NDA 209115/S-008

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING COMMITMENT

Clovis Oncology, Inc.
Attention: Amanda Cannon
Associate Director, Regulatory Affairs
5500 Flatiron Parkway, Suite 100
Boulder, CO 80301

Dear Ms. Cannon:

Please refer to your supplemental new drug application dated and received September 3, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rubraca (rucaparib), 200 mg, 250 mg, and 300 mg tablets.

This Prior Approval Supplemental new drug application provides for revisions to the Rubraca U.S. Prescribing Information, including an update to the Dosage and Administration section, based on analytical and clinical validation studies, as outlined in PMC 3833-2 from the May 15, 2020, approval letter.

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 Food and Drug Administration (FDA) automated drug registration and listing system (eLIST), as described at FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and the 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*.[2]

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] 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.

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 new drug application (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.

We reference the waiver granted on May 15, 2020, for the pediatric study requirement for this application.

FULFILLMENT OF POSTMARKETING COMMITMENT

We refer to your supplemental new drug application submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Rubraca (rucaparib) tablets.

We have received your submission dated September 3, 2020, containing the final report for the following postmarketing commitment listed in the May 15, 2020, accelerated approval letter.

3833-2 Submit the final report of analytical and clinical validation studies that use cell-free/circulating tumor DNA (cf/ctDNA) isolated from plasma specimens from the TRITON2 clinical trial that is adequate to support labeling of an in vitro diagnostic device that demonstrates the device is essential to the safe and effective use of rucaparib for prostate cancer patients with BRCA1 and BRCA2 gene alterations. The analytical validation should consist of precision, limit of detection, and accuracy studies using samples, consistent with the clinical trial patient population, to support prostate cancer indication. The clinical validation should be supported by a clinical bridging study comparing intended CDx test(s) and the clinical trial enrollment assays.

The timetable you submitted on May 12, 2020, states that you will conduct this study according to the following schedule:

PMA Submission:	12/2019 (completed)
Final Report Submission:	12/2021

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

We remind you that there is a postmarketing requirement and a postmarketing commitment listed in the May 15, 2020, approval letter that are still open.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

REPORTING REQUIREMENTS

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

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

If you have any questions, contact Jessica Kim, Regulatory Project Manager, at 240-402-0883 or Jessica.Kim1@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Amna Ibrahim, MD
Deputy Director
Division of Oncology 1
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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/

AMNA IBRAHIM
10/08/2020 01:17:57 PM