NDA 214665/S-007

CBE LABELING SUPPLEMENT –
ACKNOWLEDGEMENT/APPROVAL

Amgen, Inc.
Attention: Ramak Pourvasei
Manager, Global Regulatory Affairs (CMC)
One Amgen Center Drive
Mail Stop: 27-2-D
Thousand Oaks, CA 91320-1799

Dear Ramak Pourvasei:

Please refer to your Supplemental New Drug Application (sNDA), dated and received on February 20, 2023, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for LUMAKRAS (sotorasib) tablets.

This supplemental application, submitted as a "Changes Being Effected" supplement, proposed corrections to the Lumakras carton and container labeling for the 320mg, 90 tablets, updating the NDC number.

APPROVAL & LABELING

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

CARTON AND CONTAINER LABELING

We acknowledge your February 1, 2023, submission containing final printed carton and container labeling.

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.

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, email Maritsa Stephenson at 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

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/

ERIN A LARKINS
03/17/2023 12:28:03 PM
Supervisory Associate Director, as designated signatory authority on behalf of Dr. Harpreet Singh