CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761289Orig1s000

PROPRIETARY NAME REVIEW(S)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research

Memorandum

From:

Carlos M Mena-Grillasca, BS Pharm
Biologics Suffix Specialist, DMAMES
Office of Medication Error Prevention and Risk Management
Office of Surveillance and Epidemiology
Center for Drug Evaluation and Research

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Through:

Danielle Harris, PharmD
Director, Division of Medication Error Prevention and Analysis II
Office of Medication Error Prevention and Risk Management
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Gerald Dal Pan, MD, MHS
Director, Office of Surveillance and Epidemiology
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Subject: Evaluation of the nonproprietary name for BLA 761289

AstraZeneca UK Ltd (AstraZeneca) submitted [redacted] (b) (4)
BLA 761289) pursuant to Section 351(a) of the Public Health Service Act. (b) (4)
[redacted]

BLA 761289 for Imjudo (tremelimumab-xxxx) was submitted on February 23, 2022, to the Division of Oncology 3 and the PDUFA goal date to take action on the application is October 23, 2022 (priority review).

(b) (4)

The proposed product is a cytotoxic T-lymphocyte-associated antigen 4 (CTLA-4) blocking antibody. (b) (4) (BLA 761289 is indicated in combination with durvalumab, for unresectable hepatocellular carcinoma (uHCC) (b) (4)

(b) (4) AstraZeneca is proposing (b) (4)
(b) (4) proprietary name, Imjudo (b) (4)

(b) (4)

FDA issued a final guidance entitled Nonproprietary Naming of Biological Products on January 13, 2017, stating the Agency's intention to designate proper names that include four-letter distinguishing suffixes for biological products[c]. Both of these 351(a) applications are within the scope of this naming guidance.

(b) (4)

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[a] (b) (4).

[b] (b) (4)

[c] Available at https://www.fda.gov/downloads/drugs/guidances/ucm459987.pdf (hereafter "naming guidance").

[d] (b) (4)

(b) (4)

(b) (4)

3. AstraZeneca is proposing (b) (4) We have not identified any safety or misbranding concerns that would render the proprietary name, Imjudo, unacceptable for BLA 761289.

4. As noted in the final Nonproprietary Naming of Biological Products guidance, distinguishing nonproprietary names will facilitate pharmacovigilance when other means to track a specific dispensed product are not readily accessible or available; facilitate accurate identification of these biological products by health care practitioners and patients; and help prevent inadvertent substitution that may lead to medication errors. As the guidance explains, a distinguishing suffix supports the tracking of product-specific events over time, our ability to track adverse events to a specific manufacturer (and as appropriate, to a manufacturing lot or manufacturing site for a particular biological product), and our ability to detect safety signals throughout the life cycle of a product so that the Agency and the manufacturer can act swiftly and in a targeted manner to identify and address a problem. (b) (4)

(b) (4)

(b) (4)

This memorandum documents the justification for and supervisory concurrence with the decision to depart from the recommendations in the January 2017 final Nonproprietary Naming of Biological Products guidance in approving the (b) (4) nonproprietary name for BLA 761289[a]. We based this determination upon consideration of all the factors outlined above. If any of the factors enumerated above were to change, we may reconsider the appropriate proper name format for this BLA.

The following will be communicated to AstraZeneca in an advice letter.

Comments for AstraZeneca for BLA 761289:

We have determined that tremelimumab-actl will be the proper name designated in the license should your 351(a) BLA be approved during this review cycle. You should revise your proposed labels and labeling accordingly and submit the revised labels and labeling to your BLA for our review.

[a] See 21 C.F.R. § 10.115(d)(3) "Although guidance documents do not legally bind FDA, they represent the agency's current thinking. Therefore, FDA employees may depart from guidance documents only with appropriate justification and supervisory concurrence."

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/s/

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08/17/2022 03:34:50 PM

DANIELLE M HARRIS
08/18/2022 08:15:00 AM

PROPRIETARY NAME MEMORANDUM
Division of Medication Error Prevention and Analysis 2 (DMEPA 2)
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:	May 13, 2022
Application Type and Number:	BLA 761289
Product Name and Strength:	Imjudo (tremelimumab-xxxx)[a] injection, 25 mg/1.25 mL (20 mg/mL) or 300 mg/15 mL (20 mg/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	AstraZeneca Pharmaceuticals LP (AstraZeneca)
PNR ID #:	2022-1044724464
DMEPA 2 Safety Evaluator:	Grace P. Jones, PharmD, BCPS
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD, BCCCP
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD, BCPS

[a] Since the proper name for Imjudo has not yet been determined, "tremelimumab-xxxx" is used throughout this review as the nonproprietary name for this product.

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Imjudo, based on product characteristics for the unresectable hepatocellular carcinoma (uHCC) indication under BLA 761289.

AstraZeneca previously submitted the proposed proprietary name, Imjudo, for review (b) (4)

(b) (4)

AstraZeneca submitted the name, Imjudo, for tremelimumab-xxxx under BLA 761289 (uHCC indication) on March 2, 2022, which is the subject of this review

1.1 PRODUCT INFORMATION

The following product information is provided in the March 2, 2022, proprietary name submission.

(b) (4)

(see Table 1 below for details of the product information for BLA 761289 (b) (4)

Table 1. Product Information for the Proposed Imjudo under BLA 761289 (b) (4)		(b) (4)
	BLA 761289[d]	
Intended Pronunciation:	im-JEW-doh	
Nonproprietary Name:	tremelimumab-xxxx	

(b) (4)

[d] Tremelimumab-xxxx Solution for Injection (BLA 761289) Proprietary Name Request for Review for Imjudo. Stockholm Sweden. AstraZeneca AB. 2022 MAR 02. Available from: \\CDSESUB1\evsprod\bla761289\0003\m1\us\proprietary-names.pdf

(b) (4)

Table 1. Product Information for the Proposed Imjudo under BLA 761289 (b) (4)		(b) (4)
	BLA 761289[d]	
Indication of Use:	in combination with durvalumab for the treatment of adult patients with unresectable hepatocellular carcinoma (uHCC)	
Route of Administration:	intravenous	
Dosage Form:	injection	
Strength:	25 mg/1.25 mL (20 mg/mL) or 300 mg/15 mL (20 mg/mL)	(b) (4)
Dose and Frequency:	• The proposed usual dosage is 300 mg. • The proposed frequency of administration is one single priming dose at Cycle 1/Day 1. • There is no dosing interval applicable for this indication. • The proposed maximum daily dose is 300 mg.	(b) (4)

Table 1. Product Information for the Proposed Imjudo under BLA 761289 (b) (4)		(b) (4)
	BLA 761289[d]	
	Additional details: • Duration of therapy: As long as clinical benefit is observed or until unacceptable toxicity • Patients with a body weight of 30 kg and more: Single Tremelimumab Regular Interval Durvalumab (STRIDE): 300 mg as a single priming dose in combination with durvalumab 1500 mg at Cycle 1/Day 1, followed by durvalumab as a single agent every 4 weeks • Patients with a body weight of less than 30 kg: Single Tremelimumab Regular Interval Durvalumab (STRIDE): 4 mg/kg in combination with durvalumab 20 mg/kg followed by durvalumab as a single agent every 4 weeks	
How Supplied:	in 25 mg/1.25 mL and 300 mg/15 mL glass vials	(b) (4)
Storage:	Store in a refrigerator at 2°C to 8C (36°F to 46°F) in original carton to protect from light. Do not freeze. Do not shake.	

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Imjudo would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) concurred with the findings of OPDP's assessment for Imjudo. The Division of Oncology 3 (DO3) concurred with the findings of OPDP's assessment for Imjudo.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, we evaluated the previously identified names taking into account the change in indication of use and the dose and frequency. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Imjudo.

Additionally, we searched the USAN stem list to determine if the proposed proprietary name contains any USAN stems as of the last USAN updates. The April 5, 2022, search of USAN stems did not find any USAN stems in the proposed proprietary name, Imjudo.

2.3 COMMUNICATION OF DMEPA'S DETERMINATION

On May 13, 2022, we communicated our determination to the Division of Oncology 3 (DO3).

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, Imjudo, 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 ASTRAZENECA PHARMACEUTICALS LP

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

If any of the proposed product characteristics as stated in your submission, received on March 2, 2022, 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.

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/s/

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