find any USAN stems in the proposed proprietary name.

In an email communication dated April 10, 2018, the DHP clinical review team expressed concerns that the proposed proprietary name, Copiktra can be confused with Aliqopa (copanlisib) as "both agents are PI3K inhibitors in the same drug class and the vulnerability to name confusion could lead to medication errors.

We considered the Division's concern regarding the name pair and further evaluated the risk of confusion between Copiktra and Aliqopa as follows:

#### **Phonetic and Orthographic Differences**

In evaluating the proposed proprietary name Copiktra and the currently marketed product Aliqopa, we note that the prefixes ("Co" vs. "Al"), infixes ("pik" vs. "iqo"), and suffixes ("tra" vs. "pa") of the name pair have sufficient orthographic differences. Phonetically, the first ("Co" vs. "Al"), second/third ("pik" vs. "iqo"), and last syllables ("tra" vs. "pa") of the name pair have sufficient differences. Additionally, we note that Aliqopa has an additional syllable. Furthermore, FDA's Phonetic and Orthographic Computer Analysis (POCA) software calculates a 38% combined orthographic and phonetic score for the name pair, indicating low similarity.<sup>b</sup>

#### **Product Characteristic differences:**

We note that Aliqopa (copanlisib), a kinase inhibitor was recently approved on September 14, 2017 for the treatment of adult patients with relapsed follicular lymphoma (FL) who received at

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<sup>a</sup> Rahimi, L. Proprietary Name Review for Copiktra (duvelisib) Capsules (IND 112486) Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2018 JAN 25. Panorama No. 2018-16740010.

<sup>b</sup> POCA search conducted on May 7, 2018 in version 4.2.

least two prior systematic therapies. We acknowledge that Copiktra is also a kinase inhibitor proposed for the treatment of chronic lymphocytic leukemia (CLL/small lymphocytic lymphoma (SLL), as well as follicular B-cell non-Hodgkin lymphoma (FL) who have received at least two prior therapies. However, the products have different strength, dosage forms, doses, frequencies, and route of administration (see Table 1), which further reduces the risk of confusion between the two names.

**Table 1. Product Information**

<b>Product Characteristics</b>	<b>Copiktra</b>	<b>Aliqopa</b>
<b>Active ingredient</b>	duvelisib	copanlisib
<b>Indication</b>	1) Treatment of patients with CLL/SLL, including patients (b) (4), (b) (4), (b) (4). 2) Treatment of patients with FL who have received at least two prior therapies.	Treatment of patients with relapsed or refractory follicular lymphoma (FL) who have received at least two prior therapies
<b>Dosage Form</b>	capsules	for injection
<b>Strength</b>	(b) (4) 15 mg, and 25 mg	60 mg
<b>Route</b>	Oral	Intravenous infusion
<b>Dose and Frequency</b>	(b) (4) 25 mg (1 capsule) by mouth twice daily	60 mg administered as a 1-hour intravenous infusion on days 1, 8, and 15 of a 28-day treatment cycle on an intermittent schedule (three weeks on and one week off). Continue treatment until disease progression or unacceptable toxicity.

Furthermore, we find that any residual risk of name confusion will be further mitigated by the well-differentiated labels and labeling, which may further reduce the risk of a medication error reaching the patient.

In summary, we find that when considered in totality, these mitigations minimize the likelihood of name confusion between Copiktra and Aliqopa, resulting in errors in the clinical setting.

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

DMEPA communicated our findings to the Division of Hematology Products (DHP) via e-mail on June 07, 2018. At that time, we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the DHP on June 12, 2018, they stated no additional concerns with the proposed proprietary name, Copiktra.

### **3 CONCLUSIONS**

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 is acceptable.

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-4845.

#### **3.1 COMMENTS TO THE APPLICANT**

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

If any of the proposed product characteristics as stated in your submission, received on March 21, 2018, are altered prior to approval of the marketing application, the name must be resubmitted for review.

#### 4 REFERENCES

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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**This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.**  
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/s/  
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LEEZA RAHIMI  
06/12/2018

HINA S MEHTA  
06/12/2018