

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

208573Orig1s000

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:	December 14, 2015
Application Type and Number:	NDA 208573
Product Name and Strength:	Venclexta (venetoclax) tablet, 10 mg, 50 mg, 100 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	AbbVie, Inc.
Panorama #:	2015-1894134
DMEPA Primary Reviewer:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Yelena Maslov, PharmD

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1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Venclexta under NDA 208573. DMEPA previously found the name acceptable in OSE Review 2015-191145¹. The Applicant submitted an external name study, conducted by (b) (4), for this product. We note there is a product characteristic change in (b) (4). Table 1 below summarizes the change.

Table 1. Product Characteristics

	IND 110159	NDA 208573
Dose and Frequency	(b) (4)	Initiate therapy with 20 mg once daily for 7 days, followed by a weekly ramp-up dosing schedule to the recommended daily dose of 400 mg.

1.1 PRODUCT INFORMATION

The following product information is provided in the October 29, 2015 proprietary name submission and Prescribing Information labeling.

- Intended Pronunciation: ven-KLEKS-tuh
- Active Ingredient: Venetoclax
- Indication of Use: treatment of patients with Chronic Lymphocytic Leukemia (CLL), who have received at least one prior therapy; this includes patients with 17p deletion.
- Route of Administration: Oral
- Dosage Form: Tablets
- Strength: 10 mg, 50 mg, 100 mg
- Dose and Frequency: Initiate therapy at 20 mg once daily for 7 days, then 50 mg once daily for 7 days, then 100 mg once daily for 7 days, then 200 mg once daily for 7 days, followed by the recommended daily dose of 400 mg.

¹ Mistry M. Proprietary Name Review for Venclexta (IND 110159). 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); 2015 JUN 25. 20 p. OSE RCM No.: 2015-191145.

- How Supplied: This product is supplied as tablets of 10 mg, 50 mg, and 100 mg strengths; packaged in blister packs for the dose escalation period and in bottles for dosing at the recommended daily dose.
- Storage: This product should be stored [REDACTED] (b) (4)

2 METHODS AND DISCUSSION

To reassess the proposed proprietary name, DMEPA searched the POCA database (see Section 4) and conducted a gap analysis to identify names approved since the previous OSE Proprietary Name Review #2015-191145 that have orthographic and phonetic similarities to the proposed name Venclexta. Additionally, we re-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. In our assessment, we took into consideration the change in initial dosing using dose escalation since the previous OSE review. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. Additionally, our POCA search did not identify any new names that represent a potential source of drug name confusion. As a result, we maintain that the name is acceptable.

Additionally, DMEPA searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates. The December 3, 2015 search of USAN stems did not find any USAN stems in the proposed proprietary name.

3 CONCLUSIONS

DMEPA maintains the proposed proprietary name, Venclexta, is acceptable from both a promotional and safety perspective under NDA 208573.

If you have any questions or need clarifications, please contact Kevin Wright, OSE project manager, at 301-796-3621.

3.1 COMMENTS TO THE APPLICANT

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

4 REFERENCES

1. Mistry M. Proprietary Name Review for Venclexta (IND 110159). 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); 2015 JUN 25. 20 p. OSE RCM No.: 2015-191145.

2. *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.

3. *Phonetic and Orthographic Computer Analysis (POCA)*

POCA is a system that FDA designed. As part of the name similarity assessment, POCA is used to evaluate proposed names via a phonetic and orthographic algorithm. The proposed proprietary name is converted into its phonemic representation before it runs through the phonetic algorithm. Likewise, an orthographic algorithm exists that operates in a similar fashion. POCA is publicly accessible.

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/s/

NICOLE B GARRISON
12/14/2015

YELENA L MASLOV
12/15/2015