Bristol Myers Squibb™

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[1]

Enrolling soon ***NCT04717414 PHASE 3***

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

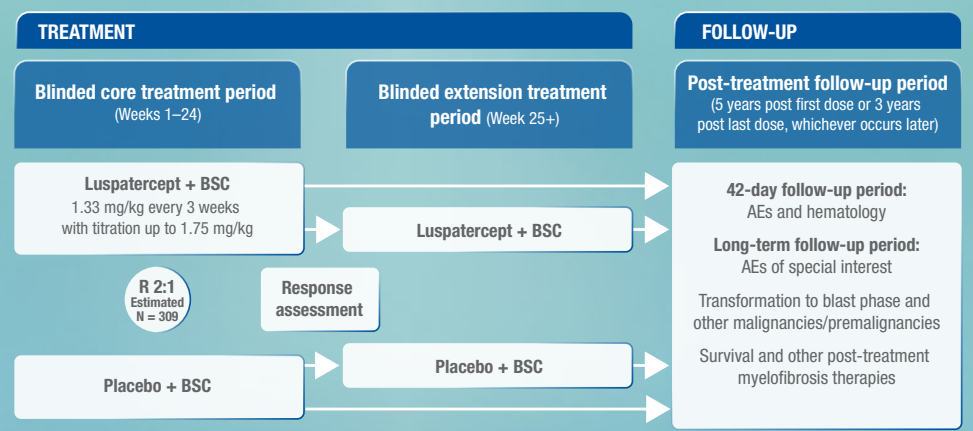
SELECT SECONDARY AND EXPLORATORY ENDPOINTS
Proportion of patients who become red blood cell–transfusion-free over any consecutive 16-week period, safety, OS

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)*



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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[2]

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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:
ACCELERON

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.