CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761069Orig1s000

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, 2016
Application Type and Number:	BLA 761069
Product Name and Strength:	Imfinzi (durvalumab) Injection, 50 mg/mL
Total Product Strength:	500 mg/10 mL and 120 mg/2.4 mL
Product Type:	Single ingredient product
Rx or OTC:	Rx
Applicant/Sponsor Name:	AstraZeneca
Panorama #:	2016-10807891
DMEPA Primary Reviewer:	Tingting Gao, PharmD
DMEPA Team Leader:	Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Imfinzi, which was found conditionally acceptable under IND (b) (4) on October 26, 2015.[a]

We note that there is a change in the proposed indication for BLA 761069. All other product characteristics remain the same.

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 Oncology Products 1 (DOP1) concurred with the findings of OPDP's assessment of the proposed name.

2.2 SAFETY ASSESSMENT

For re-assessment 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 indication (see Table 1). 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 November 2, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

As a result, we maintain that the proposed proprietary name is acceptable.

Table 1. Comparison of proposed indications between IND and BLA

	IND (b) (4)	BLA 761069
Indication of Use	(b) (4)	indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma (b) (4)

[a] Townsend, O. Proprietary Name Review for Imfinzi (IND (b) (4)). 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 OCT 26. Panorama No. 2015-599757.

3 CONCLUSIONS

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 is acceptable from promotional and safety perspective.

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

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your October 17, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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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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/s/

TINGTING N GAO
12/14/2016

CHI-MING TU
12/14/2016