ELEMENT-MDS: A Study to Compare the Efficacy and Safety of Luspatercept in Participants With Myelodysplastic Syndrome (MDS) and Anemia Not Receiving Blood Transfusions

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria * Participant has documented diagnosis of MDS according to World Health Organization (WHO) 2016 that meet IPSS-R classification of very low, low, or intermediate-risk disease, (intermediate-risk of ≤ 3.5 IPSS-R score) confirmed via bone marrow aspirate and:. i) \< 5% blasts in bone marrow and \< 1% blasts in peripheral blood. * Participant is not transfusion dependent (NTD) based on IWG2018 criteria. * Participant is erythropoiesis-stimulating agent naive. Participants may be randomized at the investigator's discretion if the participant received no more than 2 prior doses of epoetin alfa, epoetin alfa biosimilar, or darbepoetin alfa, with the last dose at least 8 weeks prior to randomization. * Participant has a baseline endogenous serum erythropoietin (sEPO) level of ≤ 500 U/L. * Participant has symptoms of anemia:. i) Participant records a severity score of "moderate" or greater on at least 1 PGI-S item of fatigue, weakness, shortness of breath, or dizziness performed during the screening period. * Participant has a baseline Hb concentration prior to randomization of ≤ 9.5 g/dL. The baseline Hb will be calculated using the mean of the two lowest available Hb measurements within 16 weeks prior to randomization and must include at least one central lab Hb reading done within the screening period (no more than 35 days before randomization). The two Hb measurements must have been performed at least seven days apart. Hb levels less than 21 days following RBC transfusion should not be used. Split samples for local assessments are not required. Exclusion Criteria * Participant with secondary MDS (that is, MDS that is known to have arisen as the result of chemical injury or treatment with chemotherapy and/or radiation for other diseases). * Participant with known history of diagnosis of AML. * Participant with history of cerebrovascular accident (including ischemic, embolic, and hemorrhagic cerebrovascular accident), transient ischemic attack, deep venous thrombosis (including proximal and distal), pulmonary or arterial embolism, arterial thrombosis, or other venous thrombosis within 6 months prior to randomization. * Participant with a history of pure red cell aplasia and/or antibody against erythropoietin. * Other protocol-defined Inclusion/Exclusion criteria apply.

Conditions & Interventions

Interventions:

BIOLOGICAL: Luspatercept, BIOLOGICAL: Epoetin Alfa

Conditions:

Myelodysplastic Syndromes

Keywords:

Luspatercept, BMS-986346, ACE-536, Myelodysplastic Syndrome, Epoetin alfa, Erythropoietin stimulating agent (ESA), Myelodysplastic Syndromes (MDS), Anaemia

More Information

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Phase: PHASE3

IRB

Number:

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