KURZPROTOKOLL
XL184-313

Öffentlicher Titel	Phase III Studie zu Cabozantinib bei unbehandeltem Nierenzellkarzinom
Wissenschaftl. Titel	A Randomized, Double-Blind, Controlled Phase 3 Study of Cabozantinib in Combination with Nivolumab and Ipilimumab versus Nivolumab and Ipilimumab in Subjects with Previously Untreated Advanced or Metastatic Renal Cell Carcinoma of Intermediate or Poor Risk
Kurztitel	XL184-313
Studienart	prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Niere/Harnwege: Nierenzellkrebs: neoadjuvant
Einschlusskriterien	- Histologically confirmed advanced (not amenable to curative surgery or radiation therapy) or metastatic (AJCC Stage IV) renal cell carcinoma with a clear-cell component - Intermediate- or poor-risk RCC as defined by International Metastatic RCC Database Consortium (IMDC) criteria - Measurable disease per RECIST 1.1 as determined by the Investigator - Karnofsky Performance Status (KPS) >= 70% - Adequate organ and marrow function
Ausschlusskriterien	- Prior systemic anticancer therapy for unresectable locally advanced or metastatic RCC including investigational agents - Uncontrolled, significant intercurrent or recent illness including, but not limited to serious cardiovascular disorders (including uncontrolled hypertension defined as sustained blood pressure (BP) > 150 mm Hg systolic or > 90 mm Hg diastolic despite optimal antihypertensive treatment), GI disorders associated with high risk for perforation or fistula formation, tumors invading GI tract, bowel obstruction, intra-abdominal abscess, clinically significant bleeding events, cavitating pulmonary lesions, or lesions invading major pulmonary blood vessels - Other clinically significant disorders such as: i. Autoimmune disease that has been symptomatic or required treatment within the past two years from the date of randomization. ii. Any condition requiring systemic treatment with either corticosteroids (> 10 mg daily prednisone equivalent) or other immunosuppressive medications within 14 days of randomization. iii. Active infection requiring systemic treatment. Acute or chronic hepatitis B or C infection, known human immunodeficiency virus (HIV) or acquired immunodeficiency syndrome (AIDS)-related illness, or known positive test for tuberculosis infection where there is clinical or radiographic evidence of active myobacterial infection - Major surgery (eg, nephrectomy, GI surgery, removal or biopsy of brain metastasis) within 4 weeks prior to randomization. Minor surgeries within 10 days prior to randomization. Subjects must have complete wound healing from major or minor surgery before randomization - Any other active malignancy at time of randomization or diagnosis of another malignancy within 3 years prior to randomization that requires active treatment, except for locally curable cancers that have been apparently cured, such as basal or squamous cell skin cancer, superficial bladder cancer, or carcinoma in situ of the prostate, cervix, or breast
Alter	18 Jahre und älter
Prüfzentren	**Urologie** (Rekrutierung beendet) Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. med. Severine Banek Tel: 069 6301-80072 Fax: 069 6301-84029 severine.banek@kgu.de

Universitätsklinikum Frankfurt (Rekrutierung beendet)
Zentrum für Chirurgie, Klinik für Urologie
Theodor-Stern-Kai 7
60590 Frankfurt am Main
Dr. med. Severine Banek
Tel: 069 6301-80072
Fax: 069 6301-84029
severine.banek@kgu.de

Sponsor	Exelixis
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03937219 (primäres Register) EudraCT 2018-004567-31