

<b>Öffentlicher Titel</b>	Phase I/II Studie zu Olutasidenib bei myeloischen Krebserkrankungen mit IDH1-Mutation
<b>Wissenschaftl. Titel</b>	A Phase 1/2, Multicenter, Open-label Study of FT-2102 as a Single Agent and in Combination with Azacitidine or Cytarabine in Patients with Acute Myeloid Leukemia or Myelodysplastic Syndrome with an IDH1 Mutation
<b>Kurztitel</b>	FORMA 2102
<b>Studennummer KN/ELN</b>	LN_NN_2019_694
<b>Studiengruppe</b>	NN
<b>Studienart</b>	multizentrisch, einarmig, offen
<b>Studienphase</b>	Phase II
<b>Erkrankung</b>	Myelodysplastisches Syndrom (MDS) - Intermediär II und Hochrisiko Akute myeloische Leukämie (AML) - AML alle außer FAB M3
<b>Leukämiestadium</b>	de novo/non-treated rezidiert/refraktär
<b>Molekularer Marker</b>	IDH1
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"> <li>- Pathologically proven acute myeloid leukemia (AML) (except acute promyelocytic leukemia [APL] with the t(15;17) translocation) or intermediate, high-risk, or very high risk Myelodysplastic Syndrome (MDS) as defined by the World Health Organization (WHO) criteria or Revised International Prognostic Scoring System (IPSS-R) which is relapsed or refractory (R/R) to standard therapy and/or for which standard therapy is contraindicated or which has not adequately responded to standard therapy</li> <li>- Patients must have documented IDH1-R132 gene-mutated disease as evaluated by the site</li> <li>- Good performance status</li> <li>- Good kidney and liver function</li> </ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"> <li>- Patients with symptomatic central nervous system (CNS) metastases or other tumor location (such as spinal cord compression, other compressive mass, uncontrolled painful lesion, bone fracture, etc.) necessitating an urgent therapeutic intervention, palliative care, surgery or radiation therapy</li> <li>- Congestive heart failure (New York Heart Association Class III or IV) or unstable angina pectoris. Previous history of myocardial infarction within 1 year prior to study entry, uncontrolled hypertension or uncontrolled arrhythmias</li> <li>- Pulmonary disease (e.g. COPD, asthma, etc) that is not controlled (moderate to severe symptoms) with current medication</li> <li>- Active, uncontrolled bacterial, viral, or fungal infections, requiring systemic therapy</li> </ul>
<b>Alter</b>	>= 18 Jahre
<b>Status</b>	Aktiv
<b>Beginn der Rekrutierung</b>	22.11.2019
<b>Sponsoren</b>	Forma Therapeutics, Inc.
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.govNCT02719574 European Clinical Trials Database - EUDRACT2017-001051-32