NDA 208712/S-004

**SUPPLEMENT APPROVAL**
**FULFILLMENT OF POSTMARKETING REQUIREMENT**

Sobi, Inc.
Attention: Elisa Fossale, MS, MSRA
Senior Director - Global Regulatory Lead
77 4th Ave, FL3
Waltham, MA 02451

Dear Elisa Fossale:

Please refer to your supplemental new drug application (sNDA) dated April 11, 2025, received April 11, 2025, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Vonjo (pacritinib) capsules.

We have also received your submission dated December 20, 2024, containing the final report for the following postmarketing requirement listed in the February 28, 2022, approval letter.

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| 4154-4 | Conduct a dedicated pharmacokinetic trial to evaluate the impact of hepatic impairment on the pharmacokinetics of Vonjo following administration of Vonjo 200 mg twice daily dosed to steady state in adults with moderate (Child-Pugh B) and severe hepatic impairment (Child-Pugh C) compared to matched healthy adult subjects. |

This Prior Approval sNDA provides for revisions to the Prescribing Information based on the results of the PAC110 study,[1] which was conducted to fulfill PMR 4154-4.

## 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.

[1] Phase 1, Open-Label, Multiple-Dose Study to Evaluate the Safety, Tolerability, and Pharmacokinetics of Pacritinib in Subjects with Varying Degrees of Hepatic Impairment Compared to Healthy Subjects

## 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.[2] 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*.[3]

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 supplemental application, you are exempt from this requirement.

## FULFILLMENT OF POSTMARKETING REQUIREMENT

We have reviewed your December 20, 2024, submission and conclude PMR 4154-4 was fulfilled.

[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[3] 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.

We remind you that accelerated approval PMR 4154-1 listed in the February 28, 2022, approval letter is still open. Pursuant to 21 CFR 314.510 (Subpart H), continued approval of the drug is contingent upon verification and description of clinical benefit and completion of the clinical trial for PMR 4154-1.

## PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

## 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 Bijal Patel, Regulatory Project Manager, at 240-402-4829 or at bijal.patel1@fda.hhs.gov.

Sincerely,

*{See appended electronic signature page}*

Tanya Wroblewski, MD
Deputy Division Director
Division of Nonmalignant Hematology
Office of Cardiology, Hematology,
Endocrinology, and Nephrology
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

- 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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10/01/2025 02:42:25 PM
Signed on behalf of Dr. Tanya Wroblewski, Division Director, DNH