KARTA BADANIA
NAZWA BADANIA: A Study of Bomedemstat (IMG-7289/MK-3543) Compared to Best Available Therapy (BAT) in Participants With Essential Thrombocythemia and an Inadequate Response or Intolerance of Hydroxyurea (MK-3543-006)
NUMER PROTOKOŁU: **MK-3543-006**
WSKAZANIE- D47.1 - Przewlekła choroba mieloproliferacyjna

Inclusion Criteria:

- Has a diagnosis of ET per WHO 2016 diagnostic criteria for myeloproliferative neoplasms
- 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
- Has a history of inadequate response to or intolerance of hydroxyurea based on modified European LeukemiaNet (ELN) criteria for hydroxyurea resistance or intolerance: hydroxyurea resistance (or inadequate response) or hydroxyurea Intolerance
- Has an inadequate or loss of response to their most recent prior ET therapy, requiring a change of cytoreductive therapy
- Has a platelet count > 450 × 10^9/L (450k /µL) assessed up to 72 hours before first dose of study intervention
- Has an absolute neutrophil count (ANC) ≥0.75 × 10^9/L assessed up to 72 hours before first dose of study intervention
- Participants may have received up to 3 prior lines of therapy including hydroxyurea

Exclusion Criteria:

- Known immediate or delayed hypersensitivity reaction or idiosyncrasy to drugs chemically related to bomedemstat or lysine demethylase or monoamine oxidase inhibitor (LSDi or MAOi) or the chosen best available therapy (including anagrelide, interferon alfa/pegylated interferon, ruxolitinib, or busulfan) that contraindicates participation
- History of any illness/impairment of GI function that might interfere with drug absorption (eg, chronic diarrhea or history of gastric bypass surgical procedure), confound the study results or pose an additional risk to the individual by participation in the study
- Evidence at the time of Screening of increased risk of bleeding
- History of a malignancy, unless potentially curative treatment has been completed with no evidence of malignancy for 2 years. Note: The time requirement does not apply to participants who underwent successful definitive resection of basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or carcinoma in situ, excluding carcinoma in situ of the bladder
- Human immunodeficiency virus (HIV)-infected participants with a history of Kaposi's sarcoma and/or Multicentric Castleman's Disease