CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761394Orig1s000

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:

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Through:

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Subject: Evaluation of the nonproprietary name for BLA 761394

Daiichi Sankyo, Inc. (Daiichi) submitted two Biologics License Applications (BLA (b) (4) and BLA 761394) pursuant to Section 351(a) of the Public Health Service Act. BLA (b) (4) for Datroway (datopotamab deruxtecan-xxxx) was submitted on December 20, 2023, to the Division of Oncology 2 (DO2) and the PDUFA goal date to take action on the application is December 20, 2024

(standard review). BLA 761394 for Datroway (datopotamab deruxtecan-xxxx) was submitted on January 29, 2024, to the Division of Oncology 1 (DO1) and the PDUFA goal date to take action on the application is January 29, 2025 (standard review).

Per Daiichi's Reviewer's Guide, as agreed with the Agency during the Type B Pre-BLA- meeting on November 28, 2023,[a] reference is made to Module 3 Quality, under BLA (b) (4) for all Chemistry, Manufacturing, and Controls (CMC) information. Furthermore, the information filed in 'Module 4 Nonclinical Study Reports' for BLA 761394 is identical to the Module 4 package for BLA (b) (4) The drug substance (DS) and drug product (DP) in BLA 761394 are the same as the DS and DP in BLA (b) (4) and both BLAs propose a lyophilized powder formulation in single-dose vials with a single-strength presentations of 100 mg/vial.

The proposed product is a TROP 2 directed antibody conjugate. Both BLAs propose the same formulation, in the same dosage form, strength, dose, and route and frequency of administration and differ only in indication. See Appendix A – Product Characteristics Comparison Table for more information.

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.[b] Therefore, both of these 351(a) applications (BLA (b) (4) and BLA 761394) are within the scope of this naming guidance.

As such, the proposed nonproprietary name suffix -dlnk was found conditionally acceptable[c] for BLA (b) (4) and if approved the proper name designated in the license will be datopotamab deruxtecan-dlnk.

We carefully considered whether the nonproprietary name for BLA 761394 should include a different distinguishing suffix than that designated for BLA (b) (4) or whether the proper name considerations for this product warrant departing from the January 2017 final guidance and designating the same proper name (i.e., datopotamab deruxtecan-dlnk) for BLA 761394. Among the factors we have considered are the following:

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[a] Tilley, A.R. Type B Pre-BLA Meeting Minutes for Datopotamab Deruxtecan. Silver Spring (MD): FDA, CDER, OND, DO1 (US); 2023 December 08. IND 155696. Available at: \\CDSESUB1\EVSPROD\bla761394\0001\m1\us\meeting-minutes1.pdf

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

[c] Mena-Grillasca, C. Suffix Review for Nonproprietary Name BLA (b) (4) Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 Sep 05. Nexus NPNS ID. 2020-80 and 2021-70.

1. The drug substance (DS) and drug product (DP) in BLA 761394 are the same as the DS and DP in BLA (b) (4)

2. The formulation, dosage form, strength, dose, and route and frequency of administration are identical for BLA (b) (4) and BLA 761394. See Appendix A – Product Characteristics Comparison Table for more information.

3. Considering that BLA 761394 share the same DS and DP as BLA (b) (4) no significant differences in immunogenicity profiles are expected.

4. Under FDA's prescription drug user fee bundling policy, after initial submission, a pending original or supplemental application should not be amended to add a new indication or claim.[a] If the original application is not yet approved, a request for approval of other new indications or claims should be submitted in a separate, original application. Thus, Daiichi submitted two separate BLAs. Had one of the BLAs been approved prior to submission of the second indication, the additional indication could be managed under a supplement to the approved BLA, which would not have resulted in a change to the proper name under the approach to nonproprietary naming described in the final guidance.

5. Daiichi is proposing to use the same proprietary name (Datroway) for both of their datopotamab deruxtecan BLAs (BLA (b) (4) and BLA 761394) and separate US Prescribing Information (USPI) for each BLA. The naming convention of using the same proprietary name for different indications is not uncommon and has been found acceptable. DMEPA 2 found the proposed name Datroway conditionally acceptable for BLA (b) (4) and BLA 761394.[b]

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

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[a] See the recommendations in section III.A.7 of Guidance for Industry, Submitting Separate Marketing Applications and Clinical Data for Purposes of Assessing User Fees (Dec. 2004), available at https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM079320.pdf

[b] Stewart, J. Proprietary Name Review for Datroway (IND 136626, BLA (b) (4) BLA 761394). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 Mar 13. PNR ID No. 2023-1044725525 and 2024-1044725596.

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. As noted above, the DS and DP in BLA 761394, datopotamab deruxtecan-xxxx, are the same as the DS and DP in BLA (b) (4) Also, as noted above, Daiichi is the applicant for BLA (b) (4) and BLA 761394.

Given the above factors, a different nonproprietary name for BLA 761394 would not be designated in this particular case. The addition of a different suffix to the nonproprietary name for BLA 761394, could create confusion and would not further the goals of the naming convention.

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 same nonproprietary name for BLA 761394.[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.

Finally, we note that Daiichi submitted the same list of suffixes to BLA (b) (4) and BLA 761394. Per our nonproprietary name suffix review for BLA (b) (4)[b] Daiichi's first proposed suffix - (b) (4) was found unacceptable and this was communicated to the applicant on an Advice Letter to BLA (b) (4)

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

Comments for Daiichi for BLA 761394:

We have determined that datopotamab deruxtecan-dlnk 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.

We also note that the first proposed suffix is unacceptable for the following reason:

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[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."

[b] Mena-Grillasca, C. Nonproprietary Name Suffix Review (BLA (b) (4) Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 Sep 05. NPNS ID No. 2023-222

1. datopotamab deruxtecan-(b) (4)

   All 4 letters in the proposed suffix (b) (4) Thus, we find the proposed suffix (b) (4), is not devoid of meaning (b) (4) and is therefore inconsistent with the principle described in the Nonproprietary Naming of Biological Products guidance.

Appendix A - Product Characteristics Comparison Table

Proprietary Name	[redacted] (b) (4)	Datroway
Application No.		BLA 761394
Initial Approval/ PDUFA Goal		PDUFA goal date January 29, 2025
Active Ingredient		datopotamab deruxtecan-xxxx
Indication		The treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior [redacted] (b) (4) for unresectable or metastatic disease.
Route of Administration	Intravenous	
Dosage Form	For Injection	
Strength	100 mg	
Dose and Frequency	Proposed: 6 mg/kg given as an intravenous infusion once [redacted] (b) (4) until disease progression or unacceptable toxicity.	
How Supplied	lyophilized powder in a single-dose vial	
Storage	Store vials in a refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of reconstitution. Do not freeze. Do not shake the reconstituted or diluted solution.	

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/

CARLOS M MENA-GRILLASCA
11/18/2024 11:15:25 AM

MISHALE P MISTRY
11/18/2024 12:21:46 PM

GERALD J DALPAN
11/18/2024 12:24:35 PM

PROPRIETARY NAME REVIEW

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:	March 13, 2024
Application Type and Number:	IND 136626 and BLA (b) (4) (DO2) BLA 761394 (DO1)
Product Name, Dosage Form, and Strength:	Datroway (datopotamab deruxtecan-xxxx)[a] For Injection, 100 mg/vial
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Daiichi-Sankyo, Inc. (Daiichi Sankyo)
PNR ID #:	2023-1044725525, 2024-1044725
DMEPA 2 Safety Evaluator:	Janine Stewart, PharmD
DMEPA 2 Team Leader:	Ashleigh Lowery, PharmD
DMEPA 2 Associate Director for Nomenclature & Labeling:	Chi-Ming (Alice) Tu, PharmD, BCPS

[a] The non-proprietary name suffix for this product has not yet been determined; therefore, the placeholder datopotamab deruxtecan-xxxx is used throughout this review to refer to the non-proprietary name and suffix for this product.

Table of Contents

1 INTRODUCTION

This review evaluates the proposed proprietary name, Datroway, from a safety and misbranding perspective. The sources and methods used to evaluate the proposed proprietary name are outlined in the Reference section and Appendix A, respectively. Daiichi Sankyo submitted external name studies, conducted by (b) (4) for this proposed proprietary name.

1.1 REGULATORY HISTORY

Daiichi Sankyo submitted the proposed proprietary name, Datroway under:

- IND 136626 on June 29, 2022,
- BLA (b) (4) on December 20, 2023, and
- BLA 761394[f] on January 29, 2024.

1.2 PRODUCT INFORMATION

The following product information is provided in the proprietary name submissions received on June 29, 2022 (IND 136626)[g], December 20,2023 (BLA (b) (4)[h], and January 29, 2024 (BLA 761394)[i]

Table 1. Relevant Product Information for Datroway	
Intended pronunciation:	dat roe' way
Nonproprietary name:	datopotamab deruxtecan-xxxx

[b] Proprietary Name Safety Summary. (b) (4): (b) (4) 2022 JUN 29. Available from: \\CDSESUB1\EVSPROD\ind136626\0439\m1\us\118-proprietary-names\prop-name.pdf.

[c] Proprietary Name Safety Report. (b) (4): (b) (4) 2023 DEC 20. Available from: \\CDSESUB1\EVSPROD\(b) (4)0001\m1\us\118-proprietary-names\prop-name-app2.pdf

[d] Proprietary Name Safety Report. (b) (4): (b) (4); 2024 JAN 29. Available from: \\CDSESUB1\EVSPROD\bla761394\0001\m1\us\proprietary-name-appendix-1.pdf

\\CDSESUB1\EVSPROD\bla761394\0001\m1\us\proprietary-name-appendix-2.pdf

[e] Division of Oncology 2 (DO2) covers BL (b) (4)

[f] Division of Oncology 1 (DO1) covers BLA 761394.

[g] Request for Proprietary Name Review (IND 136626 Datroway). Basking Ridge (NJ): Daiichi-Sankyo, Inc.; 2022 JUN 29. Available from: \\CDSESUB1\EVSPROD\ind136626\0439\m1\us\118-proprietary-names\prop-name.pdf .

[h] Request for Proprietary Name Review (BLA (b) (4) Datroway). Basking Ridge (NJ): Daiichi-Sankyo, Inc.; 2023 DEC 20. Available from: \\CDSESUB1\EVSPROD\bla(b) (4)0001\m1\us\118-proprietary-names\prop-name.pdf

[i] Request for Proprietary Name Review (BLA 761394 Datroway). Basking Ridge (NJ): Daiichi-Sankyo, Inc.; 2024 JAN 29. Available from: \\CDSESUB1\EVSPROD\bla761394\0001\m1\us\proprietary-name-review.pdf

Table 1. Relevant Product Information for Datroway	
Indication:	• (b) (4) • (BLA 761394) For the treatment of adult patients with unresectable or metastatic hormone receptor (HR)-positive, HER2-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior (b) (4) for unresectable or metastatic disease.
Dosage Form:	For Injection
Strength:	100 mg/vial
Route of administration:	Intravenous Infusion
Usual dosage and frequency:	Starting dose: 6 mg/kg/dose intravenously every 3 weeks 1st Dose Reduction: 4 mg/kg/dose 2nd Dose Reduction: 3 mg/kg/dose
How Supplied:	Carton containing 1- 100 mg single-dose vial
Storage:	Store at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light until time of reconstitution.

2 DISCUSSION

The following sections provide information obtained and considered in the overall evaluation of the proposed proprietary name, Datroway.

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Datroway 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 Datroway. The Division of Oncology 1 (DO1) concurred with the findings of OPDP's assessment for Datroway. The Division of Oncology 2 (DO2) did not comment on the findings of OPDP's assessment for Datroway,

2.2 SAFETY ASSESSMENT

The following aspects were considered in the safety evaluation of the proposed proprietary name, Datroway.

2.2.1 UNITED STATES ADOPTED NAMES (USAN) SEARCH

There is no USAN stem present in the proposed proprietary name.[j]

2.2.2 COMPONENTS OF THE PROPOSED PROPRIETARY NAME

Daiichi Sankyo did not provide a derivation or intended meaning for the proposed proprietary name, Datroway, in their submission. This proprietary name is comprised of a single word that contains the letter string "tr", which is a medical abbreviation for "time-release", which may be used as a modifier to denote that a product is a "time-released formulation". Although we typically discourage the inclusion of medical abbreviations in proprietary names, the location of the "tr" letter string embedded in the middle of the name is unlikely to be separated from the surrounding letters. Therefore, we determined it is unlikely that the "tr" letter string would lead to confusion.

Beyond the "tr" abbreviation, the proposed name, Datroway, does not contain any other components (i.e., a modifier, route of administration, dosage form, etc.) that are misleading or can contribute to medication error.

2.2.3 COMMENTS FROM OTHER REVIEW DISCIPLINES AT INITIAL REVIEW

On January 11, 2024, the Division of Oncology 2 (DO2) did not forward any comments or concerns relating to Datroway at the initial phase of the review.

On February 14, 2024, the Division of Oncology 1 (DO1) did not forward any comments or concerns relating to Datroway at the initial phase of the review.

2.2.4 FDA NAME SIMULATION STUDIES

Eighty-three (n=83) practitioners participated in DMEPA's prescription studies for Datroway. The responses did not overlap with any currently marketed products nor did the responses sound or look similar to any currently marketed products or any products in the pipeline. Appendix B contains the results from the prescription simulation studies..

2.2.5 PHONETIC AND ORTHOGRAPHIC COMPUTER ANALYSIS (POCA) SEARCH RESULTS

Our POCA search[k] identified 43 names with a combined phonetic and orthographic score of ≥55% or an individual phonetic or orthographic score ≥70%. These names are included in Table 2 below.

[j] USAN stem search conducted on January 26, 2024.

[k] POCA search conducted on February 1, 2024 in version 5.5.

2.2.6 NAMES RETRIEVED FOR REVIEW ORGANIZED BY NAME PAIR SIMILARITY

Table 2 lists the number of names retrieved from our POCA search, and the (b) (4) external study. These name pairs are organized as highly similar, moderately similar or low similarity for further evaluation.

Table 2. Names Retrieved for Review Organized by Name Pair Similarity	
Similarity Category	Number of Names
Highly similar name pair: combined match percentage score ≥70%	2
Moderately similar name pair: combined match percentage score ≥55% to ≤ 69%	39
Low similarity name pair: combined match percentage score ≤54%	6

2.2.7 SAFETY ANALYSIS OF NAMES WITH POTENTIAL ORTHOGRAPHIC, SPELLING, AND PHONETIC SIMILARITIES

Our analysis of the 47 names contained in Table 2 determined none of the names will pose a risk for confusion with Datroway as described in Appendices C through H.

2.2.8 COMMUNICATION OF DMEPA'S DETERMINATION

On March 12, 2024, DMEPA 2 communicated our determination to the Division of Oncology 1 (DO1).

On March 12, 2024, DMEPA 2 communicated our determination to the Division of Oncology 2 (DO2).

3 CONCLUSION

The proposed proprietary name, Datroway, is conditionally acceptable.

If you have any questions or need clarifications for (b) (4) please contact CAPT Latonia Ford, OSE project manager, at 301-796-4901.

If you have any questions or need clarifications for BLA 761394, please contact Frances Fahnbulleh, OSE project manager, at 301-796-0942.

3.1 COMMENTS TO DAIICHI-SANKYO, INC.

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

If any of the proposed product characteristics as stated in your submissions, received on June 29, 2022 (under IND 136626), December 20, 2023 (under BLA (b) (4) or January 29, 2024 (under BLA 761394) are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCES

1. United States Adopted Names (USAN) Stems

USAN Stems List contains all the recognized USAN stems, available at https://www.ama-assn.org/about/united-states-adopted-names/united-states-adopted-names-approved-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 https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms).

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).

Purple Book

The Purple Book is an online database that contains information about biological products, including biosimilar and interchangeable biological products, licensed (approved) by the FDA under the Public Health Service (PHS) Act. See Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations, available at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or.

Division of Medication Errors Prevention and Analysis pending proprietary name requests

This is a list of proposed and pending names that is generated by the Division of Medication Error Prevention and Analysis.

5 APPENDICES

APPENDIX A. FDA'S PROPRIETARY NAME RISK ASSESSMENT EVALUATES PROPOSED PROPRIETARY NAMES FOR MISBRANDING AND SAFETY CONCERNS

1. Misbranding Assessment: For prescription drug products, the Office of Prescription Drug Promotion (OPDP) assesses the name for misbranding concerns. For over-the-counter (OTC) drug products, the misbranding assessment of the proposed name is conducted by the Office of Non-Prescription Drugs (ONPD). OPDP or ONPD evaluates proposed proprietary names to determine if the name is false or misleading, such as by making misrepresentations with respect to safety or efficacy. For example, a fanciful proprietary name may misbrand a product by suggesting that it has some unique effectiveness or composition when it does not (21 CFR 201.10(c)(3)). OPDP or ONPD provides their opinion to DMEPA for consideration in the overall acceptability of the proposed proprietary name.

2. Safety Assessment: The safety assessment is conducted by DMEPA, and includes the following:

    a. Preliminary Assessment: We consider inclusion of USAN stems or other characteristics that when incorporated into a proprietary name may cause or contribute to medication errors (i.e., dosing interval, dosage form/route of administration, medical or product name abbreviations, names that include or suggest the composition of the drug product, etc.) See prescreening checklist below in Table 3*. DMEPA defines a medication error as any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer.[l]

*Table 3. Prescreening Checklist for Proposed Proprietary Name Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.	
Y/N	Is the proposed name obviously similar in spelling and pronunciation to other names?
	Proprietary names should not be similar in spelling or pronunciation to proprietary names, established names, or ingredients of other products.
Y/N	Are there inert or inactive ingredients referenced in the proprietary name?
	Proprietary names should not incorporate any reference to an inert or inactive ingredient in a way that might create an impression that the ingredient's value is greater than its true functional role in the formulation (21 CFR 201.10(c)(4)).
Y/N	Does the proprietary name include combinations of active ingredients?
	Proprietary names of fixed combination drug products should not include or suggest the name of one or more, but not all, of its active ingredients (see 21 CFR 201.6(b)).
Y/N	Is there a United States Adopted Name (USAN) stem in the proprietary name?
	Proprietary names should not incorporate a USAN stem in the position that USAN designates for the stem.

[l] National Coordinating Council for Medication Error Reporting and Prevention. https://www.nccmerp.org/about-medication-errors. Last accessed 10/05/2020.

*Table 3. Prescreening Checklist for Proposed Proprietary Name Answer the questions in the checklist below. Affirmative answers to any of these questions indicate a potential area of concern that should be carefully evaluated as described in this guidance.	
Y/N	Is this proprietary name used for another product that does not share at least one common active ingredient?
	Drug products that do not contain at least one common active ingredient should not use the same (root) proprietary name.
Y/N	Is this a proprietary name of a discontinued product?
	Proprietary names should not use the proprietary name of a discontinued product if that discontinued drug product does not contain the same active ingredients.

b. Phonetic and Orthographic Computer Analysis (POCA): Following the preliminary screening of the proposed proprietary name, DMEPA staff evaluates the proposed name against potentially similar names. In order to identify names with potential similarity to the proposed proprietary name, DMEPA enters the proposed proprietary name in POCA and queries the name against the following drug reference databases, Drugs@FDA, Cerner RxNorm, Purple Book, and names in the review pipeline using a 55% threshold in POCA. DMEPA reviews the combined orthographic and phonetic matches and group the names into one of the following three categories:

- Highly similar pair: combined match percentage score ≥70%.
- Moderately similar pair: combined match percentage score ≥55% to ≤ 69%.
- Low similarity: combined match percentage score ≤54%.

Using the criteria outlined in the check list (Table 4-6) that corresponds to each of the three categories (highly similar pair, moderately similar pair, and low similarity), DMEPA evaluates the name pairs to determine the acceptability or non-acceptability of a proposed proprietary name. The intent of these checklists is to increase the transparency and predictability of the safety determination of whether a proposed name is vulnerable to confusion from a look-alike or sound-alike perspective. Each bullet below corresponds to the name similarity category cross-references the respective table that addresses criteria that DMEPA uses to determine whether a name presents a safety concern from a look-alike or sound-alike perspective.

- For highly similar names, differences in product characteristics often cannot mitigate the risk of a medication error, including product differences such as strength and dose. Thus, proposed proprietary names that have a combined score of ≥ 70 percent are at risk for a look-alike sound-alike confusion which is an area of concern (See Table 4).
- Moderately similar names are further evaluated to identify the presence of attributes that are known to cause name confusion.
    - Name attributes: We note that the beginning of the drug name plays a significant role in contributing to confusion. Additionally, drug name pairs that start with the same first letter and contain a shared letter string of at least 3 letters in both names are major contributing factor in

the confusion of drug names[m]. We evaluate all moderately similar names retrieved from POCA to identify the above attributes. These names are further evaluated to identify overlapping or similar strengths or doses.

- Product attributes: Moderately similar names of products that have overlapping or similar strengths or doses represent an area for concern for FDA. The dose and strength information is often located in close proximity to the drug name itself on prescriptions and medication orders, and the information can be an important factor that either increases or decreases the potential for confusion between similarly named drug pairs. The ability of other product characteristics to mitigate confusion (e.g., route, frequency, dosage form) may be limited when the strength or dose overlaps. DMEPA reviews such names further, to determine whether sufficient differences exist to prevent confusion. (See Table 5).

- Names with low similarity that have no overlap or similarity in strength and dose are generally acceptable (See Table 6) unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

c. FDA Prescription Simulation Studies: DMEPA also conducts prescription simulation studies using FDA health care professionals.

   Four separate studies are conducted within the Centers of the FDA for the proposed proprietary name to determine the degree of confusion of the proposed proprietary name with marketed U.S. drug names (proprietary and established) due to similarity in visual appearance with handwritten prescriptions, verbal pronunciation of the drug name or during computerized provider order entry. The studies employ healthcare professionals (pharmacists, physicians, and nurses), and attempts to simulate the prescription ordering process. The primary Safety Evaluator uses the results to identify vulnerability of the proposed name to be misinterpreted by healthcare practitioners during written, verbal, or electronic prescribing.

   In order to evaluate the potential for misinterpretation of the proposed proprietary name during written, verbal, or electronic prescribing of the name, written inpatient medication orders, written outpatient prescriptions, verbal orders, and electronic orders are simulated, each consisting of a combination of marketed and unapproved drug products, including the proposed name.

d. Comments from Other Review Disciplines: DMEPA requests the Office of New Drugs (OND), Office of Generic Drugs (OGD), and/or Office of Pharmaceutical Quality (OPQ) for their comments or concerns with the proposed proprietary name, ask for any clinical issues that may impact the DMEPA review during the initial phase of the name review.

[m] Shah, M, Merchant, L, Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

Additionally, when applicable, at the same time DMEPA requests concurrence/non-concurrence with OPDP's decision on the name. The primary Safety Evaluator addresses any comments or concerns in the Safety Evaluator's assessment.

The OND/OGD Regulatory Division is contacted a second time following our analysis of the proposed proprietary name. At this point, DMEPA conveys their decision to accept or reject the name.

Additionally, other review disciplines opinions such as OPQ may be considered depending on the proposed proprietary name.

When provided, DMEPA considers external proprietary name studies conducted by or for the Applicant/Sponsor and incorporates the findings of these studies into the overall risk assessment.

The DMEPA primary Safety Evaluator assigned to evaluate the proposed proprietary name is responsible for considering the collective findings, and provides an overall risk assessment of the proposed proprietary name.

Table 4. Highly Similar Name Pair Checklist (i.e., combined Orthographic and Phonetic score is ≥ 70%).

Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may render the names less likely to confusion, provided that the pair does not share a common strength or dose.

Orthographic Checklist		Phonetic Checklist	
Y/N	Do the names begin with different first letters? *Note that even when names begin with different first letters, certain letters may be confused with each other when scripted.*	Y/N	Do the names have different number of syllables?
Y/N	Are the lengths of the names dissimilar* when scripted? **FDA considers the length of names different if the names differ by two or more letters.*	Y/N	Do the names have different syllabic stresses?
Y/N	Considering variations in scripting of some letters (such as *z* and *f*), is there a different number or placement of upstroke/downstroke letters present in the names?	Y/N	Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion?
Y/N	Is there different number or placement of cross-stroke or dotted letters present in the names?	Y/N	Across a range of dialects, are the names consistently pronounced differently?
Y/N	Do the infixes of the name appear dissimilar when scripted?		

Y/N	Do the suffixes of the names appear dissimilar when scripted?		

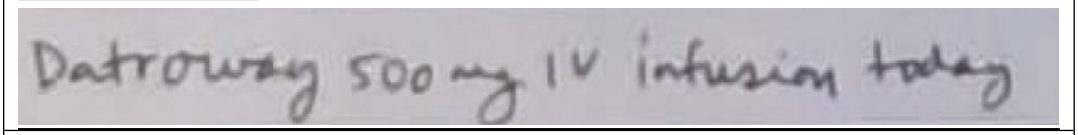
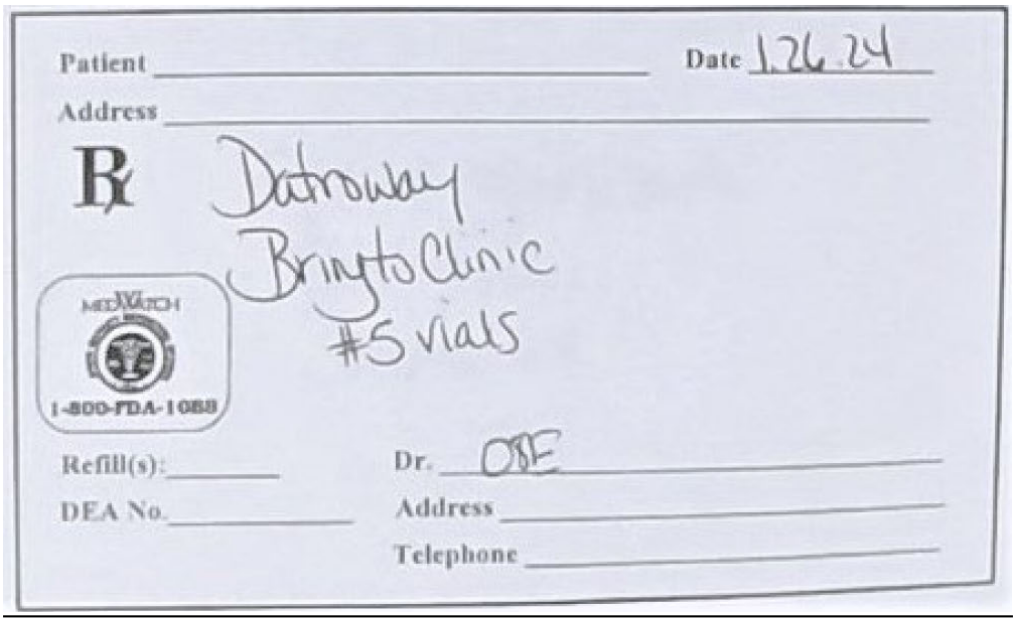
Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
Step 1	Review the DOSAGE AND ADMINISTRATION and HOW SUPPLIED/STORAGE AND HANDLING sections of the prescribing information (or for OTC drugs refer to the Drug Facts label) to determine if strengths and doses of the name pair overlap or are very similar. Different strengths and doses for products whose names are moderately similar may decrease the risk of confusion between the moderately similar name pairs. Name pairs that have overlapping or similar strengths or doses have a higher potential for confusion and should be evaluated further (see Step 2). Because the strength or dose could be used to express an order or prescription for a particular drug product, overlap in one or both of these components would be reason for further evaluation. For single strength products, also consider circumstances where the strength may not be expressed. For any i.e., drug products comprised of more than one active ingredient, consider whether the strength or dose may be expressed using only one of the components. To determine whether the strengths or doses are similar to your proposed product, consider the following list of factors that may increase confusion: • Alternative expressions of dose: 5 mL may be listed in the prescribing information, but the dose may be expressed in metric weight (e.g., 500 mg) or in non-metric units (e.g., 1 tsp, 1 tablet/capsule). Similarly, a strength or dose of 1000 mg may be expressed, in practice, as 1 g, or vice versa. • Trailing or deleting zeros: 10 mg is similar in appearance to 100 mg which may potentiate confusion between a name pair with moderate similarity. • Similar sounding doses: 15 mg is similar in sound to 50 mg	
Step 2	Answer the questions in the checklist below. Affirmative answers to some of these questions suggest that the pattern of orthographic or phonetic differences in the names may reduce the likelihood of confusion for moderately similar names with overlapping or similar strengths or doses.	
	Orthographic Checklist (Y/N to each question) • Do the names begin with different first letters? • Note that even when names begin with different first letters, certain letters may be confused with each other when scripted. • Are the lengths of the names dissimilar* when scripted? • *FDA considers the length of names different if the names differ by two or more letters. • Considering variations in scripting of some letters (such as z and f), is	Phonetic Checklist (Y/N to each question) • Do the names have different number of syllables? • Do the names have different syllabic stresses? • Do the syllables have different phonologic processes, such vowel reduction, assimilation, or deletion? • Across a range of dialects, are the names consistently pronounced differently?

Table 5: Moderately Similar Name Pair Checklist (i.e., combined score is **≥55%** to **≤69%).**		
	there a different number or placement of upstroke/downstroke letters present in the names? • Is there different number or placement of cross-stroke or dotted letters present in the names? • Do the infixes of the name appear dissimilar when scripted? • Do the suffixes of the names appear dissimilar when scripted?	

Table 6. Low Similarity Name Pair Checklist (i.e., combined score is **≤54%).**
Names with low similarity are generally acceptable unless there are data to suggest that the name might be vulnerable to confusion (e.g., prescription simulation study suggests that the name is likely to be misinterpreted as a marketed product). In these instances, we would reassign a low similarity name to the moderate similarity category and review according to the moderately similar name pair checklist.

APPENDIX B. PRESCRIPTION SIMULATION SAMPLES AND RESULTS

Figure 1. Datroway Study (Conducted on 1/26/2024)

Handwritten Medication Order Prescription	Verbal Prescription
Medication Order:  	Datroway Bring to clinic. Dispense 5 vials
Outpatient Prescription:  	
CPOE Study Sample (displayed as sans-serif, 12-point, bold font)	
Datroway	

FDA Prescription Simulation Responses (Aggregate Report)					
Study Name: Datroway People Received Study: 165 People Responded: 83					
Total	22	18	23	20	83
INTERPRETATION	INPATIENT	OUTPATIENT	VOICE	CPOE	TOTAL
DATRAWAY	0	0	1	0	1
DATROWAY	22	18	22	20	82

APPENDIX C. HIGHLY SIMILAR NAMES (e.g., combined POCA score is **≥70%)**

No.	Proposed name: Datroway. Established name: datopotamab deruxtecan-xxxx Dosage form: For Injection Strength(s): 100 mg/vial Usual dose: Starting dose: 6 mg/kg/dose intravenously every 3 weeks; 1st Dose Reduction: 4 mg/ kg/dose; 2nd Dose Reduction: 3 mg/kg/dose	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion. Other prevention of failure mode expected to minimize the risk of confusion between these two names.
1.	Datroway	100	This name is the subject of this review.
2.	Detrol LA	70	Orthographically, the suffixes of the names ('way' vs. 'ol') provide orthographic differences. Further, as a modifier, the prominent letters 'LA' are capitalized and separated from the root name, Detrol. This gives the name Detrol LA a different shape when scripted compared to the name Datroway. Phonetically, the third syllables ('way' vs. 'el' sound different and the name Detrol LA has an extra syllable.

No.	Proposed name: Datroway. Established name: datopotamab deruxtecan-xxxx Dosage form: For Injection Strength(s): 100 mg/vial Usual dose: Starting dose: 6 mg/kg/dose intravenously every 3 weeks; 1st Dose Reduction: 4 mg/ kg/dose; 2nd Dose Reduction: 3 mg/kg/dose	POCA Score (%)	Orthographic and/or phonetic differences in the names sufficient to prevent confusion. Other prevention of failure mode expected to minimize the risk of confusion between these two names.
			Although there is the potential for numerical similarity of dose (4 mg/kg vs. 4 mg), the following differences in product characteristics may help to mitigate the risk of name confusion: There is no overlap in strength (100 mg/vial vs. 2 mg and 4 mg), dosage form (for injection vs. capsule), route of administration (intravenous vs. oral), or frequency (every 3 weeks vs. once daily), which provides additional differentiating product characteristics when indicated in an order/on a prescription. Additionally, injectable oncology drug products administered by healthcare professionals are not communicated by verbal order and typically undergo independent double checks by two pharmacists in the usual clinical setting so the likelihood of both pharmacists overlooking the difference in strength, dosage form, route of administration, and frequency of administration is minimized.

APPENDIX D. MODERATELY SIMILAR NAMES (e.g., combined POCA score is **≥55%** to **≤69%)** with no overlap or numerical similarity in Strength and/or Dose.

No.	Name	POCA Score (%)
1.	Natroba	68
2.	Di-Atro	64

No.	Name	POCA Score (%)
3.	Daytrana	64
4.	Ditropan	62
5.	Nitro-Par	61
6.	Drowz-Away	60
7.	Odactra	60
8.	Detrol	59
9.	Wart Away	56
10.	Bactroban	56
11.	Statrol	56
12.	Darvon W/ Asa	55

APPENDIX E. MODERATELY SIMILAR NAMES (e.g., combined POCA score is **≥55%** to **≤69%)** with overlap or numerical similarity in Strength and/or Dose.

No.	Proposed name: Datroway. Established name: datopotamab deruxtecan-xxxx Dosage form: For Injection Strength(s): 100 mg/vial Usual dose: Starting dose: 6 mg/kg/dose intravenously every 3 weeks; 1st Dose Reduction: 4 mg/ kg/dose; 2nd Dose Reduction: 3 mg/kg/dose	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
1.	(b) (4) ***	62	This name pair has sufficient orthographic and phonetic differences.
2.	Testro-L.A.	60	This name pair has sufficient orthographic and phonetic differences.
3.	Dantrolene	59	This name pair has sufficient orthographic and phonetic differences.
4.	Daypro	58	This name pair has sufficient orthographic and phonetic differences.

No.	Proposed name: Datroway. Established name: datopotamab deruxtecan-xxxx Dosage form: For Injection Strength(s): 100 mg/vial Usual dose: Starting dose: 6 mg/kg/dose intravenously every 3 weeks; 1st Dose Reduction: 4 mg/ kg/dose; 2nd Dose Reduction: 3 mg/kg/dose	POCA Score (%)	Prevention of Failure Mode In the conditions outlined below, the following combination of factors, are expected to minimize the risk of confusion between these two names
5.	Daypro Alta	58	This name pair has sufficient orthographic and phonetic differences.
6.	Diatrizoate	58	This name pair has sufficient orthographic and phonetic differences.
7.	Diatrizoate-60	58	This name pair has sufficient orthographic and phonetic differences.
8.	Fetroja	58	This name pair has sufficient orthographic and phonetic differences.
9.	Dapzura	56	This name pair has sufficient orthographic and phonetic differences.
10.	Citroma	56	This name pair has sufficient orthographic and phonetic differences.
11.	Sfrowasa	55	This name pair has sufficient orthographic and phonetic differences.

APPENDIX F: LOW SIMILARITY NAMES (e.g., combined POCA score is **≤54%)**

No.	Name	POCA Score (%)
1.	Today	52
2.	Atropine	48
3.	(b) (4) ***	48
4.	Darvocet	46

No.	Name	POCA Score (%)
5.	Alaway	46
6.	Datscan	42

APPENDIX G. Names not likely to be confused or not used in usual practice settings for the reasons described.

No.	Name	POCA Score (%)	Failure preventions
1.	Petrola	62	Name identified in RxNorm database. Unable to find product characteristics in commonly used drug databases.
2.	(b) (4) ***	58	(b) (4)
3.	Natrecor	58	Brand discontinued with no generic equivalents available. NDA 020920 withdrawn FR effective 06/15/2020.
4.	Nitrogard	58	Name identified in RxNorm database. Per Redbook, product is deactivated and no generic equivalents are available.
5.	Nitronal	58	Brand discontinued with no generic equivalents available. NDA 018672 withdrawn FR effective 09/13/2000.
6.	(b) (4) ***	58	(b) (4)
7.	Tetroxy	58	Veterinary product.
8.	(b) (4) ***	56	(b) (4)
9.	Metrolyl	56	International product marketed in the United Kingdom.
10.	Mitrolan	56	Name identified in RxNorm database. Product is deactivated and no generic equivalents are available.
11.	(b) (4) ***	56	Proposed proprietary name for IND 073916 found unacceptable by DMEPA (OSE # 2018-215481671 dated

No.	Name	POCA Score (%)	Failure preventions
			04/22/2019). Subsequent NDA 212950 was approved under proprietary name Rukobia.

APPENDIX H. Names not likely to be confused due to absence of attributes that are known to cause name confusion[n].

No.	Name	POCA Score (%)
1.	(b) (4) ***	60
2.	Tetra Now	60
3.	Tartrate	56
4.	Naprosyn	55
5.	(b) (4) ***	55

[n] Shah, M, Merchant, L, Chan, I, and Taylor, K. Characteristics That May Help in the Identification of Potentially Confusing Proprietary Drug Names. Therapeutic Innovation & Regulatory Science, September 2016

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