Titolo:	Studio di fase 3, in aperto, randomizzato per confrontare l'efficacia e la sicurezza di luspatercept (ACE-536) rispetto a epoetina alfa per il trattamento dell'anemia dovuta a sindrome mielodisplastica (SMD) a rischio molto basso, basso o intermedio secondo il Sistema di punteggio prognostico internazionale revisionato (IPSS-R) in partecipanti naive all'Agente Stimolante l'Eritropoiesi (ESA) Non Dipendenti da Trasfusioni (NTD)
Codice studio	CA056-025
Patologia:	Sindrome mielodisplastica
Tipo di Studio:	interventistico
Tipologia	profit
Fase:	3
Principali criteri di inclusione:	• Participant has documented diagnosis of MDS according to WHO 2016 that meets IPSS-R classification of very low, low, or intermediate-risk disease • < 5% blasts in bone marrow and < 1% blasts in peripheral blood • baseline endogenous serum erythropoietin (sEPO) level of ≤ 500 U/L. • Received no RBC transfusions within the 16 weeks prior to randomization (RBC transfusions of 1 to 2 units within the 16 weeks prior to enrollment are allowed if they are administered for an acute event/illness or presence of comorbidity) • baseline Hb concentration prior to randomization of ≤9,5 g/dl • Partecipant is erythropoiesis-stimulating agent naïve (o more than2 prior doses of epoetin alfa, epoetin alfa biosimilar, or darbepoetin alfa with the last dose al least 8 weeks prior to randomization)

Principali criteri di esclusione:	• Participant with MDS associated with del(5q) cytogenetic abnormality or MDS • unclassifiable (MDS-U) according to WHO 2016 classification • following subtypes of myelodysplastic/myeloproliferative neoplasms (MDS/MPN): chronic myelomonocytic leukemia; atypical chronic myeloid leukemia, BCR-ABL1 negative; juvenile myelomonocytic leukemia; or MDS/MPN unclassifiable (Note that MDS/MPN-RS- T is not an exclusion) • secondary MDS • Persistent hypertension with systolic blood pressure ≥ 140 mmHg or diastolic blood • pressure ≥ 90 mmHg or both, during the screening period despite adequate treatment, or with a history of hypertensive crisis or hypertensive encephalopathy
Struttura	SCDU Ematologia e Terapie Cellulari
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