

Investigational Trials of Luspatercept in Myeloproliferative Neoplasm– Associated Myelofibrosis

INDEPENDENCE

A Phase 3, Double-Blind, Randomized Study to Compare the Efficacy and Safety of Luspatercept (ACE-536) Versus Placebo in Subjects With Myeloproliferative Neoplasm–Associated Myelofibrosis on Concomitant JAK2 Inhibitor Therapy and Who Require Red Blood Cell Transfusions^{1,2}

Enrolling globally

NCT04717414 PHASE 3

PRIMARY ENDPOINT

Proportion of patients who become red blood cell–transfusion-free over any consecutive 12-week period

SELECT SECONDARY AND EXPLORATORY ENDPOINTS

Proportion of patients who become red blood cell–transfusion-free over any consecutive 16-week period, safety, OS

KEY ELIGIBILITY CRITERIA

Age ≥18 years
Diagnosis of PMF or post-ET or post-PV MF
Require RBC transfusions (4–12 RBC U/12 weeks)
Require continuous JAK2 inhibitor therapy for SOC
ECOG PS ≤2

Stratification factors:

- RBC transfusion burden at baseline (4–5 vs 6–12 U/12 weeks)
- DIPSS score at baseline (intermediate-1/-2 vs high risk)

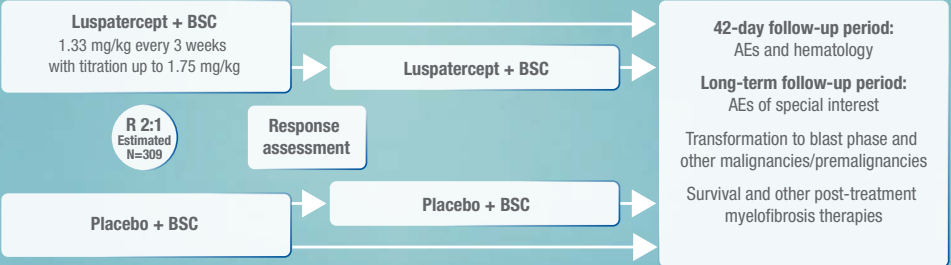
TREATMENT

Blinded core treatment period (Weeks 1–24)

Blinded extension treatment period (Week 25+)

FOLLOW-UP

Post-treatment follow-up period (5 years post first dose or 3 years post last dose, whichever occurs later)



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Enrolling

NCT03194542 PHASE 2

Study to Evaluate Luspatercept in Subjects With Myeloproliferative Neoplasm–Associated Myelofibrosis Who Have Anemia With and Without Red Blood Cell–Transfusion Dependence³

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The safety and efficacy of luspatercept for the indications under investigation have not been established. There is no guarantee that luspatercept will receive health authority approval or become commercially available in any country for the uses being investigated.