# Kompetenznetz "Akute und chronische Leukämien"

***KURZPROTOKOLL***

***FAsciNation***

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| **Öffentlicher Titel** | Phase II Studie zu Asciminib bei CML in chronischer Phase |
| **Wissenschaftl. Titel** | Frontline Asciminib Combination in Chronic Phase CML |
| **Kurztitel** | FAsciNation |
| **Studiennummer KN/ELN** | LN_CMLSTU_2019_653 |
| **Studiengruppe** | CML-Studiengruppe |
| **Studienphase** | Phase II |
| **Erkrankung** | Chronische myeloische Leukämie (CML) - Chronische Phase |
| **Molekularer Marker** | BCR-ABL |
| **Einschlusskriterien** | - Male or female patients with diagnosis of CP-CML with cytogenetic confirmation of the Ph+ chromosome [t(9;22)(q34;q11)].<br>- Ph-negative cases or patients with variant translocations who are BCR-ABL1 positive in multiplex PCR 35 will be also considered eligible.<br>- ECOG performance status of <=2.<br>- Age >= 18 years old (no upper age limit is given)<br>- Serum levels of potassium, magnesium, total calcium within the normal limits (>=LLN [lower limit of normal] and <=ULN [upper limit of normal]). Correction of electrolytes levels with supplements to fulfil enrolment criteria is allowed.<br>- AST and ALT <=2.5 x ULN or 5.0 x ULN if considered due to leukemia<br>- Alkaline phosphatase <=2.5 x ULN unless considered due to leukemia<br>- Total bilirubin <=1.5 x ULN, except known Gilbert disease<br>- Serum creatinine <=2 x ULN<br>- Written informed consent prior to any study procedures being performed |
| **Ausschlusskriterien** | - Allogeneic stem cell transplantation<br>- Known impaired cardiac function, including any of the following:<br>- 1. Congenital long QT syndrome<br>- 2. History of or presence of clinically significant ventricular or atrial tachyarrhythmia<br>- 3. QTc >450 msec on screening ECG<br>- 4. Myocardial infarction within 12 months prior to starting therapy<br>- Other clinical significant heart disease (e.g. unstable angina, congestive heart failure)<br>- Acute or chronic viral hepatitis with moderate or severe hepatic impairment (Child-Pugh scores >6), even if controlled<br>- Other concurrent uncontrolled medical conditions (e.g., active or uncontrolled infections, acute or chronic liver and renal disease) that could cause unacceptable safety risks or compromise compliance with the protocol<br>- Impaired gastrointestinal function or disease that may alter the absorption of study drug (e.g., ulcerative disease, uncontrolled nausea, vomiting and diarrhea, malabsorption syndrome, small bowel resection or gastric by-pass surgery)<br>- Concomitant medications known to be strong inducers or inhibitors of the CYP450 isoenzyme CYP3A4<br>- Patients who have undergone major surgery <=2 weeks prior to starting study drug or who have not recovered from side effects of such therapy |

- Patients who are pregnant or breastfeeding or women of reproductive potential not employing an effective method of birth control. Women of childbearing potential must have a negative serum pregnancy test within 14 days of study start. Post-menopausal women must be amenorrheic for at least 12 months in order to be considered of non-childbearing potential. Male and female patients must agree to employ an effective method of birth control throughout the study and for up to 2 weeks following discontinuation of study drug
- Known diagnosis of human immunodeficiency virus (HIV) infection (HIV testing is not mandatory)
- Known serious hypersensitivity reactions to asciminib, imatinib, nilotinib or dasatinib
- Patients with a history of another primary malignancy that is currently clinically significant or currently requires active intervention
- Patients unwilling or unable to comply with the protocol

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| **Alter** | >= 18 Jahre |
| **Status** | Aktiv |
| **Beginn der Rekrutierung** | 10.10.2019 |
| **Studienleiter/in** | Ernst, PD Dr. med. habil., Thomas<br>Hämatologisch-onkologisches Forschungslabor der Klinik für Innere Medizin II des Universitätsklinikum Jena<br>Tel: +49 (0)3641 9324563<br>Fax: +49 (0)3641 9325827<br>E-Mail: thomas.ernst@med.uni-jena.de<br>Homepage: http://www.kim2.uniklinikum-jena.de/KIM+II/H%C3%A4matologie+und+Internistische+Onkologie/Forschung/Forschungsgruppen/Molekulare+Diagnostik+und+Biobank.html |
| **Sponsoren** | Friedrich-Schiller-Universität Jena |
| **Förderer** | Novartis Pharma AG<br>Homepage: www.novartispharma.de/index.shtml |
| **Registrierung in anderen Studienregistern** | ClinicalTrials.govNCT03906292 (primäres Register)<br>European Clinical Trials Database - EUDRACT2018-002256-33 |