KURZPROTOKOLL
GO29436

Öffentlicher Titel	Phase III Studie zum PD-L1-Antikörper MPDL3280A mit Carboplatin, Paclitaxel (und Bevacizumab) als Erstlinienbehandlung bei Patienten mit NSCLC, Stadium IV
Wissenschaftl. Titel	A Phase III, Open-Label, Randomized Study of MPDL3280A (Anti-PD-L1 Antibody) In Combination With Carboplatin + Paclitaxel With or Without Bevacizumab Compared With Carboplatin + Paclitaxel + Bevacizumab In Chemotherapy-Naïve Patients With Stage IV Non-Squamous Non-Small Cell Lung Cancer (NSCLC)
Kurztitel	GO29436
Studienart	multizentrisch, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, dreiarmig
Studienphase	Phase III
Erkrankung	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - Erstlinie
Ziele	- To evaluate the efficacy of atezolizumab as measured by investigator-assessed PFS (TC2/3 or IC2/3, TC1/2/3 or IC1/2/3, and ITT populations) according to RECIST v1.1, and OS (TC1/2/3 or IC1/2/3 and ITT populations) in each of the following two treatment comparisons: - Atezolizumab + carboplatin + paclitaxel versus carboplatin + paclitaxel + bevacizumab - Atezolizumab + carboplatin + paclitaxel + bevacizumab versus carboplatin + paclitaxel + bevacizumab
Einschlusskriterien	- 18 years of age or older - Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1 - Histologically or cytologically confirmed, treatment-naïve Stage IV non-squamous NSCLC - Previously obtained archival tumor tissue or tissue obtained from a biopsy at screening - Measurable disease as defined by RECIST v1.1 - 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 PD1, 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	1200
Sponsor	Roche Pharma AG
Registrierung in anderen Studienregistern	EudraCT 2014-003207-30 ClinicalTrials.gov NCT02366143