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 sujects 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	- 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	- 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	- 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
Sponsor	Bristol-Myers Squibb (Hauptsponsor)
Registrierung in anderen Studienregistern	EudraCT 2015-001097-18