CHARITÉ

Comprehensive Cancer Center
Universitätstumorzentrum

Studientitel	**LUCAS: A Phase II, open-label, Multicenter Study of Orally Administered CA-4948 for the Treatment of Anemia in Patients with Very Low, Low Intermediate 1 Risk Myelodysplastic Syndromes (MDS)**	
EudraCT-Nummer	**2020-003986-20**	
ClinicalTrials.gov Identifier	**NCT05178342**	
Sponsor	University of Leipzig	
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Wichtigste Einschlusskriterien	1. Diagnosis of de novo myelodysplastic syndrome (MDS) OR de novo myelodysplastic/myeloproliferative neoplasias (MDS/MPN) including MDS/MPN-RS-T, MDS/MPNu, aCML or CMML 2. Very low/low/intermediate risk disease: IPSS-R up to 3.5 for MDS; MDS/MPN < 10% bone marrow blasts; for CMML low or intermediate risk according to CPSS-Score 3. Symptomatic anemia (based on valid and complete hemoglobin and transfusion history): o NTD (non transfusion dependent): < 3 RBC transfusions and mean hemoglobin level <10 g/dl within the last 16 weeks o LTB (low transfusion burden): 3-7 RBC transfusions within the last 16 weeks in at least two transfusion episodes, maximum 3 in 8 weeks o HTB (high transfusion burden): ≥ 8 RBC transfusions within the last 16 weeks, ≥ 4 in 8 weeks 4. Defined transfusion strategy 5. No available option of an approved MDS therapy and classification of prior erythropoiesis-stimulating agent (ESA) treatment as follows:	

	o Cohort A: ESA exposed (and refractory or intolerant) o Cohort B: ESA naive AND serum erythropoietin level >200 U/L