CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

212436Orig1s000

PROPRIETARY NAME REVIEW(S)

PROPRIETARY NAME REVIEW

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:	July 23, 2019
Application Type and Number:	NDA 212436
Product Name and Strength:	Ibrance (palbociclib) tablets, 75 mg, 100 mg, and 125 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Pfizer Inc. (Pfizer)
Panorama #:	2019-32308130
DMEPA Safety Evaluator:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Ibrance, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the reference section and Appendix A respectively. Pfizer did not submit an external name study for this proposed proprietary name.

1.1 REGULATORY HISTORY

Ibrance (palbociclib) capsules was approved on on February 3, 2015 under NDA 207103. Pfizer submitted the name, Ibrance, for the proposed new dosage form tablets for review under NDA 212436 on June 10, 2019.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submission received on June 10, 2019.

Table 1. Relevant Product Information for Ibrance

Product Name	**Ibrance (NDA 207103)[a]**	**Ibrance (NDA 212436)**
Intended Pronunciation	EYE-brans	EYE-brans
Initial Approval Date	February 3, 2015	Under review
Active Ingredient	palbociclib	palbociclib
Indication	indicated for the treatment of hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative advanced or metastatic breast cancer in combination with: • an aromatase inhibitor as initial endocrine based therapy in postmenopausal women; or • fulvestrant in women with disease progression following endocrine therapy.	
Route of administration	Oral	Oral
Dosage Form	Capsules	Tablets
Strength	75 mg, 100 mg, 125 mg	75 mg, 100 mg, 125 mg
Dose and Frequency	Recommended dose: 125 mg once daily for 21 consecutive days followed by 7 days off Dose modification for adverse reactions	

[a] Ibrance. [Prescribing Information]. Drugs@FDA. U.S. Food and Drug Administration. April 2019. [cited 2019 June 13]. Available from: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/207103s008lbl.pdf.

Table 1. Relevant Product Information for Ibrance		
Product Name	**Ibrance (NDA 207103)[a]**	**Ibrance (NDA 212436)**
	• First dose reduction: 100 mg/day • Second dose reduction: 75 mg/day	
How Supplied	Bottle of 21 capsules	Monthly box containing 3 weekly blister packs of 7 tablets each
Storage	Store at 20°C to 25°C (68°F to 77°F)	Store at 20°C to 25°C (68°F to 77°F)

Pfizer proposed the tablets to improve drug product dissolution and improve drug absorption over the currently marketed Ibrance capsules and to reduce the drug-drug interactions with gastric acid-reducing agents that were observed with the currently approved capsules formulation.[b] Unlike the currently marketed capsules, which must be taken with food, the proposed tablet formulation may be administered with or without food.

Pfizer plans to (b) (4) (b) (4)

2 RESULTS

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Ibrance.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Ibrance would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology Products 1 (DOP1) concurred with the findings of OPDP's assessment for Ibrance.

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[b] 2.7.1 Summary of Biopharmaceutical Studies and Associated Analytical Methods: Palbociclib (PD-0332991). New York (NY): Pfizer Inc. 2019 Jan 31. Available from: \\cdsesub1\evsprod\nda212436\0001\m2\27-clin-sum\summary-biopharm.pdf.

[c] 2.5 Clinical Overview –Introduction of Palbociclib Tablet Formulation, Appendix A. New York (NY): Pfizer Inc. 2019 Jan 31. Available from: \\cdsesub1\evsprod\nda212436\0001\m2\25-clin-over\clinical-overview-app-a.pdf

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Ibrance.

2.2.1 United States Adopted Names (USAN) Search

There is no USAN stem present in the proposed proprietary name[d].

2.2.2 Components of the Proposed Proprietary Name

Pfizer did not provide a derivation or intended meaning for the proposed proprietary name, Ibrance, in their submission. This proprietary name is comprised of a single word that does not contain any components (i.e. a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 Comments from Other Review Disciplines at Initial Review

In response to the OSE, June 27, 2019 e-mail, the Division of Oncology Products 1 (DOP1) did not forward any comments or concerns relating to Ibrance at the initial phase of the review.

2.2.4 Medication Error Data Selection of Cases

We searched the FDA Adverse Event Reporting System (FAERS) database using the strategy listed in Table 2 (see Appendix A1 for a description of FAERS database) for name confusion errors involving Ibrance that would be relevant for this review.

Table 2. FAERS Search Strategy	
Search Date	June 13, 2019
Drug Name	Ibrance [product name]
Event (MedDRA Terms)	**DMEPA Official PNR Name Confusion Search Terms Event List**
Date Limits	2/1/2015 to 6/1/2019

Each report was reviewed for relevancy and duplication. Duplicates were merged into a single case. The NCC MERP Taxonomy of Medication Errors was used to code the case outcome and error root causes when provided by the reporter.

The search yielded no cases related to name confusion with the proprietary name, Ibrance.

2.2.5 Safety Analysis of Multiple Dose Forms Under the Same Proprietary Name

Ibrance capsules, 75 mg, 100 mg, and 125 mg, were approved in 2015. Pfizer now proposes tablets in the same strengths of 75 mg, 100 mg, and 125 mg to be marketed under the same name, Ibrance. We considered the appropriateness of using the proprietary name, Ibrance, for the tablet formulation proposed under NDA 212436, which would represent an extension for this

[d] USAN stem search conducted on June 13, 2019.

product line. We note that the Ibrance capsules and the proposed tablets share the same active ingredient, indication, strengths, and routes and frequencies of administration. Additionally, the proposed tablet formulation is bioequivalent to the currently approved capsule formulation and the recommended dosage is the same for both dosage forms.

It is common and accepted practice to have a product line with multiple dosage forms share one proprietary name and, while we note the dosage forms are different, these differences can be managed via labeling. Provided that the review team confirms that these products are bioequivalent and have no clinically significant differences, we do not anticipate this product line extension will introduce clinically significant medication errors related to switching between these dosage forms. Therefore, we find it acceptable for the proposed tablet formulation to be marketed under the same proprietary name, Ibrance.

2.2.6 Communication of DMEPA's Analysis at Midpoint of Review

DMEPA communicated our findings to the Division of Oncology Products 1 (DOP1) via e-mail on July 18, 2019. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Oncology Products 1 (DOP1) on July 22, 2019, they stated no additional concerns with the proposed proprietary name, Ibrance.

3 CONCLUSION

The proposed proprietary name, Ibrance, is acceptable.

If you have any questions or need clarifications, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO PFIZER INC.

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

If any of the proposed product characteristics as stated in your submission, received on June 10, 2019, are altered prior to approval of the marketing application, the name must be resubmitted for review.

REFERENCES

1. ***USAN Stems (https://www.ama-assn.org/about/united-states-adopted-names-approved-stems)***

   USAN Stems List contains all the recognized USAN stems.

Appendix A: Description of FAERS

The FDA Adverse Event Reporting System (FAERS) is a database that contains information on adverse event and medication error reports submitted to FDA. The database is designed to support the FDA's postmarket safety surveillance program for drug and therapeutic biologic products. The informatic structure of the FAERS database adheres to the international safety reporting guidance issued by the International Conference on Harmonisation. FDA's Office of Surveillance and Epidemiology codes adverse events and medication errors to terms in the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Product names are coded using the FAERS Product Dictionary. More information about FAERS can be found at: http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/default.htm.

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