DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring, MD 20993

Yemisi Oluwatosin
Head of Global Regulatory Advertising and Promotion
Sobi, Inc.
77 Fourth Avenue, 3rd Floor
Waltham, MA 02451

RE: NDA 208712
VONJO® (pacritinib) capsules, for oral use
MA 723

Dear Yemisi Oluwatosin:

The Office of Prescription Drug Promotion (OPDP) of the U.S. Food and Drug Administration (FDA) has reviewed the promotional communication, a direct-to-consumer (DTC) broadcast advertisement (PP-28125) (TV ad) for VONJO® (pacritinib) capsules, for oral use (Vonjo) submitted by Sobi, Inc. (Sobi) under cover of Form FDA 2253. FDA has determined that the TV ad is false or misleading. Thus, the TV ad misbrands Vonjo and makes the distribution of the drug in violation of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

The TV ad includes the following claims (in pertinent parts):

- ". . . turn the page with VONJO" (VO, 0:04-0:07)
- ". . . ask your doctor if it's time to turn the page with VONJO" (VO, 0:51-0:54)

These claims are accompanied by various imagery presentations throughout the TV ad showing an elderly man engaging in various activities including walking his dog in a park, shaking hands with his friend and petting the friend's dog, eating ice cream in the park, and dancing with his dog. The totality of these claims and presentations makes the TV ad misleading by suggesting that Vonjo allows patients to "turn the page" by impacting their health-related quality of life, such as improving their emotional functioning (i.e., no longer being tired or in distress) and social functioning (i.e., having greater ability to do activities of their choosing). We note that one of the two coprimary efficacy endpoints in the PERSIST-2 trial was the proportion of patients with ≥50% reduction in the Total Symptom Score (TSS), a clinical outcome assessment of signs and symptoms of myelofibrosis (MF) that directly assess how a patient feels, functions or survives, from baseline to Week 24. However, the TSS endpoint failed when compared to the best available therapy (p=0.08).

The TV ad is misleading because it suggests the use of Vonjo in adults with certain types of MF and "low" platelet counts, without specifying what is considered "low." According to the "**What is VONJO?**" section of the FDA-approved Patient Information (PPI), "VONJO is a prescription medicine used to treat adults with certain types of myelofibrosis who have a platelet count below 50 x 10^9/L" (emphasis added). By failing to adequately communicate the

indication for Vonjo, the TV ad creates a misleading impression about the drug's FDA-approved indication.

In addition, the TV ad is misleading because it includes claims and presentations about the benefits of Vonjo, but it omits important risk information associated with the drug. First, the TV ad fails to communicate that bleeding can be severe, changes in electrical activity of the heart can be life-threatening, and diarrhea is common and can also be severe. Second, the TV fails to communicate material information from the "**What are the possible side effects of VONJO?**" section of the PPI that increased risk of major cardiovascular events such as heart attack, stroke, or death in people have happened, especially in those who have cardiovascular risk factors (emphasis added). By omitting this important risk information, the TV ad fails to provide material information about the consequences that may result from the use of Vonjo and creates a misleading impression about the drug's safety.

Furthermore, the major statement is presented during the TV ad's theme of the pop-up book. Specifically, the "paper world" shows the man bumping into his friend, and they pet each other's dogs. The pop-up book's pages turn, background music changes, and the dog is shown barking and scaring off ducks in a pond. The pages turn again, and the man and dog approach an ice cream cart, and the man buys an ice cream cone and "pup cup," with dog barking noted in the background. The pop-up book's pages turn once more, and the man and dog come up to a busker playing a guitar, and the man begins dancing with the dog and places money in the busker's guitar case. The pop-up book's pages do its final turn, and the scene shows the "paper world" man sitting on a park bench. The camera zooms out to reveal the man sitting on the same bench in the real world, and he closes the pop-up book. Therefore, the TV ad is misleading because these attention-grabbing visuals, frequent scene changes, and background music during the presentation of the major statement interfere with comprehension of the major statement.

Conclusion and Requested Action

For the reasons described above, the TV ad misbrands Vonjo and makes the distribution of the drug in violation of the FD&C Act.

This letter notifies you of our concerns and provides you with an opportunity to address them. FDA requests that Sobi take immediate action to address any violations (including, for example, ceasing and desisting promotional communications that are misleading as described above).

Please submit a written response to this letter within 15 working days from the date of receipt, addressing the concerns described in this letter, listing all promotional communications (with the 2253 submission date) for Vonjo that contain representations like those described above, and explaining your plan for the discontinuation of such communications, or for ceasing distribution of Vonjo.

If you believe that your products are not in violation of the FD&C Act, please include in your submission to us your reasoning and any supporting information for our consideration within 15 working days from the date of receipt of this letter.

The concerns discussed in this letter do not necessarily constitute an exhaustive list of potential violations. It is your responsibility to ensure compliance with each applicable requirement of the FD&C Act and FDA implementing regulations.

Please direct your response to the undersigned at the **Food and Drug Administration, Center for Drug Evaluation and Research, Office of Prescription Drug Promotion, 5901-B Ammendale Road, Beltsville, Maryland 20705-1266**. A courtesy copy can be sent by facsimile to (301) 847-8444. Please refer to MA 723 in addition to the NDA number in all future correspondence relating to this particular matter. All correspondence should include a subject line that clearly identifies the submission as a Response to Untitled Letter. You are encouraged, but not required, to submit your response in eCTD format. All correspondence submitted in response to this letter should be placed under eCTD Heading 1.15.1.6. Additionally, the response submission should be coded as an Amendment to eCTD Sequence 5719 under NDA 208712. Questions related to the submission of your response letter should be emailed to the OPDP RPM at CDER-OPDP-RPM@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Valerie Guerrier, PharmD
Regulatory Review Officer
Division of Advertising & Promotion Review 2
Office of Prescription Drug Promotion

{See appended electronic signature page}

Jina Kwak, PharmD, RAC
Team Leader
Division of Advertising & Promotion Review 2
Office of Prescription Drug Promotion

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/

VALERIE GUERRIER
02/06/2026 10:51:28 AM

JINA KWAK
02/06/2026 10:53:01 AM