KURZPROTOKOLL
FORMA 2102

Öffentlicher Titel	Phase I/II Studie zu Olutasidenib bei myeloischen Krebserkrankungen mit IDH1-Mutation
Wissenschaftl. Titel	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
Kurztitel	FORMA 2102
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig
Studienphase	Phase II
Erkrankung	Blut: Myeloische Neoplasien/Dysplasien: Myelodysplastische Syndrome (MDS) Blut: Akute myeloische Leukämie (AML): Neu diagnostiziert / de novo
Einschlusskriterien	- 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 - Patients must have documented IDH1-R132 gene-mutated disease as evaluated by the site - Good performance status - Good kidney and liver function
Ausschlusskriterien	- 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 - 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 - Pulmonary disease (e.g. COPD, asthma, etc) that is not controlled (moderate to severe symptoms) with current medication - Active, uncontrolled bacterial, viral, or fungal infections, requiring systemic therapy
Alter	18 Jahre und älter
Molekularer Marker	IDH1
Prüfzentren	**Universitätsklinikum Gießen und Marburg, Standort Marburg** (Geschlossen) Hämatologie, Onkologie und Immunologie Baldingerstraße 35043 Marburg Nina Marschalek Tel: 06421 58 63546 Fax: 06421 58 62703 studien-onkologie@uni-marburg.de
Sponsor	FORMA Therapeutics, Inc.
Registrierung in anderen Studienregistern	EudraCT 2017-001051-32 ClinicalTrials.gov NCT02719574 (primäres Register)