

KURZPROTOKOLL
CA209-331

Öffentlicher Titel	Phase III Studie zu Nivolumab oder Chemotherapie bei rezidiviertem/refraktärem SCLC nach platinbasierter Erstlinienbehandlung
Wissenschaftl. Titel	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
Kurztitel	CA209-331
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, zweiarmig
Studienphase	Phase III
Erkrankung	Lunge: Lungenkrebs: Kleinzelliges Lungenkarzinom (SCLC) - Zweitlinie oder höher
Ziele	<ul style="list-style-type: none">- To compare the overall survival (OS) of nivolumab versus chemotherapy in subjects with relapsed SCLC after platinum-based, first-line chemotherapy.- To compare the progression free survival (PFS) of nivolumab versus chemotherapy- To compare the objective response rate (ORR) of nivolumab versus chemotherapy
Einschlusskriterien	<ul style="list-style-type: none">- Adult men and women with histologically or cytologically confirmed SCLC that recurred or progressed after platinum-based, first-line chemotherapy or chemoradiation therapy.- 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- must have had a BOR of at least partial or complete response.
Ausschlusskriterien	<ul style="list-style-type: none">- Active symptomatic central nervous system metastases, documented carcinomatous meningitis,- active, known or suspected autoimmune disease- 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
Alter	18 Jahre und älter
Prüfzentren	Universitätsklinikum Frankfurt (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 wolfgang.gleiber@kgu.de
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