A Study to Compare Elritercept With Epoetin Alfa to Treat Anemia in Adults With Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes (MDS) Who Need Regular Blood Transfusions

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria 1. Male or female participants aged ≥ 18 years or older at time of signing the informed consent form (ICF). 2. Able to understand the purpose and risks of the trial and voluntarily sign an ICF prior to any trial-related procedures being conducted and authorization to use protected health information and personal data in accordance to national and local privacy regulations. 3. Documented diagnosis of myelodysplastic syndrome(s) (MDS) according to WHO 2016 classification that meets International Prognostic Scoring System

•Revised (IPSS-R) classification of very low-, low-, or intermediate-risk disease, confirmed by central laboratory independent reviewer prior to randomization. Hemoglobin (Hgb), platelet, and absolute neutrophil count (ANC) values should be collected greater than (\>) 14 days after red blood cell (RBC) transfusion or greater than (\>) 7 days after platelet transfusion, unless otherwise considered to be pretransfusion values. 4. Bone marrow less than (\<) 5% blasts in an evaluable bone marrow collected at screening and confirmed by central pathology independent reviewer. 5. Endogenous serum erythropoietin s (EPO) level of \<500 U/L. Should be results from blood samples collected \>14 days following an RBC transfusion to evaluate for eligibility unless considered pretransfusion values. 6. Participant requires RBC transfusion, as documented by the following criteria. A transfusion requirement of 2 to 6 pRBCs units/8 weeks confirmed for a minimum of 8 weeks immediately preceding randomization. • Hgb levels at the time of or within 3 days prior to administration of a RBC transfusion must have been less than or equal to (≤) 9.0 grams per deciliter (g/dL) (5.6 millimoles per liter (mmol/L)) with symptoms of anemia (or ≤7 g/dL \[4.3 mmol/L\] in the absence of symptoms) in order for the transfusion to be counted towards meeting eligibility criteria. • RBC transfusions administered when hemoglobin (Hgb) levels were \>9.0 g/dL (or \>7 g/dL in the absence of symptoms) and/or RBC transfusions administered for elective surgery, infections or bleeding events will not qualify as a required transfusion for the purpose of meeting eligibility criteria or stratification. 7. Hgb \<11.0 g/dL (6.8 mmol/L) after last RBC transfusion preceding randomization. Local laboratory is acceptable to facilitate randomization. 8. Eastern Cooperative Oncology Group score of 0, 1, or 2. Exclusion Criteria 1. Prior therapy with any of the following: 1. Epoetin alfa • At the investigator's discretion in consultation with the medical monitor, may be allowed if received no more than 2 doses of only epoetin alfa ≥8 weeks prior to randomization. No other erythropoiesis-stimulating agent (ESA) agent is allowed. 2. Darbepoetin 3. Granulocyte colony-stimulating factor or granulocyte-macrophage colony-stimulating factor administered ≤8 weeks (56 days) prior to randomization unless given for treatment of febrile neutropenia. 4. Immunomodulatory drug (IMiDs) including lenalidomide • At the investigator's discretion in consultation with the medical monitor may be allowed if received ≤1 week of an IMiD ≥8 weeks prior to randomization. 5. Hypomethylating agent • At the investigator's discretion, in consultation with the medical monitor may be allowed if received no more than 2 doses ≥8 weeks prior to randomization. 6. Luspatercept, sotatercept, imetelstat, or elritercept 7. Immunosuppressive therapy 8. Hematopoeitic cell transplant 9. Iron chelation if administered ≤8 weeks prior to randomization. Participants on stable doses of iron chelation therapy for ≥8 weeks are allowed Vitamin B12 or folate therapy initiated within 4 weeks prior to randomization. Participants on stable replacement doses for ≥4 weeks and without ongoing concurrent vitamin B12 or folate deficiency are allowed. 10. Androgen use within 8 weeks before randomization. Participants on stable androgen dosing for hypogonadism for ≥8 weeks are allowed 11. High-dose corticosteroid use within 4 weeks before randomization. Participants on stable chronic steroid doses of prednisone ≤10 mg/day or corticosteroid equivalent for ≥ 4 weeks are allowed. Other disease modifying treatments for autoimmune diseases may be allowed upon medical monitor review. 12. Investigational agent or any other agent intended for treatment MDS treatment 2. Diagnosed to have MDS associated with del(5q) cytogenetic abnormality or MDS unclassifiable according to WHO 2016 classification or secondary MDS. 3. Known history of diagnosis of acute myeloid leukemia (AML). 4. Anemia due to any other known cause including but not limited to thalassemia; hypothyroidism; due to iron, vitamin B12, vitamin B6, zinc, or folate deficiencies; autoimmune or hereditary hemolytic anemia; any type of known clinically significant bleeding or sequestration or drug induced anemia, hemolytic anemia, or bleeding events. 5. Clinically significant cardiovascular disease defined as: 1. New York Heart Association heart disease class III or IV 2. Fridericia corrected QT (QTcF) interval \>500 milliseconds during screening 3. Uncontrolled arrhythmia, myocardial infarction, or unstable angina within 6 months before screening 6. Known ejection fraction \<35%, confirmed by a local echocardiogram performed during screening, or a previously performed echocardiogram if collected within 6 months before screening. 7. Medical history of thromboembolic events within 6 months before screening, including history of cerebrovascular accident (including ischemic, embolic, and hemorrhagic cerebrovascular accident), transient ischemic attack, deep venous thrombosis (DVT; including proximal and distal), pulmonary or arterial embolism, arterial thrombosis or other venous thrombosis. Participants with prior superficial thrombophlebitis are allowed. 8. Uncontrolled hypertension, defined as repeated elevations of systolic blood pressure of ≥160 millimeters of mercury (mmHg) and/or diastolic blood pressure ≥100 mmHg despite adequate treatment. 9. Prior history of malignancies, other than MDS. Participants who are free of other malignant disease for ≥3 years and have completed treatment, including maintenance are allowed. Participants with a history or concurrent diagnosis of the following conditions are allowed if not requiring systemic therapy: 1. Basal or squamous cell carcinoma of the skin; 2. Carcinoma in situ of the cervix; 3. Carcinoma in situ of the breast; 4. Incidental histologic finding of prostate cancer (T1a or T1b using the tumor, node, metastasis \[TNM\] clinical staging system). 10. History of solid organ or bone marrow transplantation. 11. Active infection requiring intravenous antibiotics within 28 days or oral antibiotics within 14 days before randomization. 12. Known positive for human immunodeficiency virus (HIV), active infectious hepatitis B virus (HBV), or active infectious hepatitis C virus (HCV). Participants without known positive history of HIV, HBV, and/or HCV do not require further testing, unless testing is mandated per local guidelines. 13. Body mass index ≥ 40 kilograms per square meter (kg/m\^2). 14. Major surgery within 28 days before randomization. 15. New-onset seizures or poorly controlled seizures within 12 weeks prior to randomization are excluded from trial participation. 16. History of allergy/anaphylaxis to investigational product (including epoetin alfa) excipients (refer to the current elritercept investigator's brochure for a list of excipients) or recombination proteins. 17. History of pure red cell aplasia and/or antibody against erythropoietin (EPO). 18. Any of the following laboratory abnormalities: 1. ANC \<500/microliter (µL) (0.5×109/L). 2. Platelet count \<50,000/µL (50×109/L) or ≥450,000/µL (450×109/L). 3. Serum aspartate aminotransferase (AST) or alanine aminotransferase (ALT) ≥3× upper limit of the normal (ULN). 4. Total bilirubin ≥2×ULN. Participants with known history of Gilbert syndrome with unconjugated bilirubin \<3×ULN are allowed. Higher levels if attributed to active RBC precursor destruction within the bone marrow (ineffective erythropoiesis) may be allowed upon medical monitor review. 5. Estimated glomerular filtration rate \<30 mL/min/1.73 m\^2 as determined by the Chronic Kidney Disease Epidemiology (CKD-EPI) collaboration equation. 6. Ferritin ≤50 micrograms per liter (µg/L). 7. Folate ≤2.0 nanograms per milliliter (ng/mL). 8. Vitamin B12 ≤200 picograms per milliliter (pg/mL). 19. Ongoing participation in another interventional clinical trial. 20. Participant is unwilling or in the opinion of the investigator the participant is unable to comply with the requirements of the protocol. 21. Is a participant of childbearing potential (POCBP) but does not agree to use at least 1 form of highly effective contraception from the time of signing the ICF until at least 60 days after the last dose of trial intervention. 22. Participants of male birth who are fertile and who have partners of childbearing potential, who do not agree to use acceptable barrier contraception, that is, a male condom during the entire trial intervention period until at least 60 days after the last dose of trial intervention. 23. If applicable, participant with a positive serum pregnancy test during the screening period or known to be pregnant or a lactating participant who does not agree to forego breastfeeding during the entire trial intervention period until at least 60 days after the last dose of trial intervention. 24. For Participants in France: Persons under court protection, persons not affiliated with a social security system, and protected adults.

Conditions & Interventions

Interventions:

DRUG: Elritercept, DRUG: Epoetin Alfa

Conditions:

Conditions:
Myelodysplastic Syndrome, Anemia
Keywords:
TAK-226, Drug therapy

More Information

Contact(s): Takeda Contact - medinfoUS@takeda.com
Principal Investigator:
IRB
Number:
System ID: NCT07422480
