

## **KURZPROTOKOLL** **FIERCE-22**

<b>Öffentlicher Titel</b>	Phase I/II Studie zum FGFR3-Inhibitor B-701 plus Pembrolizumab bei fortgeschrittenem oder metastasiertem Blasenkrebs
<b>Wissenschaftl. Titel</b>	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
<b>Kurztitel</b>	FIERCE-22
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, einarmig, Pharma-Studie
<b>Studienphase</b>	Phase I/II
<b>Erkrankung</b>	Niere/Harnwege: Harnblasenkrebs: Zweitlinie oder höher
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- 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.</li><li>- Have progression during or following platinum-containing chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy.</li><li>- 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.</li><li>- Have measurable disease according to Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1).</li><li>- Eastern Cooperative Oncology Group (ECOG) performance status (PS) <math>\leq</math> 1</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- 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</li><li>- 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</li><li>- Patients with autoimmune disease or medical conditions that required systemic corticosteroids (<math>&gt;</math> 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</li><li>- Primary central nervous system (CNS) malignancy or CNS metastases</li><li>- History of clinically significant coagulation or platelet disorder in the past 12 months</li></ul>
<b>Alter</b>	18 Jahre und älter
<b>Sponsor</b>	BioClin
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT03123055 (primäres Register) EudraCT 2017-001292-23