KURZPROTOKOLL
GO28915

Öffentlicher Titel	Studie mit MPDL3280A im Vergleich mit Docetaxel bei Patienten mit nicht kleinzelligem Lungenkarzinom
Wissenschaftl. Titel	A Phase III, open-label, multicenter, randomized study to investigate the efficacy and safety of MPDL3280A (Anti-PD-L1 Antibody) compared with Docetaxel in patients with non-small cell lung cancer after failure with Platinum-Containing chemotherapy
Kurztitel	GO28915
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase III
Erkrankung	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - Zweitlinie oder höher
Ziele	- Overall survival (OS) - Incidence of adverse events - Overall response rate determined using Response Evaluation Criteria in Solid Tumors - Progression-free survival (PFS) evaluated with RECIST v. 1.1 - Duration of response evaluated with RECIST v. 1.1
Einschlusskriterien	- Adult patients, >/= 18 years of age - Locally advanced or metastatic (Stage IIIB, Stage IV, or recurrent) non-small cell lung cancer (NSCLC) Representative formalin-fixed paraffin-embedded (FFPE) tumor specimens - Disease progression during or following treatment with a prior platinum-containing regimen for locally advanced, unresectable/inoperable or metastatic NSCLC or disease recurrence within 6 months of treatment with a platinum-based adjuvant/neoadjuvant regimen - Measurable disease, as defined by RECIST v1.1 - Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1
Ausschlusskriterien	- Known 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 and treated with expected curative outcome - History of autoimmune disease - History of idiopathic pulmonary fibrosis (including pneumonitis), drug-induced pneumonitis, organizing pneumonia, or evidence of active pneumonitis on screening chest CT scan. History of radiation pneumonitis in the radiation field (fibrosis) is permitted. - Active hepatitis B or hepatitis C - Prior treatment with docetaxel - Prior treatment with CD137 agonists, anti-CTLA4, anti-PD-1, or anti-PD-L1 therapeutic antibody or pathway-targeting agents
Alter	18 Jahre und älter
Sponsor	Roche Pharma AG
Förderer	Roche Pharma AG
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02008227 EudraCT 2013-003331-30
Therapie	MPDL3280A Docetaxel