CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

216774Orig1s000

OTHER ACTION LETTERS

NDA 216774

TENTATIVE APPROVAL

Teva Pharmaceuticals Inc.
Attention: Alberto Rivalta
Sr. Director of Regulatory Affairs
2945 West Corporate Lakes Blvd., Suite B
Weston, FL 33331

Dear Mr. Rivalta:

Please refer to your new drug application (NDA) dated and received December 3, 2021, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Alvaiz (eltrombopag tablets).

This NDA provides for the use of Alvaiz (eltrombopag tablets) for the treatment of:

- thrombocytopenia in adult and pediatric patients 6 years and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. ALVAIZ should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding;

- thrombocytopenia in adult patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. ALVAIZ should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon-based therapy;

- adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

We have completed our review of this application, as amended. It is tentatively approved under 21 CFR 314.105 for use as recommended in the agreed-upon enclosed labeling (text for the Prescribing Information, Medication Guide, and container labeling**)**. This determination is based upon information available to the Agency at this time, [i.e., information in your application and the status of current good manufacturing practices (cGMPs) of the facilities used in the manufacture and testing of the drug product]. This determination is subject to change on the basis of any new information that may come to our attention.

Final approval of your application is subject to expiration of a period of patent protection and/or exclusivity. Therefore, final approval of your application may not be granted before the period has expired.[1]

To obtain final approval of this application, submit an amendment two or six months prior to the: (1) expiration of the patent(s) and/or exclusivity protection or (2) date you believe that your NDA will be eligible for final approval, as appropriate. In your cover letter, clearly identify your amendment as **"REQUEST FOR FINAL APPROVAL"**. This amendment should provide the legal/regulatory basis for your request for final approval and should include a copy of any relevant court order or judgment settlement, or licensing agreement, as appropriate. In addition to a safety update, the amendment should also identify changes, if any, in the conditions under which your product was tentatively approved, i.e., updated labeling; chemistry, manufacturing, and controls data; and risk evaluation and mitigation strategy (REMS). If there are no changes, clearly state so in your cover letter. Any changes require our review before final approval and the goal date for our review will be set accordingly.

Until we issue a final approval letter, this NDA is not approved.

The drug product may not be legally marketed until you have been notified in writing that this application is approved.

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 note that if this application is ultimately approved, you will need to meet these requirements.

[1] This letter does not address whether any orphan drug exclusivity (ODE) recognized for Promacta NDA 022291 affects the approvability of your application. Promacta has orphan-drug designation for "Treatment of aplastic anemia." FDA recognized Promacta as eligible for ODE, effective as of November 16, 2018, based on the approval of the indication, "in combination with standard immunosuppressive therapy for the first-line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia." This ODE period expires on November 16, 2025. The implications of the recent decision in *Catalyst Pharms., Inc. vs. Becerra (Catalyst)* for your application are still under consideration. Absent a waiver of exclusivity from the sponsor of the Promacta NDA, application of the *Catalyst* decision may block inclusion of any labeling in your NDA describing the use of eltrombopag for the treatment of aplastic anemia until the ODE period expires on November 16, 2025.

If you have any questions, call Carleveva Thompson, Regulatory Project Manager, at 301-796-1403.

Sincerely,

{See appended electronic signature page}

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

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Medication Guide
- Container Labeling

40 Page(s) of Draft Labeling have been Withheld in Full as b4 (CCI/TS) immediately following this page

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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.

/s/

ANN T FARRELL
10/03/2022 01:32:55 PM