CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213400Orig1s000

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:	February 18, 2020
Application Type and Number:	NDA 213400
Product Name and Strength:	Tazverik (tazemetostat) Tablets, 200 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Epizyme Inc. (Epizyme)
Panorama #:	2019-36566824
DMEPA Safety Evaluator:	Devin Kane, PharmD
DMEPA Team Leader:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Tazverik, which was found conditionally acceptable under NDA 211723/IND 124608 on August 9, 2019.[a]

Epizyme submitted the name, Tazverik, under NDA 213400 for review on December 18, 2019. We note that under NDA 213400, Epizyme proposes Tazverik for the treatment of patients with relapsed or refractory follicular lymphoma who have received at least two prior systemic therapies. Under NDA 211723/IND 124608, Tazverik is indicated for the treatment of adults and pediatric patients aged (b) (4) years and older with metastatic or locally advanced epithelioid sarcoma. The product characteristics for both indications are identical (i.e. dose and frequency of administration).

1.1 PRODUCT INFORMATION

The following product information is provided in the prescribing information labeling received on December 18, 2019 under NDA 213400 and in the proprietary name submission received on May 23, 2019 under NDA 211723.

Table 1. Product Characteristics of Tazverik (NDA 213400 and NDA 211723)

	Tazverik (NDA 213400)	**Tazverik (NDA 211723)**
Intended Pronunciation	taz ver' ik	
Active Ingredient	tazemetostat	
Indication of Use	Indicated for the treatment of patients with relapsed or refractory (R/R) follicular lymphoma (FL) who have received at least 2 prior systemic therapies.	Indicated for the treatment of adult patients with metastatic or locally advanced epithelioid sarcoma (ES) who are not eligible for (b) (4)
Route of Administration	Oral	
Dosage Form	Tablets	
Strength	200 mg	
Dose and Frequency[b, c]	800 mg orally twice daily with or without food until disease progression or unacceptable toxicity. Doses should be taken at least 8 hours apart and the maximum daily dose is eight tablets (1600 mg).	
How Supplied	Bottles of 240 tablets with a desiccant	
Storage	Do not store above 30°C (86°F).	

[a] Straka, Maximilian. Proprietary Name Review for Tazverik (IND 124608 and NDA 211723). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 AUG 09. Panorama No.: 2019-29387701 and 2019-31950129.

[b] *Dose reductions for adverse reactions:* 600 mg orally twice daily, 400 mg orally twice daily.

Dose modifications for drug interactions: 400 mg orally twice daily, 400 mg for first dose and 200 mg for second dose, 200 mg orally twice daily.

[C]Tu, Chi-Ming (Alice). Proprietary Name Memorandum for Tazverik (NDA 211723). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 JAN 17. Panorama No.: 2019-31950129-1.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Tazverik would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Hematologic Malignancies 2 (DHM 2) concurred with the findings of OPDP's assessment for Tazverik.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names taking into account the change in indication of use. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Tazverik.

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 7, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Tazverik.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Hematologic Malignancies 2 (DHM 2) via e-mail on February 5, 2020. At that time we also requested additional information or concerns that could inform our review. The Division of Hematologic Malignancies 2 (DHM 2) had no additional concerns with the proposed proprietary name, Tazverik.

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, Tazverik, 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 EPIZYME INC. (EPIZYME)

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

If any of the proposed product characteristics as stated in your submission, received on December 18, 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.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

DEVIN R KANE
02/19/2020 12:08:34 PM

HINA S MEHTA
02/21/2020 01:54:28 PM