CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

215833Orig1s000

PROPRIETARY NAME REVIEW(S)

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:	October 8, 2021
Application Type and Number:	NDA 215833
Product Name and Strength:	Pluvicto (lutetium (177Lu) vipivotide tetraxetan) Injection, 1000 MBq/mL (27 mCi/mL)
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Advanced Accelerator Applications USA, Inc., a Novartis Company (Advanced Accelerator Applications USA)
PNR ID #:	2021-1044724090
DMEPA 2 Safety Evaluator:	Tingting Gao, PharmD
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD, BCCCP
DMEPA 2 Associate Director for Nomenclature and Labeling:	Chi-Ming (Alice) Tu, PharmD

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Pluvicto, which was found conditionally acceptable under IND 133661 on August 3, 2021.[a]

Thus, Advanced Accelerator Applications USA submitted the name, Pluvicto, under NDA 215833 for re-review on July 29, 2021. We note that Advanced Accelerator Applications USA provided additional dosage information regarding dose modification for adverse reactions for NDA 215833 (see Table below). All other product characteristics remain the same.

Table 1. Recommended Dose Modifications for Adverse Reactions[b]

(b) (4)

[redacted]

[a] Gao, T. Proprietary Name Review for Pluvicto (IND 133661). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2021 Aug 3. PNR ID No. 2021-1044723802.

[b] Proposed Prescribing Information for Pluvicto. Millburn (NJ): Advanced Accelerator Applications USA, Inc., a Novartis Company. 2021 July 29. Available from: \\CDSESUB1\evsprod\nda215833\0000\m1\us\proposed-clean.doc.

2 METHODS AND DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Pluvicto would not misbrand the proposed product. The Division of Medication Error Prevention and Analysis 2 (DMEPA 2) and the Division of Oncology 1 (DO1) concurred with the findings of OPDP's assessment for Pluvicto.

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 previously identified names taking into account the change in dosage. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Pluvicto.

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 September 16, 2021 search of USAN stems did not find any USAN stems in the proposed proprietary name, Pluvicto.

2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW

We communicated our findings to the Division of Oncology 1 (DO1). At that time we also requested additional information or concerns that could inform our review. On October 4, 2021, the Division of Oncology 1 (DO1) stated no additional concerns with the proposed proprietary name, Pluvicto.

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, Pluvicto, 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 ADVANCED ACCELERATOR APPLICATIONS USA, INC., A NOVARTIS COMPANY

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

If any of the proposed product characteristics as stated in your submission, received on July 29, 2021, 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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