KURZPROTOKOLL
Checkmate 274

Öffentlicher Titel	Phase III Studie zur adjuvanten Gabe von Nivolumab bei Blasenkrebs
Wissenschaftl. Titel	A Phase 3 Randomized, Double-blind, Multi-center Study of Adjuvant Nivolumab versus Placebo in Subjects with High Risk Invasive Urothelial Carcinoma
Kurztitel	Checkmate 274
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Niere/Harnwege: Harnblasenkrebs: adjuvant
Einschlusskriterien	- Must have had invasive urothelial cancer at high risk of recurrence originating in the bladder, ureter, or renal pelvis - Must have had radical surgical resection (e.g. radical cystectomy), performed within the last 120 days - Must have disease free status as determined by imaging within 4 weeks of dosing - Tumor tissue must be provided for biomarker analysis - Patients who have not received prior neoadjuvant cisplatin chemotherapy must be ineligible for or refuse cisplatin-based adjuvant chemotherapy
Ausschlusskriterien	- Partial bladder or partial kidney removal (eg, partial cystectomy or partial nephrectomy) - Secondary Treatment (eg, adjuvant systemic chemotherapy for bladder cancer) following surgical removal of bladder cancer - Subjects with active, known or suspected autoimmune disease - Prior malignancy active within the previous 3 years except for locally curable cancers that have been apparently cured - Condition requiring systemic treatment with either corticosteroids or other immunosuppressive medications within 14 day of study drug administration - Positive test for hepatitis B virus surface antigen (HBV s Ag) or hepatitis C virus ribonucleic acid (HCV antibody) indicating acute or chronic infection
Alter	18 Jahre und älter
Sponsor	Bristol-Myers Squibb
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02632409 (primäres Register) EudraCT 2014-003626-40