Alvaiz™ (eltrombopag) – New drug approval

- On November 29, 2023, the FDA approved Teva's 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 (CHC) to allow the initiation and maintenance of interferon-based therapy. Alvaiz should be used only in patients with CHC 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.
- Alvaiz is not indicated for the treatment of patients with myelodysplastic syndromes (MDS) and the safety and efficacy have not been established in combination with direct-acting antiviral agents used without interferon for treatment of CHC infection.
- Eltrombopag is also available as a tablet and oral suspension under the brand name Promacta®.
    - Promacta shares the same ITP indication as Alvaiz except it is approved in pediatric patients 1 year and older.
    - Promacta shares the same CHC indication as Alvaiz.
    - In addition to sharing the indication for severe aplastic anemia in patients who have had an insufficient response to immunosuppressive therapy, Promacta is also approved in combination with standard immunosuppressive therapy for the first-line treatment of adult and pediatric patients 2 years and older with severe aplastic anemia.
- The effectiveness of Alvaiz has been established based on adequate and well-controlled studies of Promacta in adult and pediatric patients 6 years and older.
- Alvaiz carries a boxed warning for the risk of hepatic decompensation in patients with CHC and risk of hepatotoxicity.
- Additional warnings and precautions for Alvaiz include increased risk of death and progression of MDS to acute myeloid leukemia; thrombotic/thromboembolic complications; and cataracts.
- The most common adverse reactions (≥ 20%) with Alvaiz use were anemia, nausea, pyrexia, increased alanine aminotransferase, cough, fatigue, headache, and diarrhea.
- For complete oral dosing and administration recommendation, refer to the Alvaiz drug label.
- Teva's launch plans for Alvaiz are pending. Alvaiz will be available as 9 mg, 18 mg, 36 mg, and 54 mg tablets.