KARTA BADANIA
NAZWA BADANIA: A Phase 3, Open-label, Randomized Study to Compare the Efficacy and Safety of Luspatercept (ACE-536) vs Epoetin Alfa for the Treatment of Anemia Due to Revised International Prognostic Scoring System (IPSS-R) Very Low, Low, or Intermediate-Risk Myelodysplastic Syndrome (MDS) in Erythropoiesis-Stimulating Agent (ESA)-naive Participants who are Non-Transfusion Dependent (NTD): The "ELEMENT-MDS" Trial
NUMER PROTOKOŁU: **CA056-025**
WSKAZANIE- D46 - Zespoły mielodysplastyczne

Criteria

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 has never received treatment with an erythropoiesis stimulating agent (ESA).
- 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 mean baseline Hb concentration prior to randomization of ≤ 9.5 g/dL. Mean Hb is defined as the mean of all central/ local/ pretransfusion available Hb measurements during the 16 weeks prior to randomization (with a minimum of 2 measurements at least 1 week apart). Only Hb levels > 21 days following a transfusion are acceptable. The last measurement must be within 35 days of randomization.

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.