Title: **A Phase 3, Randomized, Double-blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Elritercept (KER-050) for the Treatment of Transfusion-Dependent Anemia in Adult Participants with Very Low-, Low-, or Intermediate-Risk Myelodysplastic Syndromes (MDS) (RENEW**)

Contact:

PI elena.crisa@ircc.it

Study coordinator: simone.morabito@ircc.it

Trail design : Randomization – 2:1 / elritercept:placebo.

Treatment schedule : Elritercept SC or placebo every 4 weeks

Primary objective:To evaluate the efficacy of KER-050 in reducing red blood cell (RBC) transfusions

Secondary objectives:To evaluate the efficacy of KER-050 in reducing RBC transfusions over longer intervals and/orin participants with high transfusion burden and to assess the safety and tolerability of KER-050

Inclusion criteria

- diagnosis of Very Low-, Low-, or Intermediate-Risk MDS (IPSS-R) according to WHO 2016
- transfusion-dependent anemia assessed over two 8-week periods (16 weeks) preceding randomization – with pretransfusion Hgb < 10 g/dL are counted toward eligibility
- Refractory or intolerant to prior ESA treatment (discontinued ≥8 weeks before randomization) or unlikely to respond to ESA treatment (serum EPO level > 200 U/L)
- <5% blasts in an evaluable bone marrow aspirate
- ECOG: 0-2

Exclusion criteria

- Del(5q) MDS or secondary MDS
- Prior lifetime use of TGF-β–modulating therapy, including luspatercept, sotatercept, or any investigational or commercially available TGF-β–modulating therapy
- Prior lifetime use of HMA, isocitrate dehydrogenase inhibitor, lenalidomide, imetelstat, or immune-suppressive therapy given for treatment of MDS
- Iron chelation therapy initiated within 8 weeks before randomization. Participants on stable doses of iron chelation therapy for ≥ 8 weeks are allowed.
- Serum EPO level ≥500 U/L
- Platelet count ≥ 450 × 109/L or ≤25 × 109/L
- Absolute neutrophil count ≤ 500/mL