KURZPROTOKOLL
Elevate

Öffentlicher Titel	Phase I Studie zu Cusatuzumab bei akuter myeloischer Leukämie
Wissenschaftl. Titel	An Open-label, Multicenter, Phase 1b Study of JNJ-74494550 (Cusatuzumab; Anti-CD70 Monoclonal Antibody) in Combination With Background Therapy for the Treatment of Subjects With Acute Myeloid Leukemia
Kurztitel	Elevate
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet
Studienphase	Phase I
Erkrankung	Blut: Akute myeloische Leukämie (AML): Neu diagnostiziert / de novo
Einschlusskriterien	- Diagnosis of acute myeloid leukemia (AML) according to World Health Organization 2016 criteria . Participants with acute promyelocytic leukemia (APL) are not eligible - Must be ineligible for intensive chemotherapy - De novo or secondary AML - Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2 - Previously untreated AML except: emergency leukapheresis, hydroxyurea, and/or 1 dose 1-2 gram per meter square (g/m^2) cytarabine during the Screening Phase to control hyperleukocytosis. These treatments must be discontinued greater than or equal to (>=) 24 hours prior to start of study drug. Empiric all trans retinoic acid (ATRA) treatment for presumed acute promyelocytic leukemia (APL) is permitted but APL must be ruled out and ATRA must be discontinued >=24 hours prior to the start of study drug - Contraceptive use by men or women should be consistent with local regulations regarding the use of contraceptive methods for participants participating in clinical studies
Ausschlusskriterien	- Leukemic involvement of the central nervous system - Eligible for an allogeneic hematopoietic stem cell transplantation at study entry - Received a live, attenuated vaccine within 4 weeks prior to initiation of study drug - A history of human immunodeficiency virus (HIV) antibody positive or tests positive for HIV if tested at screening - Known allergies, hypersensitivity, or intolerance to cusatuzumab, venetoclax, azacitidine, or their excipients (example: mannitol, an excipient of azacitidine)
Alter	18 Jahre und älter
Prüfzentren	**Universitätsklinikum Frankfurt** (Geschlossen) Medizinische Klinik II, Hämatologie/Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Anja Binckebanck Tel: 069 6301-6221 Fax: 069 6301-7463 binckebanck@em.uni-frankfurt.de
Sponsor	Janssen Research & Development
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04150887 (primäres Register) EudraCT 2019-002808-41