KURZPROTOKOLL
ARO-013

Öffentlicher Titel	Phase III Studie zu Crenolanib und Salvage Chemotherapie bei rezidierter/refraktärer AML mit FLT3-Mutation
Wissenschaftl. Titel	Phase III Randomized, Double-blind, Placebo-controlled Study Investigating the Efficacy of the Addition of Crenolanib to Salvage Chemotherapy Versus Salvage Chemotherapy Alone in Subjects <= 75 Years of Age With Relapsed/Refractory FLT3 Mutated Acute Myeloid Leukemia
Kurztitel	ARO-013
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Blut: Akute myeloische Leukämie (AML): Rezidiviert/refraktär
Einschlusskriterien	- Confirmed diagnosis of AML according to World Health Organization (WHO) 2016 classification - Presence of FLT3-ITD and/or D835 mutation(s) - ubjects must be primary refractory or relapsed to 1st line intensive treatment for AML or refractory or relapsed after second line of treatment for AML - Age >= 18 years and <=75 years - Adequate hepatic function - Adequate renal functions - ECOG performance status <=3
Ausschlusskriterien	- Known clinically active central nervous system(CNS) leukemia - Severe liver disease - Known, active infection with hepatitis B virus (HBV) or hepatitis C virus (HCV) - Prior anti-leukemia therapy within the 14 days prior to randomization. Prior use of quizartinib or gilteritinib must be discontinued 21 days prior to randomization. Prior use of hydroxyurea or other palliative treatment for leukocytosis is allowed - Previous treatment with crenolanib or prior participation in clinical trial involving crenolanib
Alter	18 - 75 Jahre
Molekularer Marker	FLT3
Sponsor	Arog Pharmaceuticals, Inc.
Registrierung in anderen Studienregistern	EudraCT 2017-001600-29 ClinicalTrials.gov NCT03250338 (primäres Register)