KURZPROTOKOLL
GO29537

Öffentlicher Titel	Phase III Studie zu Atezolizumab mit Carboplatin und NAB-Paclitaxel als Erstlinienbehandlung bei NSCLC
Wissenschaftl. Titel	A PHASE III, MULTICENTER, RANDOMIZED, OPEN-LABEL STUDY EVALUATING THE EFFICACY AND SAFETY OF ATEZOLIZUMAB (MPDL3280A, ANTI-PD-L1 ANTIBODY) IN COMBINATION WITH CARBOPLATIN + NAB-PACLITAXEL FOR CHEMOTHERAPY-NAIVE PATIENTS WITH STAGE IV NON-SQUAMOUS NON-SMALL CELL LUNG CANCER
Kurztitel	GO29537
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, zweiarmig
Studienphase	Phase III
Erkrankung	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - Erstlinie
Einschlusskriterien	- 18 years of age or older - Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 - Histologically or cytologically confirmed, treatment-naive Stage IV non-squamous NSCLC - Measurable disease, as defined by RECIST v1.1 - Previously obtained archival tumor or tissue obtained from a biopsy at screening - Adequate hematologic and end organ function
Ausschlusskriterien	- Active or untreated central nervous system (CNS) metastases - Malignancies other than NSCLC within 5 years prior to randomization, with the exception of those with a negligible risk of metastasis or death treated with expected curative outcome - Pregnant or lactating women - History of autoimmune disease - History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan; history of radiation pneumonitis in the radiation field (fibrosis) is permitted - Positive test for Human Immunodeficiency Virus (HIV) - Active hepatitis B or hepatitis C - Prior treatment with CD137 agonists or immune checkpoint blockade therapies, anti-PD-1, and anti-PD-L1 therapeutic antibody - Severe infection within 4 weeks prior to randomization - Significant history of cardiovascular disease
Alter	18 Jahre und älter
Fallzahl	550
Prüfzentren	**Krankenhaus Nordwest GmbH** (Rekrutierung beendet) Klinik für Onkologie und Hämatologie Steinbacher Hohl 2-26 60488 Frankfurt am Main Dr. med. Akin Atmaca atmaca.akin@khnw.de
Sponsor	Roche Pharma AG (Hauptsponsor)
Förderer	Roche Pharma AG
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02367781 EudraCT 2014-003206-32