

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

NCT06499285

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Status	RECRUITING
Phase	Phase 3
Sponsor	Takeda
Enrollment	225 participants

## Key Eligibility Criteria

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### Inclusion (13)

- Ability to understand the purpose and risks of the study and provide signed and dated informed consent and authorization to use protected health information and/or protected personal data in accordance with national and local study participant data protections and privacy regulations.
  - Male or female greater than or equal to (e)18 years of age at the time of signing informed consent.
  - Diagnosis of MDS with or without RS (as determined in an evaluable bone marrow aspirate, read by an independent central reader to confirm diagnosis at Screening) according to the World Health Organization 2016 classification that meets the International Prognostic Scoring System-Revised (IPSS-R) classification of very low, low, or intermediate risk disease.
  - Transfusion dependence assessed in the 16 weeks immediately preceding randomization in two 8-week blocks, classified as either:
    - a. Low-transfusion burden (LTB), defined as 4 to 7 red blood cells (RBC) units per 16 weeks; or b. High-transfusion burden (HTB), defined as e8 RBC units per 16 weeks; and c. For all participants: i. Only transfusion events for a pretransfusion hemoglobin (Hgb) lesser than (<)10 grams per deciliter (g/dL) are counted toward eligibility; ii. At least 1 transfusion event in each 8-week period and a minimum of 2 transfusion events separated by e7 days within the 16-week period immediately preceding randomization; and iii. No consecutive 56-day period can be RBC transfusion-free during the 16-week period immediately preceding randomization.
- ... and 8 more (see full listing online)

### Exclusion (44)

- Del(5q) MDS or therapy-related (secondary) MDS.
  - Anemia due to any other known cause (e.g., thalassemia, hemolytic anemia, bleeding events, or deficiency of iron, B12, and/or folate).
  - Receipt of RBC transfusion for any reason(s) other than underlying MDS within 16 weeks before randomization.
  - Clinically significant cardiovascular disease defined as:
    - New York Heart Association heart disease class III or IV;
- ... and 39 more (see full listing online)

## Locations (155 total)

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City of Hope, Duarte, California, United States  
Los Angeles Cancer Network, Glendale, California, United States  
UC San Diego Moores Cancer Center, La Jolla, California, United States  
... and 152 more locations

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<https://clinicaltrials.gov/study/NCT06499285>

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