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)

NCT06079879

Status	RECRUITING
Phase	Phase 3
Sponsor	Merck Sharp & Dohme LLC
Enrollment	340 participants

Key Eligibility Criteria

Inclusion (7)

- Has a diagnosis of ET per WHO 2016 diagnostic criteria for myeloproliferative neoplasms (confirmed by a central pathologist)
- Has a centrally assessed 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
- 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

... and 2 more (see full listing online)

Exclusion (5)

- 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

Locations (161 total)

Palo Verde Hematology/ Oncology Center, Ltd. (Site 3496), Glendale, Arizona, United States
Los Angeles Cancer Network (Site 3491), Glendale, California, United States
Stanford Cancer Institute (Site 0107), Stanford, California, United States
... and 158 more locations