KURZPROTOKOLL
Contact-03

Öffentlicher Titel	Phase III Studie zu Atezolizumab als Zweitlinientherapie bei fortgeschrittenem Nierenkrebs
Wissenschaftl. Titel	A Phase III, Multicenter, Randomized, Open-Label Study to Evaluate the Efficacy and Safety of Atezolizumab Given in Combination With Cabozantinib Versus Cabozantinib Alone in Patients With Inoperable, Locally Advanced, or Metastatic Renal Cell Carcinoma Who Experienced Radiographic Tumor Progression During or After Immune Checkpoint Inhibitor Treatment
Kurztitel	Contact-03
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Niere/Harnwege: Nierenzellkrebs: Zweitlinie oder höher
Einschlusskriterien	- Histologically confirmed locally advanced or metastatic clear cell or non-clear cell (papillary and unclassified only) RCC. RCC with sarcomatoid features is allowed - Radiographic disease progression during or following treatment with ICI for locally advanced or metastatic RCC either in first- or second-line treatment. ICI is defined by anti-PD-L1 or anti-PD1 antibody including atezolizumab, avelumab, pembrolizumab, or nivolumab. Only patients for whom the immediate preceding line of therapy was an ICI are allowed - Measurable disease per RECIST v1.1 - Evaluable IMDC risk score - Archival tumor specimen, and pretreatment tumor tissue from fresh biopsy at screening, if clinically feasible - KPS score of >=70 - Adequate hematologic and end-organ function - Negative HIV test at screening - Negative hepatitis B testing at screening - Negative hepatitis C virus (HCV) antibody test at screening, or positive HCV antibody test followed by a negative HCV RNA test at screening - For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraception and agreement to refrain from donating eggs - For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use a condom, and agreement to refrain from donating sperm
Ausschlusskriterien	- Treatment with anti-cancer therapy within 28 days prior to initiation of study treatment - Patients received cabozantinib at any time prior to screening - Patients who received more than 1 regimen of ICIs - Patients who received more than 2 prior lines of therapy in the advanced or metastatic setting - Patients who received ICI in the adjuvant setting (adjuvant VEGFR-TKI except cabozantinib is allowed) - Patients who have received a mammalian target of rapamycin (mTOR) inhibitor in the advanced or metastatic setting - Symptomatic, untreated, or actively progressing CNS metastases - History of leptomeningeal disease - Uncontrolled pleural effusion, pericardial effusion, or ascites requiring recurrent drainage procedures

- Uncontrolled or symptomatic hypercalcemia or symptomatic hypercalcemia requiring continued use of bisphosphonate therapy or denosumab
- History of malignancy other than renal carcinoma within 5 years prior to screening, with the exception of malignancies with a negligible risk of metastasis or death
- Radiotherapy for RCC within 14 days prior to Day 1 of Cycle 1
- Active tuberculosis
- 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
- Pregnancy or breastfeeding, or intention of becoming pregnant during study treatment or within 5 months after final dose of atezolizumab and 4 months after final dose of cabozantinib
- 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
- Uncontrolled hypertension defined as sustained blood pressure >150 mm Hg systolic or > 90 mm Hg diastolic despite optimal antihypertensive treatment
- Significant cardiovascular disease (such as New York Heart Association Class II or greater cardiac disease, MI, or cerebrovascular accident) within 3 months prior to initiation of study treatment, unstable arrhythmia, or unstable angina
- Significant vascular disease (e.g., aortic aneurysm requiring surgical repair or recent peripheral arterial thrombosis) within 6 months prior to Day 1 of Cycle 1
- History of congenital QT syndrome
- History or presence of an abnormal ECG that is clinically significant in the investigator's opinion
- Concomitant anticoagulation with coumarin agents (e.g., warfarin), direct thrombin inhibitor dabigatran, direct factor Xa inhibitor betrixaban, or platelet inhibitors (e.g. clopidogrel)

Alter	18 Jahre und älter
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Sponsor	Hoffmann-La Roche
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT04338269 (primäres Register) EudraCT 2020-000502-29