

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**213411Orig1s000**

**PROPRIETARY NAME REVIEW(S)**

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**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\*\*\***

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<b>Date of This Review:</b>	February 3, 2020
<b>Application Type and Number:</b>	NDA 213411
<b>Product Name and Strength:</b>	Tukysa (tucatinib) tablets, 50 mg and 150 mg
<b>Product Type:</b>	Single Ingredient Product
<b>Rx or OTC:</b>	Prescription (Rx)
<b>Applicant/Sponsor Name:</b>	Seattle Genetics, Inc. (Seattle Genetics)
<b>Panorama #:</b>	2019-36537911
<b>DMEPA Safety Evaluator:</b>	Tingting Gao, PharmD
<b>DMEPA Team Leader:</b>	Chi-Ming (Alice) Tu, PharmD

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## 1 INTRODUCTION

This memorandum is to reassess the proposed proprietary name, Tukysa, which was found conditionally acceptable under IND 119421 on November 13, 2019.<sup>a</sup>

Seattle Genetics submitted the name, Tukysa, under NDA 213411 for review on December 13, 2019. We noted the proposed Tukysa Prescribing Information submitted to the NDA contains information for dose reductions for adverse reactions that were not included in the Request for Proprietary Name Review received on December 13, 2019. Thus, Seattle Genetics submitted an Amendment to Request for Proprietary Name Review<sup>b</sup> on January 23, 2020 to include additional dose modifications for adverse reactions (See Table 1 below) in response to FDA's January 15, 2020 Information Request<sup>c</sup>.

Table 1. Tukysa Dose Reduction Schedule for Adverse Reactions

Dose Level	Tukysa Dose
Recommended starting dose	300 mg twice daily
First dose reduction	250 mg twice daily
Second dose reduction	200 mg twice daily
Third dose reduction	150 mg twice daily

## 2 METHODS AND DISCUSSION

### 2.1 MISBRANDING ASSESSMENT

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

### 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 additional dose reductions (250 mg, 200 mg, and 150 mg). Our evaluation has not altered our previous conclusion regarding the acceptability of the proposed proprietary name, Tukysa.

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<sup>a</sup> Straka, M. Proprietary Name Review for Tukysa (IND 119421). Silver Spring (MD): FDA, CDER, OSE, DMEPA (US); 2019 Nov 13. Panorama No.: 2019-32496865.

<sup>b</sup> Amendment to Request for Proprietary Name Review. Bothell (WA): Seattle Genetics, Inc. 2020 Jan 23. Available from: <\\cdsesub1\evsprod\nda213411\0018\m1\us\118-proprietary-names\proprietary-name-request.pdf>.

<sup>c</sup> Fahnbulleh, F. NDA 213411 Tucatinib- Information Request. Silver Spring (MD): FDA, CDER, OSE, OMEPRM (US); 2020 Jan 15.

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 January 27, 2020 search of USAN stems did not find any USAN stems in the proposed proprietary name, Tukysa.

### **2.3 COMMUNICATION OF DMEPA'S ANALYSIS AT MIDPOINT OF REVIEW**

We communicated our findings to the Division of Oncology 1 (DO1) via e-mail on February 3, 2020. At that time we also requested additional information or concerns that could inform our review. Per e-mail correspondence from the Division of Oncology 1 (DO1) on February 3, 2020, they stated no additional concerns with the proposed proprietary name, Tukysa.

## **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, Tukysa, 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 SEATTLE GENETICS, INC.**

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

If any of the proposed product characteristics as stated in your submission, received on December 13, 2019 and January 23, 2020, 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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