



NDA 213973/S-001

**SUPPLEMENT APPROVAL/
FULFILLMENT OF POSTMARKETING
COMMITMENTS**

Deciphera Pharmaceuticals, LLC.
Attention: Marc Mazzuca, Ph.D.
Manager, Regulatory Affairs
200 Smith Street
Waltham, MA 02451

Dear Dr. Mazzuca:

Please refer to your supplemental new drug application (sNDA) received December 21, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for QINLOCK (ripretinib) tablets.

This Prior Approval sNDA provides for revisions to the Dosage and Administration, Section 2.3, Dose Modifications for CYP3A Inducers, Drug Interactions, Section 7.1 Effect of Other Drugs on QINLOCK, and Clinical Pharmacology, Section 12.3, Pharmacokinetics, of the package insert to provide information on concomitant administration with strong or moderate CYP3A inducers based on the results of the postmarketing commitments (PMCs) described in the May 15, 2020, original NDA 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 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 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.

¹ <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*.²

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 COMMITMENTS

We have received your submission dated December 21, 2020, containing the final reports for the following postmarketing commitments listed in the May 15, 2020, approval letter.

3834-3 Conduct a clinical pharmacokinetic trial to evaluate the effect of repeat doses of a strong CYP3A inducer on the single dose pharmacokinetics of ripretinib and DP-5439. This trial should be designed and conducted in accordance with the FDA Guidance for Industry titled, "Clinical Drug Interaction Studies – Study Design, Data Analysis, and Clinical Implications." This trial should determine the magnitude of decreased exposure of ripretinib and DP-5439 and an appropriate dosage recommendation for ripretinib when it is administered concomitantly with strong CYP3A inducers. The results from this study may inform product labeling.

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>.

3834-4 Conduct a physiologically based pharmacokinetic modeling/simulation study to assess the effect of repeat doses of a moderate CYP3A inducer on the single dose pharmacokinetics of ripretinib and DP-5439. This study should be designed and conducted in accordance with the FDA Guidance for Industry titled, "Physiologically Based Pharmacokinetic Analyses — Format and Content Guidance for Industry." This study should estimate the magnitude of decrease in the exposure of ripretinib and DP-5439 and determine an appropriate dosage recommendation for ripretinib when it is administered concomitantly with moderate CYP3A inducers. The results from this study may inform product labeling.

We have reviewed your submission and conclude that the above commitments were fulfilled.

We remind you that there are postmarketing requirements 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, call Craig Long, Regulatory Health Project Manager, at 301-837-7646 or email at Craig.Long@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Lola Fashoyin-Aje, M.D., M.P.H
Deputy Director
Division of Oncology 3
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- 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/

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