CHARITÉ

Comprehensive Cancer Center
Universitätstumorzentrum

Studientitel	**CABL001J12301: A phase III, multi-center, open-label, randomized study of oral asciminib versus Investigator selected TKI in patients with newly diagnosed Philadelphia Chromosome Positive Chronic Myelogenous Leukemia in Chronic Phase**	
EudraCT-Nummer	**2021-000678-27**	
ClinicalTrials.gov Identifier	**NCT04971226**	
Sponsor	Novartis Pharmaceuticals	
Ansprechpartner*in	Prof. Dr. med. Philipp le Coutre	
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Wichtigste Einschlusskriterien	• Participants eligible for inclusion in this study must meet all of the following criteria: 1. Male or female patients ≥ 18 years of age. 2. Participants with CML-CP within 3 months of diagnosis. 3. Diagnosis of CML-CP (ELN 2020 criteria) with cytogenetic confirmation of Philadelphia chromosome • Documented chronic phase CML will meet all the below criteria (Hochhaus et al 2020): o < 15% blasts in peripheral blood and bone marrow, o < 30% blasts plus promyelocytes in peripheral blood and bone marrow, o < 20% basophils in the peripheral blood, o Platelet count ≥ 100 x 109/L (≥ 100,000/mm3), o No evidence of extramedullary leukemic involvement, with the exception of hepatosplenomegaly.	

	4. Eastern Cooperative Oncology Group (ECOG) performance status of 0,or 1. 5. Adequate end organ function as defined by: o Total bilirubin < 3 x ULN; patients with Gilbert's syndrome may only be included if total bilirubin ≤ 3.0 x ULN or direct bilirubin ≤ 1.5 x ULN o Creatinine clearance (CrCl) ≥ 30 mL/min as calculated using Cockcroft-Gault formula, o Serum lipase ≤ 1.5 x ULN. For serum lipase > ULN - ≤ 1.5 x ULN, value must be considered not clinically significant and not associated with risk factors for acute pancreatitis 6. Participants must have the following laboratory values within normal limits or corrected to within normal limits with supplements prior to randomization: o Potassium (potassium increase of up to 6.0 mmol/L is acceptable if associated with CrCl* ≥ 90 mL/min) o Total calcium (corrected for serum albumin); (calcium increase of up to 12.5 mg/dl or 3.1 mmol/L is acceptable if associated with CrCl* ≥ 90 mL/min) o Magnesium (magnesium increase of up to 3.0 mg/dL or 1.23 mmol/L if associated with CrCl* ≥ 90 mL/min) o For patients with mild to moderate renal impairment (CrCl* ≥ 30 mL/min and <90 mL/min) - potassium, total calcium (corrected for serum albumin) and magnesium should be ≥ LLN or corrected to within normal limits with supplements prior to randomization. o *CrCl as calculated using Cockcroft-Gault formula 7. Ability to provide written informed consent prior to any study related screening procedures being performed. 8. Evidence of typical BCR-ABL1 transcript [e14a2 and/or e13a2] at the time of screening which is amenable to standardized Real time quantitative polymerase chain reaction (RQ-PCR) quantification.