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RESEARCH**

APPLICATION NUMBER:

209606Orig1s000

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: March 21, 2017
Application Type and Number: NDA 209606
Product Name and Strength: Idhifa (enasidenib) tablet, 50 mg (equivalent to 60 mg enasidenib mesylate) and 100 mg (equivalent to 120 mg enasidenib mesylate)
Product Type: Single ingredient
Rx or OTC: Rx
Applicant/Sponsor Name: Celgene Corporation
Panorama #: 2017-12352686
DMEPA Primary Reviewer: Susan Rimmel, PharmD
DMEPA Team Leader: Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Idhifa, which was found conditionally acceptable under IND 117631 on September 20, 2016.^a

We note that there is a change in product strength, salt equivalency, dose frequency and duration, and maximum daily dose for NDA 209606. All other product characteristics remain the same. Table 1 outlines the differences for this submission.

Table 1. Product Characteristic Submission Differences

Product Characteristic	IND 117631	NDA 209606
Strength	50 mg, 100, (b) (4)	50 mg and 100 mg
Salt Equivalency	none specified	50 mg (equivalent to 60 mg enasidenib mesylate) 100 mg (equivalent to 120 mg enasidenib mesylate)
Dose Frequency and Duration	The recommended starting dose is 100 mg once daily (b) (4) Dosing is continued or modified based upon clinical and laboratory findings.	The recommended starting dose is 100 mg once daily until disease progression or unacceptable toxicity. Treat patients for a minimum of 6 months to allow time for clinical response. Treatment should be continued as long as the patient continues to benefit. <u>Dose Adjustment for Toxicities</u> IDH Differentiation Syndrome <ul style="list-style-type: none">• Administer systemic corticosteroids.• Interrupt IDHIFA if severe pulmonary symptoms and/or renal dysfunction persist after 48 hours of treatment with systemic corticosteroids.• Resume IDHIFA when symptoms improve. Other Grade 3 or Higher Toxicity Considered Related to Treatment <ul style="list-style-type: none">• Interrupt IDHIFA until toxicity resolves.

^a Garrison, N. Proprietary Name Review for Idhifa (IND 117631). Silver Spring (MD): Food and Drug Administration, Center for Drug Evaluation and Research, Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis (US); 2016 SEP 20. Panorama No. 2016-7936729.

		<ul style="list-style-type: none"> • Resume IDHIFA at 50 mg daily; may increase to 100 mg daily if patient continues to tolerate therapy. • Stop therapy if patient does not tolerate 50 mg daily.
Maximum Daily Dose	(b) (4)	none specified

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 assessment of the proposed name.

2.2 SAFETY ASSESSMENT

For reassessment 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. We also evaluated previously identified names taking into account the change in product strength, dose frequency and duration, and maximum daily dose. Our evaluation has not 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 March 3, 2017, search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

Our reassessment 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, Idhifa, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your December 30, 2016, and January 4, 2017, submission 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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