# *KURZPROTOKOLL*
# *BGBC003*

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| **Öffentlicher Titel** | Phase I/II Studie zu BGB324, Cytarabin und Decitabin bei Patienten mit AML und MDS |
| **Wissenschaftl. Titel** | 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 |
| **Kurztitel** | BGBC003 |
| **Studienart** | prospektiv, Therapiestudie, offen/unverblindet, Pharma-Studie, mehrarmig |
| **Studienphase** | Phase I/II |
| **Erkrankung** | Blut: Myeloische Neoplasien/Dysplasien: Myelodysplastische Syndrome (MDS)<br>Blut: Akute myeloische Leukämie (AML): Neu diagnostiziert / de novo<br>Blut: Akute myeloische Leukämie (AML): Rezidiviert/refraktär |

**Einschlusskriterien**

- Provision of signed written informed consent
- 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)
- 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)
- Age 18 years or older
- 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 => 3 months after the last dose of BGB324.
- Eastern Cooperative Oncology Group (ECOG) performance status 0, 1 or 2

**Ausschlusskriterien**

- Patients who have a matched donor and are candidates for allogeneic bone marrow transplantation
- Pregnant or lactating
- Abnormal left ventricular ejection fraction (less than the lower limit of normal for a patient of that age at the treating institution or <45%, whichever is lower).
- Congestive cardiac failure of >Grade 2 severity according to the NYHA defined as symptomatic at less than ordinary levels of activity
- 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
- Ischemic cardiac event including myocardial infarction within 3 months prior to first dose
- 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.
- 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.
- Radiotherapy or chemotherapy within the 14 days prior to the first dose of BGB324 being administered (other than hydroxyurea)
- Active, uncontrolled central nervous system (CNS) disease including CNS leukemia
- Major surgery within 28 days prior to the start of BGB324 - excluding skin biopsies and procedures for insertion of central venous access devices
- Prior exposure to Astellas ASP2215.

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| | - Unresolved CTCAE >Grade 2 toxicity (other than stable toxicity) from previous anti-cancer therapy excluding alopecia. |
| **Alter** | 18 Jahre und älter |
| **Prüfzentren** | **Innere Medizin 2** (Geschlossen)<br>Hämatologie / Medizinische Onkologie<br>Theodor-Stern-Kai 7<br>60590 Frankfurt am Main<br>Silvia Koss<br>Tel: 069 6301-80429<br>Fax: 069 6301-83655<br>silvia.koss@kgu.de<br><br>**Universitätsklinikum Frankfurt** (Geschlossen)<br>Medizinische Klinik II, Hämatologie/Onkologie<br>Theodor-Stern-Kai 7<br>60590 Frankfurt am Main<br>Silvia Koss<br>Tel: 069 6301-80429<br>Fax: 069 6301-83655<br>silvia.koss@kgu.de |
| **Sponsor** | BerGenBio AS (Hauptsponsor) |
| **Förderer** | BerGenBio AS |
| **Registrierung in anderen Studienregistern** | ClinicalTrials.gov NCT02488408<br>EudraCT 2014-000165-46 |
| **Links** | Studiendokumente zum Download (roXtra) |