KURZPROTOKOLL
CA209032

Öffentlicher Titel	Phase I/II Studie zu Nivolumab mit oder ohne Ipilimumab bei soliden Tumoren
Wissenschaftl. Titel	A Phase 1/2, Open-label Study of Nivolumab Monotherapy or Nivolumab combined with Ipilimumab in Subjects with Advanced or Metastatic Solid Tumors
Kurztitel	CA209032
Studienart	multizentrisch, prospektiv, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase I/II
Erkrankung	Geschlechtsorgane: Brustkrebs: Erstlinie Lunge: Lungenkrebs: Kleinzelliges Lungenkarzinom (SCLC) - Erstlinie Verdauung: Darmkrebs (Kolorektales Karzinom): Erstlinie Verdauung: Bauchspeicheldrüsenkrebs (Pankreaskarzinom): Erstlinie
Einschlusskriterien	- Subjects with histologically confirmed locally advanced or metastatic disease of the following tumor types: - Triple Negative Breast Cancer - Gastric Cancer - Pancreatic Cancer - Small Cell Lung Cancer - Subjects must have measurable disease - Eastern Cooperative Oncology Group (ECOG) of 0 or 1
Ausschlusskriterien	- Active brain metastases or leptomeningeal metastases - Subjects with active, known or suspected autoimmune disease - Subjects with a condition requiring systemic treatment with either corticosteroids (>10 mg daily prednisone equivalents) or other immunosuppressive medications within 14 days of treatment - Prior therapy with experimental anti-tumor vaccines; any T cell co-stimulation or checkpoint pathways, such as anti-PD-1, anti-PD-L1, anti-PD-L2, anti-CD137, or anti-CTLA-4 antibody, including Ipilimumab; or other medicines specifically targeting T cell is also prohibited
Alter	18 Jahre und älter
Molekularer Marker	Triple neg (HER2/ER/PR neg)
Fallzahl	240
Prüfzentren	**Krankenhaus Nordwest GmbH** (Rekrutierung beendet) Klinik für Onkologie und Hämatologie Steinbacher Hohl 2-26 60488 Frankfurt am Main Dr. med. Akin Atmaca atmaca.akin@khnw.de
Sponsor	Bristol-Myers Squibb
Förderer	Bristol-Myers Squibb
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT01928394 EudraCT 2013-002844-10