Kompetenznetz "Akute und chronische Leukämien"

KURZPROTOKOLL

VIALE-M

Öffentlicher Titel	Phase III Studie zu Venetoclax und Azacitidin as Erhaltungstherapie bei akuter myeloischer Leukämie
Wissenschaftl. Titel	Randomized, Open-label, 2-Arm, Multicenter, Phase 3 Study of Venetoclax and Azacitidine Versus Best Supportive Care as Maintenance Therapy for Patients with Acute Myeloid Leukemia in First Remission After Conventional Chemotherapy (VIALE-M)
Kurztitel	VIALE-M
Studiennummer KN/ELN	LN_NN_2020_715
Studiengruppe	NN
Studienphase	Phase III
Erkrankung	Akute myeloische Leukämie (AML) - AML alle außer FAB M3
Leukämiestadium	de novo/non-treated
Einschlusskriterien	- Diagnosis of newly diagnosed acute myeloid leukemia (AML) - Participant meets the following disease activity criteria: Confirmation of AML by World Health Organization (WHO) criteria (2016) and have confirmed complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following completion of planned induction and consolidation chemotherapy. Achieved first CR + CRi within 4 months of enrollment or be no more than 75 days since last dose of conventional therapy. AML has intermediate or poor risk cytogenetics per National Comprehensive Cancer Network (NCCN) 2016 criteria - Eastern Cooperative Oncology Group (ECOG) performance status <= 2 - Participant must have adequate hematologic, renal, and liver function laboratory values as described in the protocol
Ausschlusskriterien	- History of acute promyelocytic leukemia (APL)
Alter	>= 18 Jahre
Status	Aktiv
Beginn der Rekrutierung	29.10.2020
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Sponsoren	AbbVie (Hauptsponsor)
Registrierung in anderen Studienregistern	ClinicalTrials.govNCT04102020 European Clinical Trials Database - EUDRACT2019-002217-19