# *KURZPROTOKOLL*
# *MK 7902-002 HCC*

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| **Öffentlicher Titel** | Phase III Studie zu Lenvatinib als Erstlinientherapie bei fortgeschrittenem Leberkrebs |
| **Wissenschaftl. Titel** | Phase 3 Multicenter, Randomized, Double-blinded, Active-controlled, Clinical Study to Evaluate the Safety and Efficacy of Lenvatinib (E7080/MK-7902) in Combination With Pembrolizumab (MK-3475) Versus Lenvatinib in First-line Therapy of Participants With Advanced Hepatocellular Carcinoma (LEAP-002) |
| **Kurztitel** | MK 7902-002 HCC |
| **Studienart** | multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig |
| **Studienphase** | Phase III |
| **Erkrankung** | Verdauung: Leberkrebs (Hepatozelluläres Karzinom): Erstlinie |
| **Einschlusskriterien** | - Is male or female and >=18 years of age at the time of signing the informed consent<br>- Has a diagnosis of hepatocellular carcinoma confirmed by radiology, histology, or cytology<br>- Has Barcelona Clinic Liver Cancer (BCLC) Stage C disease, or BCLC Stage B disease not amenable to locoregional therapy or refractory to locoregional therapy, and not amenable to a curative treatment approach<br>- Has a Child-Pugh class A liver score<br>- Has a predicted life expectancy of >3 months<br>- Has at least one measurable lesion based on RECIST 1.1 as confirmed by BICR<br>- Has an Eastern Cooperative Oncology Group (ECOG) performance status (PS) of 0 to 1<br>- Participants with hepatitis B will be eligible as long as their virus is well controlled |
| **Ausschlusskriterien** | - Has had esophageal or gastric variceal bleeding within the last 6 months<br>- Has gastrointestinal malabsorption, gastrointestinal anastomosis, or any other condition that might affect the absorption of lenvatinib<br>- Has a preexisting Grade >=3 gastrointestinal or non-gastrointestinal fistula<br>- Has clinically significant hemoptysis from any source or tumor bleeding within 2 weeks prior to the first dose of study intervention<br>- Has significant cardiovascular impairment within 12 months of the first dose of study intervention such as history of congestive heart failure greater than New York Heart Association (NYHA) Class II, unstable angina, myocardial infarction or cerebrovascular accident stroke, or cardiac arrhythmia associated with hemodynamic instability<br>- Has had major surgery to the liver within 4 weeks prior to the first dose of study intervention<br>- Has had a minor surgery (ie, simple excision) within 7 days prior to the first dose of study intervention<br>- Has serious non-healing wound, ulcer, or bone fracture<br>- Has received any systemic chemotherapy for HCC or chemotherapy for any malignancy in the past 3 years<br>- Has received prior therapy with an anti-programmed cell death 1 (ant-PD-1), anti-programmed cell death ligand 1 (anti-PD-L1), or anti- programmed cell death ligand 2 (anti-PD-L2) agent or with an agent directed to another stimulatory or co-inhibitory T-cell receptor (eg, cytotoxic T-lymphocyte-associated protein 4 [CTLA-4], OX-40, or CD137)<br>- Has a diagnosis of immunodeficiency or is receiving chronic systemic steroid therapy or any other form of immunosuppressive therapy within 7 days prior the first dose of study intervention |

- Has a known additional malignancy that is progressing or has required active treatment within the past 3 years with the exceptions of basal cell carcinoma of the skin, squamous cell carcinoma of the skin, or carcinoma in situ (eg, breast carcinoma, cervical cancer in situ) that has undergone potentially curative therapy
- Has a known history of, or any evidence of, central nervous system (CNS) metastases and/or carcinomatous meningitis as assessed by local site investigator
- Has severe hypersensitivity (>=Grade 3) to study intervention and/or any of their excipients
- Has an active autoimmune disease that has required systemic treatment in past 2 years
- Has a history of (non-infectious) pneumonitis that required steroids or has current pneumonitis
- Has urine protein >=1 grams/24 hours
- Prolongation of corrected QT (QTc) interval to >480 milliseconds (corrected by Fridericia Formula)
- Has left ventricular ejection fraction (LVEF) below the institutional normal range as determined by multigated acquisition scan (MUGA) or echocardiogram (ECHO)
- Has an active infection requiring systemic therapy with the exceptions of HBV or HCV
- Has a known history of human immunodeficiency virus (HIV) infection
- Has a known history of active tuberculosis (Bacillus tuberculosis)
- Has a history or current evidence of any condition, therapy, or laboratory abnormality that might confound the results of the study, interfere with the participant's participation for the full duration of the study, or is not in the best interest of the participant to participate, in the opinion of the treating investigator
- Has a known psychiatric or substance abuse disorder that would interfere with the participant's ability to cooperate with the requirements of the study
- Is pregnant or breastfeeding or expecting to conceive or father children within the projected duration of the study, starting with the screening visit through 120 days after the last dose of study intervention
- Has had an allogenic tissue/solid organ transplant

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| **Alter** | 18 Jahre und älter |
| **Prüfzentren** | **Universitätsklinikum Frankfurt** (Nachbeobachtung)<br>Medizinische Klinik I, Gastroenterologie/Hepatologie<br>Theodor-Stern-Kai 7<br>60590 Frankfurt am Main<br>Lisa Weiss<br>Tel: 069 6301-87769<br>Fax: 069 6301-6580<br>Lisa.Weiss@kgu.de |
| **Sponsor** | MSD Sharp & Dohme |
| **Registrierung in anderen Studienregistern** | ClinicalTrials.gov NCT03713593 (primäres Register)<br>EudraCT 2018-002983-26 |