KURZPROTOKOLL
Caborise

Öffentlicher Titel	Phase II Studie zu Cabozantinib als Zweitlinientherapie bei Leberkrebs und kompensierter Leberzirrhose
Wissenschaftl. Titel	A phase II study evaluating reduced starting dose and dose escalation of Cabozantinib as second-line therapy for advanced HCC in patients with compensated liver cirrhosis
Kurztitel	Caborise
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, zweiarmig, Investigator Initiated Trial (IIT), einfach verblindet
Studienphase	Phase II
Erkrankung	Verdauung: Leberkrebs (Hepatozelluläres Karzinom): Zweitlinie oder höher
Einschlusskriterien	- Fully-informed written consent - Males and females >= 18 years of age. *There are no data that indicate special gender distribution. Therefore, patients will be enrolled in the study gender-independently. - Patients with HCC who have been previously treated with any first line therapy - Locally advanced or metastatic and/or unresectable HCC with diagnosis confirmed by histology/cytology or clinically by guideline criteria in cirrhotic patients - Disease that is not amenable to curative surgical and/or locoregional therapies, or progressive disease after surgical and/or locoregional therapies - ECOG performance status <= 2 - Resolution of any acute, clinically significant treatment-related toxicity from prior therapy to Grade 1 prior to study entry, with the exception of alopecia - For women of childbearing potential (WOCBP): agreement to remain abstinent (refrain from heterosexual intercourse) or use highly effective contraceptive methods from the time of signing the informed consent through at least 4 months after the last dose of study drug, or agree to completely abstain from heterosexual intercourse. Male patients, even if surgically sterilized (i.e. status post-vasectomy) must agree to practice effective barrier contraception (e.g. condom) and to refrain from sperm donation during the entire study treatment period and through at least 4 months after the last dose of study drug or agree to completely abstain from heterosexual intercourse - Women of childbearing potential must have a negative serum pregnancy test result within 14 days prior to initiation of study treatment
Ausschlusskriterien	- Pregnancy or breastfeeding, or intention of becoming pregnant during study treatment or within at least 4 months - Significant portal hypertension (moderate or severe ascites). Significant hypertension, defined as blood pressure >= 140 mmHg (systolic) or >= 90 mmHg (diastolic) in repeated measurements - Known fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC - Patients with impaired liver function defined as Child-Pugh B or C, if liver cirrhosis is present - Severely impaired kidney function (defined as creatinine > 2 mg/dl and/or creatinine clearance < 45 mL/min) - Elevations of AST/ALT > 5 x ULN at baseline - Presence of encephalopathy in past 12 months - Significant cardiovascular disease (such as NYHA Class II or greater cardiac disease, myocardial infarction, or cerebrovascular accident) within 3 months prior to initiation of study treatment, unstable arrhythmia, or unstable angina - Baseline QTcF > 500 ms

	- Major surgical procedure, other than for diagnosis, within 4 weeks prior to initiation of study treatment, or anticipation of need for a major surgical procedure during the study - Severe infection within 4 weeks prior to initiation of study treatment, including, but not limited to, hospitalization for complications of infection, bacteremia, or severe pneumonia - Any other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding that contraindicates the use of an investigational drug, may affect the interpretation of the results, or may render the patient at high risk from treatment complications - Treatment with investigational systemic therapy within 28 days or five times the elimination half-life of the investigational product, whichever is longer, prior to initiation of study treatment - Prior cabozantinib use - Known or suspected hypersensitivity to cabozantinib or any other excipients of the IMP - Rare hereditary galactose intolerance, total lactase deficiency or glucose-galactose malabsorption - Is currently participating in or has participated in a study of an investigational agent or has used an investigational device within 4 weeks prior to the first dose of study treatment - Patient who has been incarcerated or involuntarily institutionalized by court order or by the authorities § 40 Abs. 1 S. 3 Nr. 4 AMG - Patients who are unable to consent because they do not understand the nature, significance and implications of the clinical trial and therefore cannot form a rational intention in the light of the facts [§ 40 Abs. 1 S. 3 Nr. 3a AMG]
Alter	18 Jahre und älter
Prüfzentren	**Innere Medizin 1** (Nachbeobachtung) Gastroenterologie / Hepatologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Laura Gesell Tel: 069 6301-87769 Laura.Gesell@unimedizin-ffm.de
Förderer	Ipsen Pharma
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04522908 EudraCT 2020-000775-20 (primäres Register)
Links	Weiterführende Informationen