

# Investigational Trial 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<sup>1</sup>

Enrolling soon

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 yrs  
Diagnosis of PMF or post-ET or post-PV MF  
Require RBC transfusions (4–12 RBC U/12 wks)  
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+)

Luspatercept + BSC  
1.33 mg/kg every 3 weeks  
with titration up to 1.75 mg/kg

R 2:1  
Estimated  
N = 309

Response  
assessment

Placebo + BSC

Luspatercept + BSC

Placebo + BSC

#### FOLLOW-UP

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

42-day follow-up period:  
AEs and hematology  
Long-term follow-up period:  
AEs of special interest  
Transformation to blast phase and  
other malignancies/premalignancies  
Survival and other post-treatment  
myelofibrosis therapies

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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 Dependence<sup>2</sup>

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The safety and efficacy of luspatercept and/or its 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.

Bristol Myers Squibb in collaboration with:



AE, adverse event; BSC, best supportive care; DIPSS, Dynamic International Prognostic Scoring System; ECOG PS, Eastern Cooperative Oncology Group performance status; JAK2, Janus kinase 2; MF, myelofibrosis; OS, overall survival; PMF, primary myelofibrosis; PV, polycythemia vera; RBC, red blood cell; U, units; SOC, standard of care.

1. Clinicaltrials.gov. NCT04717414. Accessed March 18, 2021. 2. Clinicaltrials.gov. NCT03194542. Accessed March 18, 2021.

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