**MK3543-007**

A Phase 3, Randomized, Double-blind, Active-Comparator-Controlled Clinical Study to Evaluate the Efficacy and Safety of Bomedemstat (MK-3543) versus Hydroxyurea in Cytoreductive Therapy Naïve Essential Thrombocythemia Participants

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**Trattamento:** Bomedemstat

**Sindromi MIELOPROLIFERATIVE CRONICHE target:** Essential Thrombocythemia

**Principali Criteri Inclusione:**

1. Based on the WHO diagnostic criteria for myeloproliferative neoplasms has a diagnosis of ET and an indication for cytoreductive therapy regardless of age or risk status. Indications for cytoreductive therapy include but are not limited to:

• High-risk patients (history of thrombosis at any age; or age >60 years with JAK2 V617F mutation),

• Acquired VWD and/or disease-related major bleeding,

• Splenomegaly (defined as a spleen volume greater than 450 mm3),

• Progressive thrombocytosis and/or leukocytosis,

• Disease-related symptoms (eg, pruritis, fatigue, night sweats), and

• Vasomotor/microvascular disturbances not responsive to ASA (eg, erythromelalgia, headaches/chest pain).

2. Has a bone marrow fibrosis score of Grade 0 or Grade 1, as per a modified version of the European Consensus Criteria for Grading Myelofibrosis (Appendix 10).

3. Has received no prior cytoreductive treatment for their ET.

4. Has a platelet count of >450 × 109/L (450k/μL) assessed up to 72 hours before first dose of study intervention.

5. Has an ANC ≥0.75 × 109/L assessed up to 72 hours before first dose of study intervention.

6. Has a life expectancy of >52 weeks in the opinion of the investigator.

13. Has an ECOG Performance Status of 0 to 2 assessed within 7 days before the start of study intervention

**Principali Criteri Esclusione**:

3. Evidence at the time of Screening of increased risk of bleeding, including any of the following:

- History of severe thrombocytopenia or platelet dysfunction unrelated to a myeloproliferative disorder or its treatment.

- Known hereditary bleeding disorder (eg, dysfibrinogenemia, factor IX deficiency, hemophilia, VWD, disseminated intravascular coagulation, fibrinogen deficiency, or other clotting factor deficiency).

- Active or chronic bleeding within 8 weeks before randomization.

- An autoimmune disorder causing bleeding.

4. History of a malignancy, unless potentially curative treatment has been completed with no evidence of malignancy for 2 years