CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

213721Orig1s000

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:	August 31, 2020
Application Type and Number:	NDA 213721
Product Name and Strength:	Gavreto (pralsetinib) Capsules, 100 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Blueprint Medicines Corp. (Blueprint)
Panorama #:	2020-40513546
DMEPA Safety Evaluator:	Janine Stewart, PharmD
DMEPA Team Leader (Acting):	Ashleigh Lowery, PharmD, BCCCP

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Gavreto, which was found conditionally acceptable under IND 143094 on March 10, 2020.[a]

Blueprint Medicines Corp. submitted the name, Gavreto, under NDA 213721 for review on June 9, 2020 We note the proposed Gavreto Prescribing Information[b] submitted to the NDA on March 23, 2020 contains information for dose reductions for adverse reactions (See Table 1 below) that were not included in the Request for Proprietary Name Review received on December 11, 2019.

Table 1. Recommended Dose Reductions for GAVRETO for Adverse Reactions

Dose Reduction	Recommended Dosage
First	300 mg once daily
Second	200 mg once daily
Third	100 mg once daily

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Gavreto would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis (DMEPA) and the Division of Oncology 2 (DO2) concurred with the findings of OPDP's assessment for Gavreto.

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. We also evaluated the previously identified names taking into account the additional dose reductions (300 mg, 200 mg and 100 mg). Our reassessment did not change our previous conclusion regarding the acceptability of the proposed proprietary name, Gavreto. 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 July 27, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Gavreto.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Oncology 2 (DO2) via e-mail on August 24, 2020. At that time we also requested additional information or concerns that could inform our

[a] Stewart, J. Proprietary Name Review for Gavreto (IND 143094). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2020 MAY 10. Panorama No.: 2019-36403800.

[b] Prescribing Information for Gavreto. Cambridge (MA): Blueprint Medicines Corp., 2020 Mar 23, 2020. Available from: \\cdsesub1\evsprod\nda213721\0002\m1\us\pralsetinib-uspi-clean-16-mar-2020.docx

review. Per e-mail correspondence from the Division of Oncology 2 (DO2) on August 31, 2020, they stated no additional concerns with the proposed proprietary name, Gavreto.

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, Gavreto, is acceptable.

If you have any questions or need clarifications, please contact Latonia Ford, OSE project manager, at 301-796-4901.

3.1 COMMENTS TO BLUEPRINT MEDICINES CORP.

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

If any of the proposed product characteristics as stated in your submission, received on June 9, 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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09/01/2020 10:40:58 PM

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