KARTA BADANIA
NAZWA BADANIA: A Phase 2, Open-Label, Ascending Dose Study of KER-050 for the Treatment of Anemia in Patients With Very Low, Low, or Intermediate Risk Myelodysplastic Syndromes (MDS)
NUMER PROTOKOŁU: **KER050-D301**
WSKAZANIE- MDS i MF

Key Inclusion Criteria:

1. Diagnosis of MDS according to World Health Organization (WHO)/French American British (FAB) classification that meets Revised International Prognostic Scoring System (IPSS-R) classification of very low, low, or intermediate risk disease.
2. < 5% blasts in bone marrow.
3. Peripheral blood white blood cell count <13,000/µL.
4. Anemia defined as:
    1. In non-transfused participants, having received no red blood cell (RBC) transfusions within 8 weeks Hgb concentration ≤ 10.0 g/dL OR
    2. In LTB participants, having received 1 to 3 units RBCs for Hgb ≤ 9.0 g/dL within 8 weeks OR
    3. In HTB participants, having received ≥ 4 units of RBCs for Hgb ≤ 9.0 g/dL within 8 weeks
5. Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2 (if related to anemia.
6. Females of child-bearing potential and sexually active males must agree to use effective methods of contraception.

Key Exclusion Criteria:

1. Any active infection requiring parenteral antibiotic therapy within 28 days prior to Cycle 1 Day 1 or oral antibiotics within 14 days of Cycle 1 Day 1.
2. Diagnosis of secondary MDS (i.e., MDS known to have arisen as the result of chemical injury or treatment with chemotherapy and/or radiation for other diseases).
3. Vitamin B12 deficiency.
4. Prior treatment with azacitidine, decitabine, lenalidomide, luspatercept, or sotatercept.
5. Treatment within 28 days prior to Cycle 1 Day 1 with:
    1. Erythropoiesis stimulating agent (ESA) OR
    2. Granulocyte colony-stimulating factor (G-CSF) OR
    3. Granulocyte-macrophage colony-stimulating factor (GM-CSF)
6. Iron chelation therapy if initiated within 8 weeks prior to Cycle 1 Day 1.
7. Vitamin B12 therapy within 8 weeks prior to Cycle 1 Day 1.
8. Treatment with another investigational drug or device or approved therapy for investigational use < or = 28 days prior to Cycle 1 Day 1, or if the half-life of the previous product is known, within 5 times the half-life prior to Cycle 1 Day 1, whichever is longer.

9. Platelet count > 450 x 10*9/L or < 30 x 10*9/L.
10. Transferrin saturation < 15%.
11. Ferritin < 50 µg/L.
12. Folate < 4.5 nmol/L (< 2.0 ng/mL).
13. Vitamin B12 < 148 pmol/L (< 200 pg/mL).
14. Estimated glomerular filtration rate (GFR) < 40 mL/min/1.73 m2 (as determined by the Chronic Kidney Disease Epidemiology Collaboration [CKD-EPI].
15. Pregnant or lactating females