KURZPROTOKOLL
CA184104 (IDEATE)

Öffentlicher Titel	Ipilimumab bei rezidiviertem NSCLC
Wissenschaftl. Titel	Randomized, Multicenter, Double-Blind, Phase 3 Trial Comparing the Efficacy of Ipilimumab in Additin to Paclitaxel and Carboplatin versus Placebo in Addition to Paclitaxel and Carboplatin in Subjects with Stage IV / Recurrent Non-Small Cell Lung Cancer
Kurztitel	CA184104 (IDEATE)
Studienart	multizentrisch, prospektiv, randomisiert, Pharma-Studie, doppelblind, zweiarmig
Studienphase	Phase III
Erkrankung	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - Zweitlinie oder höher
Einschlusskriterien	- Signed Written Informed Consent, Willing and able to provide informed consent - Target Population 1. Subjects with NSCLC of predominantly squamous histology documented by histology or cytology from brushing, washing or needle aspiration of a defined lesion but not from sputum cytology alone 2. Subjects must present with Stage IV or Recurrent NSCLC (per the 7th International Association for the Study of Lung Cancer (IASLC) classification) 3. At least 1 measurable tumor lesion, as defined by WHO criteria, that is not 4. Eastern Cooperative Oncology Group (ECOG) performance status <= 1 at study entry 5. Accessible for treatment and follow-up. Subjects enrolled in this trial must be treated at the participating centers - Age and Reproductive Status 1. Men and Women >= 18 years of age 2. Women of childbearing potential (WOCBP) must be using an acceptable method - WOCBP must have a negative serum or urine pregnancy test (minimum sensitivity 25 IU/L or equivalent units of HCG) within 72 hours prior to the start of investigational product - Women must not be breastfeeding
Ausschlusskriterien	- Target Disease Exceptions 1. Brain metastases 2. Malignant pleural effusion that is recurrent despite appropriate supportive care - Medical History and Concurrent Diseases 1. Documented history of severe autoimmune or immune mediated symptomatic disease that required prolonged (more than 2 months) systemic - immunosuppressive (ie, steroids) treatment such as: Ulcerative colitis and Crohn’s disease, Rheumatoid arthritis, systemic progressive sclerosis (scleroderma), Systemic Lupus Erythematosus, Autoimmune vasculitis (eg, Wegener’s Granulomatosis) - Subjects with history of motor neuropathy considered of autoimmune origin (eg, - Subjects with a history of toxic epidermal necrolysis (TEN) - Dementia, altered mental status, or any psychiatric condition that would prohibit - Serious uncontrolled medical disorder that, in the opinion of the investigator, would impair the ability of the subject to receive protocol therapy - Prior malignancy, active within 5 years, except for locally curable cancers that have been apparently cured and need no subsequent therapy, such as basal or squamous cell skin cancer, superficial bladder cancer or carcinoma in situ of the cervix or breast - HIV positive or active Hepatitis B or active Hepatitis C infection - Prior systemic therapy for lung cancer including vaccines and other targeted therapies Prior radiation therapy or loco-regional surgeries are allowed if performed at least 3 weeks prior to the date of entry into randomization - Subjects with >= Grade 2 peripheral neuropathy - History of allergy or hypersensitivity to any component of the treatment

- Physical and Laboratory Test Findings: Inadequate hematologic function defined by: 1. Absolute neutrophil count (ANC) < 1,500/mm3, or 2. Platelet count < 100,000/mm3; or 3. Hemoglobin level < 9 g/dL
- Inadequate hepatic function as defined by either: 1. Total bilirubin level >= 2.5 times the upper limit of normal (ULN); 2. AST and ALT levels >= 2.5 times the ULN or >= 5 times the ULN if liver metastases are present
- Inadequate renal function defined as calculated creatinine clearance < 50 ml/min based on the standard Cockroft and Gault formula
- Prohibited Treatments and/or Therapies: Chronic use of immuno-suppressive drugs (ie, corticosteroids used in the management of cancer or non-cancer related illnesses). Use of corticosteroids areallowed if used as premedication for chemotherapy administration or on study management of an AE, Any non-oncology vaccine therapy used for prevention of infectious disease (for up to 4 weeks prior to or after any dose of blinded study drug), Any immunotherapy for the treatment of cancer, Prior treatment with any inhibitor or agonist of T-cell co-stimulation
- Sex and Reproductive Status: Sexually active fertile men not using effective birth control if their partners are WOCBP
- Prisoners or subjects who are involuntarily incarcerated, Subjects who are compulsorily detained for treatment of either a psychiatric or physical (eg, infectious disease) illness

Alter	18 Jahre und älter
Sponsor	Bristol-Myers Squibb
Förderer	Bristol-Myers Squibb
Registrierung in anderen Studienregistern	EudraCT 2009-017396-19