KURZPROTOKOLL
GS-US-590-6154

Öffentlicher Titel	Phase III Studie zu Magrolimab bei neu aufgetretener Akuter myeloische Leukämie
Wissenschaftl. Titel	A Phase 3, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of Magrolimab versus Placebo in Combination with Venetoclax and Azacitidine in Newly Diagnosed, Previously Untreated Patients with Acute Myeloid Leukemia Who Are Ineligible for Intensive Chemotherapy
Kurztitel	GS-US-590-6154
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Blut: Akute myeloische Leukämie (AML): Neu diagnostiziert / de novo
Einschlusskriterien	- Previously untreated individuals with histological confirmation of acute myeloid leukemia (AML) by World Health Organization (WHO) criteria who are ineligible for treatment with a standard cytarabine and anthracycline induction regimen due to age, or comorbidity. Individuals must be considered ineligible for intensive chemotherapy - 75 years of age; Or - 18 to 74 years of age with at least 1 of the following comorbidities: Eastern Cooperative Oncology Group (ECOG) performance status of 2 or 3 Diffusing capacity of the lung of carbon monoxide 65% or forced expiratory volume in 1 second 65% Left ventricular ejection fraction 50% Baseline creatinine clearance 30 mL/min to < 45 mL/min calculated by the Cockcroft Gault formula or measured by 24-hour urine collection Hepatic disorder with total bilirubin > 1.5 x upper limit of normal (ULN) Any other comorbidity that the investigator judges to be incompatible with intensive chemotherapy - ECOG performance status: Of 0 to 2 for individuals 75 years of age Or Of 0 to 3 for individuals 18 to 74 years of age - ndividuals with white blood cell (WBC) count 20 x 10^3/L prior to randomization. If the individual's WBC is > 20 x10^3/L prior to randomization, the individual can be enrolled, assuming all other eligibility criteria are met. However, the WBC should be 20 x 10^3/L prior to the first dose of study treatment and prior to each magrolimab/placebo dose during Cycle 1. - Hemoglobin must be 9 g/dL prior to initial dose of study treatment - Pretreatment blood cross-match completed
Ausschlusskriterien	- Prior treatment with any of the following: cluster of differentiation 47 (CD47) or signal regulatory protein alpha (SIRP)-targeting agents Antileukemic therapy for the treatment of AML (eg, hypomethylating agents (HMAs), low-dose cytarabine, and/or venetoclax), excluding hydroxyurea - Clinical suspicion of or documented active central nervous system (CNS) involvement with AML - Individuals who have acute promyelocytic leukemia - Second malignancy, except MDS, treated basal cell or localized squamous skin carcinomas, localized prostate cancer, or other malignancies for which individuals are not on active anticancer therapies and have had no evidence of active malignancy for at least 1 year
Alter	18 Jahre und älter

Prüfzentren	**Innere Medizin 2** (Rekrutierung beendet) Hämatologie / Medizinische Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Tim Strauch Tel: 069 6301 83359 Fax: 069 69 6301 4797 tim.strauch@unimedizin-ffm.de **Universitätsmedizin Frankfurt** (Rekrutierung beendet) Medizinische Klinik II, Hämatologie/Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Tim Strauch Tel: 069 6301 83359 Fax: 069 69 6301 4797 tim.strauch@unimedizin-ffm.de
Sponsor	GILEAD
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT05079230 EudraCT 2021-003434-36 (primäres Register)
Links	Zu den Ein- und Ausschlusskriterien