CHARITÉ

Comprehensive Cancer Center
Universitätstumorzentrum

Studientitel	**STIMULUS-AML1 (CMBG453C12201): A Phase II Multi-center, Single Arm, Safety and Efficacy Study of MBG453 in Combination With Azacitidine and Venetoclax for the Treatment of Acute Myeloid Leukemia (AML) in Adult Patients Unfit for Chemotherapy**	
EudraCT-Nummer	**2019-000439-14**	
ClinicalTrials.gov Identifier	**NCT04150029**	
Sponsor	Novartis Pharmaceuticals	
Ansprechpartner*in	Prof. Dr. med. Jörg Westermann	
Kontakt Studienzentrale	An-schrift	Charité - Universitätsmedizin Berlin Campus Virchow-Klinikum Augustenburger Platz 1, 13353 Berlin
	Tel.	+49 30 450 553 141
Kontakt Cancer-Hotline	+49 30 450 564 222 Email: cccc@charite.de	
Wichtigste Einschlusskriterien	1. Signed informed consent must be obtained prior to participation in the study. 2. Age ≥ 18 years at the date of signing the informed consent form (ICF) 3. Newly diagnosed with AML based on 2016 WHO classification (Arber et al 2016) and not suitable for intensive chemotherapy defined as: age ≥75, ECOG performance Status 2 or 3, or any of the following comomorbitities: severe cardiac comorbities (including congestive heart failure, LVEF ≤ 50%, chronic stable Angina) , pulmonary comorbidity (DLCO ≤ 65% or FEVI ≤ 65%). moderate hepatic impairment (with total Bilirubin >1.5 to 3x ULN) , renal impairment (eGFR≥ 30 ml/min/1.73m^2 to 45 30 ml/min/1.73m^2), or other comorbidity incompatible with intensive chemotherapy per Investigator assessement and approved by the Novartis Medical monitor) 4. Not planned for hematopoietic stem-cell transplantation (HSCT) 5. Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1 , 2 or 3	