CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213793Orig1s000

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:	June 10, 2020
Application Type and Number:	NDA 213793
Product Name and Strength:	Imcivree (setmelanotide) injection, 10 mg/mL
Total Product Strength:	10 mg/mL
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Rhythm Pharmaceuticals (Rhythm)
Panorama #:	2020-38818831
DMEPA Safety Evaluator:	Melina Fanari, RPh
DMEPA Team Leader:	Sevan Kolejian, PharmD, MBA

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Imcivree, which was found conditionally acceptable under IND 112595 on August 26, 2019.[a] Thus, Rhythm submitted the name, Imcivree, under NDA 213793 for review on March 27, 2020. 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 Imcivree would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) concurred with the findings of OPDP's assessment for Imcivree.

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. Our reassessment did not change our conclusion regarding the previously identified names of concern. Additionally, we searched the United States Adopted Name (USAN) stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The April 13, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Imcivree.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) via e-mail on June 10, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Diabetes, Lipid Disorders, and Obesity (DDLO) on June 10, 2020, they stated no additional concerns with the proposed proprietary name, Imcivree.

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, Imcivree, is acceptable.

If you have any questions or need clarifications, please contact Terrolyn Thomas, OSE project manager, at 240-402-3981.

3.1 COMMENTS TO RHYTHM PHARMACEUTICALS

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

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[a] Fanari, M. Proprietary Name Review for Imcivree (IND 112595). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 AUG 26. Panorama No.: 2019-32203865.

If any of the proposed product characteristics as stated in your submission, received on March 27, 2020, 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/

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06/10/2020 02:54:11 PM

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06/10/2020 04:53:50 PM