KURZPROTOKOLL
FIERCE-22

Öffentlicher Titel	Phase I/II Studie zum FGFR3-Inhibitor B-701 plus Pembrolizumab bei fortgeschrittenem oder metastasiertem Blasenkrebs
Wissenschaftl. Titel	A Multi-Center, Open-Label Phase 1b/2 Study of a Novel FGFR3 Inhibitor (B-701) Combined with Pembrolizumab in Subjects with Locally Advanced or Metastatic Urothelial Carcinoma who have Progressed Following Platinum-based Chemotherapy
Kurztitel	FIERCE-22
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase I/II
Erkrankung	Niere/Harnwege: Harnblasenkrebs: Zweitlinie oder höher
Einschlusskriterien	- Have locally advanced (on TNM staging: T4b and any N, or any T and N2-3) or metastatic transitional cell carcinoma of the urothelium, including of the urinary bladder, urethra, ureter, and/or renal pelvis. The diagnosis must be histologically or cytologically confirmed. - Have progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy. - Have available archival tumor or be willing to undergo diagnostic biopsy at screening. Sample must be of suitable quality and quantity to satisfy group assignment and biomarker endpoints. - Have measurable disease according to Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1). - Eastern Cooperative Oncology Group (ECOG) performance status (PS) <= 1
Ausschlusskriterien	- Participants with a history of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on the Screening chest CT scan - Prior therapy with an anti-programmed cell death 1 (PD-1) or anti-PD-Ligand 1 agent, or with an agent directed to another co-inhibitory T-cell receptor or FGFR inhibitor - Patients with autoimmune disease or medical conditions that required systemic corticosteroids (> 10 mg/day prednisone or its equivalent) or other immunosuppressive medications or any other form of systemic immunosuppressive therapy within 7 days prior to the first dose of study treatment. Note: Replacement therapy (e.g. physiologic corticosteroid replacement therapy for adrenal or pituitary insufficiency, etc.) is not considered a form of systemic treatment - Primary central nervous system (CNS) malignancy or CNS metastases - History of clinically significant coagulation or platelet disorder in the past 12 months
Alter	18 Jahre und älter
Prüfzentren	**Krankenhaus Nordwest GmbH** (Rekrutierung beendet) Institut für klinisch-onkologische Forschung Steinbacher Hohl 2-26 60488 Frankfurt am Main Dr. med. Mohammad-Reza Rafiyan Tel: 069 76 01 44 20 Fax: 069 76 01 36 55 rafiyan.reza@khnw.de
Sponsor	BioClin
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03123055 (primäres Register) EudraCT 2017-001292-23