CHARITÉ

Comprehensive Cancer Center
Universitätstumorzentrum

Studientitel	**CABL001A2302: A Phase 3b, Multi-center, Open-label, Treatment Optimization Study of Oral Asciminib in Patients With Chronic Myelogenous Leukemia in Chronic Phase (CML-CP) Previously Treated With 2 or More Tyrosine Kinase Inhibitors.**	
EudraCT-Nummer	**2020-006057-21**	
ClinicalTrials.gov Identifier	**NCT04948333**	
Sponsor	Novartis Pharmaceuticals	
Ansprechpartner*in	Prof. Dr. med. Philipp le Coutre	
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Wichtigste Einschlusskriterien	Male or female patients with a diagnosis of CML-CP ≥ 18 years of age Patients must meet all the following laboratory values at the screening visit: • < 15% blasts in peripheral blood and bone marrow • < 30% blasts plus promyelocytes in peripheral blood and bone marrow • < 20% basophils in the peripheral blood • ≥ 50 x 109/L (≥ 50,000/mm3) platelets • Transient prior therapy related thrombocytopenia (< 50,000/mm3 for ≤ 30 days prior to screening) is acceptable • No evidence of extramedullary leukemic involvement, with the exception of hepatosplenomegaly Prior treatment with a minimum of 2 prior TKIs (i.e. imatinib, nilotinib, dasatinib, bosutinib, radotinib or ponatinib) Warning or failure (adapted from the 2020 ELN Recommendations) or intolerance to the most recent TKI therapy at the time of screening • Warning is defined as:	

	o Three months after the initiation of treatment: BCR-ABL1 > 10% IS o Six months after the initiation of treatment: BCR-ABL1 >1-10% IS o Twelve months after the initiation of treatment BCR-ABL1>0,1-1% IS o At any time after the initiation of therapy BCR-ABL1 >0.1-1% IS, loss of MMR (>0.1% with 5-fold increase of BCR-ABL1 transcripts). • In addition, patients with failure of treatment according to the ELN 2020 recommendations will be eligible: o Three months after the initiation of treatment: BCR-ABL1 > 10% IS if confirmed within 1-3 months o Six months after the initiation of treatment: BCR-ABL1 >10% IS o Twelve months after the initiation of treatment BCR-ABL1 >1% IS o At any time after the initiation of therapy BCR-ABL1 >1% IS, emergence of resistance mutations, high-risk ACA • Intolerance is defined as: o Non-hematologic intolerance: Patients with grade 3 or 4 toxicity while on therapy, or with persistent grade 2 toxicity, unresponsive to optimal management, including dose adjustments (unless dose reduction is not considered in the best interest of the patient if response is already suboptimal) o Hematologic intolerance: Patients with grade 3 or 4 toxicity (absolute neutrophil count [ANC] or platelets) while on therapy that is recurrent after dose reduction to the lowest doses recommended by manufacturer