

**KURZPROTOKOLL**  
**CA209-331**

<b>Öffentlicher Titel</b>	Phase III Studie zu Nivolumab oder Chemotherapie bei rezidiviertem/refraktärem SCLC nach platinbasierter Erstlinienbehandlung
<b>Wissenschaftl. Titel</b>	An open-Label, randomized, Phase 3 study of nivolumab or chemotherapy(Topotecan i.v.) in subjects with relapsed SCLC after platinum-based first line chemotherapy
<b>Kurztitel</b>	CA209-331
<b>Studienart</b>	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
<b>Studienphase</b>	Phase III
<b>Erkrankung</b>	Lunge: Lungenkrebs: Kleinzelliges Lungenkarzinom (SCLC) - Zweitlinie oder höher
<b>Ziele</b>	<ul style="list-style-type: none"><li>- To compare the overall survival (OS) of nivolumab versus chemotherapy in subjects with relapsed SCLC after platinum-based, first-line chemotherapy.</li><li>- To compare the progression free survival (PFS) of nivolumab versus chemotherapy</li><li>- To compare the objective response rate (ORR) of nivolumab versus chemotherapy</li></ul>
<b>Einschlusskriterien</b>	<ul style="list-style-type: none"><li>- Adult men and women with histologically or cytologically confirmed SCLC that recurred or progressed after platinum-based, first-line chemotherapy or chemoradiation therapy.</li><li>- Subjects must have had at least 4 cycles of platinum-based, first-line chemotherapy for either limited or extensive stage disease or if less than 4 cycles</li><li>- must have had a BOR of at least partial or complete response.</li></ul>
<b>Ausschlusskriterien</b>	<ul style="list-style-type: none"><li>- Active symptomatic central nervous system metastases, documented carcinomatous meningitis,</li><li>- active, known or suspected autoimmune disease</li><li>- prior treatment with anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-CTLA-4 antibody (including ipilimumab or any other antibody or drug specifically targeting T-cell co-stimulation or checkpoint pathways), topotecan, or amrubicin</li></ul>
<b>Alter</b>	18 Jahre und älter
<b>Prüfzentren</b>	<b>Universitätsklinikum Frankfurt</b> (Geschlossen) Medizinische Klinik I, Pneumologie/Allergologie Theodor-Stern-Kai 7 60590 Frankfurt am Main Dr. med. Wolfgang Gleiber Tel: 069 6301-6337 Fax: 069 6301-7391 <a href="mailto:wolfgang.gleiber@kgu.de">wolfgang.gleiber@kgu.de</a>
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<b>Registrierung in anderen Studienregistern</b>	EudraCT 2015-001097-18