

**KURZPROTOKOLL**  
**FORMA 2102**

<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>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig
<b>Studienphase</b>	Phase II
<b>Erkrankung</b>	Blut: Myeloische Neoplasien/Dysplasien: Myelodysplastische Syndrome (MDS) Blut: Akute myeloische Leukämie (AML): Neu diagnostiziert / de novo
<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 und älter
<b>Molekularer Marker</b>	IDH1
<b>Prüfzentren</b>	<b>Universitätsklinikum Gießen und Marburg, Standort Marburg</b> (Geschlossen) Hämatologie, Onkologie und Immunologie Baldingerstraße 35043 Marburg Nina Marschalek Tel: 06421 58 63546 Fax: 06421 58 62703 <a href="mailto:studien-onkologie@uni-marburg.de">studien-onkologie@uni-marburg.de</a>
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<b>Registrierung in anderen Studienregistern</b>	EudraCT 2017-001051-32 ClinicalTrials.gov NCT02719574 (primäres Register)