CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761040Orig1s000

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:	July 28, 2017
Application Type and Number:	BLA 761040
Product Name and Strength:	Besponsa (inotuzumab ozogamicin) For injection 0.9 mg/vial
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Pfizer, Inc.
Panorama #:	2017-15922194
DMEPA Primary Reviewer:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Hina Mehta, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Besponsa, based the revised strength. The proposed proprietary name, Besponsa, was found acceptable in OSE review # 2015-368478 dated October 7, 2015[a] and OSE review # 2016-7445662 dated May 16, 2016[b]. The product strength was originally presented as (b) (4) mg per vial. Based on the recommendation by the Office of Product Quality (OPQ), Pfizer, Inc. revised the strength of the product to more accurately represent the deliverable amount of product and extractable volume after reconstitution. The strength of Besponsa is now 0.9 mg per vial.[c]

2 METHODS AND DISCUSSION

2.1 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, DMEPA evaluated the previously proprietary name review dated May 16, 2016 to assess whether the change in strength would alter our previous conclusion regarding the acceptability of the proposed proprietary name. We searched the USAN stem list to determine if the name contains any USAN stems as of the last USAN updates[d]. Our search did not identify any USAN stems present in the proprietary name.

We evaluated the results of our previous POCA search in OSE review# 2016-7445662[e] to identify names with overlapping strength and/or dose with the new 0.9 mg strength. Our search did not identify any names with an overlap in strength and/or dose with the 0.9 mg strength.

Additionally, since Besponsa is being proposed in a strength that is not commonly marketed, we searched the Electronic Drug Registration and Listing System (eDRLS) database to identify any names with potential orthographic, spelling, and phonetic similarities with Besponsa that were not identified in POCA, and found to have an overlap in strength with Besponsa[f]. Our search identified two new names in eDRLS, Bromday and Bromfenac. These names identified in the eDRLS database are not likely to be confused due to notable spelling, orthographic and phonetic differences.

Our USAN stem search, evaluation of previous POCA search results, and eDRLS search did not identify any new names that represent a potential source of drug name confusion. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name. As a result, we maintain that the name is acceptable.

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[a] Rutledge M. Proprietary Name Review for Besponsa (IND 065658). 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 07. 31 p. OSE RCM No.: 2015-368478.

[b] Garrison N. Proprietary Name Review for Besponsa (BLA 761040). 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); 2016 May 16. 5 p. OSE RCM No.: 2016-7445662.

[c] Office of Product Quality Type C Meeting Minutes. Silver Spring (MD): FDA, CDER, OND, DHP (US); 2017 May 6.

[d] USAN stem search conducted on July 14, 2017.

[e] POCA search conducted on April 15, 2016.

[f] eDRLS search conducted on July 14, 2017.

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.

If you have any questions or need clarifications, please contact Neil Vora, OSE project manager, at 240-402-4845.

3.1 COMMENTS TO THE APPLICANT

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

If any of the proposed product characteristics as stated in your June 22, 2017 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

If your application receives a complete response, please submit a new request for review of your proposed proprietary name when you respond to the application deficiencies.

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.

2. **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.

   Drugs@FDA

   Drugs@FDA is an FDA Web site that contains most of the drug products approved in the United States since 1939. The majority of labels, approval letters, reviews, and other information are available for drug products approved from 1998 to the present. Drugs@FDA contains official information about FDA-approved brand name and generic drugs; therapeutic biological products, prescription and over-the-counter human drugs; and discontinued drugs (see Drugs @ FDA Glossary of Terms, available at http://www.fda.gov/Drugs/InformationOnDrugs/ucm079436.htm#ther_biological).

   RxNorm

   RxNorm contains the names of prescription and many OTC drugs available in the United States. RxNorm includes generic and branded:

   - Clinical drugs – pharmaceutical products given to (or taken by) a patient with therapeutic or diagnostic intent
   - Drug packs – packs that contain multiple drugs, or drugs designed to be administered in a specified sequence

   Radiopharmaceuticals, contrast media, food, dietary supplements, and medical devices, such as bandages and crutches, are all out of scope for RxNorm (http://www.nlm.nih.gov/research/umls/rxnorm/overview.html#).

   Division of Medication Errors Prevention and Analysis proprietary name consultation requests

   This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis from the Access database/tracking system.

3. **Electronic Drug Registration and Listing System (eDRLS) database**

   The electronic Drug Registration and Listing System (eDRLS) was established to supports the FDA's Center for Drug Evaluation and Research (CDER) goal to establish a common Structured Product Labeling (SPL) repository for all facilities that manufacture regulated drugs. The system is a reliable, up-to-date inventory of FDA-regulated, drugs and establishments that produce drugs and their associated information.

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/s/

NICOLE B GARRISON
07/28/2017

HINA S MEHTA
07/28/2017

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)

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Date of This Review:	May 16, 2016
Application Type and Number:	BLA 761040
Product Name and Strength:	Besponsa (inotuzumab ozogamicin) For injection (b) (4) mg per vial
Product Type:	Single-Ingredient Product
Rx or OTC:	Rx
Applicant/Sponsor Name:	Wyeth
Panorama #:	2016-7445662
DMEPA Primary Reviewer:	Nicole Garrison, PharmD, BCPS
DMEPA Team Leader:	Yelena Maslov, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Besponsa, which was found conditionally acceptable under IND 065658 on October 7, 2015.[1]

We note that there is a change in therapy duration for cycle 1 for BLA 761040. All other product characteristics remain the same.

Table 1 below summarizes the change.

Table 1. Product Characteristics

	IND 065658	**BLA 761040**
Dose and Frequency	The usual dosage and frequency for this product is 1.8 mg/m2/cycle administered at a dose of 0.8 mg/m2 on Day 1 and 0.5 mg/m2 on Days 8 and 15 of a 21 day cycle. For patients not achieving CR or CRi, the recommended subsequent dose of inotuzumab ozogamicin is 0.8 mg/m2 on Day 1 and 0.5 mg/m2 on Days 8 and 15 of a 28 day cycle. For patients achieving CR or CRi, the recommended dose of inotuzumab ozogamicin is 0.5 mg/m2 on Days 1, 8, and 15 of a 28 day cycle.	For the first cycle, the recommended total dose of inotuzumab ozogamicin for all patients is 1.8 mg/m^2 per cycle, administered as 3 divided doses on Days 1 (0.8 mg/m^2), 8 (0.5 mg/m^2), and 15 (0.5 mg/m^2). Cycle 1 is 3 weeks in duration, but may be extended to 4 weeks if the patient achieves a CR or Cri and/or to allow from toxicity. For subsequent cycles, the recommended total dose of inotuzumab ozogamicin is 1.5 mg/m^2 per cycle administered as 3 divided doses on Days 1 (0.5 mg/m^2), 8 (0.5 mg/m^2), and 15 (0.5 mg/m^2) for patients who achieve a CR or CRi or 1.8 mg/m^2 per cycle given as 3 divided doses on Days 1 (0.8 mg/m^2), 8 (0.5 mg/m^2), and 15 (0.5 mg/m^2) for patients who do not achieve a CR or Cri. Subsequent cycles are 4 weeks in duration.

[1] Rutledge, M. Proprietary Name Review for Besponsa (IND 065658). 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 07. Panorama No. 2015-368478.

2 METHODS AND DISCUSSION

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. Since our last review, we identified three new names in POCA and determined they will not pose a risk for confusion as described in Appendices A and B. We also evaluated previously identified names taking into account the change in therapy duration for cycle 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 April 18, 2016 search of USAN stems did not find any USAN stems in the proposed proprietary name.

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 Hematology Products (DHP) concurred with the findings of OPDP's assessment of the proposed name.

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.

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, Besponsa, and have concluded that this name is acceptable.

If any of the proposed product characteristics as stated in your March 30, 2016 submission are altered prior to approval of the marketing application, the name must be resubmitted for review.

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.**

2. **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.

APPENDICES

Appendix A: Moderately Similar Names (e.g., combined POCA score is ≥50% to ≤69%) with no overlap or numerical similarity in Strength and/or Dose

No.	Name	POCA Score (%)
1.	(b) (4)***	51
2.	B-Donna	51

Appendix B: Names not likely to be confused or not used in usual practice settings for the reasons described**.**

No.	Name	POCA Score (%)	Failure preventions
1.	(b) (4)***	50	This name was not found acceptable from a safety perspective by DMEPA in OSE # 2015-1210669 and 2015-1210671). The Applicant submitted an alternate name, Erelzi*** which was found acceptable by DMEPA in OSE #: 2015-2121226.

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/s/

NICOLE B GARRISON
05/16/2016

YELENA L MASLOV
05/16/2016