

NDA 212526/S-004

## **SUPPLEMENT APPROVAL**

Novartis Pharmaceuticals Corporation  
Attention: Sadia Afrin, MS  
Global Program Regulatory Manager, Regulatory Affairs, Oncology  
One Health Plaza  
East Hanover, NJ 07936

Dear Ms. Afrin:

Please refer to your supplemental new drug application (sNDA) dated January 22, 2021, received January 22, 2021, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Piqray (alpelisib), 50 mg, 150 mg, and 200 mg film-coated tablets.

This Prior Approval sNDA provides for revisions to the following sections of the Full Prescribing Information(FPI):

- Section 2 Dosage and Administration Subsection 2.3 Dose Modifications for Adverse Reactions to update dose modification and management guidelines
- Section 5 Warnings and Precautions Subsection 5.3 Hyperglycemia to add the adverse reaction of hyperglycemic hyperosmolar non-ketotic syndrome
- Section 6 Adverse Reactions Subsection 6.2 Postmarketing Experience to add hyperglycemic hyperosmolar non-ketotic syndrome

Corresponding changes were made to the Highlights of Prescribing Information and Patient Package Insert with minor formatting and editorial changes throughout the FPI.

### **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 and Patient Package Insert), 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.

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).

### **CARTON AND CONTAINER LABELING**

We acknowledge your May 7, 2021, 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.

### **REPORTING REQUIREMENTS**

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

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

<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>.

If you have any questions, contact Alice Lee, Regulatory Project Manager, at (301) 796-8881 or at [Alice.Lee@fda.hhs.gov](mailto:Alice.Lee@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Abhilasha Nair, MD  
Supervisory Associate Director for Safety(Acting)  
Office of Oncologic Diseases  
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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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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