CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

219713Orig1s000

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:	December 13, 2024
Application Type and Number:	NDA 219713
Product Name, Dosage Form, and Strength:	Ibtrozi (taletrectinib) Capsule, 200 mg
Product Type:	Single Ingredient Product
Rx or OTC:	Prescription (Rx)
Applicant/Sponsor Name:	Nuvation Bio, Inc. (Nuvation Bio)
PNR ID #:	2024-1044726015
DMEPA 2 Safety Evaluator:	Janine Stewart, PharmD
DMEPA 2 Team Leader:	Tingting Gao, PharmD
DMEPA 2 Deputy Director:	Chi-Ming (Alice) Tu, PharmD, BCPS

1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Ibtrozi, which was found conditionally acceptable under IND 122347 on April 2, 2024.[a]

Thus, Nuvation Bio submitted the proposed proprietary name, Ibtrozi, under NDA 219713 for re-review on September 30, 2024.[b] We note that there is a change in the proposed indication for use and the proposed recommended dose reductions for adverse reactions under NDA 219713 (see Table 1). All other product characteristics remain the same.

Table 1. Product Characteristic Changes for Ibtrozi

	IND 122347	NDA 219713[c]
Indication of Use	For the treatment of: •ROS proto-oncogene 1 receptor tyrosine kinase (ROS1) positive non-small cell lung cancer (NSCLC) •Neurotrophic Tyrosine Kinase Receptor 1 (NTRK) fusion positive solid tumors (ST)	For the treatment of adult patients with locally advanced or metastatic ROS proto-oncogene 1 receptor tyrosine kinase (ROS1)-positive non-small cell lung cancer (NSCLC).
Recommended Dose Reduction	None proposed	First Dose Reduction: 400 mg once daily Second Dose Reduction: 200 mg once daily Permanently discontinue IBTROZI capsules in patients unable to tolerate 200 mg once daily.

[a] Stewart, J. Proprietary Name Review for Ibtrozi (IND 122347). Silver Spring (MD): FDA, CDER, OSE, DMEPA 2 (US); 2024 APR 02. PNR ID No. 2024-1044725566.

[b] Request for Proprietary Name Review NDA 219713 Ibtrozi. New York (NY): Nuvation Bio, Inc.; 2024 SEP 30. Available from: \\CDSESUB1\EVSPROD\nda219713\0001\m1\us\118-proprietary-names\prop-name-ibtrozi.pdf.

[c] Proposed prescribing information for Ibtrozi. New York (NY): Nuvation Bio, Inc.; 2024 Oct 23. Available from: \\CDSESUB1\EVSPROD\nda219713\0002\m1\us\114-labeling\draft\labeling\draft-pi.docx.

2 DISCUSSION

2.1 MISBRANDING ASSESSMENT

The Office of Prescription Drug Promotion (OPDP) determined that Ibtrozi 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 Ibtrozi. The Division of Oncology 2 (DO2) did not comment on the findings of OPDP's assessment for Ibtrozi.

2.2 SAFETY ASSESSMENT

For re-assessment of the proposed proprietary name, Ibtrozi, 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 change in the proposed indication for use and the proposed recommended dose reductions for adverse reactions. Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Ibtrozi.

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 November 21, 2024, search of USAN stems did not find any USAN stems in the proposed proprietary name, Ibtrozi..

2.2.1 COMMUNICATION OF DMEPA'S DETERMINATION

On December 13, 2024, DMEPA 2 communicated our determination to the Division of Oncology 2 (DO2).

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, Ibtrozi, is conditionally acceptable.

3.1 COMMENTS TO NUVATION BIO, INC.

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

If any of the proposed product characteristics as stated in your submission, received on September 30, 2024 are altered prior to approval of the marketing application, the proprietary name must be resubmitted for review.

4 REFERENCE

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.

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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