KURZPROTOKOLL
WO41535 IMbrave050

Öffentlicher Titel	Phase III Studie zu Atezolizumab Plus Bevacizumab als adjuvante Therapie bei Leberzellkrebs
Wissenschaftl. Titel	A Phase III, Multicenter, Randomized, Open-Label Study of Atezolizumab (Anti-PD-L1 Antibody) Plus Bevacizumab Versus Active Surveillance as Adjuvant Therapy in Patients With Hepatocellular Carcinoma at High Risk of Recurrence After Surgical Resection or Ablation
Kurztitel	WO41535 IMbrave050
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Verdauung: Leberkrebs (Hepatozelluläres Karzinom): adjuvant
Einschlusskriterien	- Participants with a first diagnosis of HCC who have undergone a curative resection or ablation (radiofrequency ablation [RFA] or microwave ablation [MVA] only) - Documented diagnosis of HCC that has been completely resected or ablated (RFA or MVA only) - Absence of major macrovascular invasion (except Vp1/Vp2) and extrahepatic spread - Full recovery from surgical resection or ablation within 4 weeks prior to randomization - High risk for HCC recurrence after resection or ablation - For patients who received post-operative transarterial chemoembolization: full recovery from the procedure within 4 weeks prior to randomization - For patients with resected HCC, availability of a representative baseline tumor tissue sample - ECOG Performance Status of 0 or 1 - Child-Pugh Class A status - Adequate hematologic and end-organ function - For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods - For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agreement to refrain from donating sperm
Ausschlusskriterien	- Known fibrolamellar HCC, sarcomatoid HCC, or mixed cholangiocarcinoma and HCC - Recurrent HCC prior to randomization - Evidence of residual, recurrent, or metastatic disease at randomization - Clinically significant ascites - History of hepatic encephalopathy - Prior bleeding event due to untreated or incompletely treated esophageal and/or gastric varices within 6 months prior to randomization - Have received more than 1 cycle of adjuvant TACE following surgical resection - Active or history of autoimmune disease or immune deficiency - History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, or idiopathic pneumonitis, or evidence of active pneumonitis on screening chest CT scan - Significant cardiovascular disease within 3 months prior to Day 1 of Cycle 1, unstable arrhythmia, or unstable angina - History of malignancy other than HCC within 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death - Active tuberculosis

- 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
- Pregnant or breastfeeding, or intending to become pregnant during the study or within 5 months after the final dose of atezolizumab or within 6 months after the final dose of bevacizumab. Women of childbearing potential must have a negative serum pregnancy test result within 14 days prior to Day 1 of Cycle 1
- Co-infection with HBV and HCV
- Uncontrolled or symptomatic hypercalcemia
- Any treatment for HCC prior to resection or ablation, including systemic therapy and locoregional therapy such as TACE
- Treatment with systemic immunostimulatory or immunosuppressive agents
- Inadequately controlled arterial hypertension
- History of hypertensive crisis or hypertensive encephalopathy
- Significant vascular disease
- Evidence of bleeding diathesis or significant coagulopathy
- Current or recent use of aspirin or full-dose oral or parenteral anticoagulants
- Core biopsy within 3 days of Day 1 of Cycle 1
- History of abdominal or tracheoesophageal fistula, GI perforation, or intra-abdominal abscess
- Serious non-healing or dehiscing wound
- Major surgical procedure within four weeks
- Chronic daily treatment with a non-steroidal anti-inflammatory drug

Alter	18 Jahre und älter
Prüfzentren	**Innere Medizin 1** (Nachbeobachtung) Gastroenterologie / Hepatologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Lisa Weiss Tel: 069 6301-87769 Fax: 069 6301-6580 Lisa.Weiss@unimedizin-ffm.de
Sponsor	Hoffmann-La Roche
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04102098 (primäres Register) EudraCT 2019-002491-14