

## **KURZPROTOKOLL** **GO29537**

<b>Öffentlicher Titel</b>	Phase III Studie zu Atezolizumab mit Carboplatin und NAB-Paclitaxel als Erstlinienbehandlung bei NSCLC
<b>Wissenschaftl. Titel</b>	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
<b>Kurztitel</b>	GO29537
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, zweiarmig
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - Erstlinie
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- 18 years of age or older</li><li>- Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1</li><li>- Histologically or cytologically confirmed, treatment-naive Stage IV non-squamous NSCLC</li><li>- Measurable disease, as defined by RECIST v1.1</li><li>- Previously obtained archival tumor or tissue obtained from a biopsy at screening</li><li>- Adequate hematologic and end organ function</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Active or untreated central nervous system (CNS) metastases</li><li>- 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</li><li>- Pregnant or lactating women</li><li>- History of autoimmune disease</li><li>- 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</li><li>- Positive test for Human Immunodeficiency Virus (HIV)</li><li>- Active hepatitis B or hepatitis C</li><li>- Prior treatment with CD137 agonists or immune checkpoint blockade therapies, anti-PD-1, and anti-PD-L1 therapeutic antibody</li><li>- Severe infection within 4 weeks prior to randomization</li><li>- Significant history of cardiovascular disease</li></ul>
<b>Alter</b>	18 Jahre und älter
<b>Fallzahl</b>	550
<b>Prüfzentren</b>	<b>Krankenhaus Nordwest GmbH</b> (Rekrutierung beendet) Klinik für Onkologie und Hämatologie Steinbacher Hohl 2-26 60488 Frankfurt am Main Dr. med. Akin Atmaca <a href="mailto:atmaca.akin@khnw.de">atmaca.akin@khnw.de</a>
<b>Sponsor</b>	Roche Pharma AG (Hauptsponsor)
<b>Förderer</b>	Roche Pharma AG
<b>Registrierung in anderen Studienregistern</b>	ClinicalTrials.gov NCT02367781 EudraCT 2014-003206-32