KURZPROTOKOLL
Potomac

Öffentlicher Titel	Phase II Studie zu Durvalumab und BCG bei Blasenkarzinom
Wissenschaftl. Titel	A Phase III, Randomized, Multi-Center, Open-Label, Multi-Center, Global Study of Durvalumab and Bacillus Calmette-Guerin (BCG) Administered as Combination Therapy Versus BCG Alone in High-Risk, BCG-Naïve Non-Muscle-Invasive Bladder Cancer Patients (POTOMAC)
Kurztitel	Potomac
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Niere/Harnwege: Harnblasenkrebs: Erstlinie
Einschlusskriterien	- Aged at least 18 years - BCG-naïve (patients who have not received prior intravesical BCG or who previously received but stopped BCG more than 3 years before study entry are eligible) - Local histological confirmation (based on pathology report) of high-risk transitional cell carcinoma of the urothelium of the urinary bladder confined to the mucosa or submucosa. A high risk tumor is defined as one of the following T1 tumor High grade/ G3 tumor CIS Multiple and recurrent and large (with diameter of largest tumor >=3 cm) tumors (all conditions must be met in this point) - Complete resection of all Ta/T1 papillary disease prior to randomization, with the TURBT removing high-risk NMIBC performed not more than 4 months before randomization in the study. Patients with residual CIS after TURBT are eligible - No prior radiotherapy for bladder cancer - No prior exposure to immune-mediated therapy of cancer including, but not limited to, other anti CTLA-4, anti-PD-1, anti-PD-L1, and anti-programmed cell death ligand 2 antibodies. Patients who have been treated with anticancer vaccines will be excluded
Ausschlusskriterien	- Evidence of muscle-invasive, locally advanced, metastatic, and/or extra vesical bladder cancer (ie, T2, T3, T4, and / or stage IV) - Concurrent extravesical (ie, urethra, ureter, or renal pelvis), non-muscle-invasive transitional cell carcinoma of the urothelium - Previous investigational product (IP) assignment in the present study - Any concurrent chemotherapy, IP, biologic, or hormonal therapy for cancer treatment. Concurrent use of hormonal therapy for noncancer related conditions (eg, hormone replacement therapy) is acceptable. Chemotherapy for previous instances of NMIBC is acceptable - Active or prior documented autoimmune or inflammatory disorders (including inflammatory bowel disease [eg, colitis or Crohn's disease], diverticulitis [with the exception of diverticulosis], systemic lupus erythematosus, Sarcoidosis syndrome, or Wegener syndrome [granulomatosis with polyangiitis, Graves' disease, rheumatoid arthritis, hypophysitis, uveitis, etc]). The following are exceptions to this criterion: Patients with vitiligo or alopecia, Patients with hypothyroidism (e.g., following Hashimoto syndrome) stable on hormone replacement, Any chronic skin condition that does not require systemic therapy, Patients without active disease in the last 5 years may be included but only after consultation with the Study Physician, Patients with celiac disease controlled by diet alone - History of another primary malignancy except for - Malignancy treated with curative intent and with no known active disease >= 2 years before the first dose of IP and of low potential risk for recurrence during the study period Adequately treated nonmelanoma skin cancer or lentigo maligna without evidence of disease, Adequately treated CIS without evidence of disease, Prostate cancer (tumor/node/metastasis stage) of stage <= T2cN0M0 without biochemical recurrence or progression that in the opinion of the Investigator does not require active intervention

	- Current or prior use of immunosuppressive medication within 14 days before the first dose of durvalumab. The following are exceptions to this criterion: Intranasal, inhaled, topical steroids, or local steroid injections (eg, intra articular injection), Systemic corticosteroids at physiologic doses not to exceed 10 mg/day of prednisone or its equivalent, Steroids as premedication for hypersensitivity reactions (eg, computed tomography [CT] scan premedication)
Alter	18 - 130 Jahre
Prüfzentren	**Universitätsklinikum Gießen und Marburg, Standort Marburg** (Rekrutierung beendet) Klinik für Urologie und Kinderurologie Baldingerstraße 35043 Marburg Bettina-Petra Seifert-Heinze Tel: 06421 58 63695 Seifertk@med.uni-marburg.de
Sponsor	Astra Zeneca
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03528694 EudraCT 2017-002979-26