Bristol Myers Squibb™

Investigational Trial of Luspatercept in Lower-Risk Myelodysplastic Syndromes

COMMANDS

Study of Luspatercept (ACE-536) Versus Epoetin Alfa for the Treatment of Anemia Due to IPSS-R Very Low, Low or Intermediate Risk Myelodysplastic Syndromes (MDS) in ESA Naïve Patients Who Require Red Blood Cell Transfusions[1,2]

CURRENTLY ENROLLING IN MDS

NCT03682536 *PHASE 3*

PRIMARY ENDPOINT

Proportion of patients who achieve red blood cell transfusion independence for ≥12 weeks within the first 24 weeks of study, with a concurrent mean hemoglobin increase of ≥1.5 g/dL compared with baseline

SELECT SECONDARY ENDPOINTS

Hematologic improvement (including time to and duration of improvement), duration of red blood cell transfusion independence ≥24 weeks, safety, pharmacokinetics, HRQoL, progression to AML, and OS

KEY ELIGIBILITY CRITERIA

Age ≥18 years

Diagnosis of IPSS-R classification of very low, low, or intermediate risk of MDS

- <5% blasts in bone marrow

Require red blood cell transfusions (2–6 U/8 weeks)

<3 doses of ESAs ≥8 weeks from randomization

sEPO <500 U/L

TREATMENT

Luspatercept 1.0 mg/kg subcutaneous every 3 weeks

R 1:1
Estimated N=350

Epoetin alfa 450 IU/kg subcutaneous weekly

FOLLOW-UP

Follow-up for survival, subsequent therapies, and progression of MDS to AML

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The safety and efficacy of luspatercept for 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.

ACCELERON in collaboration with Celgene Corporation, a Bristol Myers Squibb company

AML, acute myeloid leukemia; **ESA**, erythropoiesis-stimulating agent; **HRQoL**, health-related quality of life; **IPSS-R**, Revised International Prognostic Scoring System; **MDS**, myelodysplastic syndrome; **OS**, overall survival; **R**, randomized; **sEPO**, serum erythropoietin.

1. Della Porta M et al. The COMMANDS trial: a phase 3 study of the efficacy and safety of luspatercept versus epoetin alfa for the treatment of anemia due to Revised International Prognostic Scoring System Very Low-, Low-, or Intermediate-risk myelodysplastic syndromes in erythropoiesis stimulating agent-naive patients who require red blood cell transfusions. Poster presentation at ASH 2020. Abstract 2198. **2.** ClinicalTrials.gov. NCT03682536. https://clinicaltrials.gov. Accessed April 23, 2021.