NDA 212327/S-003

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENT

Impact Biomedicines, Inc.
Attention: Amandeep Riar
Manager, Global Regulatory Strategy and Policy
86 Morris Avenue
Summit, NJ 07901

Dear Mr. Riar:

Please refer to your supplemental new drug application (sNDA) dated and received June 3, 2021, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Inrebic (fedratinib) oral capsules.

We also refer to your submission dated June 3, 2021, containing the final report(s) for g postmarketing requirement 3664-4 and postmarketing commitment 3664-5 listed in the August 16, 2019 approval letter.

This Prior Approval sNDA provides for:

- Revisions to section 7.1 Effect of Other Drugs on Inrebic, Strong and Moderate CYP3A4 Inducers to include subsection *Strong and Moderate CYP3A4 Inducers*

- Revisions to section 7.2 Effect of Inrebic on Other Drugs to include subsection *OCT2 and MATE1/2-K Substrate Drugs*

- Revisions to section 12.3 Pharmacokinetics subsection Clinical Studies and Model-Informed Approaches to include study data

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), 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]

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 REQUIREMENT(S)/COMMITMENT(S)

We have reviewed your submission containing the final study report for the following postmarketing requirement/commitment and conclude that the below requirement and commitment were fulfilled.

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[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.

3664-4: Conduct a clinical trial to evaluate the effect of single dose of fedratinib on the single dose pharmacokinetics and safety of sensitive substrates of P-gp, BCRP, MATE-1/2K, and OCT2 transporters. Design and conduct the trial in accordance with the FDA guidance for industry entitled, Clinical Drug Interaction Studies – Study Design, Data Analysis, and Clinical Implications.

Final Protocol Submission: 09/2019
Study/Trial Completion: 03/2021
Final Report Submission: 09/2021

3664-5: Conduct a clinical pharmacokinetic trial to determine an appropriate dose of fedratinib when fedratinib is coadministered with and without multiple doses of strong and moderate CYP3A4 inducers. Design and conduct the trial in accordance with the FDA guidance for industry entitled, Clinical Drug Interaction Studies – Study Design, Data Analysis, and Clinical Implications.

Final Protocol Submission: 09/2019
Study/Trial Completion: 12/2020
Final Report Submission: 06/2021

We remind you that there are postmarketing requirement(s) listed in the August 16, 2019, approval that are still open.

If you have any questions, contact Courtney Hamilton, Regulatory Project Manager at 301-796-6849 or at Courtney.Hamilton@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Ann T. Farrell, MD
Director
Division of Nonmalignant Hematology
Office of Cardiology, Hematology,
Endocrinology, and Nephrology
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
    - Prescribing Information

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/

ANN T FARRELL
12/03/2021 08:14:37 AM