

## **KURZPROTOKOLL** **BGBC003**

<b>Öffentlicher Titel</b>	Phase I/II Studie zu BGB324, Cytarabin und Decitabin bei Patienten mit AML und MDS
<b>Wissenschaftl. Titel</b>	A Phase Ib/II Multicenter Open-label Study of BGB324 as a Single Agent and in Combination With Cytarabine or Decitabine in Patients With Acute Myeloid Leukemia or as a Single Agent in Patients With Myelodysplastic Syndrome
<b>Kurztitel</b>	BGBC003
<b>Studienart</b>	prospektiv, Therapiestudie, offen/unverblindet, Pharma-Studie, mehrarmig
<b>Studienphase</b>	Phase I/II
<b>Erkrankung</b>	Blut: Myeloische Neoplasien/Dysplasien: Myelodysplastische Syndrome (MDS) Blut: Akute myeloische Leukämie (AML): Neu diagnostiziert / de novo Blut: Akute myeloische Leukämie (AML): Rezidiert/refraktär
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Provision of signed written informed consent</li><li>- Histological, molecular or cytological confirmation of: (I.) AML (with the exception of AML M3), patients with relapsed or refractory AML following treatment with cytotoxic chemotherapy or a targeted or biologic agent; (II.) high risk group MDS, according to IPSS Risk Stratification (Norway Only)</li><li>- Histological, molecular or cytological confirmation of: (I.) AML (with the exception of AML M3); (II.) AML unsuitable for intensive chemotherapy; (III.) newly diagnosed AML unsuitable for intensive chemotherapy; (IV.) MDS: a.) high/intermediate (int-2) risk group MDS, according to IPSS Risk Stratification (Norway Only); b.) patients with previously treated MDS (with the exception of deletion 5q MDS) (US only)</li><li>- Age 18 years or older</li><li>- Female patients of childbearing potential must have a negative serum pregnancy test within 3 days prior to taking their first dose of BGB324. Male patients and female patients of reproductive potential must practice highly methods of contraception throughout the study and for =&gt; 3 months after the last dose of BGB324.</li><li>- Eastern Cooperative Oncology Group (ECOG) performance status 0, 1 or 2</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Patients who have a matched donor and are candidates for allogeneic bone marrow transplantation</li><li>- Pregnant or lactating</li><li>- Abnormal left ventricular ejection fraction (less than the lower limit of normal for a patient of that age at the treating institution or &lt;45%, whichever is lower).</li><li>- Congestive cardiac failure of &gt;Grade 2 severity according to the NYHA defined as symptomatic at less than ordinary levels of activity</li><li>- Unstable cardiac disease, including unstable angina or unstable hypertension, or need to change medication within 6 weeks of provision of consent due to lack of disease control</li><li>- Ischemic cardiac event including myocardial infarction within 3 months prior to first dose</li><li>- Current treatment with any agent known to cause Torsades de Pointes which cannot be discontinued at least five half-lives or two weeks prior to the first dose of study treatment.</li><li>- Treatment with any of the following; histamine receptor 2 inhibitors, proton pump inhibitors or antacids within 3 days or 5 half-lives of administration of BGB234, whichever is longer.</li><li>- Radiotherapy or chemotherapy within the 14 days prior to the first dose of BGB324 being administered (other than hydroxyurea)</li><li>- Active, uncontrolled central nervous system (CNS) disease including CNS leukemia</li><li>- Major surgery within 28 days prior to the start of BGB324 - excluding skin biopsies and procedures for insertion of central venous access devices</li><li>- Prior exposure to Astellas ASP2215.</li></ul>

**KURZPROTOKOLL**  
**BGBC003**

- Unresolved CTCAE >Grade 2 toxicity (other than stable toxicity) from previous anti-cancer therapy excluding alopecia.

<b>Alter</b>	18 Jahre und älter
<b>Prüfzentren</b>	<b>Universitätsklinikum Frankfurt</b> (Geschlossen) Medizinische Klinik II, Hämatologie/Onkologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Silvia Koss Tel: 069 6301-80429 Fax: 069 6301-83655 <a href="mailto:silvia.koss@kgu.de">silvia.koss@kgu.de</a>
<b>Sponsor</b>	BerGenBio AS (Hauptsponsor)
<b>Förderer</b>	BerGenBio AS
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT02488408 EudraCT 2014-000165-46
<b>Links</b>	<a href="#">Studiendokumente zum Download (roXtra)</a>