

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	<ul style="list-style-type: none">- 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	<ul style="list-style-type: none">- Adult patients, \geq 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	<ul style="list-style-type: none">- 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
Prüfzentren	Krankenhaus Nordwest GmbH (Nachbeobachtung) 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
Förderer	Roche Pharma AG

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Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT02008227 EudraCT 2013-003331-30
Therapie	MPDL3280A Docetaxel