NDA 211192/S-007

SUPPLEMENT APPROVAL

Agios Pharmaceuticals, Inc.
Attention: Charlotte Heyman, MSc
Associate Director, Regulatory Affairs
88 Sidney Street
Cambridge, MA 02139

Dear Ms. Heyman:

Please refer to your supplemental new drug application (sNDA) dated December 22, 2020, received December 22, 2020, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for TIBSOVO (ivosidenib tablets), for oral use.

This Prior Approval supplemental new drug application provides for the following changes:

- Revised carton labeling to change the country of origin statement from "Made in Portugal" to "Product of Portugal"
- New carton labeling with country of origin statement "Product of USA" to reflect the addition of (b) (4) as a site of manufacture of TIBSOVO
- Revised container labeling to remove the country of origin statement "Made in Portugal"

APPROVAL & LABELING

We have completed our review of this 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

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling, as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 211192/S-007**." Approval of this submission by FDA is not required before the labeling is used.

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).

If you have any questions, call Esther Park, Senior Regulatory Health Project Manager, at (301) 796-2811.

Sincerely,

{See appended electronic signature page}

R. Angelo de Claro, MD
Division Director
Division of Hematologic Malignancies I
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE:

- Carton and Container Labeling

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/

ROMEO A DE CLARO
03/18/2021 03:02:45 PM