KURZPROTOKOLL
FORCE

Öffentlicher Titel	Phase II Studie zu Nivolumab und Radiotherapie bei metastasiertem nicht-kleinzelligem Lungenkrebs
Wissenschaftl. Titel	Fostering efficacy: Nivolumab plus radiotherapy in advanced NSCLC (FORCE)
Kurztitel	FORCE
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig, Investigator Initiated Trial (IIT)
Studienphase	Phase II
Erkrankung	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - Zweitlinie oder höher
Einschlusskriterien	- Age >= 18 years at time of study entry. - ECOG performance status 0-1. - Patients with metastatic non-squamous non-small cell lung cancer after failure of platinum-based doublet chemotherapy and (a) no necessity of radiotherapy (Group B) or b) the necessity of radiotherapy of a metastatic bone lesion or soft tissue lesion (Group A); (b) For details see protocol section 3.2. - Patients must have measurable disease by CT or MRI per RECIST 1.1 criteria. For details see protocol section 3.2. - For each patient a formalin fixed, paraffin-embedded tumor tissue block (archival or recent) or a minimum of 15 unstained slides of tumor sample (slices must be recent and collected on slides provided by the sponsor) must be available for biomarker (PD -L1) evaluation. Biopsy should be excisional, incisional or core needle. Fine needle aspiration is insufficient.
Ausschlusskriterien	- Patients who require ongoing treatment with more than 10mg of prednisone (or steroid equivalent, excluding inhaled or topical steroids) daily. - Prior therapy with anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-CTLA-4 antibody (including ipilimumab or any other antibody or drug specifically targeting T-cell co-stimulation or checkpoint pathways). - Patients with an active or recent history of a known or suspected autoimmune disease or recent history of a syndrome that required systemic corticosteroids/immunosuppressive medications EXCEPT for syndromes which would not be expected to recur in the absence of an external trigger. (Subjects with type 1 diabetes mellitus, hypothyroidism only requiring hormone replacement or skin disorders, (such as vitiligo, psoriasis, or alopecia) not requiring systemic treatment are permitted to enroll.) - Any serious or uncontrolled medical disorder or active infection that would impair the ability of the subject to receive protocol therapy (see section 3.3 for details). - Subjects with previous malignancies (except non-melanoma skin cancers, and the following in situ cancers: bladder, gastric, colon, cervical/dysplasia, melanoma, or breast) are excluded unless a complete remission was achieved at least 2 years prior to study entry AND no additional therapy is required or anticipated to be required during the study period. - Brain metastases mandating active treatment in terms of WBI (whole brain irradiation). Subjects with brain metastases are eligible if metastases have been treated and there is no magnetic resonance imaging (MRI) evidence of progression for 12 weeks after treatment is complete and within 28 days prior to the first dose of nivolumab administration. There must also be no requirement for immunosuppressive doses of systemic corticosteroids (> 10 mg/day prednisone equivalents) for at least 2 weeks prior to study drug administration.

	- Subjects with brain metastases are eligible if metastases have been treated and treatment has been completed at least 12 weeks before inclusion in this study for group B and 2 weeks for group A. Moreover, there must be no magnetic resonance imaging (MRI) evidence of progression within 28 days prior to the first dose of nivolumab administration. There must also be no requirement for immunosuppressive doses of systemic corticosteroids (> 10 mg/day prednisone equivalents) for at least 2 weeks prior to study drug administration. Patients with stable/asymptomatic brain metastases that do not require local therapy with irradiation (whole brain irradiation or stereotactic brain irradiation) can be included. In ambiguous cases, consultation with the LKP or his/her delegate is advised - Known activating EGFR mutation or a known ALK translocation.
Alter	18 Jahre und älter
Molekularer Marker	ALK wt EGFR wt
Sponsor	Bristol-Myers Squibb
Förderer	AIO-Studien GmbH
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03044626 EudraCT 2015-005741-31