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APPLICATION NUMBER:

216774Orig1s000

NON-CLINICAL REVIEW(S)

MEMORANDUM

DATE: September 26, 2022

TO: File for NDA 216774

FROM: Marieli Gonzalez-Cotto, PhD
Pharmacology-Toxicology Reviewer
Division of Pharmacology & Toxicology-CHEN
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THROUGH: Natalie Simpson, PhD
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SUBJECT: NDA 216774 SDN 1
NDA type: 505(b)(2)
Applicant: TEVA Pharmaceuticals Inc.
Drug: Alvaiz (eltrombopag choline) tablets EQ to 9 MG, 18 MG, 36 MG and 54 MG of eltrombopag
Indication: 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. For the treatment of thrombocytopenia in patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. For the treatment of adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.

TEVA Pharmaceuticals Inc. originally submitted NDA 216774, for Alvaiz (eltrombopag choline) oral tablets on 12/03/2021 under a 505(b)(2) NDA pathway. The drug product has the same active moiety, indication, dosage form, dosing regimen and route of administration as the Listed Drug (LD) Promacta (NDA 022291). Alvaiz differs from the LD with respect to the active ingredient salt and strengths.

Nonclinical Data
No nonclinical study reports were provided with this application. Eltrombopag is a small molecule thrombopoietin receptor (TPO) agonist that interacts with the transmembrane domain of the human TPO-receptor and initiates signaling cascades that induce proliferation and differentiation from bone marrow progenitor cells.

Labeling
The label was reviewed based on the currently listed LD label (NDA #022291 Promacta from Novartis). Minor revisions in Section 8.2 regarding the use of the tradename were discussed with the review team. No revisions were necessary from the Pharmacology-Toxicology perspective.

Regulatory Recommendation

TEVA Pharmaceuticals Inc.'s Alvaiz for oral administration 505(b)(2) NDA 216774 is approvable from the perspective of Pharmacology-Toxicology.

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/

MARIELI GONZALEZ-COTTO
09/28/2022 10:16:06 AM

NATALIE E SIMPSON
09/28/2022 10:28:32 AM