# *KURZPROTOKOLL*
# *GO28915*

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| **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)<br>- Incidence of adverse events<br>- Overall response rate determined using Response Evaluation Criteria in Solid Tumors<br>- Progression-free survival (PFS) evaluated with RECIST v. 1.1<br>- Duration of response evaluated with RECIST v. 1.1 |
| **Einschlusskriterien** | - Adult patients, >/= 18 years of age<br>- Locally advanced or metastatic (Stage IIIB, Stage IV, or recurrent) non-small cell lung cancer (NSCLC) Representative formalin-fixed paraffin-embedded (FFPE) tumor specimens<br>- 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<br>- Measurable disease, as defined by RECIST v1.1<br>- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 |
| **Ausschlusskriterien** | - Known active or untreated central nervous system (CNS) metastases<br>- 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<br>- History of autoimmune disease<br>- 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.<br>- Active hepatitis B or hepatitis C<br>- Prior treatment with docetaxel<br>- 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)<br>Klinik für Onkologie und Hämatologie<br>Steinbacher Hohl 2-26<br>60488 Frankfurt am Main<br>Dr. med. Akin Atmaca<br>atmaca.akin@khnw.de |
| **Sponsor** | Roche Pharma AG |
| **Förderer** | Roche Pharma AG |

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| **Registrierung in anderen Studienregistern** | ClinicalTrials.gov NCT02008227<br>EudraCT 2013-003331-30 |
| **Therapie** | MPDL3280A Docetaxel |