



NDA 214665/S-004

**SUPPLEMENT APPROVAL/  
FULFILLMENT OF POSTMARKETING REQUIREMENT**

Amgen, Inc.  
Attention: Ariana Ayon Verduzco, PharmD, RAC  
Manager Regulatory Affairs  
One Amgen Center Drive  
Mail Stop: 27-2-D  
Thousand Oaks, CA 91320-1799

Dear Dr. Verduzco:

Please refer to your supplemental new drug application (sNDA) dated and received October 26, 2022, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for LUMAKRAS (sotorasib) tablets.

This Prior Approval sNDA provides for updates to section 8 (8.6, Hepatic Impairment) and section 12 (12.3, Pharmacokinetics) of the US Prescribing Information, based on results of the final study report for Study 20200362, entitled “An Open-label Single-dose Study to Evaluate the Pharmacokinetics of Sotorasib in Healthy Subjects and Subjects with Moderate or Severe Hepatic Impairment” (in fulfillment of PMR 4071-3).

**APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

**CONTENT OF LABELING**

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at FDA.gov.<sup>1</sup> Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information), with the addition of any labeling changes in pending “Changes Being Effected” (CBE) supplements, as well as annual reportable changes not included in the enclosed labeling.

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.<sup>2</sup>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in Microsoft Word format, that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

### **REQUIRED PEDIATRIC ASSESSMENTS**

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your application, you are exempt from this requirement.

### **FULFILLMENT OF POSTMARKETING REQUIREMENT**

We have received your submission dated October 26, 2022, containing the final report for the following postmarketing requirement listed in the May 28, 2021 approval letter.

- 4071-3 Conduct a hepatic impairment clinical trial to determine a safe and appropriate dose of sotorasib in patients with moderate and severe hepatic impairment. Design and conduct the trial in accordance with the FDA Guidance for Industry titled "Pharmacokinetics in Patients with Impaired Hepatic Function: Study Design, Data Analysis, and Impact on Dosing and Labeling".

We have reviewed your submission and conclude that the above requirement was fulfilled.

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<sup>2</sup> We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

We remind you that there are postmarketing requirements and a postmarketing commitment listed in the May 28, 2021, approval letter that are still open.

### **PATENT LISTING REQUIREMENTS**

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

### **REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, contact Maritsa Stephenson, PharmD, BCPS, via email at [maritsa.stephenson@fda.hhs.gov](mailto:maritsa.stephenson@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Harpreet Singh, M.D.  
Director  
Division of Oncology 2  
Office of Oncologic Diseases  
Center for Drug Evaluation and Research

#### ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information

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**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.**  
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/s/  
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ERIN A LARKINS

04/24/2023 04:27:48 PM

Supervisory Associate Director, as designated signatory authority for Dr. Harpreet Singh